BLUE

Plant-Derived Fatty Acid Oils Group

CIR EXPERT PANEL MEETING MARCH 3-4, 2011

Cosmetic Ingredient Review

Commitment . . . Credibility Since 1976



Memorandum

To: CIR Expert Panel Members and Liaisons

From: Christina L. Burnett and Monice Fiume, Scientific Writers/Analysts

Date: February 10, 2011

Subject: Final Report of the Plant-Derived Fatty Acid Oils Group (Draft)

At the December 2010 meeting, the CIR Expert Panel reviewed the report on 244 plant-derived fatty acid oils. A Tentative Report was issued, with the conclusion that all of the oils included in the report, with the exception of those lacking chemical composition data, were safe as used. Those lacking chemical composition data had insufficient data to make a determination of safety. The Panel agreed that, with receipt of chemical composition data, those ingredients that had insufficient data would be considered safe as used.

At the time of the December meeting, 10 ingredients had insufficient data. Currently, with the inclusion of new published and unpublished data, 241 of the 244 of the oils are safe as used. The three oils with insufficient data are:

Fragaria Chiloensis (Strawberry) Seed Oil Fragaria Vesca (Strawberry) Seed Oil Fragaria Virginiana (Strawberry) Seed Oil

The unpublished data submitted by the Council, as listed below, are included in Tab 3 of this report:

- 1. Composition of Orbignya Speciosa Kernel Oil. Memo dated Jan. 10, 2011.
- 2. Composition of Lycium Barbarum Seed Oil. Memo dated Jan. 18, 2011.
- 3. Updated Concentration of Use Information Plant Oils. Memo dated Jan. 20, 2011.

The Panel should anticipate issuing a Final Report at this meeting.

SAFETY ASSESSMENT FLOW CHART



*The CIR Staff notifies of the public of the decision not to re-open the report and prepares a draft statement for review by the Panel. After Panel review, the statement is issued to the Public.

** If rDraft Amended Report (DAR) is available, the Panel may choose to review; if not, CIR staff prepares DAR for Panel Review.

Expert Panel Decision Document for Panel Review

Updated Search (Jan 20, 2011) - focus was on insufficient ingredients

((ORYZA AND SATIVA) OR RICE) AND BRAN AND OIL

SCLEROCARYA AND BIRREA AND SEED AND OIL

(((ARCTIUM AND LAPPA) OR (COIX AND LACRYMA) OR ((FRAGARIA AND (CHILOENSIS OR VESCA OR VIRGINIANA)) OR (MORINDA AND CITRIFOLIA) AND SEED)) OR (SCHINZIOPHYTON AND RAUTANENII AND KERNEL) AND OIL)

| Ingredients | Toxline PubMed | ChemIDplus | HSDB | CAplus | NTIS | HPV | Merck USP |
|-------------|-------------------|--------------|--------------|--------------|------|--------------|--------------|
| | | | | | | | |
| | | \checkmark | \checkmark | \checkmark | | \checkmark | \checkmark |

Additional searches were performed on USDA's GRIN and AGRICOLA databases and via general search engines.

Ingredients were searched by Latin botanical (INCI) names, common names, and CAS numbers, when available. The list of ingredients searched is found in Table 1 of the vegetable oil report.

Literature searches included chemical composition, fatty acid composition, dermal toxicity, irritation, and sensitization qualifiers.

Searches were performed between November 20, 2009 and March 30, 2010; June 30 through July 8, 2010; and updated September 1through October 15, 2010.

March 2010:

CAS No. Except for Coconut, Corn, and Sesame - too big

(68956-68-3 OR 68334-28-1 OR 68956-68-3 OR 8001-29-4 OR 68308-51-0 OR 68334-00-9 OR 8001-25-0 OR 92044-96-7 OR 156798-12-8 OR 8002-75-3 OR 8023-79-8 OR 8033-29-2 OR 68514-74-9 OR 68990-82-9 OR 84540-04-5 OR 8002-75-3 OR 61790-79-2 OR 61789-89-7 OR 8002-03-7 OR 68425-36-5 OR 91051-35-3 OR 8002-13-9 OR 84681-71-0 OR 8002-13-9 OR 120962-03-0 OR 8001-23-8 OR 8001-22-7 OR 91770-67-1 OR 8016-70-4 OR 8001-21-6 OR 84625-38-7 OR 8016-49-7 OR 97676-19-2 OR 225234-12-8 OR 72869-69-3 OR 923029-60-1 OR 8024-32-6 OR 91770-40-0 OR 91078-92-1 OR 8002-31-1 OR 192230-28-7 OR 8001-21-6 OR 68424-45-3 OR 8024-22-4 OR 68553-81-1 OR 84696-37-7 OR 93165-33-4 OR 8006-95-9 OR 68917-73-7 OR 68938-32-9 OR 394236-97-6 OR 68920-03-6 OR 194043-92-0 OR 225234-14-0 OR 70955-25-8 OR 8015-88-1 OR 8002-78-6 OR 8023-98-1 OR 85085-28-5) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERG*)

All CAS No. Except for Coconut, Corn, Sesame, Pumpkin, BlackCurrant, Burago, Artichoke, Babassu, Dika, Grapeseed, Capuacu, Cucumber, Carrot - 505

(68956-68-3 OR 68334-28-1 OR 68956-68-3 OR 8001-29-4 OR 68308-51-0 OR 68334-00-9 OR 8001-25-0 OR 92044-96-7 OR 156798-12-8 OR 8002-75-3 OR 8023-79-8 OR 8033-29-2 OR 68514-74-9 OR 68990-82-9 OR 84540-04-5 OR 8002-75-3 OR

61790-79-2 OR 61789-89-7 OR 8002-03-7 OR 68425-36-5 OR 91051-35-3 OR 8002-13-9 OR 84681-71-0 OR 8002-13-9 OR 120962-03-0 OR 8001-23-8 OR 8001-22-7 OR 91770-67-1 OR 8016-70-4 OR 8001-21-6 OR 84625-38-7 OR 72869-69-3 OR 8024-32-6 OR 91770-40-0 OR 8002-31-1 OR 8001-21-6 OR 68424-45-3 OR 68553-81-1 OR 84696-37-7 OR 93165-33-4 OR 8006-95-9 OR 68917-73-7 OR 68938-32-9 OR 68920-03-6 OR 194043-92-0 OR 225234-14-0 OR 8002-78-6 OR 8023-98-1 OR 85085-28-5) AND (SENSITIZ* OR SENSITIS*OR IRRITA* OR ALLERG*)

CAS No. - Pumpkin, Black Currant, Burago, Artichoke, Babassu, Diks, Grapeseed, Capuacu, Cucumber, Carrot - 103

(8016-49-7 OR 97676-19-2 OR 225234-12-8 OR 923029-60-1 OR 91078-92-1 OR 192230-28-7 OR 8024-22-4 OR 394236-97-6 OR 70955-25-8 OR 8015-88-1) AND (SENSITIZ* OR SENSITIS*OR IRRITA* OR ALLERG*)

All CAS No. Except for Coconut, Corn, Cottonseed, Palm, Peanut, Sesame, and Rice - 635

(68956-68-3 OR 68334-28-1 OR 68956-68-3 OR 8001-25-0 OR 92044-96-7 OR 156798-12-8 OR 8002-75-3 OR 61790-79-2 OR 61789-89-7 OR 8002-13-9 OR 84681-71-0 OR 8002-13-9 OR 120962-03-0 OR 8001-23-8 OR 8001-22-7 OR 91770-67-1 OR 8016-70-4 OR 8001-21-6 OR 84625-38-7 OR 8016-49-7 OR 97676-19-2 OR 225234-12-8 OR 72869-69-3 OR 923029-60-1 OR 8024-32-6 OR 91770-40-0 OR 91078-92-1 OR 8002-31-1 OR 192230-28-7 OR 8001-21-6 OR 68424-45-3 OR 8024-22-4 OR 8006-95-9 OR 68917-73-7 OR 68938-32-9 OR 394236-97-6 OR 68920-03-6 OR 194043-92-0 OR 225234-14-0 OR 70955-25-8 OR 8015-88-1 OR 8002-78-6 OR 8023-98-1 OR 85085-28-5) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERG*)

CAS No. - Coconut, Corn, Sesame - since 2005 - 28

(8001-31-8 OR 61788-47-7 OR 68938-18-8 OR 84836-98-6 OR 61789-30-8 OR 61789-31-9 OR 8001-30-7 OR 68308-50-9 OR 61789-23-9 OR 8008-74-0) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERG*)

CAS No. - Cottonseed, Palm, Peanut - since 1997 - 55

(8001-29-4 OR 68308-51-0 OR 68334-00-9 OR 8002-75-3 OR 8023-79-8 OR 8033-29-2 OR 68514-74-9 OR 68990-82-9 OR 84540-04-5 OR 8002-03-7 OR 68425-36-5 OR 91051-35-3) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERG*)

CAS No. – Rice – since 2003 - **4**

(68553-81-1 OR 84696-37-7 OR 93165-33-4) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERG*)

Terms - Coconut, Olive, Palm - 627

((COCOS OR COCONUT) AND SEED AND BUTTER) OR ((HYDROGENATED OR UNSAPONIFIABLE OR HUSK) AND (OLIVE OR OLEA) AND OIL) OR ((PALM OR ELAEIS) AND (BUTTER OR ACID)) OR (((ELAEIS AND OLEIFERA) OR PALM) AND KERNEL AND OIL) OR ((POTASSIUM OR SODIUM) AND (PALMATE OR KERNELATE)) AND (SENSITIZ* OR SENSITIS*OR IRRITA* OR ALLERGE* OR ALLERGI*)

Terms – Peanut, Rapeseed, Sesame - 17

(((POTASSIUM OR SODIUM) AND PEANUTATE) OR ((BRASSICA AND CAMPESTRIS) OR RAPESEED AND OIL AND

UNSAPONIFIABLE) OR ((POTASSIUM OR SODIUM) AND RAPESEEDATE) OR (RAPESEED AND ACID) OR ((HYDROGENATED OR UNSAPONIFIABLE) AND CANOLA AND OIL) OR (((SESAMUM AND INDICUM) OR SESAME) AND SEED AND BUTTER)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

Terms – Safflower, Sunflower, Pumpkin, Acai - 5

((HYDROGENATED AND SAFFLOWER AND SEED AND OIL) OR (SAFFLOWER AND ACID) OR ((POTASSIUM OR SODIUM) AND SAFFLOWERATE) OR (((HELAINTHUS AND ANNUUS) OR SUNFLOWER) AND (HYDROGENATED OR UNSAPONFIABLE) AND SEED AND OIL) OR (HYDROGENATED AND (PUMPKIN OR (CUCURBITA AND PEPO)) AND SEED AND OIL) OR ((ACAI OR (EUTERPE AND OLERACEA)) AND FRUIT AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

Terms – Watermelon, Black Currant, Currant, Borage, Evening Primrose - 2

(((WATERMELON OR (CITRULLUS AND VULGARIS)) AND SEED AND OIL) OR (HYDROGENATED AND ((BLACK AND CURRANT) OR (RIBES AND NIGRUM)) AND SEED AND OIL) OR (((RIBES AND RUBRUM) OR CURRANT) AND SEED AND OIL) OR ((BORAGE OR (BORAGO AND OFFICINALIS)) AND SEED AND OIL) OR (((EVENING AND PRIMROSE) OR (OENTHERA AND BIENNIS)) AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI OR ALLERGE*)

Terms - Amaranth, Apricot Kernel, Apple, Argan, Avocado - 6

(((AMARANTH OR (AMARANTHUS AND HYPOCHONDRIACUS)) AND SEED AND OIL) OR ((APRICOT OR (PRUNUS AND ARMENIACA)) AND (HYDROGENATED OR UNSAPONIFIABLE) AND KERNEL AND OIL) OR ((APPLE OR (PYRUS AND MALUS)) AND OIL) OR ((ARGAN OR (ARGANIA AND SPINOSA)) AND KERNEL AND OIL) OR (AVOCADO OR (PERSEA AND GRATISSIMA)) AND (BUTTER OR (HYDROGENATED AND OIL)) OR (SODIUM AND AVOCADOATE)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI OR ALLERGE*)

Terms – Babassu, Ben, Cocoa, Cohune, False Flax - 0

((BABASSU AND ACID) OR ((POTASSIUM OR SODIUM) AND BABASSUATE) OR (MORINGA AND (OLEIFERA OR PTERYGOSPERMA) AND SEED AND OIL) OR (SODIUM AND (COCOA OR (THEOBROMA AND CACAO)) AND BUTTERATE) OR ((COHUNE OR (ORGIBNYA AND COHUNE)) AND SEED AND OIL) OR (((FALSE AND FLAX) OR (CAMELINA AND SATIVA)) AND SEED AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

Terms – Grapeseed, Marula, Meadowfoam, Papaya, Perilla, Pequi, Prune/Plum - 2

((((GRAPE AND SEED) OR GRAPESEED OR (VITIS AND VINIFERA)) AND HYDROGENATED AND OIL) OR (SODIUM AND GRAPESEEDATE) OR ((MARULA OR (SCLEROCARYA AND BIRREA)) AND SEED AND OIL) OR ((MEADOWFOAM OR (LIMNANTHES AND ALBA)) AND SEED AND OIL)OR ((PAPAYA OR CARICA) AND SEED AND OIL) OR ((PERILLA OR OCYMOIDES) AND SEED AND OIL) OR ((PEQUI OR (CARYOCAR AND BRASILIENSE)) AND FRUIT AND OIL) OR ((PRUNE OR PLUM OR (PRUNUS AND DOMESTICA)) AND SEED AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*) Terms - Quinoa, Ramtil, Rice, Sacha, Tea Seed, Thistle - 2

(((QUINOA OR CHENOPODIUM) AND SEED AND OIL) OR ((RAMTIL OR (GUIZOTIA AND ABYSSINICA)) AND SEED AND OIL) OR ((RICE OR (ORYZA AND SATIVA)) AND ((HYDROGENATED AND BRAN) OR SEED) AND OIL) OR (((SACHA AND INCHI) OR (PLUKENETIA AND VOLUBILIS)) AND SEED AND OIL) OR (((TEA AND SEED) OR (CAMELLIA AND OLEIFERA)) AND SEED AND OIL) OR ((THISTLE OR (SILYBUM AND MARIANUM)) AND SEED AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

Terms – Tomato, Wheat, Kiwi, Baobab, Wild Celery, Burdock - 6

(((TOMATO OR (SOLANUM AND LYCOPERSICUM))AND (SEED OR FRUIT) AND OIL) OR ((WHEAT OR (TRITICUM AND VULGARE)) AND GERM AND (HYDROGENATED OR UNSAPONIFIABLE) AND OIL) OR ((KIWI OR (ACTINIDIA AND CHINENSIS)) AND SEED AND OIL) OR ((BAOBAB OR (ADANSONIA AND DIGITATA)) AND OIL) OR (((WILD AND CELERY) OR (ANGELICA AND ARCHANGELICA)) AND SEED AND OIL) OR ((BURDOCK OR (ARCTIUM AND LAPPA)) AND SEED AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

Terms – Murumuru, Kaya, Cupuacu, Broccoli, Oat Kernel - 3

(((MURUMURU OR ASTROCARYUM) AND SEED AND BUTTER) OR (SODIUM AND ASTROCARYUM AND MURUMURU) OR ((KAYA OR (TORREYA AND NUCIFERA)) AND SEED AND OIL) OR ((CAPUACU OR (THEOBROMA AND GRANDIFLORUM)) AND SODIUM AND SEEDATE) OR ((BROCCOLI OR (BRASSICA AND OLERACEA AND ITALICA)) AND SEED AND OIL) OR ((OAT OR (AVENA AND SATIVA)) AND KERNEL AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

Terms – Shea, Job's Tears, Cucumber, Carrot, Strawberry, Cranberry - 2

(((SHEA OR (BUTYROSPERMUM AND PARKII)) AND OIL) OR (((JOBS AND TEARS) OR (COIX AND LACRYMA AND JOBI)) AND SEED AND OIL) OR ((CUCUMER OR (CUCUMIS AND SATIVUS)) AND OIL) OR ((CARROT OR (DAUCUS AND CAROTA AND SATIVA)) AND SEED AND OIL) OR ((STRAWBERRY OR (FRAGARIA AND (ANANASSA OR CHILOENSIS OR VESCA OR VIRGINIANA))) AND SEED AND OIL) OR ((CRANBERRY OR (VACCINIUM AND MACROCARPON)) AND SEED AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

Terms – Peach Kernel, Raspberry, Mango, Sweet Cherry, Orange, Lime, Grapefruit - 3

(((PEACH OR (PRUNUS AND PERSICA)) AND HYDROGENATED AND KERNEL AND OIL) OR ((RASPBERRY OR (RUBUS AND IDAEUS)) AND SEED AND OIL) OR ((MANGO OR (MANGIFERA AND INDICA)) AND SEED AND (OIL OR BUTTER)) OR (SODIUM AND MANGOSEEDATE) OR (((SWEET AND CHERRY) OR (PRUNUS AND AVIUM)) AND SEED AND OIL) OR ((ORANGE OR (CITRUS AND AURANTIUM AND DULCIS)) AND SEED AND OIL) OR ((LIME OR (CITRUS AND AURANTIFOLIA)) AND SEED AND OIL) OR ((GRAPEFRUIT OR (CITRUS AND (GRANDIS OR PARADISI))) AND SEED AND OIL)) AND (SENSITIZ* OR SENSITIS* OR IRRITA* OR ALLERGI* OR ALLERGE*)

| Oils Data Profile* – March 2011 – Wri | ters, Christin | a Burnett and | Monice Fiur | ne (updated 1 | /21/2011) | | |
|---|------------------------|---------------|------------------------|---------------------------|---|---|----------------------|
| | Previously Reviewed | Reported Use | Chemical Properties | Fatty Acid Composition | Irritation/ Sensitization- Animal | Irritation/ Sensitization- Clinical | Ocular Irritation |
| Actinidia Chinensis (Kiwi) Seed Oil | | Х | Х | Х | | | |
| Adansonia Digitata Oil | | Х | Х | Х | | | |
| Adansonia Digitata Seed Oil | | | | | Х | Х | Х |
| Hydrogenated Adansonia Digitata Seed Oil | | 37 | N/ | 17 | | N/ | V |
| Alcurities Moluccana Seed Oil | | X | X | Х | | X | X |
| Alguritas Moluccanus Bakoly Seed Oil | | | | | | | |
| Amaranthus Hypochondriacus Seed Oil | | | | X | | | |
| Anacardium Occidentale (Cashew) Seed Oil | | Х | Х | X | | | |
| Arachis Hypogaea (Peanut) Oil | Х | Х | Х | Х | Х | Х | |
| Hydrogenated Peanut Oil | Х | Х | | | | | |
| Potassium Peanutate | | | | | | | |
| Sodium Peanutate | | | | | | | |
| Peanut Acid | X | | | V | | | |
| Arctium Lappa Seed Oil | | v | v | X | | v | |
| Hydrogenated Argania Spinosa Kernel Oil | | Λ | Λ | Λ | | Λ | |
| Astrocaryum Murumuru Seed Butter | | X | X | X | | X | |
| Sodium Astrocaryum Murumuruate | | X | | 1 | | ~~~~ | |
| Avena Sativa (Oat) Kernel Oil | | Х | Х | Х | | Х | |
| Bassia Butyracea Seed Butter | | | | Х | | | |
| Bassia Latifolia Seed Butter | | Х | | Х | | Х | |
| Bertholletia Excelsa Seed Oil | | Х | Х | Х | | | |
| Borago Officinalis Seed Oil | | X | X | X | | X | |
| Brassica Campestris (Rapeseed) Seed Oil | | Х | X | Х | | | |
| Brassica Campestris (Rapeseed) Oli Unsaponiliables | | v | v | v | | v | |
| Rapeseed Acid | | Λ | Λ | X | | Λ | |
| Potassium Rapeseedate | | | | 21 | | | |
| Sodium Rapeseedate | | | | | | | |
| Brassica Napus Seed Oil | | | | Х | | | |
| Brassica Oleracea Acephala Seed Oil | | | Х | Х | | | |
| Brassica Oleracea Italica (Broccoli) Seed Oil | | Х | Х | Х | | Х | |
| Butyrospermum Parkii (Shea) Oil | | X | X | X | | | |
| Butyrospermum Parkii (Shea) Butter | | X | X | Х | Х | X | Х |
| Butyrospermum Parkii (Snea) Butter Unsaponinables | | A V | | | | | |
| Camelina Sativa Seed Oil | | X | | Х | | X | |
| Hydrogenated Camelina Sativa Seed Oil | | | | | | | |
| Camellia Japonica Seed Oil | | Х | | Х | | | |
| Camellia Kissi Seed Oil | | Х | | Х | | | |
| Camellia Oleifera Seed Oil | | Х | Х | Х | | | |
| Hydrogenated Camellia Oleifera Seed Oil | | Х | | | | | |
| Camellia Sinensis Seed Oil | | Х | N/ | X | | X | |
| Canarium Indicum Seed Oil | | v | X | X | | v | |
| Canola Oli | | A X | Λ | Λ | | Λ | |
| Hydrogenated Canola Oil | | X | | | | | |
| Carica Papaya Seed Oil | | X | Х | Х | | | |
| Carthamus Tinctorius (Safflower) Seed Oil | Х | Х | Х | Х | Х | Х | |
| Hydrogenated Safflower Seed Oil | | | | | | | |
| Potassium Safflowerate | | | | | | | |
| Sodium Safflowerate | | | | | | | |
| Sattlower Acid | | | V | 37 | | | |
| Carya IIInoensis (Pecan) Seed Uil | | v | X | X | | v | |
| Chenopodium Quinoa Seed Oil | | A V | Λ | A V | | A Y | |
| Citrullus Lanatus (Watermelon) Seed Oil | | | X | A X | | | |
| Citrus Aurantifolia (Lime) Seed Oil | | 11 | X | X | | | |
| Citrus Aurantifolia (Lime) Seed Oil Unsaponifiables | | | | | | | |
| Hydrogenated Lime Seed Oil | | | | | | | |
| Hydrogenated Lime Seed Oil Unsaponifiables | | | | | | | |
| Citrus Aurantium Dulcis (Orange) Seed Oil | | | Х | Х | | | ļ |
| Citrus Aurantium Dulcis (Orange) Seed Oil Unsaponifiables | | | | | | | |

| Oils Data Profile* – March 2011 – Wri | ters, Christin | a Burnett and | l Monice Fiur | ne (updated 1 | 1/21/2011) | | |
|--|----------------------|---------------|----------------------|-------------------------|--------------------------------------|---------------------------------------|--------------------|
| | reviously eviewed | eported Use | hemical roperties | atty Acid omposition | ritation/ ensitization- .nimal | ritation/ ensitization- linical |)cular ritation |
| | P R | К | Р | ЧО | II S A | Ir S C | С |
| Hydrogenated Orange Seed Oil | | | | | | | |
| Hydrogenated Orange Seed Oil Unsaponifiables | | | | | | | |
| Citrus Grandis (Grapefruit) Seed Oil | | Х | | Х | | | |
| Citrus Grandis (Grapefruit) Seed Oil Unsaponifiables | | | | | | | |
| Hydrogenated Grapefruit Seed Oil | | | | | | | |
| Hydrogenated Grapetruit Seed Oil Unsaponifiables | | | | | | | |
| Citrus Paradisi (Graperruit) Seed Oil | | X | X | X | | | |
| Citrus Linion (Lenion) Seed On Cocos Nucifera (Cocoput) Oil | x | x | x | A X | x | x | x |
| Hydrogenated Coconut Oil | X | X | | Λ | X | X | X |
| Cocos Nucifera (Coconut) Seed Butter | | | | | | | |
| Magnesium Cocoate | X | Х | | | | | |
| Potassium Cocoate | X | Х | | | | Х | |
| Potassium Hydrogenated Cocoate | X | | 1 | | | | |
| Sodium Cocoate | X | Х | | | Х | | |
| Sodium Hydrogenated Cocoate | Х | | | | | | |
| Coconut Acid | X | Х | | | Х | | Х |
| Hydrogenated Coconut Acid | X | Х | | | | | |
| Coix Lacryma-Jobi (Job's Tears) Seed Oil | | | | Х | | | |
| Corylus Americana (Hazel) Seed Oil | X | Х | | Х | | | |
| Hydrogenated Hazelnut Oil | | •• | | | | | |
| Corylus Avellana (Hazel) Seed Oil | X | X | X | X | X | X | 37 |
| Crambe Abyssinica Seed Oil | | X | | X | X | X | Х |
| Cucumis Sanvus (Cucumber) Seed Oil | | A V | v | | | | |
| Hydrogenated Pumpkin Seed Oil | | Λ | Λ | Λ | | | |
| Cynara Cardunculus Seed Oil | | | | X | | | |
| Elaeis Guineensis (Palm) Oil | x | X | x | X | x | x | X |
| Elaeis Guineensis (Palm) Kernel Oil | X | X | X | X | | | |
| Hydrogenated Palm Kernel Oil | X | X | | | | | |
| Elaeis (Palm) Oil | | | | | | | |
| Hydrogenated Palm Oil | X | Х | | | | | Х |
| Elaeis Guineensis (Palm) Butter | | | | | | | |
| Palm Kernel Acid | | Х | | | | | |
| Potassium Palm Kernelate | | Х | | | | | |
| Potassium Palmate | | Х | | | | | |
| Potassium Hydrogenated Palmate | | | | | | | |
| Sodium Palm Kernelate | | X | | | | X | |
| Sodium Palmate | | X | | | | X | |
| Palm Acid | | v | 1 | | | | |
| Hydrogenated Palm Acid | | Λ | | | | | |
| Elaeis Oleifera Kernel Oil | | X | | X | | | |
| Euterpe Oleracea Fruit Oil | | X | | X | | Х | |
| Fragaria Ananassa (Strawberry) Seed Oil | | | Х | Х | | | Х |
| Fragaria Chiloensis (Strawberry) Seed Oil | | | | | | | |
| Fragaria Vesca (Strawberry) Seed Oil | | | | | | | |
| Fragaria Virginiana (Strawberry) Seed Oil | | | | | | | |
| Garcinia Indica Seed Butter | | X | X | Х | | Х | |
| Gevuina Avellana Oil | | X | | Х | | | |
| Genuina Avellana Seed Oil | | | | | | | |
| Glycine Soja (Soybean) Oil | | X | X | X | | V | |
| Hydrogeneted Soybean Oil | | X V | | | | Λ V | |
| Sov Acid | | Λ | | | | Λ | |
| Potassium Sovate | | | | | | | |
| Sodium Sovate | | | 1 | | | | |
| Gossypium Herbaceum (Cotton) Seed Oil | X | Х | X | Х | X | Х | |
| Hydrogenated Cottonseed Oil | X | X | | | | X | Х |
| Cottonseed Acid | Х | | | | | | |
| Guizotia Abyssinica Seed Oil | | | X | Х | | | |
| Helianthus Annuus (Sunflower) Seed Oil | | Х | Х | Х | | Х | |
| Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables | | Х | | | | Х | |
| Hydrogenated Sunflower Seed Oil | | Х | | | | | |

| Oils Data Profile* – March 2011 – Wri | ters, Christin | a Burnett and | Monice Fiur | ne (updated 1 | 1/21/2011) | | | | |
|--|------------------------|---------------|------------------------|---------------------------|---|---|----------------------|--|--|
| | Previously Reviewed | Reported Use | Chemical Properties | Fatty Acid Composition | Irritation/ Sensitization- Animal | Irritation/ Sensitization- Clinical | Ocular Irritation | | |
| Sunflower Seed Acid | | | | Х | | | | | |
| Hippophae Rhamnoides Oil | | Х | | | | | | | |
| Hippophae Rhamnoides Fruit Oil | | Х | Х | Х | | | | | |
| Hippophae Rhamnoides Seed Oil | | | X | Х | X | Х | X | | |
| Irvingia Gabonensis Kernel Butter | | X | X | X | | X | | | |
| Juglans Regia (Walnut) Seed Oil | | X | X | X | | v | | | |
| Limnantnes Alba (Meadowfoam) Seed Oil | | X | | X | | X | | | |
| Linum Usitatissimum (Linseed) Seed Oil | | x | x | x | | x | x | | |
| Linseed Acid | | X | A | Λ | | Α | Λ | | |
| Luffa Cylindrica Seed Oil | | X | | Х | | Х | | | |
| Lupinus Albus Seed Oil | | X | | X | | | | | |
| Lupinus Albus Oil Unsaponifiables | | | | | | | | | |
| Lycium Barbarum Seed Oil | | Х | | Х | | | | | |
| Macadamia Integrifolia Seed Oil | | Х | Х | Х | | | | | |
| Hydrogenated Macadamia Seed Oil | | | | | | | | | |
| Macadamia Ternifolia Seed Oil | | Х | Х | | | Х | | | |
| Sodium Macadamiaseedate | | | | | | | | | |
| Mangifera Indica (Mango) Seed Oil | | X | X | Х | | X | | | |
| Mangifera Indica (Mango) Seed Butter | | X | | | | X | | | |
| Sodium Mangoseedate | | X | | v | | | | | |
| Moringa Oleifera Seed Oil | | v | v | | | v | | | |
| Moringa Pterygosperma Seed Oil | | | Λ | Λ | | | | | |
| Oenothera Biennis (Evening Primrose) Oil | | X | X | X | | X | | | |
| Hydrogenated Evening Primrose Oil | | X | | | | | | | |
| Olea Europea (Olive) Fruit Oil. | | Х | Х | Х | Х | Х | Х | | |
| Olea Europaea (Olive) Oil Unsaponifiables | | Х | | | | | | | |
| Hydrogenated Olive Oil | | Х | | | | Х | | | |
| Hydrogenated Olive Oil Unsaponifiables | | Х | | | | Х | | | |
| Potassium Olivate | | Х | | | | | | | |
| Sodium Olivate | | X | | | | X | | | |
| Olea Europaea (Olive) Husk Oil | | | X | X | | | | | |
| Olive Acid | | v | | X | | | | | |
| Orbignya Conune Seed Oil | | | v | | | v | | | |
| Potassium Babassuate | | Λ | Λ | Λ | | Λ | | | |
| Sodium Babassuate | | x | | | | | | | |
| Babassu Acid | | | | | | | | | |
| Orbignya Speciosa Kernel Oil | | Х | | Х | | Х | | | |
| Oryza Sativa (Rice) Bran Oil | Х | Х | Х | Х | Х | Х | Х | | |
| Hydrogenated Rice Bran Oil | | | | | | | | | |
| Oryza Sativa (Rice) Germ Oil | Х | Х | | Х | Х | | Х | | |
| Oryza Sativa (Rice) Seed Oil | | | | | | | | | |
| Rice Bran Acid | X | | | | | | | | |
| Passiflora Edulis Seed Oil | | X | X | Х | | | | | |
| Hydrogenated Passiflora Edulis Seed Oil | | v | | V | | | | | |
| Perilla Ocymoldes Seed Oll Perilla Ocymoldes Seed Oll | v | | v | | | v | | | |
| Persea Gratissima (Avocado) Oil | Λ | | Λ | Λ | | Λ | | | |
| Hydrogenated Avocado Oil | | X | | | | | | | |
| Persea Gratissima (Avocado) Butter | х | X | | | | | | | |
| Sodium Avocadoate | | X | | | | | | | |
| Pistacia Vera Seed Oil | | X | X | Х | | | | | |
| Hydrogenated Pistachio Seed Oil | | | | | | | | | |
| Plukenetia Volubilis Seed Oil | | Х | Х | Х | | Х | | | |
| Prunus Amygdalus Dulcis (Sweet Almond) Oil | X | Х | Х | Х | X | Х | Х | | |
| Prunus Amygdalus Dulcis (Sweet Almond) Oil Unsaponifiables | | | | | | | | | |
| Hydrogenated Sweet Almond Oil | | Х | | | | | | | |
| Hydrogenated Sweet Almond Oil Unsaponifiables | | v | | | | | | | |
| Prunus Armeniaca (Apricot) Kernel Oil | | | v | v | | v | | | |
| Prinus Armeniaca (Apricot) Kernel Oil Unsaponifiables | | Λ | Λ | Λ | | Λ | | | |
| Hydrogenated Apricot Kernel Oil | | Х | | | | | | | |
| | | | | | | | | | |

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|---|------------------------|---------------|------------------------|---------------------------|---|---|----------------------|
| | Previously Reviewed | Reported Use | Chemical Properties | Fatty Acid Composition | Irritation/ Sensitization- Animal | Irritation/ Sensitization- Clinical | Ocular Irritation |
| Hydrogenated Apricot Kernel Oil Unsaponifiables | | | | | | | |
| Prunus Avium (Sweet Cherry) Seed Oil | | Х | Х | Х | | | |
| Prunus Domestica Seed Oil | | Х | Х | Х | | Х | |
| Prunus Persica (Peach) Kernel Oil | | Х | Х | Х | | Х | |
| Hydrogenated Peach Kernel Oil | | | | | | | |
| Punica Granatum Seed Oil | | Х | Х | Х | | | |
| Hydrogenated Punica Granatum Seed Oil | | | | | | | |
| Pyrus Malus (Apple) Seed Oil | | Х | Х | Х | | | |
| Ribes Nigrum (Black Currant) Seed Oil | | Х | Х | Х | | X | Х |
| Hydrogenated Black Currant Seed Oil | | | | | | | |
| Ribes Rubrum (Currant) Seed Oil | | | Х | Х | | | |
| Rosa Canina Fruit Oil | | Х | | | | Х | |
| Hydrogenated Rosa Canina Fruit Oil | | | | | | | |
| Rubus Chamaemorus Seed Oil | | Х | Х | Х | | X | Х |
| Rubus Idaeus (Raspberry) Seed Oil | | X | X | X | | X | |
| Hydrogenated Raspberry Seed Oil | | | | | | | |
| Schinziophyton Rautanenii Kernel Oil | | X | Х | Х | | | |
| Sclerocarva Birrea Seed Oil | | X | X | X | | | |
| Sesamum Indicum (Sesame) Seed Oil | x | X | | X | x | x | x |
| Sesamum Indicum (Sesame) Oil Unsaponifiables | X | X | | 24 | 21 | 21 | 24 |
| Hydrogenated Sesame Seed Oil | X | Δ | | | | | |
| Seconum Indicum (Secone) Seed Butter | Δ | | | | | | |
| Sodium Sesameseedate | x | | | | | | |
| Silvbum Marianum Seed Oil [Thistle] | Δ | x | | x | | | |
| Solanum I vcopersicum (Tomato) Fruit Oil | | X | | X | | | |
| Solanum Lycopersicum (Tomato) Seed Oil | | X | x | X | | x | |
| Theobroma Cacao (Cocoa) Seed Butter | | X | X | X | | X | |
| Sodium Cocoa Butterate | | | | 11 | | | |
| Theobroma Grandiflorum Seed Butter | | x | | X | | x | |
| Sodium Theobroma Grandiflorum Seedate | | | | | | | |
| Torreva Nucifera Seed Oil | | | | X | | | |
| Triticum Vulgare (Wheat) Germ Oil | x | x | | X | x | x | X |
| Triticum Aestivum (Wheat) Germ Oil | | | | | | | |
| Triticum Vulgare (Wheat) Germ Oil Unsaponifiables | | X | | | | | |
| Hydrogenated Wheat Germ Oil Unsaponifiables | | | | | | | |
| Hydrogenated Wheat Germ Oil | | | | | | | |
| Wheat Germ Acid | | Х | | | | | |
| Vaccinium Corymbosum (Blueberry) Seed Oil | | | X | X | | | |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | | Х | Х | Х | | X | |
| Hydrogenated Cranberry Seed Oil | | | | | | | |
| Vaccinium Myrtillus Seed Oil | | Х | X | X | | X | |
| Vaccinium Vitis-Idaea Seed Oil | | Х | Х | Х | | Х | Х |
| Vegetable (Olus) Oil | | Х | | X | | X | |
| Hydrogenated Vegetable Oil | | Х | | | | | |
| Vitis Vinifera (Grape) Seed Oil | | X | Х | Х | | Х | |
| Hydrogenated Grapeseed Oil | | Х | | | | Х | |
| Sodium Grapeseedate | | Х | | | | | |
| Zea Mays (Corn) Oil | Х | Х | Х | Х | Х | Х | Х |
| Zea Mays (Corn) Oil Unsaponifiables | Х | Х | | | | | |
| Zea Mays (Corn) Germ Oil | Х | Х | | | | | |
| Potassium Cornate | Х | | | | | | |
| Corn Acid | Х | | | | | | |

*"X" indicates that data were available in a category for the ingredient

with a tentative report.

DR. BERGFELD: May I ask a question as the chair? And that is, the read-across information, is there a need to do anything in the discussion regarding it?

DR. BELSITO: I think that should go in almost all discussions because there probably is not a single ingredient family we're looking at where we're not using read-across.

DR. BERGFELD: So, to reiterate, the read-across boilerplate specifics should go into the discussion for each of our ingredients? Okay. If there's no other discussion then I'll call for the vote. All those in favor indicate by raising your hand.

Unanimous. Thank you. The next large group is by Dr. Marks, the edible oils as stated here. Now the oils.

DR. MARKS: Well, there are 244 plant-derived oils. We felt that the title of this report could be changed to plant-derived fatty acid oils and in reviewing the data we had,

that we didn't have fatty acid composition. DR. MARKS: We had a discussion about whether the fatty acid composition was necessary or not, so we went one step back in saying is this really necessary, and finally deciding on the safety of those oils where it was missing. And if I capture the team's discussion, we felt it wasn't, but if the concern was the arachidonic acid level, say, that we don't know that level, we have rice as a prototype, that contains 5 percent arachidonic acid so we could craft the conclusion if we wanted or in the discussion, that it should be within that range of arachidonic acid.

So, I guess my question, that's longwinded, Don, in your team not having the fatty acid composition, what was your concern?

DR. BELSITO: Well, I think that we grappled with that too since we had gone out -since we are on record saying that the data for arachidonic acid are insufficient and yet here we have rice germ oil that we've already approved containing 5 percent arachidonic acid. However, a we felt we could move forward with a tentative report with a conclusion that these fatty acid oils are safe. And that's a move that these are safe.

DR. BERGFELD: Is there a second or discussion? Don?

DR. BELSITO: Well, there were, by our count, approximately 10, I believe, particular plant-derived oils for which we didn't have fatty acid composition, and we were going to go insufficient on those until we knew what the composition was. And I can read them if you want. Arctium lappa seed oil, the Citrus paradisi, which is a different cultivar of the grapefruit than the one we had information on, the Coix lacryma-jobi seed oil, the three different cultivars of strawberry, Fragaria chiloensis, Fragaria vesca, Fragaria virginiana, for which we didn't have amino acid -- or fatty acid composition. Lycium barbarum seed oil, Morinda citrifolia seed oil, Orbignya speciosa kernel oil, Schinziophyton rautanenii kernel oil, and those were the ones

particular ingredient is used only at 1 percent in cosmetic products, so you're looking at 1 percent of 5 percent, and then you're looking at whether, in fact -- how much free arachidonic acid will be broken down from these fatty esters. So we felt that that was low.

I think if we have, you know, concentration information, which I don't think we have on the ones where we're missing data, that would be helpful. But you have ingredients like shea butter that are used up to 96 percent, so our concentration range that we're going out in the present practices reviews is theoretically up to 100 percent. And if we don't know the arachidonic acid concentration, we could be saying it's okay to use a product up to -- with 8 percent potential arachidonic acid. So, that was our level of discomfort in not knowing concentration of use for these particular vegetable derived fatty acids and knowing the amino acid composition.

DR. SLAGA: You're referring to free

arachidonic acid, right?

DR. BELSITO: Well, we don't know how much they'll be broken down, but, yeah, I mean, when we -- the arachidonic acid report was specifically looking at arachidonic acid and we were unable to reach a safe as used conclusion. So, you know, I think that we can finesse the fact that we've approved rice bran germ oil and we can, you know, finesse the 8 percent in the Spyro-whatever, but I find it hard to finesse when we don't know what the concentration of use is going to be for these plant-derived oils and we don't know what the arachidonic acid --

DR. SLAGA: What level of arachidonic acid would you be uncomfortable with?

DR. BELSITO: We never reached that, that's the problem, otherwise it would have been a safe in used up to conclusion.

DR. BERGFELD: Dan?

DR. LIEBLER: One point that I'd like to raise is that as you look at the fatty acid composition tables for all of these oils, one of the things that struck me is how unusual

DR. SLAGA: Are we asking them for a reevaluation of the rice?

DR. BERGFELD: Don?

DR. BELSITO: There's a -- we were told yesterday there's a book that's been published by FDA that we haven't been able to get our hands on that may well provide all of the information we need, and also it was recommended that we double-check against that book the reported arachidonic acid concentrations in the rice bran oil and the Spyro-whatever.

DR. BERGFELD: Any other comment?

DR. MARKS: Well, I think despite the level -- if the level of arachidonic acid is truly what is published in rice, we still came to a conclusion in spite of that that the -- that rice was safe with all the biologic endpoints. So I'm -- I heard you earlier say, Don, about somewhere around 5 percent we can finesse it. I think for rice it's fine. I think it's the other oils that if we don't have all the data we've got to say it's similar to rice so we feel it's safe. arachidonate is in the plant oils and, you know, with that many analyses, you begin to wonder about the possibility of false positive results. And it may be that indeed rice does produce arachidonate incorporated into, you know, glyceride, esters, and so forth, and it also may be that that measurement, that determination is incorrect, and I would like to see, if possible, whether or not there are any additional analyses available on rice oils because it looks like such an outlier.

Now, it might be biologically true, but it looks like such an outlier that it may be incorrect and it may essentially, you know, obviate this entire discussion.

DR. BERGFELD: Jim?

DR. MARKS: I hear the Belsito team's rationale and I am willing to withdraw the move that I made earlier that we have a tentative report with all of them safe, and amend that to say, all of them safe with the exception of the ten oils you mentioned and the insufficient need is the fatty acid composition.

DR. BERGFELD: Did you also include in the discussion from one side or the other use -concentrations of use that you wanted to know? DR. BELSITO: Right. Yeah, well, I mean, if we don't get --DR. BERGFELD: Fatty acid. DR. BELSITO: -- fatty acid composition, then we -- I mean, if they tell us it's being used at 0.5 percent, we may be less concerned because obviously it's not going to be 100 percent arachidonic acid. In fact, it will probably, at least based upon all the information we see, be negative or negligible. DR. BERGFELD: So, your request really is for composition and concentrations of use? DR. BELSITO: That would help. DR. BERGFELD: Yeah. And that is your

DR. MARKS: So, the motion was that we move forward to issue a tentative report, that 234 of these oils are safe and the other 10 we need

the fatty acid composition --

motion?

| | | | | | BELSITO | TEAM | - | December | 2010 | |
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| DR. BELSITO: Or concentration of use. |
|--|
| DR. MARKS: Or concentration of use, |
| yes. |
| DR. BERGFELD: Is there a second? |
| DR. BELSITO: Second. |
| DR. BERGFELD: Any further discussion? |
| Seeing none, I'll call the question. All those in |
| favor of safe? Thank you. Unanimous. |
| Then moving on to the last group or |
| last item in this particular grouping, Disperse |
| Blue. Dr. Belsito? |
| DR. BELSITO: So, I'm missing my notes |
| here, but anyway, we decided to go ahead and begin |
| opening this report to look at new data, including |
| IARC data, and also because of concerns that this |
| material is no longer permitted in Europe, and so |
| a full document has been prepared. And with the |
| help of many people, including most recently Ivan |
| Boyer, risk assessments were prepared under |
| various scenarios. And regarding that, it appears |
| that our original conclusion that these could |
| this material could be safely used up to 1 percent |

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| 1 | to print it. The main printer at the Council |
| 2 | sometimes will go down, which normally captures |
| 3 | color. But if we go to a different printer |
| 4 | DR. LIEBLER: But if it was printed to |
| 5 | a.pdf, the color should come through. |
| 6 | MS. FIUME: Unless we run out of color |
| 7 | ink. Yeah, it should have at least |
| 8 | DR. LIEBLER: It should have come |
| 9 | through. It's all in the computer. |
| 10 | MS. FIUME: I don't know because some |
| 11 | are and some aren't, and they're generally scanned |
| 12 | the same way so I don't know what happened. |
| 13 | DR. LIEBLER: It wasn't editable on |
| 14 | the.pdf, so I think it was scanned in. |
| 15 | DR. BELSITO: So moving on to the next |
| 16 | super group, Edible Oils, and I guess |
| 17 | MS. FIUME: I did have two corrections |
| 18 | on the composition that I did not capture that are |
| 19 | now marked by hand. These aren't updated on data |
| 20 | profile for as of Thursday afternoon are |
| 21 | captured on here. |
| 22 | DR. BELSITO: Great. Okay. I guess the |
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| 1 | mean, even it they're hydrogenated. |
|----|--|
| 2 | DR. EISENMANN: You have fatty acids in |
| 3 | there and also unsaponifiables. |
| 4 | DR. LIEBLER: So I guess the question is |
| 5 | does the oils, does the term "oils," encompass all |
| 6 | that stuff already? That's what I'm wondering. |
| 7 | DR. BELSITO: Well, but I like it |
| 8 | because it implies that it's not just the pressed |
| 9 | processed oil from a plant, that there are things |
| LO | other than the pure oil. So I titled it just to |
| L1 | say "plant-derived oils," I would think that |
| 12 | that's all that you're dealing with. |
| 3 | DR. LIEBLER: Okay. |
| 14 | DR. BELSITO: Okay, so we're getting rid |
| 15 | of "edible," which is good. And then we have this |
| 16 | large group of oils to look at. And then what |
| 17 | Monice has supplied is sort of a read across here |
| 18 | in terms of what we previously reviewed and more |
| 19 | importantly those that we have the fatty acid |
| 20 | composition for. And basically we're going for |
| 21 | safety based upon knowing what the fatty acid |
| 22 | composition of these was. So the issue is where |

| 1 | first order of business and Carol had raised |
|----|--|
| 2 | this as the title of this report are all of |
| 3 | these oils truly edible? |
| 4 | DR. EISENMANN: Especially I think |
| 5 | besides oils with high Oryza acid. The FDA limits |
| 6 | food use of Grape seed oil if it contains less |
| 7 | than 2 percent. And even Rapeseed oil with less |
| 8 | than 2 percent Oryza acid is not permitted for use |
| 9 | in infant formulas. |
| 10 | DR. BELSITO: Right. So I guess the |
| 11 | title of the report I would recommend would just |
| 12 | be "Plant-derived oils and their derivatives as |
| 13 | used in cosmetic products." Is everyone happy |
| 14 | with that? |
| 15 | DR. LIEBLER: So are there any |
| 16 | derivatives that aren't the oils? In other words |
| 17 | is "and derivatives" redundant? |
| 18 | DR. BELSITO: Well, there |
| 19 | MS. FIUME: They're hydrogenated. |
| 20 | DR. BELSITO: Right, but they're |
| 21 | MS. FIUME: They're soft. |

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DR. LIEBLER: They're still oils, I

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| 1 | we don't have it, are we going "insufficient" with |
|----|--|
| 2 | these or in some cases we have like well, I |
| 3 | guess we have it for all of those but we'll |
| 4 | have it for the oil, but not for hydrogenated or |
| 5 | salts, and I think we can probably include those. |
| 6 | So we need to look at that, but the other issue is |
| 7 | I want to go to that Table is that a couple |
| 8 | of these have arachidonic acid, which we reviewed |
| 9 | back in the '90s and the data for that were |
| 10 | insufficient. And interestingly, one that has |
| 11 | arachidonic acid we now say is "safe as used" and |
| 12 | that's one of the rice ingredients. So it creates |
| 13 | a little bit of a dilemma here as to where we're |
| 14 | going. |
| 15 | DR. SNYDER: What about Ron? Wasn't it |
| 16 | Ron who argued that these are not as a free acid, |
| 17 | but a part of |
| 18 | DR. LIEBLER: I think that's the key |
| 19 | point. I'd noticed that one when I was looking |
| 20 | over the discussion from the last meeting. Tom |
| 21 | Slaga actually mentioned that these acids, the |
| 22 | acids that we're talking about here in this case, |

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| 1 | be some literature on it. I don't know if there | |
| 2 | is any. But what this the practical | |
| 3 | implication of this is even for an oil that | |
| 4 | contains arachidonic acid, it looks at 5 percent | |
| 5 | There are actually two oils in our report that | |
| 6 | contain arachidonic acid in the Table. The rice | |
| 7 | oil and the | |
| 8 | DR. BELSITO: Sclerocarya. | |
| 9 | DR. LIEBLER: Sclerocarya, right, which | |
| 10 | was about percent listed. Those are the only | |
| 11 | ones. And if they release a small fraction of the | |
| 12 | arachidonic acid in the skin by lipase activity, I | |
| 13 | think that would realistically be a very small | |
| 14 | amount. And for that reason, any concern I would | |
| 15 | have would be considerably reduced because I think | |
| 16 | the issue with the arachidonic acid report was | |
| 17 | that was a report on the free acid, and there was | |
| 18 | insufficient data on the free acid issues in | |
| 19 | cosmetics products? | |
| 20 | DR. BELSITO: It had to do with | |
| 21 | metabolic effects in the skin and the potential to | |
| 22 | increase, I think, risks of | |

| 1 | arachidonic acid, are actually part of a |
|----|--|
| 2 | triglyceride. They're all esterified. I don't |
| 3 | know that we know whether any of these have free |
| 4 | arachidonic acid, but they're all esterified in |
| 5 | triglycerides. It's possible that a small amount |
| 6 | of the triglycerides would be de- esterified in |
| 7 | the skin if there was any dermal penetration. I |
| 8 | don't think we know enough to know what fraction |
| 9 | of the applied dose would be de-esterified, and |
| 10 | there are multiple positions on these |
| 11 | triglycerides. I know that lipases display |
| 12 | selectivity for doing that, the esterification |
| 13 | reaction, but I would expect that the fraction |
| 14 | that would be de-esterified would be relatively |
| 15 | low. So we would probably be talking about an |
| 16 | unknown, but probably very low, amount of any of |
| 17 | the fatty acids being released from the |
| 18 | triglycerides in the skin. And there may be a |
| 19 | literature on triglyceride metabolism, which would |
| 20 | be by lipases, not the phospholipases because they |
| 21 | won't act on these compounds, but |
| 22 | triglyceride-type lipases in the skin. There may |

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| 1 | DR. KLAASSEN: Proliferation. | |
| 2 | DR. BELSITO: Proliferation, cancers. | |
| 3 | DR. LIEBLER: Right. | |
| 4 | DR. BELSITO: And we never got that | |
| 5 | data. | |
| 6 | DR. LIEBLER: So I think it's actually | |
| 7 | not as big an issue as we thought it might be in | |
| 8 | our discussion previously, at least from a | |
| 9 | chemical and metabolic perspective. I would | |
| 10 | expect it to be minor. | |
| 11 | DR. BELSITO: I think that we're going | |
| 12 | to have to be very clear in a discussion as to w | ny |
| 13 | we think that because otherwise we look very | |
| 14 | foolish coming out and saying these are safe and | |
| 15 | they have arachidonic acid, and we've said | |
| 16 | arachidonic acid previously was insufficient. | |
| 17 | DR. LIEBLER: Right. No, I agree, and | |
| 18 | so I think what we really need to do is to look | |
| 19 | and see what we can find in the literature on | |
| 20 | lipase activity in the skin. | |
| 21 | DR. BERGFELD: On hair-bearing surface | 5 |
| 22 | there's a lot of lipases in there. | |

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| 1 | DR. LIEBLER: Right. I'm sure they're |
|----|---|
| 2 | there, and the real question, I guess, is how much |
| 3 | arachidonic would be released from a typical |
| 4 | applied dose of a rice oil- containing product. |
| 5 | DR. BELSITO: Well, I guess one way of |
| 6 | doing that is we have Oryza sativa Rice Germ oil. |
| 7 | It has about 5.48 percent. We can go back to the |
| 8 | rice report and see what kind of information we |
| 9 | have on dermal effects of the germ oil, whether in |
| 10 | fact it's there. |
| 11 | MS. FIUME: When you say dermal |
| 12 | irritation, sensitization, do you mean |
| 13 | DR. BELSITO: Anything dermal whether it |
| 14 | would help us further argue that the small amounts |
| 15 | of arachidonic acid in these two plant oils are |
| 16 | not issues because specifically we're already |
| 17 | signed off on germ oil. So it would be nice to |
| 18 | know what data we signed off on. |
| 19 | DR. BERGFELD: So are you wanting to do |
| 20 | that today because the books are in the |
| 21 | DR. BELSITO: Well, I mean, this is |
| 22 | still Pink. I think, I mean, we can still go |
| | Anderson Court Reporting 703-519-7180 www.andersonreporting.net |

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| 1 | DR. BELSITO: Well, why don't we mull |
| 2 | that over and look at the new Table that Monice |
| 3 | has handed out and look at the ones that we don't |
| 4 | have any fatty acid composition and decide where |
| 5 | we want to go with those. |
| 6 | DR. SNYDER: Is it still 23 that we |
| 7 | don't have or did we reduce it with this Table? |
| 8 | Do we know? |
| 9 | DR. LIEBLER: It's been reduced quite a |
| 10 | bit. |
| 11 | DR. SNYDER: It went from 46 to they |
| 12 | cut it in half, but I don't know. This new data |
| 13 | refines it even further? I see we've added some |
| 14 | in there by hand it looks like. |
| 15 | MS. FIUME: Those were I believe they |
| 16 | were already there. |
| 17 | DR. SNYDER: Okay. |
| 18 | DR. LIEBLER: If you go by families, |
| 19 | which are in the hard copy that we have, if |
| 20 | there's an "X" in the fourth column from the left $% \left[{{\left[{{X_{\rm{T}}} \right]}_{\rm{T}}}} \right]$ |
| 21 | for each colored group, either white or colored |
| 22 | group, then I consider that evidence that we have |

| think it's something that we can do today. That rice report was huge. But we can just look at what information we had in the report on the germ oil because I remember I mean, if you remember, that report was years in the making and we're looking for data on all the individual ingredients and compositions of the husk and the whatever. MS. FIUME: Dr. Belsito, on page 8, it summarizes the data from that report that was specifically rice bran and/or rice germ to the animal. DR. BELSITO: Okay. So it looks like we had irritation sensitization, phototoxicity, and photosensitization. MS. FIUME: On those specific ingredients? DR. BELSITO: Right. On those ingredients. MS. FIUME: And then in Table 7, which is Panel Book 95, this is a very brief summary of saying it was found clinically for Rice Bran oil. | 1 | forward and always reassess the data. I don't |
|--|----|--|
| 3 rice report was huge. But we can just look at 4 what information we had in the report on the germ 5 oil because I remember I mean, if you remember, 6 that report was years in the making and we're 7 looking for data on all the individual ingredients 8 and compositions of the husk and the whatever. 9 MS. FIUME: Dr. Belsito, on page 8, it 10 summarizes the data from that report that was 11 specifically rice bran and/or rice germ to the 12 animal. 13 DR. BELSITO: Okay. So it looks like we 14 had irritation sensitization, phototoxicity, and 15 photosensitization. 16 MS. FIUME: On those specific 17 ingredients? 18 DR. BELSITO: Right. On those 19 ingredients. 20 MS. FIUME: And then in Table 7, which 21 is Panel Book 95, this is a very brief summary of 22 saying it was found clinically for Rice Bran oil. | 2 | think it's something that we can do today. That |
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| 22 saying it was found clinically for Rice Bran oil. | 21 | is Panel Book 95, this is a very brief summary of |
| | 22 | saying it was found clinically for Rice Bran oil. |

CIR Meeting day 1 of 2 (Breakout Session) Page: 60 data on the content for that family. And the only 1 2 one that I think we have missing is on the last 3 page, page 4 of the Table, which is the Schinziophyton. It's probably about a third of 4 the way down. It's a blue color -- Schinziophyton 5 Rautanenii kernel oil. And I think that's in four 6 7 loco, isn't it? Just kidding. DR. BELSITO: Well, we also on a 8 different species of Grapefruit seed oil, Citrus 9 10 Paradisi, as opposed to Citrus Grandis. We don't know fatty acid composition. And then Coix 11 12 Lacryma-Jobi, Job's Tears seed oil. DR. LIEBLER: On page 3, Orbignya 13 14 Speciosa kernel oil. Page 3. 15 DR. BELSITO: And then a couple of 16 different cultivars of Strawberry Fragaria. We 17 have that stuff, but we don't have Chiloensis, the 18 Vesca, and the Virginiana. The question is are 19 they going to significantly differ? And then 20 Lycium Barbarum seed oil, Morinda Citrifolia. 21 DR. EISENMANN: Monice, have you had an 22 opportunity to look at that FDA book edited by

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| 1 | Daniel Firestone? |
|----|---|
| 2 | MS. FIUME: We're in the process of |
| 3 | trying to get it. |
| 4 | DR. EISENMANN: It had a compilation of |
| 5 | it's titled Physical and Chemical |
| 6 | Characteristics of Oils, Fats, and Waxes. It was |
| 7 | published in 2006. Somebody sent me one page of |
| 8 | it and it goes through all kinds of sources and |
| 9 | summarizes the data. It's available on the |
| 10 | Internet and it looks like it has a fairly |
| 11 | comprehensive number of oils in it. It might be |
| 12 | another source for some of these. |
| 13 | DR. BERGFELD: I thought that the actual |
| 14 | botanical ingredients to read across were very |
| 15 | hard because of the source of the material varying |
| 16 | so much in the plant. Don? |
| 17 | DR. BELSITO: I'm sorry, I was trying to |
| 18 | finish |
| 19 | DR. BERGFELD: I said to read across |
| 20 | these oils are probably very hard because of the |
| 21 | source of each part of the plant in which the oil |
| 22 | is derived gives you a different composition. So |
| | Anderson Court Reporting 703-519-7180 www.andersonreporting.net |

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| 1 | 1 Arctium Lappa seed oil. Okay. So on the f | irst |
| 2 | 2 page, we have that one. When we go into the | e |
| 3 | 3 second page, the issue is we don't have it : | Eor |
| 4 | 4 Citrus Paradisi, which is a different cultiv | var |
| 5 | 5 than Citrus Grandis for which we have it. | This is |
| 6 | 6 a Grapefruit seed oil. So do we need it? 2 | Are we |
| 5 | 7 assuming Grapefruit is Grapefruit? I mean, | I know |
| 6 | 8 that when we did other species, there were a | some |
| 9 | 9 significant differences. Was it Kava where | there |
| 10 | 0 were differences in composition depending up | oon the |
| 11 | 1 or lavender? | |
| 12 | 2 DR. BRESLAWEC: There are differen | nces |
| 13 | 3 and there's variability, depending where the | ey're |
| 14 | 4 grown. | |
| 15 | 5 DR. BELSITO: Right. | |
| 16 | 6 DR. BRESLAWEC: There's a pretty 1 | oroad |
| 17 | 7 range of variability. | |
| 18 | 8 DR. LIEBLER: I would say that we | just |
| 19 | 9 don't know, and we don't have any basis for | |
| 20 | 0 knowing. I could probably sit here and try | and |
| 21 | convince you that the cultivars of strawber: | ries |
| 22 | 2 all make strawberries so the oils ought to 1 | ce |
| | | |

| 1 | $\ensuremath{I'm}$ not sure \ensuremath{I} can understand all these blue marks |
|----|--|
| 2 | and the lack of data in the fatty acid, realizing |
| 3 | the fatty acid composition is key, at least was |
| 4 | determined to be key. If they are lacking |
| 5 | information on fatty acid contact, we probably |
| 6 | cannot deal with them. Is that correct? |
| 7 | DR. BELSITO: Well, um |
| 8 | DR. BERGFELD: Because I don't think you |
| 9 | can read across. |
| 10 | DR. BELSITO: No. Yeah, I mean, it I |
| 11 | think that within a family, for instance, all the |
| 12 | peanut ingredients, even though we don't have |
| 13 | fatty acid composition on all of them as Dan said |
| 14 | we can. The ones where we don't, I mean I think |
| 15 | we'll have to go insufficient data. So that's why |
| 16 | I wanted to look at this Table first and decide |
| 17 | where are our needs. And looking at the first |
| 18 | page, I think all of the groups are covered unless |
| 19 | I'm missing something. |
| 20 | MS. FIUME: The Arctium Lappa seed? |
| 21 | It's right under the peanut. |
| 22 | DR. BELSITO: Oh, yeah, thank you. |

| CIR | Meeting day 1 of 2 (Breakout Session) P | age: 64 |
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| 1 | pretty similar, but frankly I'd be making it up. | |
| 2 | I mean, either we have the data or we don't have | |
| 3 | b the data. | |
| 4 | DR. BELSITO: Okay. So then for Citrus | |
| 5 | Paradisi Grapefruit seed oil, that would be | |
| 6 | insufficient. But then and this may beg the | |
| 7 | question stuff that is labeled as Hydrogenated | |
| 8 | Grapefruit seed oil and Unsaponifiables, are we | |
| 9 | 9 sure that comes from Citrus Grandis? Because if | |
| 10 |) we're not, then that falls into the insufficient. | |
| 11 | MS. FIUME: I will check the dictionary | |
| 12 | and see if it says that's where they're coming | |
| 13 | from. | |
| 14 | DR. LIEBLER: I would suggest with the | |
| 15 | by hydrogenated oils, it becomes less of a concern | |
| 16 | because you're taking out all the double bonds and | ł |
| 17 | hydrogenating these. So you're essentially making | 1 |
| 18 | just a series of long chained fatty acids that are | 9 |
| 19 | fully saturated. I think our main concerns about | |
| 20 |) the fatty acids have to do with those that have | |
| 21 | either a large number of double bonds, i.e., | |
| 22 | 2 arachidonic acid. | |

concerned about?

acid, for example.

DR. KLAASSEN: I think that's kind of

DR. KLAASSEN: I don't think so either.

DR. LIEBLER: I mean, arachidonic is

DR. LIEBLER: So that's an activity

DR. BELSITO: Okay. So then what Dan's

what it boils down to. I mean is there any fatty acid other than Aracadonic acid that we might be

DR. LIEBLER: I don't think so.

special in large because there are a lot of $\ensuremath{\mathsf{--}}$

there are enzymes that metabolize it to highly

bioactive products, and there are receptors for

DR. KLAASSEN: Exactly.

arachidonic has over and above any other fatty

acids that are highly oxidizable like Linolenic

suggesting is when it's hydrogenated, we really

essentially don't care about it, and it can be

moved into the discussion as to why we are less

concerned about hydrogenated. Okay. So we are

saying Citrus Paradisi, though, in the fatty acid. Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

those highly bioactive products.

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| 1 | Coix Lacryma-Jobi Job's Tears seed oil we need. |
|----|---|
| 2 | The different cultivars of Strawberry Fragaria for |
| 3 | which we don't have chemical composition. But the |
| 4 | Chiloensis, the Vesca, and the Virginiana would be |
| 5 | insufficient. Lycium Barbarum seed oil, Morinda |
| 6 | Citrifolia seed oil, Orbygna Speciosa kernel oil |
| 7 | this looks like schizophrenia Schinziophyton |
| 8 | kernel oil. And then I guess the last question |
| 9 | is, moving down to the V's, vegetable oil? |
| 10 | MS. FIUME: We received information |
| 11 | saying what it can be a combination of, but the |
| 12 | exact composition wasn't given. So that's why ${\tt I}$ |
| 13 | left that open. |
| 14 | DR. LIEBLER: I thought I'd looked at |
| 15 | that yesterday, and I noticed that on that list |
| 16 | those were all ingredients for which we had fatty |
| 17 | acid composition. So I think we can include |
| 18 | vegetable oil. It's okay. |
| 19 | DR. BELSITO: Okay. So then we have |
| 20 | one, two, three, four, five, six, seven, eight, |
| 21 | nine, ten that should be going insufficient for |
| 22 | lack of fatty acid composition. |
| | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 |

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| CIR Me | eeting day 1 of 2 (Breakout Session) Page: 6 | 7 CIR |
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| 1 | DR. EISENMANN: So I have to clarify the | 1 |
| 2 | memo. I wrote it, and I was trying to include | 2 |
| 3 | ones that are highly used. And my understanding | 3 |
| 4 | is they use the term vegetable oil for blends of | 4 |
| 5 | oils. So I think it would be better rather than | 5 |
| 6 | to refer to the memo to say you're okay with the | 6 |
| 7 | blend as long as it's one of those with a | 7 |
| 8 | composition known. Is there any other limitation? | 8 |
| 9 | DR. LIEBLER: Right. | 9 |
| 10 | DR. EISENMANN: Is that what I'm | 10 |
| 11 | hearing? | 11 |
| 12 | DR. LIEBLER: Yeah. | 12 |
| 13 | DR. EISENMANN: I mean I don't want to | 13 |
| 14 | limit to the list. I was just using those as an | 14 |
| 15 | example of what the blend may contain. | 15 |
| 16 | DR. LIEBLER: So you're saying vegetable | 16 |
| 17 | oil is sort of the scrapple of oils? | 17 |
| 18 | DR. EISENMANN: Well, no, no, it's | 18 |
| 19 | some of I want a petrolatum-like material | 19 |
| 20 | that's made of vegetable oil so we can put | 20 |
| 21 | together a blend for that. | 21 |
| 22 | DR. BELSITO: Uh-huh, and that blend | 22 |

| R | Meeting day 1 of 2 (Breakout Session) Page: 6 |
|----|--|
| 1 | could consist of any of these oils? Is that what |
| 2 | you're saying? Or is it specific for what Monice |
| 3 | told us it could be? |
| 4 | DR. EISENMANN: No, I'm saying it's |
| 5 | specific for any of the oils. I don't know what |
| 6 | I don't know if Dennis, you can I mean he's |
| 7 | from Presperse. |
| 8 | MR. LABA: I think if the fatty acid |
| 9 | composition is known, those would be the compounds |
| 0 | that would be used for those blends. So I think |
| .1 | you're on the right track with that. |
| .2 | DR. BRESLAWEC: Could you identify |
| .3 | yourself, please? |
| 4 | MR. LABA: Dennis Laba with Presperse. |
| .5 | We represent a company that does a number of oils. |
| 6 | DR. BELSITO: Okay. |
| .7 | DR. LIEBLER: So we can use the we |
| 8 | can include the vegetable oils as long as they are |
| 9 | composed of oils for which the fatty acid |
| 0 | composition is known. |
| 1 | DR. BELSITO: Yeah. |
| 2 | DR. LIEBLER: Are you okay with that? |

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| 1 | DR. BELSITO: Okay, so before we get |
|----|---|
| 2 | back to the go ahead. |
| 3 | MS. FIUME: Before we go past, can I go |
| 4 | back to two points just so I have it correct? |
| 5 | First, Dr. Liebler, when you were talking about |
| 6 | the lipase, did you say it was specifically to |
| 7 | triglyceride in the skin? |
| 8 | DR. LIEBLER: Well |
| 9 | MS. FIUME: Look for published |
| 10 | literature? |
| 11 | DR. LIEBLER: Yeah, I would look for |
| 12 | literature on triglyceride lipases. Most of the |
| 13 | fatty acids in these oils are going to be in the |
| 14 | form of triglycerides, mono-, di-, and |
| 15 | triglycerides. So I would look for glycerol |
| 16 | lipases, and I would exclude phospholipases |
| 17 | because they operate on phospholipids and these |
| 18 | are not none of these phospholipids. |
| 19 | MS. FIUME: And the second question is |
| 20 | for so I know for the discussion the ten |
| 21 | that are insufficient because of composition, |
| 22 | should I leave it because the major concern is not |
| | Anderson Court Reporting 703-519-7180 www.andersonreporting.net |

CIR Meeting day 1 of 2 (Breakout Session) Page: 71 1 derived from a seed on the list? MS. FIUME: I'd have to --2 DR. SNYDER: That goes to Wilma's 3 4 question about what constituent of the plant is 5 actually what we are talking about for the oils. So are there some oils that are derived from 6 7 non-seed? DR. BRESLAWEC: Olive oil. And for 8 Adansonia there's the Digitata oil and then 9 10 there's the Digitata seed oil. 11 DR. SNYDER: But is that one in the same? It may just be a --12 13 DR. BRESLAWEC: It's two separate and 14 unique names. 15 DR. BELSITO: Yeah, but the more 16 important one is olive oil, but it's not from the seed. It is from the seed? 17 18 DR. SNYDER: Because -- I mean, I think 19 the refined is --20 DR. EISENMANN: No, it's from the fruit. 21 It depends on how --22 DR. SNYDER: Well, the fruit or the

| 1 | knowing the arachidonic acid component or just |
|----|---|
| 2 | because it's insufficient because we don't know |
| 3 | anything about it? |
| 4 | DR. BELSITO: We don't have the |
| 5 | composition. We're not going to do Aracadonic |
| 6 | acid. We'll get back to that at the end and how |
| 7 | we're going to finesse that in the discussion. |
| 8 | MS. FIUME: So just lack of information? |
| 9 | DR. BELSITO: Lack of information as to |
| 10 | what's in them. |
| 11 | DR. SNYDER: So can I go back to a |
| 12 | little bit to what someone Wilma kind of |
| 13 | mentioned? So the title of this would a better |
| 14 | title for this be "plant-derived refined oils or |
| 15 | derived from seeds?" |
| 16 | DR. BELSITO: Well, seeds are |
| 17 | DR. SNYDER: Because aren't these all |
| 18 | derived would that help us? I mean, if we more |
| 19 | specifically refined |
| 20 | DR. BELSITO: Well, seeds are parts of |
| 21 | plants. I mean I would just say the plants |
| 22 | DR. SNYDER: Where in here is it not |
| | Anderson Court Deporting 703 E10 7190 set andersonreporting not |

CIR Meeting day 1 of 2 (Breakout Session) Page: 72 seed, yeah. I mean, I'm okay with that. 1 DR. LIEBLER: Fruit contains the seed, 2 but it's from the fruit. You throw away the seed 3 4 before you make the olive oil. 5 DR. SNYDER: I mean from seeds or fruit. DR. BELSITO: I would just say 6 7 "plant-derived oils." I think we're trying to --DR. SNYDER: I mean, they are refined 8 oils. They're not -- I mean they're --9 10 DR. BERGFELD: We could put it in the 11 discussion because it's majorly from the fruit or 12 the seed. Because the leaves and the stem and the 13 other composite parts from rice we know have 14 totally different compositions. 15 DR. SNYDER: So we can more specifically 16 define that in the -- under the Method of 17 Manufacture or under the Source or something here, 18 Processing. 19 DR. BELSITO: You have a comment? 20 MR. RE: Yeah. Tom Re from L'Oreal. 21 Can't you define the class as "fatty acid oils?" 22 It's closed to things like essential oils, which

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| 1 | are very different in composition. |
|----|---|
| 2 | DR. EISENMANN: Triglyceride oils or |
| 3 | something. |
| 4 | DR. BELSITO: Okay, so then |
| 5 | "plant-derived fatty oils." |
| 6 | DR. EISENMANN: Fatty acid oils. |
| 7 | DR. BELSITO: Fatty acid oils, okay. |
| 8 | DR. LIEBLER: "Plant-derived fatty acid |
| 9 | oils and their derivatives." |
| 10 | DR. BELSITO: "As used in cosmetics." |
| 11 | That's good. |
| 12 | DR. LIEBLER: And we did that without a |
| 13 | fruit or a seed. |
| 14 | DR. SNYDER: But I think we need to |
| 15 | capture that in the Processing about what the $\ensuremath{\mathtt{I}}$ |
| 16 | mean, we're not talking about roots and leaves and |
| 17 | all those other constituents. $\ \mbox{I}$ mean, we need to |
| 18 | capture some of that. |
| 19 | DR. BELSITO: Okay. So in the |
| 20 | Processing, mention that basically most of these |
| 21 | are coming from seeds, some of them from the |
| 22 | fruit, but none of them from the plant, the root, |
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| 1 | it as an impurity. So I was recommending | |
| 2 | DR. BELSITO: Possible impurities? | |
| 3 | DR. SNYDER: Well, bringing all that | |
| 4 | impurity stuff together because we have the | |
| 5 | impurities-related Aflatoxin, the protein | |
| 6 | constituent for allergic reaction, so if we can | |
| 7 | bring that altogether in one impurity paragraph, | |
| 8 | it would succinctly deal with all the impurities | |
| 9 | except now it's spread over four paragraphs. So | |
| 10 | I've got a lot written here for that. | |
| 11 | DR. BELSITO: Other? | |
| 12 | DR. BERGFELD: I want to make another | |
| 13 | statement for clarity. I think that after you | |
| 14 | clean up the Summary as suggested, that when you | |
| 15 | come to the discussion, you have to declare what | |
| 16 | you're actually talking about, what group of oil: | 5 |
| 17 | you're actually talking about. | |
| 18 | DR. SNYDER: We go straight into | |
| 19 | impurities so we need to cover that. | |
| 20 | DR. BERGFELD: Fatty acid plant oils. | |
| 21 | DR. SNYDER: So based upon the previous | 3 |
| 22 | discussion, I would more thoroughly define what | |
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| 2 DR. SNYDER: Other constituents of the 3 plant. 4 DR. BELSITO: Okay, before we get back 5 to the arachidonic acid issue, are there issues 6 for this report? 7 DR. SNYDER: Glycidol. Glycidol 8 content? 9 DR. BELSITO: Yeah, I thought that was 10 handled somewhere in the discussion, that we 11 expected them to be free of Glycidol. 12 DR. SNYDER: But we considered that an 13 impurity, right? So I had on page 46 of the book, 14 I mean we don't have a discussion except for at 15 the end. 16 DR. BELSITO: Yeah we do, page 15, last 17 paragraph, deals with Glycidol. "Panel considered 18 safety of Glycidol and Glycidol fatty acids and 19 refined vegetable oils." 20 DR. SNYDER: Okay, it mentions it there, | 1 | the stem, the husk. |
|--|----|---|
| 3 plant. 4 DR. BELSITO: Okay, before we get back 5 to the arachidonic acid issue, are there issues 6 for this report? 7 DR. SNYDER: Glycidol. Glycidol 8 content? 9 DR. BELSITO: Yeah, I thought that was 10 handled somewhere in the discussion, that we 11 expected them to be free of Glycidol. 12 DR. SNYDER: But we considered that an 13 impurity, right? So I had on page 46 of the book, 14 I mean we don't have a discussion except for at 15 the end. 16 DR. BELSITO: Yeah we do, page 15, last 17 paragraph, deals with Glycidol. "Panel considered 18 safety of Glycidol and Glycidol fatty acids and 19 refined vegetable oils." 20 DR. SNYDER: Okay, it mentions it there, | 2 | DR. SNYDER: Other constituents of the |
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| refined vegetable oils." DR. SNYDER: Okay, it mentions it there, | 18 | safety of Glycidol and Glycidol fatty acids and |
| 20 DR. SNYDER: Okay, it mentions it there, | 19 | refined vegetable oils." |
| | 20 | DR. SNYDER: Okay, it mentions it there, |
| 21 but on the previous page it's mentioned as a | 21 | but on the previous page it's mentioned as a |
| 22 possible constituent and that's basically stating | 22 | possible constituent and that's basically stating |

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|-----|--|---------|
| 1 | we're evaluating here. | |
| 2 | MS. FIUME: And before you go to | |
| 3 | arachidonic acid, I just want to be sure you're | |
| 4 | aware the next time you see it, I've created two | |
| 5 | new Tables that came in Wave 2 so the text on th | e |
| 6 | dermal animal dermal irritation and ocular | |
| 7 | irritation will be out and just replaced like | |
| 8 | everything else with the Table. | |
| 9 | DR. LIEBLER: Yeah, I looked at those | |
| 10 | Tables. They're very helpful. | |
| 11 | DR. BELSITO: Okay. Anything else? S | 0 |
| 12 | do you want to take a 10-minute break before we | |
| 13 | get to the arachidonic acid discussion on these? | |
| 14 | Good. Wilma, did you have something else on | |
| 15 | these? | |
| 16 | DR. BERGFELD: Well, I was just going | to |
| 17 | say maybe we could deal with page 16 and make su | re |
| 18 | that whatever we've said that is on that list th | at |
| 19 | that's complete. You said "the chemical | |
| 20 | composition specifically fatty acid profiles. | |
| 21 | Oils in which those data were not given in the | |
| 22 | report are needed." I don't want to go back and | |

| CIR Meeting day 1 of 2 (Breakout Session) | CI | R | Meeting | day | 1 | of | 2 | (Breakout | Session) |
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|---|----|---|---------|-----|---|----|---|-----------|----------|

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| 1 | check all those, but you just put in ten. |
|----|---|
| 2 | DR. BELSITO: Right. |
| 3 | DR. BERGFELD: So those should go in. |
| 4 | DR. BELSITO: Right. So that list would |
| 5 | go away and the new list would just be the ten |
| 6 | that we just |
| 7 | DR. BRESLAWEC: Can I raise the |
| 8 | possibility that between now and when you see the |
| 9 | report next time |
| 10 | DR. BELSITO: If you get the |
| 11 | composition, yeah. |
| 12 | DR. KLAASSEN: Sure. That'd be great. |
| 13 | DR. BELSITO: It's the sense of the |
| 14 | Panel that that's what's holding any of these |
| 15 | ingredients up, so if we get a composition for one |
| 16 | of the group, they're off that list. |
| 17 | Okay, so it's about 10:20, is that |
| 18 | right? 10:18, be back at 10:30? |
| 19 | (Recess) |
| 20 | DR. BELSITO: Okay. We all back? So |
| 21 | the last little bit that we need to figure out |
| 22 | with these oils is how we're going to handle the |
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|-----|---|---------|
| 1 | DR. LIEBLER: So I would like to raise | |
| 2 | the possibility that the measurement reported of | |
| 3 | arachidonic acid in rice oil, it looked like such | |
| 4 | an outlier that I think it would be worth trying | |
| 5 | to verify that. If there has only been one | |
| 6 | analysis of the fatty acid composition of rice oi | 1 |
| 7 | in the history of mankind, than it's worth gettin | g |
| 8 | another one. | |
| 9 | DR. EISENMANN: That compilation might | |
| 10 | be a good source for because, you know, the FD | A |
| 11 | worker who has compiled a bunch of | |
| 12 | DR. LIEBLER: It's such an outlier. It | |
| 13 | makes me wonder whether it's actually true, and i | f |
| 14 | it isn't, then we're tying ourselves in knots ove | r |
| 15 | something that's a false positive measurement. | |
| 16 | DR. BELSITO: Okay. | |
| 17 | DR. SNYDER: Rice rice never dies. | |
| 18 | DR. BELSITO: Right. Assuming it's not | |
| 19 | | |
| 20 | DR. LIEBLER: Not an outlier. | |
| 21 | DR. BELSITO: not an outlier, then w | re |
| 22 | still have to look at potentially dealing with th | e |
| | Indexage Count Deporting 702 E10 7100 (FEE) and exagencementing not | |

| 1 | arachidonic acid content in the two that contain |
|----|---|
| 2 | in, and particularly pressing is the fact, no pun |
| 3 | intended, that we've already approved one of them |
| 4 | as safe as used that now is said to be tainted. |
| 5 | DR. EISENMANN: You might also want to |
| 6 | look at the mink oil report. |
| 7 | DR. BELSITO: The mink oil. |
| 8 | DR. EISENMANN: I don't know if there is |
| 9 | any arachidonic in mink oil or not, but I've heard |
| 10 | that animal oil is more likely to contain it than |
| 11 | plants. |
| 12 | DR. BELSITO: Probably. Okay. So |
| 13 | Carol's point was to check the mink oil report and |
| 14 | see if though we probably didn't have |
| 15 | information on the composition. So the |
| 16 | DR. EISENMANN: I don't remember. |
| 17 | DR. BELSITO: the next step would be |
| 18 | to check that report to see if we can get |
| 19 | composition information from mink oil. And also |
| 20 | we've been asked to speak up because we are being |
| 21 | recorded, so make sure you keep your voices up |
| 22 | when you want to be heard and low when you don't. |
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|---------|---|---------|
| 1 | sclerocarya birrea seed oil and any of these othe | er |
| 2 | oils that contain arachidonic acid. | |
| 3 | So, Dan, your point was to look at | |
| 4 | lipase activity in the skin. | |
| 5 | DR. LIEBLER: To see if there's any | |
| 6 | information on lipase activity, to see if that | |
| 7 | would help us interpret the likelihood of | |
| 8 | generating significant quantities of free | |
| 9 | arachidonic acid from these esterified forms. | |
| 10 | DR. BELSITO: And Wilma says there will | L |
| 11 | be high levels in the follicles. So if that, in | |
| 12 | fact, is borne out we would (inaudible). | |
| 13 | DR. LIEBLER: So it's possible Wilma | a |
| 14 | says high Wilma is not here, but Wilma says | |
| 15 | high levels of lipase activity in follicles. The | at |
| 16 | doesn't necessarily mean there will be a high rat | te |
| 17 | of desertification of arachidonic acid or any | |
| 18 | other fatty acids from these lipases. | |
| 19 | My experience on this comes from work : | in |
| 20 | our lab that was done on vitamin E esters in mous | se |
| 21 | skin, and when alpha-tocopheryl or vitamin ${\ensuremath{E}}$ | |
| 22 | acetate or alpha-tocopheryl acetate is applied to | C |
| | | |

look up the original work.

the mouse skin, we were interested in whether or

not the acetate ester was hydrolyzed to yield the

And we were able to document enzymatic hydrolysis,

We actually did assays for substrates of

So I realize that does not necessarily

free tocopheryl, which is the antioxidant form.

but it was a very small fraction of the applied dose. It was like less than a percent. I could

esterases and were able to document enzymatic

activity, and, although it was true that there is

activity there, the amount of conversion of the

diglycerides that contain arachidonic acid, but

that example leads me to raise the question of

lipase activity, whether or not there is a

suspect we won't find the data that will

whether or not -- even though there is detectable

significant amount of arachidonic released. And I

unambiguously answer the question, but I think

it's important to keep in mind that even though Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

applied material was vanishingly small.

apply to the triglycerides or mono and

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| 1 | you do technically have these enzymatic |
|----|---|
| 2 | activities, when you're applying relatively |
| 3 | whooping doses of substrates, it's impossible to |
| 4 | convert very much of the applied substrate to |
| 5 | products. |
| 6 | I don't know if that actually really |
| 7 | helps us deal with the question in our review, but |
| 8 | at least it provides the perspective that I bring |
| 9 | to this, which is that the amount that's released |
| 10 | is likely to be very small. |
| 11 | DR. BELSITO: Well, I guess I'm just |
| 12 | looking for why am I not seeing Oryza sativa in |
| 13 | the frequency and concentrations of use. |
| 14 | MS. FIUME: It might be is that under |
| 15 | the previously reviewed ingredients. |
| 16 | DR. BELSITO: Oh, maybe. Because the |
| 17 | other argument is the sclerocarya birrea seed oil |
| 18 | leave on and rinse off is 1 percent is what is |
| 19 | listed as the concentration. So another argument |
| 20 | would be here you're using it at 1 percent, and it |
| 21 | has at most 8 percent arachidonic acid. And on |
| 22 | top of it the panels believes that the amount of |
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CIR Meeting day 1 of 2 (Breakout Session) Page: 83 release of free arachidonic acid would be low and 1 that the amounts would be trivial and, therefore, 2 not of concern. 3 4 Oryza -- what is that 5B release? 5 MS. FIUME: Yes. It's Panel Book 84. The germ oil is used at most at 3 percent, but the 6 7 rice brand use up to 78 percent in them. 8 DR. BELSITO: But it's the germ oil that has it 9 10 MS. FLUME: That has it. Okay. So 11 that's used up to 3 percent. DR. BELSITO: So, you know, that could 12 13 be part of our argument that the concentration of 14 use of these reported to have arachidonic acid is 15 low to begin with. 16 DR. LIEBLER: I agree. 17 DR. BELSITO: So the germ oil is 3 18 percent you said? 19 MS. FLUME: Mm-hmm. 20 DR. BELSITO: And then the sclero is 1 21 percent. Anything else we can argue as to why 22 we're not concerned about --

don't have fatty acid composition, if you know their concentration of use and it is low, then are 3 4 they still -- should they still be placed on the 5 insufficient list, if arachidonic acid is your only concern. Or because you don't have 6 7 composition, they should just be (inaudible). 8 DR. BELSITO: Well, I mean, we already heard that the only fatty acid we'd be concerned 9 10 about is arachidonic acid. We heard that from Dan 11 and Curt. 12 DR. LIEBLER: I think it's two different 13 issues. One is not having composition. In my 14 view, that sort of violates our obligation to have 15 diligence on these ingredients. Not evening knowing the composition in my view is 16 17 unsatisfactory to begin with. So even if it's a 18 small amount, it's still unknown.

MS. FLUME: If the ingredients that you

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19 DR. BELSITO: But we've had -- we have 20 instances all the time where there is information 21 lacking, and it's the view of the panel that 2.2 they're too big. They wouldn't be absorbed and,

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21 22 Page: 85

| you know, the long chain alkyl groups just did | 1 | DR. BELSITO: I mean, just, again, this |
|--|----|--|
| that. | 2 | is pink. We still have this book that was written |
| So if your real concern is we know these | 3 | that we need to consult. It may answer all of the |
| are going to be fatty acids, and if your only | 4 | questions we have. Certainly |
| concern with a fatty acid would be arachidonic | 5 | DR. BERGFELD: So are you going to go as |
| acid, and we're already making the argument that | 6 | insufficient right now, or what |
| we're okay with the sclerocarya because it's low | 7 | DR. BELSITO: Yeah. I mean, I would |
| level, you know, we could say in the discussion | 8 | just do insufficient for all the ones we don't |
| that the panel noted the absence of the fatty acid | 9 | have chemical composition, and then we can always |
| composition for the following. However, current | 10 | |
| concentration of use is low, and the one fatty | 11 | DR. KLAASSEN: See what happens. |
| acid we would be concerned about, arachidonic | 12 | DR. BELSITO: Yeah. We can always |
| acid, would you know, we've already made that | 13 | finesse it later. I mean, it's still pink. |
| argument. | 14 | DR. SNYDER: (Inaudible) finessed. |
| DR. BRESLAWEC: Do we have | 15 | DR. BELSITO: Right. So basically the |
| concentrations of use on all the ones that are | 16 | 10 without chemical composition, insufficient, the |
| missing? | 17 | others, sufficient. It would be nice if the next |
| MS. FLUME: It would be bring the list | 18 | time we see it I know normally discussions |
| down to six. We have it on four of that. | 19 | often times aren't made until does this go |
| DR. BELSITO: Right. | 20 | blue? |
| MS. FLUME: We haven't looked at what | 21 | DR. BRESLAWEC: This will go blue. |
| they are. | 22 | DR. BELSITO: Okay. So there will be a |

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| 1 | discussion. So the discussion on arachidonic |
| 2 | acid, we'll see what the other panel says, but |
| 3 | basically the two that have it, low use lipase |
| 4 | concentration, unlikely to be significant |
| 5 | conversion to free arachidonic acid to any |
| 6 | significant extent. |
| 7 | DR. LIEBLER: I would since rice oil |
| 8 | seems like it's more of a major ingredient, I |
| 9 | would really like to see if we could verify |
| 10 | whether or not that reported arachidonic acid |
| 11 | measurement is correct or not, if we can get |
| 12 | additional data on that. So even though we |
| 13 | presumably have composition on the rice oils, I'm $% \mathcal{T}_{\mathrm{r}}$ |
| 14 | a little suspicious of it, and I'd like to see if |
| 15 | there are other measurements that have been made. |
| 16 | DR. BELSITO: Well, I think that when |
| 17 | and if we are able to get that book from FDA. |
| 18 | DR. EISENMANN: The FDA (inaudible). |
| 19 | MS. FLUME: We've contacted the author |
| 20 | for the book |
| 21 | DR. BELSITO: Okay. |
| 22 | MS. FLUME: and we're just waiting to |
| _ | Anderson Court Reporting 703-519-7180 www.andersonreporting.net |

| DR. | BELSITO: | Okay. | So | there | will | be | a |
|-----|----------|-------|----|-------|------|----|---|
| | | | | | | | |

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CIR Meeting day 1 of 2 (Breakout Session) Page: 88 1 get it. DR. BELSITO: So it's expected that we 2 will get it. So, I mean, I would cross-reference 3 even what we already have here to see that if it's 4 5 in general agreement. 6 Anything else on the now non-edible 7 fatty acid-containing oils? Okay. DR. BERGFELD: I just have one technical 8 question. So we have a bunch that are safe, and 9 10 we have the insufficient list. So what we've got 11 is a blue with partial safe and partial 12 insufficient (inaudible). DR. BELSITO: Right. And the general 13 14 agreement, Wilma, was that if the writer gets information on the composition, the ones that we 15 16 said were insufficient, we'll move over to 17 sufficient. 18 Okay. CAPB. Okay. At the August 19 meeting we finally issued a tentative report that 20 the 31 ingredients are safe in cosmetics when 21 formulated to be non-sensitizing based on 22 quantitative risk assessment. Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

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|---------|---|
| 1 | move to issue the I should say presumably the |
| æ | Belsito Team will move to issue a final amended |
| 3 | report on these compounds as safe, and then I will |
| 4 | bring up the potential editorial change in the |
| 5 | conclusion, and that should engender a likely |
| 6 | discussion, just as we've had now. |
| 7 | Next, should we do the edible oils |
| 8 | before or after lunch? What time is it? |
| 9 | SPEAKER: It's only 11:15. |
| 10 | DR. MARKS: Oh, it's only 11:15. We |
| 11 | definitely want to know that what we're eating for |
| 12 | lunch is safe. |
| 13 | (Laughter) |
| 14 | DR. HILL: Let me just add on that last |
| 15 | discussion. I'm sorry that I'm sort of grasping |
| 16 | on how to interject this, that my impression was |
| 17 | from the QRA that because it was actually building |
| 18 | in a margin of safety and that sensitization was a |
| 19 | proxy for any other biological activity for that |
| 20 | amidoamine impurity that that was a comfort level |
| 21 | in moving this forward associated with that, and, |
| 22 | so, I mean, if you were using a different betaine |
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|----------|---|-------|-----|
| 1 | to have the DMAPA. But you're building in an | | |
| 2 | additional margin of safety on the amidoamine by | 7 | |
| 3 | virtue of doing a Q, R, and A, which effectively \ensuremath{S} | 7 | |
| 4 | removes any other concerns with biological | | |
| 5 | activities of those impurities. So, based on | | |
| 6 | that, I was comfortable moving forward. I'm not | : | |
| 7 | sure if you remove the Q, R, and A that you'd co | ome | |
| 8 | to the same place. So, I'll have to think about | : | |
| 9 | that again between now and tomorrow, but I don't | 2 | |
| 10 | really plan on saying anything on that score | | |
| 11 | tomorrow, but I'm just tossing that out there as | за | |
| 12 | counterargument for removing it, even though I \underline{c} | get | |
| 13 | the simplicity argument. | | |
| 14 | DR. MARKS: Okay. Ron Shank? | | |
| 15 | DR. SHANK: If you already have | | |
| 16 | empirical human skin sensitization data, I don't | 2 | |
| 17 | see any need to do a QRA. We seem to keep losin | ıg | |
| 18 | sight of the fact that there have been 13 studie | es, | |
| 19 | human skin sensitization studies on formulation | | |
| 20 | that are in the book, and every one of them is | | |
| 21 | entirely negative. The only positive is when yo | bu | |
| 22 | have single ingredient studies, but on the | | |

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| 1 | besides cocamidopropyl betaine, the sensitization |
|----|--|
| 2 | studies would have to be there and then you will |
| 3 | use a Q, R, and A that will build in an additional $% \left({{\left[{{R_{\rm{s}}} \right]}_{\rm{s}}}} \right)$ |
| 4 | margin of safety beyond what's there. So, I'm not |
| 5 | sure if you remove that language that you aren't |
| 6 | removing sort of a layer of safety, a margin |
| 7 | that's built in that. So, I'll just throw that |
| 8 | out there between now and tomorrow because ${\tt I'm}$ not |
| 9 | likely to say anything tomorrow. |
| 10 | DR. MARKS: Ron, I'm not quite sure what |
| 11 | I think this is the read across. Is that what |
| 12 | you're talking about? That the data we have now, |
| 13 | if we do a quantitative risk assessment on some of |
| 14 | these related betaines? |
| 15 | DR. HILL: I think to do the Q, R, and |
| 16 | A, you still need some original sensitization data |
| 17 | on the particular component if I'm understanding |
| 18 | correctly. But with the Q, R, and A, you're also |
| 19 | building in an additional margin on particularly |
| 20 | that amidoamine. |
| 21 | DR. MARKS: Right. |
| 22 | MR. HILL: Because all of them are going |

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|----------|--|
| 1 | formulations, they've all been negative. If you |
| 2 | have a formulization and you have negative human |
| 3 | skin sensitization, why would you have to do a |
| 4 | QRA? |
| 5 | DR. HILL: But my understanding of the |
| 6 | reason of why those were negative is because, |
| 7 | essentially, there was tight quality control on |
| 8 | the ingredients that were used to generate the |
| 9 | sensitization studies. They didn't use the lower |
| 10 | grade material; they used prime grade stuff in |
| 11 | order to do the sensitization studies. And, so, |
| 12 | the point was if you source from a different |
| 13 | vendor which happened to have a higher |
| 14 | concentration of that amidoamine impurity or |
| 15 | you're going off the map and you're not using |
| 16 | cocamidopropyl betaine, then you might expect a |
| 17 | different result, and that was my distillation, |
| 18 | the impression I got from the Q, R, and $\ensuremath{\mathtt{A}}$ |
| 19 | presentation last time. |
| 20 | DR. MARKS: Correct. I think that's |
| 21 | exactly correct, which would be addressed by a |
| 22 | RIPT on whatever that compound is or product is, $\ensuremath{\mathtt{I}}$ |
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| 1 | should say. |
|----|---|
| 2 | DR. HILL: I mean, I guess I just need |
| 3 | to ask myself the question between now and |
| 4 | tomorrow is: Without the margin of safety that's |
| 5 | billed in with the Q, R, and A, is there a margin |
| 6 | of safety that is lost for any other potential |
| 7 | biological activities of those amides because I |
| 8 | still had that remaining concern. |
| 9 | DR. BAILEY: I would only add to that |
| 10 | because I thought about that same issue, is the |
| 11 | language in the discussion is really quite crisp |
| 12 | and concise, and I think it captures it quite well |
| 13 | there. So, as long as it's captured in the |
| 14 | discussion, then I feel comfortable taking it out. |
| 15 | Not so much because I think it should come out, |
| 16 | but I think that the precedent of putting it in |
| 17 | there and your point about having real RIPT needs |
| 18 | to be encompassed within the language. So, I |
| 19 | think by doing that, we met those requirements. |
| 20 | DR. HILL: Okay. |
| 21 | DR. SHANK: Here's one question on |
| 22 | interpretation of a conclusion as it stands now. |
| L | Anderson Court Reporting 703-519-7180 www.andersonreporting.net |

| 2 | ingredients and formulations for which they |
|----|---|
| 3 | already have empirical data on human skin |
| 4 | sensitization? |
| 5 | DR. HILL: Good point. |
| 6 | DR. SHANK: I don't think that's what we |
| 7 | intend. |
| 8 | DR. HILL: Good point. |
| 9 | DR. SHANK: Yes. |
| 10 | DR. ANDERSEN: Well, that was what I |
| 11 | intended when I wrote it. But now that you say |
| 12 | it, it doesn't seem to make a whole heck of a lot |
| 13 | of sense. |
| 14 | DR. MARKS: So, I'm going to bring up |
| 15 | that editorial comment tomorrow, and then, Ron |
| 16 | Shank, I think your reasoning is absolutely crisp |
| 17 | and clear, and I don't need to speak for you in |
| 18 | this case. So, I may ask you, Ron, to bring that |
| 19 | forward. |
| 20 | DR. SHANK: What time does this come up? |
| 21 | Is this going to be 8:00 in the morning? |
| 22 | DR. MARKS: Ron, if you feel |
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| | |

For industry, will they have to do a QRA on

uncomfortable, I'll bring it up. 1 2 DR. SHANK: Thank you. 3 DR. MARKS: Yes, I will discuss it, and 4 you can add on. 5 Any other comments about --6 DR. ANDERSEN: 8:20. 7 DR. MARKS: So, I feel comfortable, Ron, talking about the sensitization issue on this. 8 9 And as you recall, I'll probably close with this, 10 is there was an attempt to try and quantitate how 11 much of the impurities could be acceptable in the 12 final product, and there was a great deal of 13 difficulty trying to arrive at a conclusion concerning the quantification of the impurities. 14 Okay, next, the edible oils. And as you 15 16 recall in the August meeting, we reviewed reports 17 on edible vegetable and nut oils and decided to 18 combine all of these into one report. And we 19 wanted to have data on fatty acid profiles and 20 we're at the point now where we have a combined 21 report. We have some extra data here, and I guess 22 the question is: Can we move on with a tentative Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

| 1 | report of safe, and if we do that, which of these |
|----|---|
| 2 | ingredients are we going to delete, if any? |
| 3 | And there was some concern when you look |
| 4 | at the minutes on CIR Panel Book page 24. Let me |
| 5 | see. Concerning arachidonic acid and then also |
| 6 | how much arachidonic acid these might contain in |
| 7 | the decahexanoic acid and the linoleic acids. And |
| 8 | is that still a concern? |
| 9 | So, I'll open it up for discussion. |
| 10 | DR. SLAGA: I'd like to make a comment. |
| 11 | The tables and everything, the way it's put |
| 12 | together, we discussed that you did a great job of |
| 13 | making a complicated topic much easier to review. |
| 14 | DR. MARKS: Just to put this in |
| 15 | perspective, there are 244 at the latest count, $\ensuremath{\mathtt{I}}$ |
| 16 | think. So, is this the largest number of |
| 17 | ingredients we've seen grouped together? |
| 18 | DR. BAILEY: I sure hope so. (Laughter) |
| 19 | DR. SLAGA: I hope I don't see any more. |
| 20 | (Laughter) |
| 21 | DR. HILL: I think Alkyl PEG beats it, |
| 22 | but I'm not sure. |

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|---|----------|
| DR. BAILEY: Yes. | |
| DR. ANDERSEN: (Off Mike) | |
| DR. MARKS: Which one was that, Ron? | |
| DR. HILL: Alkyl PEG Ethers. | |
| DR. MARKS: Oh, okay. | |
| DR. ANDERSEN: But you can eat them. | |
| DR. MARKS: So, moving forward, I get a | |
| lot of positives in terms of now the formatting o | f |
| the tables. Are there any ingredients in here | |
| that we should not? Say there's, and we had a | |
| Wave 2 information to lots of data there, all the | |
| skin sensitization data, as expected, was fine | |
| from any irritation and sensitization point of | |
| view. | |
| Ron, Ron, Tom, anything that you want t | 0 |
| delete among this 244? Shall we make it 242? | |
| DR. HILL: The individual composition | |
| files, I didn't crosscheck. They're not in the | |
| Wave 2. There were individual compositions that | |
| came in even after the Wave 2, correct? It was | |
| about, what 12, 17 more? They're not part of the | |
| Wave 2, right? There were individual files on th | e |

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CIR Meeting day 1 of 2 (Main Session) Page: 112 1 DR. HILL: Oh. 2 MS. FIUME: Was updated with the composition. 3 DR. HILL: But those individual 4 5 composition files that were like 17 are already rolled into --6 7 MS. FIUME: Right. The only thing that 8 would not then --DR. HILL: It looked like to me there 9 10 were some that I thought came in after the Wave 2 11 file was put together, but I wasn't sure. MS. FIUME: Luffa. Let me find my 12 13 original table. 14 DR. HILL: I guess I could go out to the 15 Web Site and look at the file (inaudible) dates. 16 MS. FIUME: Luffa Cylindrica came in 17 Thursday, I believe, of last week, Wednesday or 18 Thursday. And then there were a few of the acids 19 like olive acid. There were four acids that were 20 added that were already part of the main 21 ingredient that came in on Thursday. 22 DR. HILL: Okay.

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| 1 | Web Site. |
|----|--|
| 2 | MS. FIUME: Yes, in the table that was |
| 3 | sent on Wave 2, that is updated to include |
| 4 | anything that had come in by Wave 2. |
| 5 | DR. HILL: Right. But there were more, |
| 6 | right? |
| 7 | MS. FIUME: There were a few more. It |
| 8 | was things like olive acid, and the data profile |
| 9 | that I just handed out, is complete as of Thursday |
| 10 | afternoon, and we hadn't received any new |
| 11 | composition information since then. |
| 12 | So, if you're looking at a quick list of |
| 13 | what is and is not in there, column four is as |
| 14 | much up to date as we have. |
| 15 | DR. MARKS: Monice, you're talking about |
| 16 | the fatty acid composition in column four? |
| 17 | DR. HILL: Yes, sir. |
| 18 | MS. FIUME: Yes. |
| 19 | DR. HILL: But for the actual |
| 20 | compositions, we have to look at the files. |
| 21 | MS. FIUME: The table is updated. The |
| 22 | table that came in Wave 2. |

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CIR Meeting day 1 of 2 (Main Session) Page: 113 1 MS. FIUME: They were rapeseed acid, 2 sunflower seed acid, olive acid, and caryocar brasiliense fruit oil. Those specifications and 3 4 composition came in on December 9. Otherwise, 5 everything else should have been included in the 6 table. 7 DR. HILL: Okay. DR. ANDERSEN: And just going down the 8 9 list, I was pleasantly surprised at the fact that 10 we now have fatty acid composition data for most 11 of the plant groups from which these oils are 12 derived. 13 There are a couple of missing pieces, 14 and if you follow through with the approach you've 15 been taking, for oils where you don't have a fatty 16 acid profile, I can't even pronounce most of 17 these. Aleurites Moluccanus, bakoly seed oil on 18 the first page of the new table that Monice handed 19 out is blank all the way across. And you could 20 easily say the data are insufficient for that oil. 21 But everything else on page 1, all the families 22 seem to have something. I did the same thing for Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

page 2 and the only hole I found was Coix

Lacryma-Jobi seed oil. So, it's surprising that this trickle, well, a flood and then a trickle of

data that have continued to come in have filled in

DR. MARKS: Which one again on the second page so I can highlight that? I was trying

DR. MARKS: Well, I'm looking at this

DR. ANDERSEN: It's about one-third of

most of the gaps. So, there really are only a handful of oils, I think, that are left for which

you don't have that fatty acid profile.

DR. BAILEY: (Off Mike.)

SPEAKER: That's a Thursday.

the way down, Jim, on the second. Coix, C-o-i-x

or Coix. And, again, just screening through, my impression is there's a handful. We ought to do

Monice's more accurate accounting for which ones

glitch from how we approach things of saying that Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

are left. But, procedurally, I don't see any

SPEAKER: No, no --

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file here.

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| 1 | okay, these are all oils, they're from plants. |
|----|--|
| 2 | You can argue whether they're all edible |
| 3 | or not, but they're oils from plants, and, for the |
| 4 | most part, they can be considered safe for use in |
| 5 | the yadda, yadda, yadda, except for those where |
| 6 | there are no fatty acid profile data and those |
| 7 | would have to be insufficient, and that could be |
| 8 | issued as a tentative conclusion. Industry would |
| 9 | have one more shot at uncovering the fatty acid |
| 10 | profile data for the remaining handful, and we can |
| 11 | proceed at normal pace. |
| 12 | DR. MARKS: And, Alan, if you want to or |
| 13 | Ron, Ron, or Tom, so, the logic in terms of being |
| 14 | reassured with a fatty acid composition, what is |
| 15 | the toxicologic effect that we're concerned about |
| 16 | if we don't know? I know we talked about |
| 17 | arachidonic acid, and then there were a couple of |
| 18 | other fatty acids, but could you because that's |
| 19 | going to have to be part of the discussion. |
| 20 | Because we're using that as a cutoff as to |
| 21 | determining insufficient data. |
| 22 | DR. HILL: I think the specific concern |

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| 1 | that came up last time, and Dan Liebler raised it |
|----|--|
| 2 | and I chimed in because I was sitting on it, was |
| 3 | for fatty acids where there are known specific |
| 4 | receptors, and that's why arachidonic acid was |
| 5 | specifically raised, if those appear in the |
| 6 | profile, then those could potentially have safety |
| 7 | issues associated with them that would not be |
| 8 | associated with other oils. And then you look at |
| 9 | those in particular and see what particular safety |
| 10 | information is available on them or is not |
| 11 | available, decide whether they can be supported or |
| 12 | not. |
| 13 | DR. MARKS: So, in some of these we have |
| 14 | the fatty acid profile of say, for instance, |
| 15 | arachidonic acid is present. Does it then become |
| 16 | a margin of safety issue? So, if I go on page 28 |
| 17 | of the book. No, not 28. Let me see. It's a |
| 18 | read-across. Where we find arachidonic acid, |
| 19 | maybe that's not a good one, but I look on 28, |
| 20 | there's linoleic. I think Dan had brought that |
| 21 | up, also, but I may remember incorrectly. |
| 22 | DR. HILL: Well, at first, he mentioned |

ones that had double bonds were extensively unsaturated, and then I think he later qualified 2 his remarks to say we might not need to be 3 4 concerned with ones beyond where we know there's a

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6 7

5 specific biological target I guess is a better way

to state it. I said receptor, but just specific

biological target.

| 8 | DR. MARKS: So, if I go on page 34, for |
|----|---|
| 9 | an instance, arachidonic, if I look under |
| 10 | Mangifera or Macadamia seed oil, there's 1.5 to 5, |
| 11 | 1 to 7, 2 to 5 of arachidonic acid. I know I'm |
| 12 | not looking at the right column. Sorry. But I |
| 13 | guess what I'm saying is if arachidonic acid is |
| 14 | present in any of these, do we eliminate it or we |
| 15 | just say the concentration is so low it's not a |
| 16 | problem? |
| 17 | DR. ANDERSEN: I think at the meeting |
| 18 | last time there was a specific focus on the |
| 19 | massive work that we had done ${\tt X}$ years ago on rice |
| 20 | and the realization that the rice germ oil |
| 21 | contains up to 5.48 percent arachidonic acid and |
| 22 | the empirical data on rice germ oil showed none of |

the concerns that had existed previously for

arachidonic acid. So, arguably, that then becomes the cutoff point and maybe then for moving over on

page 37, we've got Sclerocarya Birrea Seed Oil,

whatever that heck that is, as 8.46 arachidonic. You could say well, we're not comfortable with

comfortable with that because we looked at it up,

have concerns about arachidonic. So, I could see

down, and sideways. This one is higher, and we

that as an approach. For the most part, these

things don't have arachidonic, but there's one

those where you don't have full fatty acid

discussion where you do itemize some of the

concerns after the toxins and heavy metals and

pesticide residues and so forth, you could put a

short paragraph on there on arachidonic acids and Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

was found in rice germ oil.

that does. And you could say in a conclusion for

profiles that arachidonic should be no more than

DR. BAILEY: In fact, during the

We have the baseline of rice and we're

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that.

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| 1 | sort of capture the level that has been assessed. |
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| 2 | DR. SHANK: There won't be any free |
| 3 | fatty acids in these oils. I'm sorry. We keep |
| 4 | going over this business about the fatty acids. |
| 5 | These are oils, they are not fatty acids. |
| 6 | DR. HILL: But, however, our bodies can |
| 7 | carve the fatty acids off of oils. I mean, we |
| 8 | don't have any problem doing that biologically in |
| 9 | our bodies. So, if we take it up by whatever |
| 10 | route and it gets into the system, you can assume |
| 11 | that those fatty acids become available to at |
| 12 | least cell membranes. |
| 13 | DR. MARKS: Ron Shank? |
| 14 | DR. SLAGA: I believe these are |
| 15 | basically edible plant oils, right? I mean, all |
| 16 | of them. And I agree with Ron. They're not |
| 17 | arachidonic acids or any other unsaturated. I |
| 18 | mean, I seek out oils that have more unsaturated |
| 19 | fatty acids. I mean, a lot of people do. I mean, |
| 20 | so, what are we telling people? You can't put it |
| 21 | on your skin? |
| 22 | DR. HILL: Well, in |
| | |

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| 1 | DR. SLAGA: In a percentage, it would be |
| 2 | converted, and the skin would be a small level. |
| 3 | DR. HILL: I don't know if we know that. |
| 4 | Do we know that? Dr. Bronaugh is not in here at |
| 5 | the moment, but I don't know if we know that. On |
| 6 | the other hand, I mean, certainly, we have plenty |
| 7 | of arachidonic acid in our cells already. |
| 8 | DR. SLAGA: Yes. |
| 9 | DR. HILL: I mean, the question is: If |
| 10 | you really bathe skin cells with an artificially |
| 11 | high amount of this stuff from an exogenous source |
| 12 | as triglyceride, would that cause any concern? |
| 13 | And, I mean, I think that's the only thing, but |
| 14 | with having studied the rice germ question whether |
| 15 | going from five to eight would really matter |
| 16 | DR. SLAGA: I doubt it. |
| 17 | DR. HILL: Because I wouldn't expect to |
| 18 | be seeing something that had that sharp of a |
| 19 | threshold. But if you went from 5 to 20, now, |
| 20 | that might be |
| 21 | DR. SHANK: I can't give you a |
| 22 | reference, but I don't think there are significant |

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| 1 | lipase activity in human skin. |
|----|---|
| 2 | DR. HILL: Yes, there is. |
| 3 | DR. SHANK: Can you document that? |
| 4 | DR. HILL: Dr. Bronaugh basically told |
| 5 | us that there was, but he wasn't certain. Well, |
| 6 | he gave us indirect evidence that, in fact, there |
| 7 | probably is. And I asked that question, and I |
| 8 | haven't had it answered yet one way or the other. |
| 9 | I haven't seen a reference that said no, there is |
| 10 | not or yes, there is, but there seem to be some |
| 11 | indirect evidence suggestive that there very well |
| 12 | might be. |
| 13 | SPEAKER: Yes. |
| 14 | DR. HILL: It'd be nice to know one way |
| 15 | or another, wouldn't it? |
| 16 | DR. MARKS: Ron Shank, I want to circle |
| 17 | back to your original statement in terms of these |
| 18 | fatty acids because if I interpret it correctly, |
| 19 | you weren't very concerned at all because these |
| 20 | are edible oils, and, so, if that's the case, then |
| 21 | why are we looking at a column that says "Fatty |
| 22 | Acid Composition" and we are considering having |
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| 1 | insufficient data when no fatty acid composition |
|----|---|
| 2 | is included? |
| 3 | DR. HILL: But |
| 4 | DR. MARKS: No, I'm talking to Ron |
| 5 | Shank. |
| 6 | DR. HILL: I know you are. But I guess |
| 7 | what I'm saying is when you eat something, fats |
| 8 | are handled very differently than they might be in |
| 9 | skin, and I'm not sure we totally know what |
| 10 | happens in skin. I'm not concerned about any of |
| 11 | these ingredients quite frankly, I'm not, but I'm |
| 12 | just suggesting there's a gap in the science that |
| 13 | it might be nice to have filled. |
| 14 | DR. MARKS: Ron, did I interpret what |
| 15 | you said correctly? |
| 16 | DR. SHANK: You did. These |
| 17 | triglycerides are triglycerides, and the fact that |
| 18 | their component fatty acids are going to produce a |
| 19 | problem in the skin I don't think is a real |
| 20 | problem. |
| 21 | DR. BAILEY: (Off Mike.) |
| 22 | THE REPORTER: Microphone. |
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| 1 | DR. HILL: I thought we settled on |
| 2 | something like that last time. |
| 3 | DR. MARKS: Yes. |
| 4 | DR. HILL: I thought we had. |
| 5 | DR. SHANK: They said fatty acid oils as |
| 6 | opposed to essential oils and things. |
| 7 | MS. FIUME: Yes. |
| 8 | DR. SHANK: Okay. |
| 9 | MS. FIUME: To make clear that it was |
| 10 | not essential oils. |
| 11 | DR. SHANK: Okay. |
| 12 | DR. MARKS: So, that will obviously be a |
| 13 | discussant point tomorrow. Ron, Ron, Tom, do you |
| 14 | have feelings one way or another? It sounds like |
| 15 | we're going to delete edible since we're not |
| 16 | certain of that. And I guess if it's not edible, |
| 17 | then it gets back to do we feel comfortable with |
| 18 | this safety of it? |
| 19 | DR. HILL: I'll just say that I do. |
| 20 | DR. MARKS: So, what title do we want to |
| 21 | go forward tomorrow or let me see who's I'm |
| 22 | presenting it, so, do you want me to present |

| 1 | DR. MARKS: So, I think we can move |
|----|--|
| 2 | forward if our team agrees that we can issue a |
| 3 | tentative report that it sounds like we can say |
| 4 | all these oils are safe and that we don't have any |
| 5 | insufficient needs. |
| 6 | DR. SHANK: Have we determined that all |
| 7 | of these are edible? |
| 8 | DR. SLAGA: That's an important |
| 9 | question. |
| 10 | DR. SHANK: No? Because it's in the |
| 11 | title now, isn't it? "Edible Plant Oils." |
| 12 | MS. FIUME: In the other team, they were |
| 13 | discussing the same issue. Carol raised the point |
| 14 | about the erucic acid content, and Dr. Re from |
| 15 | L'Oreal actually came up with a suggestive title |
| 16 | of plant-derived fatty acid oils and their |
| 17 | derivatives. If you feel that that is more |
| 18 | appropriate or not, I just wanted to throw that |
| 19 | out there that that was suggested and the other |
| 20 | team. |
| 21 | DR. MARKS: Yes, being a minimalist, I |
| 22 | like plant-derived oil group. But Ron |
| | |

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| 1 | plant-derived oil group? | |
| 2 | DR. BAILEY: (Off Mike.) | |
| 3 | MS. FIUME: Plant-derived fatty acid | |
| 4 | oils and their derivatives, and it's to | |
| 5 | differentiate from the essential oils. | |
| 6 | DR. SHANK: What derivatives are in | |
| 7 | here? They're just oils. | |
| 8 | MS. FIUME: I think its referring to | the |
| 9 | hydrogenated, the salts, and things like that. | |
| 10 | DR. SHANK: Oh, all right. I think I | |
| 11 | would take out the derivatives and just say | |
| 12 | plant-derived fatty acid oils. | |
| 13 | DR. HILL: They're still derived from | |
| 14 | plants if they're hydrogenated, and why would | |
| 15 | there be salts? Salts would be only for the fa | tty |
| 16 | acids, but here, they're oils, so, there should | n't |
| 17 | be any significant pre-fatty acid right? | |
| 18 | DR. MARKS: Okay, so, tomorrow, I'm | |
| 19 | going to move that we issue a tentative report, | |
| 20 | that these ingredients are safe, and the title : | I'm |
| 21 | going to propose is plant- derived fatty acid | |
| 22 | oils. And we have can have a discussion | |
| | Anderson Court Reporting 703-519-7180 www.andersonreporting.ne | et |

| 1 | concerning the derivatives if the other team feels |
|----|--|
| 2 | strongly. |
| 3 | Any other comments? Rachel, do you have |
| 4 | any? |
| 5 | MS. WEINTRAUB: I had one comment, but I |
| 6 | think it's more based in my own lack of knowledge |
| 7 | about the particular scientific issue. I was just |
| 8 | thinking about oils in general and how they |
| 9 | interact with sunlight, and there's not all that |
| 10 | much photo toxicity data. I think there were only |
| 11 | two studies. So, I was wondering, I assume since |
| 12 | it hasn't been raised, it's not a concern? |
| 13 | DR. MARKS: Rachel, I'm not concerned |
| 14 | other than the optical effect that an oil has when |
| 15 | you put it on the skin. So, I think any oil has a |
| 16 | physical optical effect. But it's not related to |
| 17 | this here. |
| 18 | MS. WEINTRAUB: Okay, okay. |
| 19 | DR. MARKS: That it increases photo |
| 20 | sensitivity per se. |
| 21 | DR. SLAGA: How hard would it be to find |
| 22 | out how many are edible? I mean, just for our |

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|--|--|--|--|
| 1 | information for all of the ingredients, all the | | |
| 2 | oils here. So, is that important or not? | | |
| 3 | DR. MARKS: My take from a toxicologic | | |
| 4 | and safety point of view, no. That's what I asked | | |
| 5 | Ron earlier because we were considering do an | | |
| 6 | insufficient data for a handful of these, which | | |
| 7 | Alan had pointed out we don't have that, and then | | |
| 8 | it got into the discussion, well, is this really | | |
| 9 | necessary? We know these have fatty acids. Is | | |
| 10 | the composition really going to make a significant | | |
| 11 | difference when it's unknown to us at this point, | | |
| 12 | and the conclusion was no. So, we can include | | |
| 13 | these even though we don't have the composition. | | |
| 14 | It's certainly nice to happen. | | |
| 15 | DR. SLAGA: (Off mike.) | | |
| 16 | DR. SHANK: Are you asking why do we say | | |
| 17 | fatty acid oils? | | |
| 18 | MS. WEINTRAUB: I think I understand | | |
| 19 | because you were making a distinction with the | | |
| 20 | essential oils. | | |
| 21 | DR. SHANK: Yes. | | |
| 22 | MS. WEINTRAUB: Yes. | | |

| 1 | almost impossible, right? | | |
|----|---|--|--|
| 2 | DR. ANDERSEN: (Nodding) | | |
| 3 | DR. BAILEY: I think for most of them, | | |
| 4 | we could find that out, but there may be a few | | |
| 5 | that are a little more exotic and would be edible | | |
| 6 | in certain limited settings, populations, yes. | | |
| 7 | DR. ANSELL: And then we'd have to | | |
| 8 | define what we meant by "edible." | | |
| 9 | SPEAKER: Yes. | | |
| 10 | DR. ANSELL: Because in performance with | | |
| 11 | the food chemicals codex or available in a super | | |
| 12 | market or exactly what. I mean, we struggled with | | |
| 13 | this in-house and felt that plant-derived or some | | |
| 14 | language along those lines were probably a better | | |
| 15 | | | |
| 16 | DR. SLAGA: I'm not saying I have a | | |
| 17 | concern versus edible or plant ones. I mean, I | | |
| 18 | think the majority of these oils not free fatty | | |
| 19 | acids; it's not going to be a problem. | | |
| 20 | MS. WEINTRAUB: One other question just | | |
| 21 | about the title being linked to fatty acids, as | | |
| 22 | you can see, we don't have fatty acid composition | | |
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CIR Meeting day 1 of 2 (Main Session) Page: 129 1 DR. SHANK: Which are chemically quite 2 different and biologically quite different? 3 MS. WEINTRAUB: Yes. Okay. So, I did understand, I guess. 4 DR. MARKS: Any other comments? If not, 5 6 then I will move tomorrow that we issue a 7 tentative report that these ingredients are safe 8 as used and that the title we're going to suggest 9 is plant-derived fatty acid oils. Thanks, Monice, 10 for giving us a little bit of an inside scoop on 11 that. 12 Do we have time for the next one? The 13 alkyl PEG ethers group. 14 (Pause) 15 DR. MARKS: Do we want to move on and 16 consider this one before lunch? 17 SPEAKER: (Off Mike.) 18 DR. MARKS: Sure. Good. So, in the 19 June meeting, the panel issued a tentative report 20 that these 369, yes, Ron Hill, you're absolutely 21 correct, (inaudible) are safe for use in cosmetic 22 and the present practice of use in concentration Anderson Court Reporting -- 703-519-7180 -- www.andersonreporting.net

| | I PARICIPANIS: |
|---|--|
| | 2 Voting Members: |
| | |
| | 3 DONALD V. BELSITO, M.D. |
| | Clinical Professor, Medicine (Dermatology) |
| | 4 University of Missouri, Kansas City |
| | |
| | 5 CURTIS D. KLAASSEN, Ph.D. |
| 116th COSMETIC INGREDIENT REVIEW EXPERT PANEL | University Distinguished Professor and Chair |
| | 6 School of Medicine |
| MEETING | University of Kansas Medical Center |
| | / |
| BREAKOUT SESSION | 8 Director Jim Wors Institute for Presencer |
| | Detection |
| | 9 Diagnosis Professor of Biochemistry, Pharmacology, |
| | and Biomedical Informatics |
| | 10 Vanderbilt University School of Medicine |
| | |
| | 11 PAUL W. SNYDER, D.V.M., Ph.D. |
| | School of Veterinary Medicine |
| | 12 Department of Veterinary Patholobiology |
| | Purdue University |
| | 13 |
| | Liaison Members: |
| | 14 |
| | JAY ANSELL, Ph.D. |
| | 15 Personal Care Products Council |
| | |
| | Food and Drug Administration |
| | 17 |
| | DON BIERKE |
| | 18 Procter & Gamble |
| | |
| | 19 SAMUEL COHEN |
| | University of Nebraska |
| | 20 |
| | ROBERT FINKING |
| Washington, D.C. | 21 BASF |
| | |
| Monday, August 30, 2010 | 22 |
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| PARTICIPANTS (CONT'D): areas or non-commuting intrinsity intermediation of the second secon | | 3 | we certainly don't want to start getting into PC |
|--|----|--|---|
| PARTICIPANTS (CONT'D): area-or-non-commetic-from-aregulatory TRACY GUERREDO standpoint. Silicones Environment. Health and Safety Council R. BEISJTO: Okie doke. Anything-else of North America on-the-isoparafine? So we're ready to go back to vegetable oil at this point? Oky. so the isoparafine? So we're ready to go back to vegetable oil at this point? Oky. so this is Green 2 followed by Green 3. ALLLAN C. BECKRR So this is Green 2 followed by Green 3. HALVIN P. BESLAWEC, Ph.D. betweet before we start I just want to point out that at least for one of the vegetable oils, mainly rice germ oil, there's a content of Sciencific Analyst mainly rice germ oil, there's a content of Sciencific Analyst but I don't think anyone else was on the panel MOUTOR FUMME sector of cientific Analyst MOUTOR FUMME guestions about dermal carcinogenicity. So we're sciencific Analyst guestions about dermal carcinogenicity. So we're sciencific Analyst guestions about dermal carcinogenicity. So we're MOUTOR FUMME senior Gientific Analyst guestions about dermal carcinogenicity. So we're Senior Gientific Analyst guestions about dermal carcinogenicity. So we're going to have going forward, you know, wi | | | |
| 2 TAXY GUERRERO Stillcones Environment, Health and Safety Council standpoint. 3 of North America DR. BELSITO. Okie-doke. Anything else 4 Staff Members: on the isoparaffine? So we're ready to go back to 5 P. ALAN ANDERSEN, Ph.D. Director vegetable oil at this point? Okay. 6 LILLIN C. BECKER So this is Green 2 followed by Green 3. 7 Scientific Analyst And I guess before we start I just want to point 8 HALYNA P. BRESLAWBC, Ph.D. Deputy Director out that at least for one of the vegetable oils, 9 CHRISTINA L. BURNETT scientific Analyst mainly rice germ oil, there's a content of 10 Scientific Analyst but I don't think anyone else was on the panel when we looked at that, the conclusion for 11 CANCLE FILME Scientific Analyst arachidonic acid was insufficient because of guestions about dermal carcinogenicity. So we're 13 Scientific Analyst arachidonic acid, like rice germ oil is said to 14 MILIER JOHNSON, JR. Steinor Scientific Analyst arachidonic acid, like rice germ oil is said to 15 JULIE SKARE Procter & Gamble arachidonic acid, like rice germ oil is said to 17 Other Attendees: arachidonic acid, l | 1 | PARTICIPANTS (CONT'D): | areas or non- cosmetic from a regulatory |
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| 3 of North America DR. BELSITO. Okie doke. Anything else 4 Staff Members: on the isoparaffins? So we're ready to go back to 5 F. ALAN ANDERSEN, Ph.D. vegetable oil at this point? Okay. 6 LILLIAN C. BECKER So this is Green 2 followed by Green 3. 7 Scientific Analyst And I guess before we start I just want to point 8 HALYNA P. BRSDLAWEC, Fh.D. out that a least for one of the vegetable oils, 9 CHISTINA L. BURNET mainly rice germ oil, there's a content of 10 Scientific Analyst mainly rice germ oil, there's a content of 11 CANCE FILME but I don't think anyone else was on the panel 12 WINICE FILME when we looked at that, the conclusion for 13 Scientific Analyst arachidonic acid was insufficient because of 14 WILDER JOHNSON, JR. going to have going forward, you know, with these 15 Other Attendees: the issue being out there that if they contain 16 ADULIE SKARE arachidonic acid, like rice germ oil is said to 17 Other Attendees: the issue being out there that if they contain 18 JULIE SKARE arachidonic acid, like | | Silicones Environment, Health and Safety Council | |
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| 17 Other Attendees: arachidonic acid, like rice germ oil is said to arachidonic acid, like rice germ oil is said to contain 5 percent. And then there's an ingredient that we previously found not to be not to have adequate data. 20 And then in the nut oil report, I'll | | | the issue being out there that if they contain |
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| 10 Boom Status 19 contain 5 percent. And then there's an ingredient 20 that we previously found not to be not to have 21 * * * * * 22 And then in the nut oil report, I'll | 18 | JULTE SKARE | arachidonic acid, like rice germ oil is said to |
| 19 contain 5 percent. And then there's an ingredient 20 that we previously found not to be not to have 21 * * * * * 22 And then in the nut oil report, I'll | 10 | Procter & Gamble | |
| 20 that we previously found not to be not to have 21 * * * * * 22 And then in the nut oil report, I'll | 19 | | contain 5 percent. And then there's an ingredient |
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| 21 * * * * * adequate data. 22 And then in the nut oil report, I'll | 20 | | that we previously found not to be not to have |
| 22 And then in the nut oil report, I'll | 21 | * * * * * | adequate data. |
| 22 And then in the nut oil report, I'll | | | |
| | 22 | | And then in the nut oil report, I'll |
| | | | |

just jump to that, if you scan the tables there, arachidonic acid isn't even listed as one of the fatty acids that could be in nut oils. And I don't know if that's just an oversight or it's just not there.

Having said that, except for the arachidonic acid issue I thought that these could be safe as used and basically go from there. But we also had the chance to see comments from the Personal Care Product Council on these and I guess that is nice, but it raises, I guess, the issue why they're getting a preview before the panel is getting a look.

MS. BURNETT: That was for the SLR. The comments were for the SLR. We have new comments on the document that we received last week. We've been including comments that we had for the previous drafts into these packets. So they saw -- you guys do not see the scientific literature review, but it goes out for public comment and that's what we received.

DR. SNYDER: So during the -- so the

of the Personal Care Product Council? MS. BURNETT: No. It's made public. DR. BELSITO: And how is it made public? MS. BURNETT: Announcement goes out. The industry submits their interested parties. We have it on the website. And then that way anyone who has data can submit it. DR. BELSITO: Okay. MS. BURNETT: And by the time you see it usually data has been submitted. DR. BELSITO: Okay. So I was never aware of it. I thought the first time we were seeing it was the scientific literature review. MS. BURNETT: It's called a draft when you see it. DR. BELSITO: Yeah. So it's a step after. Okay. So then that's fair. MS. BURNETT: And we try to address whatever comments we can. There were a few repeat comments because we didn't know necessarily how to handle them and then we do want your input on some

of them, so.

generation of the SLR during the public comment period is when the scientific advisory you think is -- that's when they're making their comments -initial comments? MS. BURNETT: Yes. DR. SNYDER: And then they make subsequent comments after each draft of the document? MS. BURNETT: Mm-hmm. DR. BELSITO: So I guess I was never aware of this since it's never happened before. So the scientific -- so the first time we look at the book it's beyond the scientific literature review point? MS. BURNETT: It's a draft. DR. SNYDER: That's if you look at the flowchart. DR. BELSITO: Right. Okay. But the scientific literature review has been made available to interested public members? MS. BURNETT: Mm-hmm. DR. BELSITO: Or just interested members

DR. BELSITO: So I guess the biggest issue I have, and again this is where a read across would be helpful, is do we have all of the information for the ingredients of all the many vegetable oils we're including here? And I know the answer to that is no.

MS. BURNETT: No. And we have data. You saw the second wave. Monice and I are still working on summarizing it.

DR. BELSITO: Yeah. I saw that's all the second wave. But I think the issue is going to be unless we go back and look at arachidonic acid and find that it's safe as used or go back at the Noone and DeFavo data and try and do some kind of risk assessment on concentration based upon those vegetable oils, like rice germ oil that contain arachidonic acid, then any vegetable oil where we don't have full ingredient listing or full knowledge of the composition where the chain lengths are going to be lower than arachidonic acid or any that will be insufficient, as will any that contain arachidonic acid, the ones that we don't know are insufficient for composition and the ones that do are insufficient because arachidonic acid is insufficient. Because otherwise it seems irrational that the panel found arachidonic acid to not have sufficient data yet we're approving vegetable oils that contain it.

The others in my estimation are safe as used. And then, of course, we have the heavy metal boilerplate, the aflatoxin, the pesticide. We have those issues that go into the discussion. Those were the only comments I had.

- Curt, Paul, Dan?
- DR. LIEBLER: I --

DR. SNYDER: I didn't have anything additional.

DR. LIEBLER: I was not on the panel when arachidonic acid was reviewed, but I've studied, you know, fatty acids and liquid oxidation on mechanisms and toxicity related to their oxidation products for a long time and I know that -- I'm not surprised that arachidonic acid would have issues, particularly in relatively

Christina, in here, a table? And I'm just not finding it here. DR. SNYDER: Well, we did receive a whole bunch of data on the composition. DR. BELSITO: Yeah. For vegetable oils. DR. LIEBLER: And the nut oils. DR. BELSITO: Yeah. We're in vegetable oils right now. DR. LIEBLER: Okay. DR. BELSITO: Yeah. DR. LIEBLER: Oh, yeah. Table 3. Sorry. Table is a lengthy table, but had most of these. So most of these oils are actually restricted to, like linoleic acid is a polyunsaturated fatty acid with two double bonds. So I didn't see this as likely to be much of an issue Rapeseed oil (Discussion off the record) DR. LIEBLER: But I think almost all the oils, maybe all the oils we're looking at here did not contain significant amounts of any fatty acid

with more than two double bonds. And those oils

high concentrations because it has such high liability than to go autoxidation to a variety of products that would have toxic properties.

I would imagine -- I remember reading through this I was interested in -- I was just looking for the table on the fatty acid compositions which I don't have in front of me at the moment, but I was struck by the fact that most of the oils we're talking about here don't have high polyunsaturated fatty acid concentrations. They're relatively low. You would sorry about linoleic acid, arachidonic acid, docosahexaenoic acid, anything with a lot of double bonds based by one carbon each. And those are relatively infrequently found. And I think this problem would be relatively self-limiting because oils that are high in those products would tend to go bad quickly and have undesirable properties because the oxidation products have a lot of awful smells.

And so I didn't notice any of the oils, at least I know that you had a list. Did you,

-- those fatty acids would be pretty stable to most conditions of storage or use. So there are a couple of oils. It's hard to read this table -this version of the table. Sometimes the computer fails me. Yeah, most of these don't contain polyunsaturated with more than two double bonds, if at most a percent or so, and that's probably not going to be cause for concern.

I didn't have any comment beyond that. I just wanted to point that out.

DR. BELSITO: So other than arachidonic acid, are there any fatty acids looking at their molecular structure that would concern you?

DR. LIEBLER: Well, the ones that would have a high liability to oxidation to obnoxious, you know, potentially dangerous products would be arachidonic, docosahexaenoic, which is 22:6, linolenic, which is 18:3 and that's kind of borderline. And those are the only ones listed on the table here that would have much of a liability. Things that have two double bonds, like linoleic, which is a major constituent of many of these, or docosadienoic, which is 22:2 or eicosadienoic, which is 22 double bonds, those are very slowly oxidizing in comparison to arachidonic and docosahexaenoic.

SPEAKER: Which are the three again? DR. LIEBLER: So the three that have the greatest liability of oxidation are arachidonic, docosahexaenoic. So arachidonic is 20:4. Docosahexaenoic is 22:6. And I would throw linolenic in there. It's borderline. That's 18:3. But all the fatty acids with no double bonds or one double bond are going to be essentially resistant to oxidation under any normal conditions.

DR. BELSITO: Okay.

DR. LIEBLER: Again, I think this might be a somewhat self-limiting problem because the oils that would have high fatty acid -- high polyunsaturated fatty acid content generally aren't plant oils in the first place. And they would have sort of been weeded out of product use because they would have had undesirable qualities.

sensitization, and photosensitization. Anyway, interestingly, Monice wrote this report. It was quite a contentious meeting. What year was that? Not because Monice wrote it, but --

MS. FIUME: I think it was published in

DR. BELSITO: October '93.

93.

DR. LIEBLER: There's been a lot of arachidonic acid biology falling under the bridge since then so maybe one of the other things with arachidonic particularly is it's a fatty acid precursor to numerous bioactive prostaglandins and other eicosanoids, some of which have been very clearly shown since then to be key drivers of skin carcinogenesis. So there would be a lot of reasons to have concern.

DR. BELSITO: Well, you said there's been a lot of data in the past 17 years --

DR. LIEBLER: Since the early '90s, yeah.

DR. BELSITO: Okay. So then the question is whether, I mean, because again I don't

They would have smelled bad from the beginning because it's very hard to --

DR. KLAASSEN: Rancid.

DR. LIEBLER: Yeah. Rancidity. That's what rancidity is, exactly, all those aldehyde fragments of the oxidized fatty acids.

DR. BELSITO: Yeah, so let me just read you the discussion from arachidonic acid. Dermal absorption data are lacking in this report and we thought that the data -- that data was necessary for a determination of safety. Based upon the results of dermal absorption we felt there may be additional data needs. Referred to the studies about UV light-induced cutaneous immunosuppression and immunomodulatory data might be requested. Also, dermal carcinogenicity, photocarcinogenicity, human irritation, sensitization, and photosensitization. So basically we went insufficient for

dermal absorption and then if absorbed, immunomodulatory data, carcinogenicity and photocarcinogenicity, and human irritation,

feel that we can logically rule on the safety of these if we don't have all the compositions. Or if we have the composition and it contains arachidonic acid, unless we first reopen the arachidonic acid report and decide whether the data that's occurred in the past 17 years is sufficient to support the safety of that, then it becomes a non-issue to this report.

So I guess I would say safe as used assuming we have all the components and there's no arachidonic acid. Rice germ oil is insufficient because it's reported to contain arachidonic acid. And or the other alternative would be to table this and reopen the arachidonic acid report.

DR. SNYDER: I have a question. So how come our insufficient reports don't arise to the top of our priority list periodically? Or do we have any? Because that --

DR. BELSITO: It's surprising because if it was reported in '93, that's more than 15 years. DR. SNYDER: Correct. So why isn't -why isn't it a CIR report safety assessment? DR. BELSITO: Why hasn't it come up for

DR. SNYDER: It went insufficient that long ago, not (unintelligible).

review?

DR. BRESLAWEC: I think the assumption is that if there were data available, that industry would have provided them and we would have considered the new data and reopened the report based on the new data. But as a routine we do not look at --

DR. BELSITO: Well, there were two ingredients when I came on that were highly contentious. This was one. The other was urocanic acid for many of the same issues. So I suspect perhaps the reason it hasn't come back up is it sounds like form Dan that there is a lot of new data, but industry probably just stopped using it in cosmetics because of the brouhaha that went around. But now we're confronted with the fact that there are things like vegetable oils that at least partially may be composed of this fatty acid.

C18 fatty acids with no more than two double bonds and usually just one or none. And that's the bulk of these oils.

I guess the only question that comes up is if you flag arachidonic acid, do we get ourselves into a situation where we have to have some minimum value and have some basis for coming up with a minimum content of arachidonic acid?

DR. BELSITO: Well, I mean, that's the issue. But we need to go back and look at arachidonic acid to do that.

DR. SNYDER: We don't have the data.

DR. BELSITO: Right. So we can't do it without reopening that report and tabling this pending a conclusion on arachidonic acid.

DR. LIEBLER: If you ever open arachidonic acid you'd have a lot of new data to go through I'm sure. So.

DR. SNYDER: It seems as though that only two paths forward are insufficient here because the arachidonic acid report was insufficient, or safe here, and then reopen the DR. ANSELL: Well, I think John -- John will be reporting tomorrow that the industry, through the Scientific Scholar Committee, has taken this whole insufficient issue on. We conducted an extensive analysis of all of the insufficient and are proposing some changes to the CIR procedures which would clarify the whole situation. We agree that this hanging out in this vague netherworld of neither safe nor unsafe is inappropriate. We have some proposals that I'm sure John is going to talk about tomorrow.

DR. BELSITO: Okay. Well, so I guess we'll have this discussion tomorrow. I mean, other than for the arachidonic acid issue I have no issues with them. The report is rather extensive and complete.

DR. LIEBLER: Yeah. I agree with you, safe as used. And arachidonic acid should be a flag. You know, it just looks like -- just look at these fatty acid compositions. It seems like at least for the (unintelligible) that were selected here they -- nature tends to make C12 to

record on the acid.

DR. LIEBLER: You could say safe as used as long as they don't contain arachidonic acid and cite the previous report.

DR. BELSITO: But then how can we -when you have -- again, rice germ oil is reported to have -- I believe, have 5 percent arachidonic acid. When you say arachidonic acid, the data are insufficient, we haven't even said for arachidonic acid he data are insufficient at a concentration above whatever --

DR. LIEBLER: It's just insufficient.

DR. BELSITO: Just insufficient.

DR. LIEBLER: Yeah, so you could simply say that except for oils that contain arachidonic acid data is insufficient. You can just throw that oil out.

DR. ANSELL: This is still very early in the report process. I think this is an important issue and perhaps we could take it back to the CSSC and get some advice as to how we might address the arachidonic acid. I'm just not aware of what to do at this point. It's quite possible that the users are quite aware of it and control the concentration because of, you know, very practical issues.

DR. LIEBLER: Can I ask either Jay or Monice or somebody else here who might know, the data in Table 3, were they from sort of a variety of sources?

MS. BURNETT: Yes.

DR. LIEBLER: A variety of sources? So it wasn't like it'll be great if one lab just had all these samples and did them all on a common platform.

MS. BURNETT: No. Some came from --

DR. LIEBLER: And put lower limits on -if something is listed as blank, does zero mean less than, you know, some amount? I guess if that's a hodgepodge of sources then it's going to be very difficult --

MS. BURNETT: For each -- I'm not sure I should say this. For each entry there's either one or two references.

-- well, it's the other report, but hazelnut oil -- that gave very succinct, you know, 14.1, you know, percent. And it would be a whole plethora of, you know, the fatty acids. And then you'd go to a textbook and it would just give you a rounded range.

DR. LIEBLER: That's precise.

MS. BURNETT: So there will be variability within the table.

DR. LIEBLER: We don't need to beat it to death.

DR. BELSITO: Yeah. But just since we're on that table, you know, if it wasn't for the fact that I was a member of the panel or a new member as it was when we did arachidonic acid, I would have looked at the highlighting and assumed not only that we had reviewed it, but that we had reviewed it and it was safe as used. So I don't know how to do it in a black-and-white copy, but if there was some way in the future when we're putting these tables together where there are individual ingredients that we previously DR. LIEBLER: I see.

MS. BURNETT: For each oil.

DR. ANSELL: But Carol, in her search, identified potential databases. Not on the tox side, but on the agriculture side.

MS. BURNETT: Right. Agriculture.

DR. ANSELL: And thinks that there's probably a lot more compositional data.

MS. BURNETT: We received some

composition data from suppliers I think they were that I couldn't access, but a member could. So we were provided that data. Some of it came from books, textbooks, source books.

DR. SNYDER: So that goes to the table. So the blank spaces do mean zero.

MS. BURNETT: There's, yeah. Nothing entered, there's nothing there.

DR. LIEBLER: No reported venture

(inaudible) means it's below the limited platform, right?

MS. BURNETT: I would find a published study that had done a chemical analysis maybe on

reviewed, to do it in a different color or to do it -- I don't know how you do it. You know, italicize it and underline it. DR. SNYDER: Put another column. DR. BELSITO: And, you know, indicate that --MS. BURNETT: We can separate it out. DR. BELSITO: Right. That, you know, the data was insufficient. I just looked up myristic acid. That was safe as used. DR. SNYDER: It was? Okay. MS. FIUME: Table 2 gets you the conclusions. DR. BELSITO: I understand. But, you know --MS. FIUME: No, I know you mean for the table, but you said you looked up (unintelligible). DR. BELSITO: Right. MS. BURNETT: And we do have -- I mean, we have some color printing capabilities, but when it comes to producing the Panel Book we don't
always know if we're going to have color or not. So. And then when it goes to the Journal it's not going to have a color option. DR. BELSITO: No, no, no. That's fine. MS. BURNETT: Okay. DR. BELSITO: Okay. I suppose you're right. Monice, Table 2. MS. BURNETT: No, I mean, I know it doesn't crossover, but rather if you were --DR. BELSITO: Right. MS. BURNETT: -- interested rather than having to go through a compendium. DR. BELSITO: Right. Okay. So we'll see what the other group wants to do and Jay will bring it back to the Scientific Committee and see what they want to do about arachidonic acid. Whether tomorrow we go ahead with an insufficient for those that contain it or those that we don't have all the ingredients. The rest are safe as used. Or whether we table it to await a decision as to whether to reopen arachidonic acid. And, I mean, we can do nut oils, but it's going to be the same issue with nut oils. Only with nut oils the aflatoxins come in with the vegetable oils, you know, so heavy metals, pesticides. Otherwise, safe as used as long as they don't have arachidonic acid, aflatoxins, heavy metals, and pesticides.

MS. BURNETT: Did you feel that the two reports could be combined into one data plan throughout?

DR. BELSITO: I don't care.

MS. BURNETT: You don't care?

DR. BELSITO: Do you know what I mean? It's a rather mega report so I guess to have two different reports -- I guess the only reason to do -- the strongest argument to do two reports are that with the nut oils we need to do the discussion about protein versus fatty acid. So from that regard I would want a separate report for nut oils.

MS. BURNETT: But there's already the same discussion in the vegetable oil. DR. SNYDER: Yeah. We have the same for

| vegetable oil. | |
|--|---|
| MS. BURNETT: Because there are | |
| vegetable oil and fruits that can cause | |
| DR. BELSITO: Avocado oil? Yeah. Okay. | |
| So, fine. I mean, what does the other group want | |
| to do? Make it one big mammoth | 116th COSMETIC INGREDIENT REVIEW EXPERT PANEL |
| MS. BURNETT: And one is only 30 | MEETING |
| ingredients; the other is 200-something, so. | |
| DR. BELSITO: Oh, well, 230-something, | |
| might as well try and go for a record after we did | |
| what was our record before? | |
| DR. ANSELL: 368. | |
| DR. BELSITO: I mean, we have to do that | |
| in the discussion. You know, I'm fine with that | |
| if that's what they want to do. I think the | |
| longer discussion will occur as to what to do with | |
| arachidonic acid rather than combine the two | |
| reports. | |
| Okay. Did anyone have anything to say | |
| on nut oil? | |
| So, cocoamidopropyl betaine. Well, we | Washington, D.C. |
| got this wonderful presentation this morning. | Monday, August 30, 2010 |

- 1 PARTICIPANTS:
- 2 Voting Members:
- 3 WILMA F. BERGFELD, M.D., F.A.C.P. Head of Clinical Research and Dermatopathology 4 The Cleveland Clinic Foundation
- DONALD V. BELSITO, M.D. 5 Clinical Professor, Medicine (Dermatology) University of Missouri, Kansas City
- 6 RONALD A. HILL, Ph.D. 7
- Associate Professor of Medicinal Chemistry College of Pharmacy 8 The University of Louisiana at Monroe
- 9 CURTIS D. KLAASSEN, Ph.D.
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- 11 University of Kansas Medical Center
- 12 DANIEL C. LIEBLER, Ph.D. Director, Jim Ayers Institute for Precancer 13 Detection Diagnosis Professor of Biochemistry, Pharmacology, 14 and Biomedical Informatics Vanderbilt University School of Medicine 15 JAMES G. MARKS, JR., M.D. Professor of Dermatology 16
- Chairman, Department of Dermatology 17 Pennsylvania State University College of Medicine
- 18 RONALD C. SHANK, Ph.D. Professor and Chair Department of Community and Environmental Medicine 19 University of California, Irvine 20 THOMAS J. SLAGA, Ph.D.
- 21 Department of Pharmacology
- University of Texas Health Science Center 22

PARTICIPANTS (CONT'D): PAUL W. SNYDER, D.V.M., Ph.D. School of Veterinary Medicine 3

(1:01 p.m.)

- 3 Department of Veterinary Patholobiology Purdue University
- 4 Liaison Members:

1

2

- 5
- JOHN BAILEY, Ph.D. Personal Care Products Council 6
- JAY ANSELL, Ph.D. 7 Personal Care Products Council
- 8 RACHEL WEINTRAUB
- 9 Consumer Federation of America
- 10 LINDA KATZ, M.D. Food and Drug Administration 11
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- MONICE FIUME 19 Scientific Analyst
- 2.0 KEVIN STONE FRIES Technical Librarian/Editor 21
- BART HELDRETH, Ph.D. 22 Chemist
- PARTICIPANTS (CONT'D): AFTERNOON SESSION WILBUR JOHNSON Senior Scientific Analyst DR. MARKS: What time is it? Other Attendees: DR. BERGFELD: It's 1:01. JULIE SKARE Procter & Gamble DR. MARKS: It's 1:01, so it's time to DAVID STEINBERG begin. Everybody get enough vegetable oil over Steinberg & Associates lunch? MICHELLE ANDROIT Dow Corning Okay, we're going to go to the next CAROL EISENMANN, Ph.D. group of ingredients, the vegetable oils, which Sciences International, Inc. also include fruit oils, too, if I read this correctly as to the ingredients. * * * * * Is that correct, Christina? MS. BURNETT: (off mic) REPORTER: Microphone, please. MS. BURNETT: Anything that can be expressed from something that you can eat, except for nuts, is in that report. DR. MARKS: Okay. And then I guess one also -- the issue was raised -- we'll start with the vegetable and fruits, and then we'll move on to the second group of oils, the nut oils, in this Green Book, but one might consider combining all

the oils together.

Okay. So this is the first time we've seen -- I'm going to refer to it as the vegetable and fruit oils. And as always, the first question is, do we have all the data we need to consider these ingredients are safe for including in cosmetics or do we have data needs?

So, I'll ask my teammates, do they feel comfortable with the data we have in hand?

MS. BURNETT: As you are aware, you received a second wave, it was composed of 800 pages, not -- that data was not in the report. You have not seen it, and we have not -- we're still in the process of summarizing it, so --

DR. MARKS: Most of that, yeah. So, what Christina is clarifying is that we have over 800 pages of supplementary data that was sent to us electronically by a for now unnamed individual, and there was no summary of it either in this paper document nor preceding that. Most of that, as I recollect, was sensitization, irritation, but there were some other toxicologic papers mixed in. So, thank you, Christina, for mentioning that. So, large -- not large -- huge group of oils. I didn't tally it up -- did you, Christina? -- what the number of oils in fruit and --MS. BURNETT: I lost track --

DR. MARKS: -- vegetable.

MS. BURNETT: -- but it's around 200.

DR. MARKS: Two hundred. So,

approximately 200 cosmetic ingredients.

DR. SLAGA: So, we could make one big -so, yeah, just before the meeting we were talking, Ron and I, about the magnitude of this and that how many years people have been eating vegetable oils of all type and putting it on their skin for centuries and centuries. And it would be hard to believe that there would be some other potential contaminants in that type of thing that we really would have to worry about. And I'd start right in the beginning, recommend we should -- since the nut oils are very edible, too, and they're very similar, so combine it all together into one document.

DR. MARKS: The two Rons, do you want to just proceed and discuss this as all one document and include the nut oils, which are how many more ingredients? About 30, 40?

MS. BURNETT: (Shaking head)

DR. MARKS: Yeah, so what's another 30 or 40 when we're up to 200? Does that make sense from a, let me see, both an ingredient toxicologic point of view that we should put these all together?

DR. SHANK: Yes.

DR. MARKS: Is there any alerts that should separate out the nuts from the vegetables

and the fruits?

David, don't laugh. Did you like the way I worded that?

MR. STEINBERG: Loved it.

DR. MARKS: Is there any scientific reason, let's -- that we should separate all these oils?

No. Okay, so I think the first

business, then, is we think we should combine

them as one group: The edible oil group. DR. SHANK: How about plant-derived oils? DR. MARKS: Plant-derived oils. Sounds good.

these two reports and proceed with considering

DR. SHANK: Better than edible to me.

DR. SLAGA: (off mic)

DR. MARKS: Now, so I'm just going to start it off by saying when we look at the plant oil from hazelnuts, that if I'm correct, the panel in the past felt there was insufficient data and issued a report of insufficient data. And the needs were concentration of use, manufacture contaminants, irritants, and sensitization, UV absorption, a 28-day dermal tox, a reproductive and developmental tox, and genotox were all the eight needs for hazelnut seed oil.

I think probably many of those needs are present with this, or not, when we expand it to over to 200 oils? And if that's the case, how do we reconcile a previous report? Do we reopen it? Is the seed -- I don't think the seed oil is different than the oils we're taking about here. That's on page 20 in the second report, but let me see what that -- so, if you look on page 20, that's Panel Book page 172, you'll see under hazel seed oil, insufficient data.

DR. ANDERSEN: Yeah, I think, Jim, that's one example of why we thought there was actually benefit to combining all of these together. There are bits and pieces to address those issues from other oils, and if we can do a read across from those, because while there are composition differences, those composition differences may not be toxicologically relevant, then we have a big picture that we can paint even though for hazelnut there are missing pieces.

So, that's what we were thinking would be the strategy for this, not that we have actually found data on hazelnut, but we may be able to use a read across approach to say that data on other vegetable oils are applicable across the board.

reader it's nice to have all of the same things in one place so that you know what the perspective was on this group of chemically similar ingredients being used in cosmetics.

DR. SHANK: In the new data submissions that were sent to us as electronic files, PDF files, one of the studies was done on the massage oil that was a mixture of several oils, including hazel seed oil, and it was not sensitizing, so we have data for hazelnut on sensitization.

DR. MARKS: So, we're going to combine these two as, I like that, plant oils. Data needs? Or we can just start with the manufacturing. These oils are squeezed out of their plant source. Is that enough for a method of manufacture?

DR. SHANK: Yes. Yes.

DR. MARKS: Because we aren't going to obviously have the method of manufacture for each one of them. I think it could be put in the report that these are manufactured along the same way. How about impurities? We can obviously DR. MARKS: And Alan, then, would you leave hazelnut seed oil standalone or would you reopen that to include it in this? Because under Table 1, which is on the preceding page, 171, that's included under the nut oils under derivatives, so presumably everything in Table 1 would be included in this or else we'd have to carve out the oils that we previously had made a --

DR. ANDERSEN: I don't think there's any sense in carving it out. I think we bring it into this report and once we get to the end of this we would say that there is now an amended conclusion for hazelnut seed oil.

DR. MARKS: Okay. And the same, presumably if it's all safe, the same would be that we would just note that peanut oil was previously safe and it's included in this report as safe?

DR. ANDERSEN: Yeah.

DR. MARKS: Okay.

DR. ANDERSEN: Yeah, I think for the

cover some of the concerns with our boilerplates, like pesticides and heavy metals. I guess what I'm doing is going down the data needs. Maybe I should just say, Ron, Tom, and Ron, are there any striking data needs that we should have asked for from industry?

DR. SHANK: I had no data needs.

DR. SLAGA: I have none.

- DR. MARKS: None.
- DR. SLAGA: I do not either.

DR. HILL: I have two general questions.

One is related to the bleaching. It says, the statement is made in here, "bleaching the neutralized oil with activated earth." The activated earth is not a bleach, is it? So, does that mean that there's a bleaching process carried

out with, I don't know, hypochlorite or something?

And then "activated earth" is used either

simultaneously or subsequently to remove highly colored pigments?

Because I also had a similar question

about what exactly the deodorization process

entails, and I realize that's all going to be proprietary, but can we get some generalities as to what's actually going on?

MS. BURNETT: I can probably get more information on that. I have this textbook that's this big and I only gave a purview from that, so I have as much more information as you'd like on those processes.

DR. HILL: Well, some generalities as to what's known about those processes.

MS. BURNETT: Okay.

DR. HILL: And then we have to talk about the glycidols issue, right?

DR. SHANK: Right.

DR. HILL: (off mic)

DR. MARKS: And then, Ron, what you were talking with the bleaching, is that a data need or just a clarification?

DR. HILL: It's a clarification, information need that ought to go in the report, I guess. Well, but, however, for me it's less a

data need than an informational need.

I don't know quite how to deal with that. Can you help me? DR. SHANK: We have human sensitization on 40 percent sunflower seed. DR. MARKS: Right. DR. SHANK: Forty percent. DR. MARKS: Okay. DR. SHANK: It's as high as I can find. DR. MARKS: That must be the supplemental. I was going back in the report. Wilma? DR. BERGFELD: I thought that within the document there was enough citation regarding when the protein from the plant was included in the oil

the protein from the plant was included in the oil that that's when the sensitization occurred. And if it was properly refined and the protein was not there, that these oils were not sensitizing. And they had cited several where the protein was the specific allergen.

DR. MARKS: I think that's relevant to Type I immediate type hypersensitivity reactions in which you're concerned, like, for example, DR. ANDERSEN: Well, it's a staff

assignment to finish the homework.

DR. HILL: Yeah.

DR. MARKS: One of the -- and I'll ask the panel members how to reconcile this because I have difficulty, if I look at, for example, sunflower oil, there's certainly not an alert in the literature that this is a sensitizer. It's used up to 96 percent concentration, yet we have only an HRIPT of 2 percent confirming its safety. So I think this is going to cut across -- that's just the most extreme example, but it's going to cut across lots of these oils where, although I don't have an alert of sensitization from either my experience or the literature, I have difficulty reconciling our historic use of either local lymph node assays to predict which are sensitizers or HRIPT are maxed to confirm they aren't. So, I need some help in reconciling that before -- you know, I don't want to put an insufficient. You've got to come back with an HRIPT that says sunflower oil at 96 percent is safe, but, at the same time,

peanuts, that an individual might be sensitive from a Type I reaction. But what I was referring to is a Type IV delayed type hypersensitivity reaction, and whether the protein is there or not is really, by and large, irrelevant.

I think, to me, one of the things that stuck out, again, with proper processing it wouldn't be an issue, but if you take cashews, as long as you take the nut of the cashew, you're fine. If it's contaminated with shell oil, the oil from the shell, then it can be a dramatic sensitizer.

So, presumably in the manufacturing of mango- derived -- or not mango, cashew -- mango's the same issue. You get rid of the -- if you get rid of the skin of the mango, you're not concerned. But if it weren't processed in the right way, manufactured, you could potentially contaminate the mango seed oil.

So, I am back to I don't know how to --I'm not particularly concerned, but I don't have specific sensitization data, say, like sunflower. DR. HILL: I didn't see any for sesame either. Did I just miss it?

DR. MARKS: Oh, I think there will be plenty in here you don't find a sensitization.

DR. EISENMANN: They recently reviewed sesame in 2009, so I think we might -- I don't know how much of the original data in that report is in here, details.

DR. ANDERSEN: So, I think, thinking strategically, Jim, what I would like to be able to do is to show that there are some data across the entire spectrum of use concentration and if we're missing any irritation sensitization data in the high 90 percent exposure category, then that could still pop up as a data need. But if we have another oil that's been tested at 100 percent, and many of them have been, and it's not irritating or sensitizing, then the opportunity for extrapolating those data exists. So, even though there would be a missing piece for safflower, we would be arguing that the oil is not going to be significantly different from those that were

MS. BURNETT: I think there's some that are, if not 100 percent, pretty high.

DR. MARKS: That sounds fine, and then just to be -- for full disclosure, Christina sent me an e-mail concerning the Chenopodium quinoa seed oil where that was found to be -- when you look at the HRIPT there was clearly irritant reactions. There was erythema produced by a sunscreen containing that. And again, I think that could pretty much be ignored because it was a combination product, not just the Chenopodium quinoa oil. I thought if there was alert we would then focus more on that, but using what you have presented, I think it's quite reasonable to cut across.

So, sounds like we -- let me see here. So, Dr. Belsito and I will both be presenting this, so unless Dr. Belsito moves to include the vegetable, fruit, and nut oils all as one report, I will move to make it one report and with a conclusion of safe. Any further comments? tested at 100 percent.

So, we would want to be painting that picture of which oil do we have what data for and at what level, so that at least for, as was discussed in the other team, but you guys sound like you're asking the same questions, that this becomes a table, not necessarily to go in the report, but one that you can look at, to see what data elements are available for which oil at what level. And if that picture looks like there's enough filled in, you can be comfortable. If there are gaps you're not comfortable with, you get to flag them.

DR. MARKS: Christina, you are the most familiar. Is what Alan saying correct, that we have some HRIPT with 100 percent, or at least sensitization data for 100 percent of an oil? Without me going back and looking at those -- I was just picking on her.

MS. BURNETT: Eighty-six percent.

DR. MARKS: Eighty-six. Well, that's

close. That's fine.

DR. BERGFELD: Are you going to put in your discussion some of these elements that have just been discussed especially the plant-derived, the crosstalk or read-across information and support of safety?

DR. MARKS: Sure.

DR. ANDERSEN: Also, the issues of preservatives, heavy metals, that we traditional include --

DR. MARKS: Pesticides.

DR. ANDERSEN: -- in -- I'm sorry,

pesticides. You've seen one P, you've seen them all. Yes. And that would be, again, an admonition to the people who source this material

to continue what we expect is a longstanding practice.

DR. HILL: And so what's the story with the glycidols?

DR. SHANK: That can be handled in the discussion. Glycidol fatty acids is a contaminant. They're precursors to carcinogens, but in the purification process they are not present in these plant-derived oils. That can be handled in the discussion.

DR. ANDERSEN: But we would want to be, again, advising industry that care needs to be taken to ensure that they are eliminated as the oils are processed.

DR. BERGFELD: Was there any concern about the reclassification of the document from -between the fatty acids to triglycerides?

DR. SHANK: (off mic)

DR. BERGFELD: Yeah. But there were some fatty acids in there, too, were there not? DR. SHANK: Free fatty acids.

DR. SHANK. Free facty actus.

DR. BERGFELD: I think there were in all three, but associated.

DR. MARKS: My sense is they were predominantly a mixture of triglycerides, is that correct?

DR. HILL: Some of them have mono- and diglycerides, I think.

MS. BURNETT: I put in the citations for previously reviewed fatty acids so that you were

aware --

DR. MARKS: Right.

MS. BURNETT: -- and you could base

safety on what the previous conclusions were.

DR. ANDERSEN: But the generic title that you've come to of plant-derived oils says it all.

DR. MARKS: Correct.

DR. HILL: Does that make sure that we're not thinking about things like limonene when you just say oils? Dr. Bailey raised that specifically in his memo to make sure that -- and then I think those were removed before we ever saw it. But if we just say oils are we making sure that it's clear that we don't mean volatile oils?

MS. BURNETT: It's no volatile oils.

DR. SHANK: Triglycerides, not essential oils.

MS. BURNETT: No essential oils, all -- sorry, blanked.

DR. ANDERSEN: Yeah, I think, Ron, I'm comfortable with plant-derived oils in the title

with a very early in the introduction explaining that some things are not included for good reason. MS. BURNETT: And there are in the list hydrogenated oils and some salts, simple salts, if

DR. ANDERSEN: I think for generic, short title, we're still okay with plant-derived oils. The reader will very quickly see that it includes some that are further processed in terms of hydrogenation.

you're okay with those.

DR. BERGFELD: Can I ask a question? In several of these documents there is a statement both in the text as well as in the summary that with -- in regards to the plant oil is dependent on the region its grown, individual cultivars --I'm not sure what that is -- and plant genetics. And I have written in here "plant part," for instance, seed versus kernel versus shell versus stem versus -- what are cultivars?

DR. MARKS: Cultivars are actually different varieties of the same plant. DR. BERGFELD: Okay. So the plant part

DR. MARKS: Like mums have multiple -- they're -- if you take the lay term --

DR. BERGFELD: Species?

DR. MARKS: No, it's not exactly a --

it's all the same species, but there are different variations within that species. So if you look at a mum, for instance, I'll use the lay word, there are spider mums, there are pompom mums, there are daisy mums, and those would be all considered cultivars, if I understand the floral/botany portion of this. That's my understanding of a cultivar.

And I think the differences in essentially different parts of the oils, my -- I thought in here the oils were basically from the nuts or the seeds within these plants because we get back to -- if it's just any place, then you get into, do you take a whole mango and squeeze that down and get a fair amount of caranols and anacardic acid and such, which are highly sensitizing in humans. And the same with a mango, if you included the shell -- not the mango, the cashew -- if you included the shell you would have the same issue. It's just the nut, not the shell. DR. BERGFELD: Do you think that you

need to state that? I mean, because here on page -- Panel Book 20, just in the summary portion, the sentence is, "The percentage of chemical constituents and nutritional content in individual oil types is dependent on the region where the oil plant is grown, individual cultivars, and plant genetics."

The chemical constituents is also whether it's a seed versus the shell, so that's why I said plant part. I'm not sure that's a correct term. But this appears in many places, not in this particular document, but in others.

DR. MARKS: Right.

DR. ANDERSEN: But, Wilma, I think you're right. If you added "plant part" to that sentence, it's still a true sentence.

DR. BERGFELD: Right.

DR. ANDERSEN: That contributes to

an extract that we could include by way of example?

DR. MARKS: Sure.

DR. ANDERSEN: Thank you.

DR. MARKS: Remind me. I can send you an endemic of cashew shell oil dermatitis which occurred in Pennsylvania a couple decades ago because of contaminated cashew nuts by the shell oil with the chemical analysis of that material actually.

DR. ANDERSEN: Thank you.

DR. MARKS: It's in the Journal of American Academy of Dermatology, probably about 1983? I'll give you the pertinent information.

Okay, Christina, if you don't find that reference, let me know.

MS. BURNETT: I am aware that there are some, so I can probably find some on my own.

Editorial question for you. On Table 7 in the vegetable oils, it's not very long right now that you see, but because of the data that we have received it's growing. What would be the variability and, yes, you want to constrain that variability in this report to the identified sources which are mostly seed, but not entirely. There is bran oil, there's -- I won't go through the whole list, but the admonition to not -- not to be, I guess for supplier -- I guess it's mostly targeted to supplier, in preparing these to not cross-contaminate with other parts of the plant.

DR. MARKS: Correct.

DR. ANDERSEN: Saying that there's a seed butter or a seed oil that's okay if you are not careful, you could screw up that expectation of safety.

DR. MARKS: Which I think could be handled in the discussion, also, like we mentioned earlier.

Any other comments? So, we are going to combine these two reports.

DR. ANDERSEN: Jim, can I interrupt?

DR. MARKS: Oh, sure.

DR. ANDERSEN: Do you have a good

citation to an example of the shell contaminating

best way you would like that organized? Alphabetized? By concentration? Section off each different oil? I don't know how easy it is for you to read right now and it could get really cumbersome. It starts on Panel Book page --

DR. MARKS: Fifty-four?

MS. BURNETT: Fifty-four. Yes.

DR. MARKS: Right. Can you be creative like you did with the use and concentration?

MS. BURNETT: Right now it's loosely alphabetized, so if it is -- if a related oil -like in Table 1, I have it alphabetized for the most part. And then with hydrogenated I have categories with the hydrogenated -- what the parent is before it's hydrogenated. And that's what I tried to do on this to kind of mimic it, but if it doesn't make sense that way I can do it here, an alphabetized list or however.

DR. HILL: Could that be handled with some sort of a cross index table, just simply -and I don't know, maybe that would just make matters worse. But, I mean, you're right, finding things is important and it will be worse when it's getting longer. And I struggled with that a number of times when I was trying to go back and forth.

MS. BURNETT: Cross index --

DR. HILL: Some means of -- I mean, it would just list all the ingredients and give a table line or something. I mean, I don't know, some quick way of finding things.

DR. BERGFELD: (off mic)

DR. HILL: Yeah, because, I mean, you're referencing things by species name in some cases and common name in other cases and it would be nice to be able to quickly find both. And I'm not talking about for the whole document, I'm just talking about in that table.

MS. BURNETT: For the purposes of the report I did not write up a description of each study.

DR. MARKS: Correct.

MS. BURNETT: The table stands alone and that's it.

other direction, which is signposts? I'm looking at page 46 and I've got four entries for olive -six, seven -- it's seven or so entries in the olive category. If there was a subheading that said, okay, here's the olive stuff --

DR. MARKS: Right, I think that's appropriate.

DR. ANDERSEN: Some of it's the oil, fruit oil, some of it's hydrogenated, but within that group it's -- you can look and see what your options are.

DR. MARKS: I think --

DR. ANDERSEN: And the olive gave you that signpost.

DR. MARKS: Right. I think that's perfectly acceptable to try and reduce and just give the ranges in that.

DR. ANDERSEN: Okay, we'll see what we can do.

DR. MARKS: Any other comments before we complete this discussion?

So, again, I'll reiterate, tomorrow I'm

DR. HILL: Well, just finding things in that, what you said, relatively lengthy table, I mean, maybe that's a nonissue, but it is when you combine them.

MS. BURNETT: We'll brainstorm something and try to figure something out.

DR. MARKS: Quite frankly, I kind of like Table 7 because you can scan this pretty quickly in terms of concentrations and you can get the results and then you give a reference if you want more detail. So, I --

MS. BURNETT: I do see 100 percent oil on here, the babao.

DR. MARKS: Yeah, I noticed that, too, now that I immediately go to the table, so that takes care of that issue, Alan. But I think it would be difficult, probably, to condense this even though it might take -- you know, it's going to take more pages because we have more studies, but at least here it is and you have lots of sensitization.

DR. ANDERSEN: Well, what about the

going to move that we combine both of these oils into one report, the plant oils, and that our conclusion will be safe as used for cosmetic ingredients.

DR. BERGFELD: And that's inferring that you've already commented on the protein and the soy and the nut?

DR. MARKS: Oh, yeah. That's all in the discussion. Absolutely. Yeah, it's going to be a very robust discussion.

DR. HILL: When we're back on the table, to give an example of what I meant when I said cross-referencing, in some cases, like raspberry, that's not too far different in the alphabet from -- I might slaughter the Latin -- Rubus idaeus, right? But on something like cranberry seed, Vaccinium macrocarpon, is quite a bit different to be looking at "c" in one case versus "v" in the other. So if you had something like cranberry, see the Latin name, or the other way around, if you go with olive and raspberry.

DR. MARKS: I would suggest we use the

INCI name and alphabetize it like that and just put in parentheses the lay name.

DR. HILL: But I was just -- if the table gets a lot longer I was just thinking in terms of having some way to do a look up so that you -- because otherwise you end up scanning the whole doggone table to try to find something, which even during the review is cumbersome. And I like the table, I agree.

DR. ANDERSEN: It's a challenge on how to work those signposts, there's no question about it. The reality is that the Latin name, while it's a good way of standardizing all of this stuff, they do not trip off the tongue lightly. And if we're doing a signpost, maybe cranberry is the better signpost under which you find the Latin name, et cetera, et cetera.

So, we'll take a look at it and see what seems to make sense because the average consumer looking at this isn't going to be thinking from Linnaean descriptions. It's going to be, oh, I'm supposed to stay away from cranberry. DR. MARKS: I don't know, I would ask John and Carol's input. Because to me it's -- if you look at it from a world point of view, the only commonality is going to be the INCI name, which is the botanical name, not the lay name. So for us, even between Boston and perhaps someplace else, there might be different common names for the same cosmetic ingredient.

At any rate, we'll let you figure that out and we'll see it in the next edition with a tentative report with a conclusion of safe.

Next we're on to the 2011 Priority List and that's in the Buff Book 1, Panel Book page 16, et cetera.

Any comments about that? And my understanding is we're going to include a hair dye ingredient also in this.

DR. BRESLAWEC: If I could just point out that the only difference -- there are some differences between the list as you saw it in June and this list, and the changes reflect your comments and comments that we've received from

| | type in there, Alan, or intended use? |
|---|--|
| | DR. ANDERSEN: No. I think that will be |
| | elear from the discussion that it's you have |
| | lots of options on how to modify either the |
| | concentration of the ingredient, the level of |
| 116th COSMETIC INGREDIENT REVIEW EXPERT PANEL | impurities, or product type. |
| MEETING | DR. BERGFELD: So, it's my understanding |
| | on page CIR Panel Book, page 76, under |
| | Quantitative Risk Assessment, that will be greatly |
| | expanded with the examples as indicated or |
| | suggested by Dr. Belsito? Okay. |
| | Any other discussion? I'm going to call |
| | for the vote, then. |
| | All those for the approval of the first |
| | version with amendment indicate by raising your |
| | hand. Thank you, unanimous. |
| | Wow, that was a good one. Let's move |
| | on, then, to the next one, which is the plant |
| | oils. Dr. Belsito presenting. |
| | DR. BELSITO: Yes. This is the first |
| Washington, D.C. | time that we're seeing this report, which is |
| Tuesday, August 31, 2010 | probably the largest report we've ever had to |
| | |

review. And we received a whole lot of unpublished data, et cetera, et cetera.

In looking at this in general, my team felt that we could go safe as used with the usual plant boilerplates, with the exception that there is one component -- at least, of rice germ oil -and that's arachidonic acid that we previously reviewed and found to be insufficient. Also, Dr. Liebler had some concerns not only about arachidonic acid, but dodeca-hexanoic acid and linolenic acid as having more than two double bonds that could be relatively unstable.

So, what we need would be to actually take a look at all of the vegetable oils in this report and for those in which we don't have composition, those would be insufficient awaiting composition. Those that contained arachidonic dodeca-hexanoic or linolenic acid would be insufficient for data on that.

Alternatively, if we wouldn't want to take that approach, my team suggested tabling this and reopening the arachidonic acid report, since

DR. BERGFELD: Do you wish to discuss this? Marks' team?

DR. MARKS: Oh, yes. We had similar feelings that we would move toward safe. I think how handling at this point we felt we could actually move forward with a tentative report of safe, but we hear the insufficient data needs.

One of the discussion instances we felt that we would take this whole Green Book and combine the vegetable -- there's actually fruit oils in here along with nut oils -- and just make it one large document with over 200+ ingredients and call it Plant Oils. So we would suggest combining these two.

And then I think going forward, as you suggested, Don, with an insufficient clarifying -it's interesting. If we do arachidonic acid, then that will come up in a priority list, obviously, on the re-reviews.

DR. BELSITO: But if --

DR. BERGFELD: I'm unclear what you want

it's been 16 years since we last looked at it and there's been 16 years' worth of data on it. And see, perhaps, we could find the cosmetic uses if there are any -- I don't know, John, that was one of the insufficients when you reviewed it. Is it still being used?

DR. BAILEY: Yes.

DR. BELSITO: So, maybe we want to table it and go back to arachidonic acid and reopen that and see what we're looking at.

DR. BAILEY: I mean, it's still being used, but the use frequency is quite low. So, it's not a real widely used material.

I think it would be very difficult to find someone to support the providing the safety data for it. But that's just sort of my best guess at this point.

DR. BELSITO: But there may be data out in the public literature since we looked at it in '93 that would support our data needs.

DR. BAILEY: There's a huge amount of data, yes.

DR. BELSITO: Well, I mean, I think that we were unclear as to where the panel would want to go, because if -- and I guess partly we're curious why arachidonic acid hasn't come up since it was last reviewed in '93 and the data were found to be insufficient. But I think in some ways if we look at this and we call these ingredients insufficient -- those that contain arachidonic acid -- and arachidonic acid comes up and we find that the available data in the literature then supports the safety of arachidonic acid as used in cosmetics, then we would have to go back and reopen this document to change our conclusion about all of the plant oils that contain arachidonic acid.

So, personally, I would be in favor of tabling this, reopening the arachidonic acid report, seeing where that goes, and then coming back to this report knowing that the biggest issue was those plant oils that contain, potentially, arachidonic acid.

DR. BERGFELD: Alan?

DR. ANDERSEN: Monice has some

information. But the answer to the question of why hasn't arachidonic acid come up -- the panel made the policy decision early on for re-reviews that we were not going to initiate a re-review of an ingredient for which the data were insufficient. That was industry's problem. If they wanted to come forward with the data, knock your socks off. But we weren't going to do their job for them.

MS. FIUME: I just wanted to add, I did check the FDA frequency of use. It is only 14 uses. And then I just did a very quick search on Tox Net using arachidonic acid and dermal carcinogen; there's no new data for dermal carcinogenicity, which I believe was one of the reasons it went insufficient.

DR. SHANK: The arachidonic acid isn't in these oils as a free acid, it's part of a triglyceride. So why pick out arachidonic acid? Or are you concerned about peanut oil? I don't understand why you need to table this to find out

the reports, and it looks like the only one that has any reported arachidonic is the rice oil. And, you know, that's the only -- that's actually sort of an outlier among all of the oils in having a longer chain polyunsaturated fatty acid, because for the most part these are at most diunsaturated -- mostly monounsaturated, mostly shorter chain length, which I think removes most of the concerns I would have.

I pointed out yesterday in our discussion that part of the problem of lipid oxidation products is going to be somewhat self-limiting in that the oils that have a higher propensity to undergo oxidation are going to probably be unacceptable for use in these products anyway because of, you know, generating undesirable smells and things like that. So, I think the -- one possible approach to this could be to just consider everything but the rice oil. And with the concern there being the relatively high arachidonic content relative to all the other plant and nut oils that are being considered -- about arachidonic acid as a free fatty acid, because these are triglycerides.

DR. LIEBLER: Arachidonic acid -- I'm --I guess I'm not sure whether I should be surprised that there aren't any more dermal carcinogenicity data on arachidonic acid since the mid-'90s. But there's a tremendous amount of research that's been done on arachidonic acid and eicosanoid metabolites of arachidonic acid in modulating skin carcinogenesis. I mean, this has been a huge area of research, as Tom is quite aware. There's a lot of data. I'm not sure exactly where it comes down.

Admittedly, most of the arachidonic acid physiologically that's released is coming from phospholipids, released by phospholipases. These are on triglycerides. It's possible they could be released by lipases also in the skin, but I'm not sure about, you know, how efficient that process would be.

If I -- I just eyeballed the charts on the arachidonic composition of the oils in both of

DR. BAILEY: I thought rice oil had already been reviewed and is, you know, safe based on an earlier review. So, you know, I'm just not sure that those dots connect, so. DR. BERGFELD: Dr. Hill? DR. HILL: Yeah, I was just going to point out that -- but I agree with only arachidonic acid. But if your concern is three or four bond unsaturated acids, then cherry kernel oil has a high percentage of eleostearic acid, borage oil has a high percent -- a relatively high percentage of -- oh, it's pretty small of gamma-linolenic. Black currant seed oil has a reasonable percentage of gamma-linolenic and stearidonic. Evening primrose oil has a pretty high concentration of gamma-linolenic and cranberry seed oil has a high concentration of 18-3 ethyl- linolenic, so. DR. LIEBLER: Right, those points are well taken. I also noticed that. I think the additional concern with

arachidonic is that there's specific receptors for

many of the arachidonic metabolites that potentially amplify its biological effects.

Now, if rice oil has already been reviewed and is safe as used, it's something I didn't catch. And that may preempt this whole discussion.

DR. MARKS: John, I'm looking on page 172 of the Panel Book. And, you know, that's nut oil, so that wouldn't be rice, I'm sorry. I guess I need to do the -- I was --

DR. BELSITO: (Off mic)

DR. MARKS: Been approved, yes. That's page --

MS. BURNETT: Panel Book, page 27.

DR. MARKS: Twenty-seven, so it had been approved before.

MS. BURNETT: In 2006.

DR. BAILEY: These are edible oils, you know. Vegetable oils. So, I mean, they've been around a long time, we have a lot of experience with them. And, I mean, I think these are valid points. Maybe they should be addressed in the

the fact that they're edible has nothing to do with it in this case, because the question is what happens in the skin. Because the processing of lipids in the gut is totally different than what happens in the skin.

Well, totally, that's not quite accurate. But quite different.

DR. BELSITO: Dan, do you want to comment?

DR. LIEBLER: Well, the only -- I think that I would want to see more data. I suppose -well, I guess I would want to see more data on the arachidonic for plant oils, for which there wasn't a safe as used, and a high arachidonic content. I think that probably -- unless there are plant oils that we're considering, we don't have composition data for that -- that concern kind of goes away. I would point out that actually, fatty acids don't need to be released from phospholipids or triglycerides to be toxic. In terms of

oxidation products -- my colleagues Jason Morrow and Jack Roberts of Vanderbilt have done a lot of

part of the discussion and, you know, if there's concern about arachidonic acid specifically, that could be captured also in a part of a discussion. I'm just not sure it's really -- these are points to hold up the process.

DR. BELSITO: Well it's certainly -- for rice germ oil, a small percentage of the total composition. I guess the issue would then become what about the oils for which we do not have composition. If you're concerned about arachidonic acid, I mean, I don't know. I mean, it's potentially that specific oil might have a very high percentage of arachidonic acid and the absence of knowing the composition, I think we'd have to go insufficient on that basis.

DR. SLAGA: But keep in mind, it's (off mic) about there's no free acids in this that would have to be released. And the odds of that happening in the stratum corneum area are essentially zilch.

DR. BERGFELD: Dr. Hill?

DR. HILL: I was just going to say that

work over the years demonstrating the formation of isoprostanes by non- enzymatic oxidation processes that result in products with significant activities, even when they're still connected to phospholipids and triglycerides.

But I think based on the data we have on the charts in front of us, the only component I would have had any concern about would have been the rice germ oil, and that's safe as used already. So, I think -- I feel like Emily Litella, right? "Never mind."

DR. MARKS: Right. Actually, there are a number of oils that have been felt to be safe with the exception of hazel seed oil, that's the only one when you look at this entire group. And that was an insufficient data.

DR. BRESLAWEC: But that was hazel seed oil. Wasn't that addressed subsequently?

REPORTER: Microphone, please.

MS. BURNETT: We have received HRIPT data on hazelnut oil. I'm not sure which species. Might be both, might be just one of them. DR. MARKS: So that really has no relevance to this issue of the arachidonic acids. So, do you feel comfortable, Diane, at this point? DR. BELSITO: But we don't have the composition of all the vegetable oils that we're reviewing in this document.

DR. MARKS: Well, we have, what, 250, approximately? Do you think we're going to get that? Or can we use crossover -- cross-reading when we say rice is safe. And that was the one that, Dan, you altered?

DR. BELSITO: But that had 5 percent. We don't know that some of them that are out there that we don't know composition for could have 85 percent arachidonic acid. We just -- if we -- I think if we don't know the composition, you know, and perhaps we can get this from Dr. Dan's -- I don't know if you already sourced that or not. But I think we really -- since arachidonic acid has not been found to be safe, then I think we need to know the composition of all the vegetable oils that we're going to say are safe. And if we

you know, because we allowed wheat germ oil at 5 percent to go forward that everything else -- and where are we getting this 5 percent? Simply from -- or look at the data from rice germ oil, rather. Look at that data and see what kind of data did we specifically have on rice germ oil in that safety report. Or were we doing read-across on rice?

DR. BERGFELD: Alan?

DR. ANDERSEN: I -- it's interesting that all of the composition reports that were available when we reviewed the rice group -- only one study from '86 demonstrated any arachidonic as a component. There's '99, 2000, 2002, subsequent with no arachidonic acid identified in the composition.

So, it's -- the data that show -- and the 1986 report was at 5.48 percent arachidonic. So, it wasn't a huge composition issue, and it hasn't been repeated in subsequent analyses. I don't know, Christina, if we have additional data beyond that. But it's just -- it wasn't a significant issue and maybe even wasn't a real don't have a composition, then the data would be insufficient for composition. Specifically, of arachidonic acid.

DR. MARKS: Or, another way to handle that, Don, would be to come to a conclusion, again, using a disqualifier that it doesn't contain -- if we want to quantify it -arachidonic acid above a certain level or whatever. I don't know. That would be another -rather than what I'm afraid is, we're going to go down 250, get a list, and we're only going to have a small number that has arachidonic acid levels in it. But I'm not sure that we haven't looked yet.

DR. BELSITO: I think if you do that, then you'd have to justify it with a QRA. And you'd have to go back and look at the dermal carcinogenicity studies that we looked at for arachidonic acid, and do some type of QRA. And I don't know, based on the literature, if that's doable. But then, if we're going to do that, we might as well open the arachidonic acid report before we do it. But I don't think you can say,

issue, which probably is why the panel didn't flag it when we did the rice.

DR. BERGFELD: Dan, please?

DR. LIEBLER: I just want to suggest that I think the minimal level of due diligence that this panel should apply is to known the compositions of the products that we're talking about here. And in the case of the oils, the main products are the oils that stearified in these triglycerides. So, I'm not comfortable even though we might suspect that plant oils are all going to be in the range of about C12-C18 with usually no more than two double bonds. I'm not comfortable as taking that as a given without knowing the composition of the other oils. So, I would suggest -- I would not be in favor of -- I would consider lack of composition to be insufficient from the get-go.

- DR. BERGFELD: Dr. Hill?
- DR. HILL: I was --
- DR. BERGFELD: Are you agreeing?
- DR. HILL: I was just agreeing with what

he just said.

DR. BERGFELD: Dr. Slaga?

MR. KLAASSEN: One of the problems with, you know, when you're talking about these natural products is the amount of certain oils that you have this year is different than next year. And this -- if it had more rain or less rain or more stress or less stress, you get different components. So it's a little different in that regard.

Now, another question I have is with our real problem here. I mean, what is known about --Tom maybe has the best background in this. What's known about any fatty acid producing carcinogenesis in the skin? I mean, I can -- you -- there's many theoretical reasons why they might. I assume there have been a fair number of experiments and kind of what's the general knowledge?

DR. SLAGA: There's a lot of data (off mic) free form. But I know of no studies with (off mic) complex oil that has shown to be

is that it would be an insufficient data. DR. BELSITO: That's what we want, composition for each of the oils. And for those that don't have composition, they're insufficient pending data on the -- it could be complete composition of arachidonic acid.

DR. LIEBLER: I agree with that. I mean, I think that one of the things that you have to deal with when you decide you're going to take on 200 ingredients is that they all are -- you know, they all have compositions. And we're still responsible for them. The fact that it's a logistical nightmare is really -- doesn't change that fact. We need to know the composition of these ingredients.

So, ultimately there would have to be a table. A huge mega table of some sort that would have all that information in it. I realize that would be a terrible pain in the neck. There might be some other way -- graphical way to illustrate the composition trends across oils. If that turns out to be important, I have a feeling there'll carcinogenic. It's always the free fatty acids, the unsaturated --

MR. KLAASSEN: (Off mic) triglyceride of any -- it's just not been done or they don't cause --

DR. SLAGA: No, no, there's -- it's a lot been used as vehicles. And the vehicles come out to be negative. It's -- tremendous literature on arachidonic acid, and some other related type of unsaturated fatty acids. But that they do have some type of activity -- not cancer-causing, they're more tumor promoting or enhancing activity.

DR. BERGFELD: Dr. Marks?

DR. MARKS: Dan, maybe you can give Christina some guidance in terms of this -- the composition of each one of these 250. Would you like that in some sort of tabular form where you could have ranges, almost like the use in concentration? Or do you want to see each oil with a composition under it? And if we don't have a composition, then I think the -- what you infer

just be a cluster of points from C12-C18 for most of these. But we -- I think we just have to look.

DR. BRESLAWEC: May I ask a question? Dr. Liebler, if you look at Table 3, CIR Panel Book 33, as an example, the compositions as we -as available are presented for a for a number of oils on those pages. Is that adequate in terms of composition for those oils?

DR. LIEBLER: Yes, that's fine.

DR. BRESLAWEC: Thank you.

DR. SLAGA: The fact that we want to

combine nut oil and the edible plant oils,

wouldn't this be the opportunity then to combine it all and try to get all the compositions at one time?

DR. BELSITO: Exactly.

DR. BERGFELD: Is there a general

agreement to combine these two documents? It's sort of a straw vote, all those in favor --

DR. BELSITO: Yes.

DR. BERGFELD: Yes. Good. So, now

we're needing a motion to how we're going to act

on this. Is it going to go insufficient, or is it going to go tabled, both for the same reason -- composition.

DR. BELSITO: Well, this is the first time we're looking at it, so go insufficient and try and get the composition data.

DR. BERGFELD: And so that's a motion?

Motion? Is it seconded?

DR. BELSITO: Yes.

- DR. MARKS: Second.
- DR. BERGFELD: Any further discussion,

then? Dr. Bailey, any discussion?

DR. BAILEY: No, I think these are

reasonable explorations. I think the reality of ingredients that are botanical or isolated from natural sources is that the table is not going to be complete. But it's worth, you know, adding as many interests as we can, and then if we find patters that we're comfortable with, then that may suffice. But, you know, expanding the table, I think, is a reasonable step.

DR. BERGFELD: Thank you. Any other

comments? Seeing none, call for the vote. All those in favor of going insufficient notice? Thank you, unanimous. So, we've now covered the nut oils as well, because they're being grouped with the plant oils. We're moving on to triclosan. Dr. Belsito.

DR. BELSITO: Yes, triclosan. This is the first time that we're seeing the report, and I'd like to congratulate the CIR staff for taking a novel approach to what otherwise could have been an extremely overwhelming document, given the plethora of studies in the literature on this antimicrobial.

And the approach that the CIR took was first to identify issues surrounding triclosan --safety issues where we'd like to key in. And those included the exposure -- so, how were we being exposed to it in cosmetics? Potential dioxin impurities, photostability in dioxin, photo products, carcinogenicity, potential endocrine disruption, and then the potential for the bacterial resistance.

Draft Final Report

Plant-Derived Fatty Acid Oils Group

March 4, 2011

The 2011 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Ronald A Hill, Ph.D. James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is F. Alan Andersen, Ph.D. This report was prepared by Christina L. Burnett and Monice Fiume.

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ABSTRACT

The CIR Expert Panel assessed the safety of 244 Plant-Derived Fatty Acid Oils as used in cosmetics. Oils are used in a wide variety of cosmetic products for their skin conditioning, occlusive, emollient, and moisturizing properties. Since many of these oils are edible, and their systemic toxicity potential low, the review of the Panel focused on their potential dermal effects. The Expert Panel concluded that 241 of the 244 Plant-Derived Fatty Acid Oils are safe as used in cosmetics. Chemical composition data, particularly fatty acid profiles, were absent for 3 of the oils; therefore, these oils were found to have insufficient data for a determination of safety.

INTRODUCTION

Oils derived from edible vegetables, fruits, seeds, and tree and ground nuts have been safely consumed by humans for millennia. While nuts and some fruits and vegetables themselves may cause allergic reactions in certain individuals, the refined oils derived from these plants generally pose no significant safety concern following oral exposure, and their general biology is well characterized due to extensive use in food materials. All of the ingredients in this report are mixtures of triglycerides containing fatty acids and fatty acid derivatives, the safety of which in cosmetics have been established. This safety assessment will focus solely on the basic chemistry, manufacturing/production, uses, and irritation and sensitization data available on these oils as they are used in cosmetic ingredients.

Various oils have been used on the skin since antiquity. Initially used for anointing in religious ceremonies, oils and their components have also been long used on the skin for cosmetic purposes. They are used in a wide variety of cosmetic products for their skin conditioning, occlusive, emollient, moisturizing and other properties. The full list of ingredients in this report, which includes oils, hydrogenated oils, unsaponifiables, oil fatty acids, and salts of the fatty acids, is found in Table 1. While a large number of oils derived from plants are included in this literature review, there is a commonality in that they all are mixtures of triglycerides containing fatty acids and fatty acid derivatives, the safety of which in cosmetics have been established.

In preparing this report, numerous inconsistencies were noted with both taxonomic and INCI naming conventions. For example, this report includes the macadamia nut ingredients, Macadamia Integrifolia Seed Oil and Macadamia Ternifolia Seed Oil, which are described in the International Cosmetic Ingredient Dictionary and Handbook.¹ The species *M. integrifolia* is currently the only species of macadamia nut that is used for oil production. The name *M. ternifolia* is an old naming convention for the edible nut that is currently used to describe a non-cultivated, inedible species.^{2,3} Macadamia Integrifolia Seed Oil and Macadamia Ternifolia Seed Oil are the same ingredient. Similar naming conflicts have been discovered with Triticum Vulgare (Wheat) Germ Oil and Triticum Aestivum (Wheat) Germ Oil, Orbignya Oleifera Seed Oil and Orbignya Speciosa Kernel Oil, and Moringa Pterygosperma Seed Oil and Moringa Oleifera Seed Oil, with these pairs being synonyms for each other. The shea plant also has two species names, *Butyrospermum parkii* and *Vitellaria paradoxa*. Only *B. parkii* (as Butyrospermum Parkii [Shea] Oil or Butter) is the current naming convention described by the cosmetics industry.

This report includes cosmetic ingredients that have been previously reviewed by the Cosmetic Ingredient Review Expert Panel. The ingredients, their conclusions, and published citations are found in Table 2. Previously reviewed fatty acids and glyceryl triesters are also found in Table 2.

CHEMISTRY

The group of ingredients characterized as fats and oils are the glyceryl esters of fatty acids (triglycerides) normally found in plants, including those which have been hydrogenated to reduce or eliminate unsaturation.⁴ Figure 1 represents the general structure of fats and oils. The raw oil may include diglycerides, monoglycerides, free fatty acids, plant sterols, pigments, glucosides, proteins, natural antioxidants, vitamins and impurities.^{5,6} The extent to which these components are removed during processing varies. The available information on chemical properties of oils in this report, including Food Chemicals Codex

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specifications when provided, are found in Table 3.⁷ The available fatty acid compositions for the oils in this report are found in Table 4.

The percentage of chemical constituents in individual oil types is dependent on the region where the oilseed plant is grown, individual cultivars, and plant genetics.⁶ This is especially true with rapeseed, where the erucic acid content varies from 1% to 58.6%. Low erucic acid rapeseed oil is also known as canola oil.

The nutritional content of these oils varies with oil type. For example, sunflower oil contains high levels of vitamins A, D, and K, while palm oil is a rich source of vitamins A and E. Crude sunflower oil also has the highest content of vitamin E in the form of α -tocopherol amongst vegetable oils.⁶

Vegetable Oil and Hydrogenated Vegetable Oil are cosmetic labeling names for blends of plant-derived oils.⁸ The composition of a blend is determined by the desired physical properties. Vegetable Oil and Hydrogenated Vegetable Oil may include, but are not limited to: Canola Oil, Brassica Campestris (Rapeseed) Oil, Carthamus Tinctorius (Safflower) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Sesamum Indicum (Sesame) Seed Oil, Elaeis Guineensis (Palm) Oil, Elaeis Guineensis (Palm Kernel) Oil, Cocos Nucifera (Coconut) Oil, Gossypium Herbaceum (Cottonseed) Oil, Glycine Soja (Soybean) Oil, Zea Mays (Corn) Oil, Olea Europaea (Olive) Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, and hydrogenated products of these oils.

Processing

The oil may be directly expressed from the source (seed or pulp) followed by solvent extraction. *Bailey's Industrial Oil and Fat Products* states that the removal of pigments and polar materials is mandatory for most cosmetic applications.⁹ The process used for oil refining for foods may be adequate for this purpose, or additional steps may be required. Special refining methods to yield colorless and odorless oils are used by the cosmetic industry and include proprietary adsorption chromatography and supercritical fluid extractions.

The majority of the oils presented in this report are produced either from mechanical extraction or solvent extraction or a hybrid of both methods, known as prepress solvent extraction.⁶ In solvent extraction, hexane is the most commonly used solvent, as it is economical and easily removed from the extracted oil. Seeds that are rich in oil can be cold pressed to extract oil without the use of solvents.¹⁰

After the initial extraction by methods such as solvent extraction, the crude (degummed) oil is often refined.⁶ The first step is treating the oil with caustic soda to neutralize free fatty acids, hydrolyze phosphatides, and remove some colored pigments and unsaponifiable materials. Soap stock is usually a by-product of this step. The next step involves treating the neutralized oil with activated earth to further adsorb pigments. The last major step in refining oil is deodorizing, usually by a type of steam distillation, which is intended to remove all oxidative cleavage products that impart odor or flavor to the oil. Deodorization also removes tocopherols, sterols, and other minor constituents of free fatty acids and undesirable foreign materials. Figure 2 is a flowchart of the basic refinement process.

After deodorization, oils can be further processed by hydrogenation, which makes oil more resistant to oxidative and thermal damage, and by winterization, where oil is slowly cooled to promote formation of crystals that cause cloudiness, and then filtered to remove the crystals.

Cosmetic grade fatty acid plant oils may include a physical refining step that involves heating crude oil under vacuum.¹⁰ This step allows for the removal of volatile components such as color compounds, odor compounds, and free fatty acids, which gives the refined oil a lighter color, less odor, and lower acid values.

Analytical Methods

Near infrared spectroscopy and gas chromatography have been used, respectively, to phenotype and analyze fatty acid profiles in shea fat (described as *Vitellaria paradoxa*, not *Butyrospermum parkii*).¹¹ The fatty acid composition of hazel seed oil

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(*Corylus avellana*, in crude form) has also been analyzed by gas chromatography.¹² The triacylglycerol and diacylglycerol composition oils from hazelnut, pistachio, almond, Brazil nut, and macadamia nuts have been characterized with high-performance liquid chromatography with atmospheric pressure chemical ionization and UV detection.¹³ The triacylglycerol profile of Brazil nut oil has also been quantified using dry matrix-assisted laser desorption/ionization time-of flight mass spectrometry.¹⁴

Impurities

Proteins

Many edible fatty acid oils are derived from foods that are recognized as potent food allergens. It has been shown that often an individual that is allergic to a food will generally not react to the refined oil, especially if the oil has been "hot-pressed" or has undergone more processing.^{15,16} A prime example is Arachis Hypogaea (Peanut) Oil. Peanuts are extremely allergenic to a large population, but reaction to the oil is rare. In its safety assessment on Arachis Hypogaea (Peanut) Oil, the Expert Panel noted that the major concern associated with allergic reactions to peanuts is the protein.¹⁷ The protein does not partition into the refined oil, and therefore the oil is safe for use in cosmetics. However, researchers have reported protein levels in processed oils. Halsey et al. reported that Lowry protein determinations of cold-pressed and refined sunflower oil found 2-8 µg/ml protein,¹⁸ while Zitouni et al. reported trace amounts of protein in the refined oil.¹⁹ Olszewski et al. found 0.1-0.2 µg protein per g of peanut oil,²⁰ while Ramazzotti et al. reported finding IgE responsive residual proteins in peanut oil extracts.²¹ Porras et al. found soy protein in some samples of soy oil, but not others.²² Awazuhara et al. reported 1.4-4.0 µg protein per 100 g of soy oil.²³ Although Paschke et al. found approximately 35 µg/l protein content in refined soybean oil, no IgE-binding activity was detectable.²⁴

While the Panel has found a general lack of clinical effects for fatty acid oils already reviewed,^{17,25-33} other groups have raised concerns. The European Medicines Agency (EMEA) Working Party on Herbal Medicinal Products concluded that soy and peanut products "should be treated as allergenic unless they have an analytically-monitored non-allergenic specification and a safe maximum daily dose."³⁴ The EMEA found that threshold concentrations for induction of a protein contact dermatitis were not available and recommended, "all medications for topical use containing soya or peanut products should be treated as allergenic."

Aflatoxin

Aflatoxins are metabolic products of the molds *Aspergillus flavus* and *Aspergillus parasiticus*. They are most often produced in stored agricultural crops (such as peanuts and other nut crops) when growth conditions and genetic requirements are favorable.³⁵⁻³⁷ The International Agency for Research on Cancer (IARC) categorized aflatoxins as group 1 agents, "carcinogenic to humans".^{38,39}

The United States government places the following limitations on peanuts to be considered "negative" for aflatoxin: ≤ 15 ppb for "peanuts which have been certified as meeting edible quality grade requirements" and ≤ 25 ppb for "non-edible quality categories" (7 CFR Sections 997.30 and 998.200).⁴⁰

A study reported that crude peanut oil (obtained by solvent extraction or hydraulic pressing) has reduced aflatoxin concentration compared to peanut kernels, and that subsequent processing (alkali refining and bleaching) reduces the concentration still further.¹⁷ In one example, processed peanut oil from moldy peanuts (contaminated with 5500 ppb aflatoxin) had an aflatoxin concentration of < 1ppb. [From CIR assessment on Arachis Hypogaea (Peanut) Oil, 2001.]¹⁷

In 50 samples of hazel nuts from Spain, all samples showed fungal contamination, but no aflatoxin contamination.⁴¹ Of the 50 fungal strains identified, 25 were aflatoxigenic strains. In 20 hazel nut samples collected in Egypt, however, aflatoxin (25-175 μ g/kg) was reported as a contaminant in 90% of samples. [From CIR assessment on Hazel Seed Oil, 2001.]⁴²

Aflatoxin contamination of raw and dried coconut copra has been reported.³³ Improper drying, handling, and storage greatly increase the possibility of contamination by aflatoxins growing on copra. Smoke drying of copra inhibited aflatoxin formation. [From CIR assessment on Cocos Nucifera (Coconut) Oil, 2008.]⁴³

Glycidol

Glycidol and glycidol fatty acid esters have been detected in refined fatty acid oils.⁴⁴⁻⁴⁷

USE

Cosmetic

There are 244 oil ingredients included in this safety assessment, 146 of which are reported to be used; 118 of the in-use ingredients have never been reviewed by CIR, while 28 have been reviewed previously. For the ingredients being reviewed for the first time, the frequency of use, as supplied to the Food and Drug Administration (FDA) by industry as part of the Voluntary Cosmetic Registration Program (VCRP),⁴⁸ and/or concentration of use, as supplied by industry in response to a Personal Care Products Council (Council) survey,⁴⁹⁻⁵¹ can be found in Table 5a. (Also included in Table 5a are three ingredients, Citrullus Vulgaris (Watermelon) Seed Oil, Macadamia Nut Oil, and Vaccinium Oxycoccos (Cranberry) Seed Oil, that do not have identifiable International Nomenclature Cosmetic Ingredient (INCI) names. While these ingredients are not part of this assessment, they are very similar to the oils that are identified and information on them is included in this report for completeness.) For the ingredients that have been reviewed previously, the current and historical^{26-28,32,52-55} frequency and concentration of use is given in Table 5b. The 98 ingredients not currently reported to be used are listed in Table 5c. ^{48-51,56,57}

It should be noted that the names vegetable oil and hydrogenated vegetable oil, are used in cosmetic formulations, refer to a blend of plant-derived oils, and the composition of the blend varies.⁸

Of the oils included in this report, Butyrospermum Parkii (Shea) Butter has the most reported uses in cosmetic and personal care products, with a total of 1950; 1680 of those uses are in leave-on formulations. A recent survey of use concentrations for Butyrospermum Parkii (Shea) Butter reports a maximum use concentration of 60% in leave-on products as a cuticle softener, a manicuring application.⁵⁸ Helianthus Annuus (Sunflower) Seed Oil has the second greatest number of overall uses reported, with a total of 1414; 1054 of those uses are in leave-on formulations, having use concentrations up to 96%. Many other ingredients are used in an extensive number of formulations. For example, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Olea Europaea (Olive) Fruit Oil, and Glycine Soja (Soybean) Oil have 1127, 915, and 912 uses, respectively. Most of the in-use ingredients have uses in both leave-on and rinse-off product types, many are used in products that are applied around the eye and some are used in a way they can possibly be ingested. Some are used in products that involve mucous membrane exposure, and a few are used in underarm deodorant formulations. Many of the products are used in formulations at relatively high concentrations. Olea Europaea (Olive) Fruit Oil is used at up to 100%, Persea Gratissima (Avocado) Oil is used at up to 98%, Helianthus Annuus (Sunflower) Seed Oil at up to 96%, and Glycine Soja (Soybean) Oil at 95%.

Oils are used in a wide variety of cosmetic products for their skin conditioning, occlusive, emollient, moisturizing and other properties. The oil ingredients described in this report may be used in hair sprays, and effects on the lungs that may be induced by aerosolized products containing these ingredients are of concern.

The aerosol properties that determine deposition in the respiratory system are particle size and density. The parameter most closely associated with deposition is the aerodynamic diameter, d_a , defined as the diameter of a sphere of unit density possessing the same terminal settling velocity as the particle in question. In humans, particles with an aerodynamic diameter of $\leq 10\mu$ m are respirable. Particles with a d_a from 0.1 - 10 μ m settle in the upper respiratory tract and particles with a $d_a < 0.1 \mu$ m settle in the lower respiratory tract.^{59,60}

Particle diameters of 60-80 μ m and \geq 80 μ m have been reported for anhydrous hair sprays and pump hairsprays, respectively.⁶¹ In practice, aerosols should have at least 99% of their particle diameters in the 10 – 110 μ m range and the mean

particle diameter in a typical aerosol spray has been reported as $\sim 38 \ \mu m$.⁶² Therefore, most aerosol particles are deposited in the nasopharyngeal region and are not respirable.

None of the oils, hydrogenated oils, unsaponifiables, oil fatty acids, and salts of the fatty acids described in this report were restricted from use in any way under the rules governing cosmetic products in the European Union.⁶³

Non-Cosmetic

The primary uses for plant-derived fatty acid oils are for cooking. Palm oil is the world's most widely consumed edible oil (41.7 million metric tons), followed by soybean oil, rapeseed oil, sunflower seed oil, cottonseed oil, peanut oil, palm kernel oil, coconut oil, and olive oil.^{6,64} Non-food, non-cosmetic uses for edible fatty acid oils are found in Table 6.

ANIMAL TOXICOLOGY

Many of the fatty acid oils in this assessment are edible, <u>and exposure to the oils from food use would result in a much</u> <u>larger systemic dose that that resulting from use in cosmetic products</u>. Consequently, their systemic toxicity potential is not addressed in this report. The safety focus of use of these oils as cosmetic ingredients is on the potential for irritation and sensitization.

CARCINOGENICITY

The safety of glycidol fatty acid esters in refined vegetable oils was assessed by IARC. Glycidol was determined to be a Group2A (probably carcinogenic to humans) chemical while glycidol fatty acid esters was determined to be a Group 3 (not classifiable as to carcinogenicity to humans) chemical.^{46,47}

The Federal Institute for Risk Assessment in Germany released a summary of their initial evaluation of the assessment of levels of glycidol fatty acid esters detected in refined vegetable fats.⁴⁵ While acknowledging that the levels of glycidol that may be released from glycidol fatty acid esters are not known, the evaluation noted that glycidol is classified as probably carcinogenic to humans. The evaluation was based on findings of the German Chemical and Veterinary Test Agency (CVUA) that noted that glycidol is converted to 3-chloropropanediol and it appeared to be the 3-chloropropanediol that was detected in the vegetable fat.⁴⁴ The levels of 3-chloropropanediol were negligible at the crude oil, degummed, neutralized, and bleached stages, but levels were significant at the deodorized stage.

Anacardium Occidentale (Cashew) Seed Oil

Singh et al. investigated the modulatory effect of Anacardium Occidentale (Cashew) Seed Oil on antioxidant potential in female Swiss albino mice in a 120 day skin papillomagenesis study.⁶⁵ The mice were divided into 4 groups of 15 and 1 group of 10 (vehicle control). Test groups were as follows: Group I was the vehicle control, receiving 0.1 ml acetone; Group II was the positive control, receiving a single dose of 7,12-dimethylbenz(a)anthracene (DMBA) (0.005 mg/0.05 ml acetone) followed by applications of 2% croton oil 3 times a week until study termination; Group III received a single dose of DMBA followed by applications of 2.5% cashew nut kernel oil 3 times a week until study termination; Group IV received a single dose of DMBA followed by applications of 5% cashew nut kernel oil 3 times a week until study termination; and Group V was 5% cashew nut kernel oil applied until study termination. The oil was applied to the clipped dorsal scapular region that was 2 cm in diameter. Body weights were recorded at regular intervals. Skin papillomas greater than 1 mm in diameter at the application sites were recorded weekly and included in the data analysis if they persisted for more than 2 weeks. The positive control group yielded expected results (86% tumor incidence). No tumors were observed in the vehicle control or the other test groups. The authors concluded that cashew nut kernel oil did not exhibit any solitary carcinogenic activity.

IRRITATION AND SENSITIZATION

Dermal Effects

<u>Non-Human</u>

Dermal irritation and sensitization studies were performed in animals on a number of the plant-derived fatty acid oils, and the results were mostly negative in all of the studies. These studies are summarized in Table 7. Photosensitization data, when available, are also included in Table 7. None of the tested oils were phototoxic. Any comedogenic studies in animals are also included in Table 7.

<u>Human</u>

Plant-derived fatty acid oils are commonly believed to be safe for use on the skin.⁹ de Groot notes that no documentation exists to show that high quality edible lipids cause adverse reactions in normal individuals (except for potential comedogenicity).⁶⁶ Very few reports of adverse reactions to cosmetic use of edible fatty acid oils have been reported.

Many plant-derived fatty acid oils are derived from foods that are recognized as potent food allergens. The allergic reactions are thought to be caused by the proteins present in the food. It has been shown that often an individual that is allergic to a food will generally not react to the refined oil, especially if the oil has been "hot-pressed" or has undergone more processing.^{15,16} In its safety assessment on Arachis Hypogaea (Peanut) Oil, the CIR Expert Panel noted that while peanuts are extremely allergenic to a large population, reaction to the oil is rare . Because the major concern associated with allergic reactions to peanuts is the protein¹⁷ which does not partition into the refined oil; therefore the oil is safe for use in cosmetics. Crevel et al. also concluded that chemically refined peanut oil is safe for the majority of peanut allergic individuals.¹⁶ They stated that "as peanut is acknowledged to be one of the most potent food allergens, it is reasonable to extrapolate the conclusions drawn up for peanut oil to other edible oils." However, they concede that validated analytical methodology for establishing the protein content of oil is needed.

In support of the conclusions stated earlier, Crevel et al. also examined the allergenicity of some other oils. Very few instances of allergic reactions to other major edible fatty acid oils have been reported. Even sesame oil, which differs from the other oils in that it is used as a flavorant and, therefore, is not as refined and is expected to contain significantly more protein that the other edible fatty acid oils, has had very few reports of allergic reaction. Additional studies demonstrating safety are summarized later in this section.^{18,67}

A large amount of clinical irritation and sensitization studies were made available on many of the oils, primarily in formulation, and these studies are summarized in Table 8. All of the data indicated that the oils were not irritants or sensitizers. Also included in this table are summary statements of findings from CIR reports of oils that have previously been reviewed.

Summary statements on phototoxicity/photosensitization data from CIR reports of oils that have previously been reviewed are also included in Table 8. Also included are the results of a comedogenicity study.

Mucosal Irritation

<u>Non-Human</u>

Ocular irritation studies were performed using animals on a number of plant-derived fatty acid oils. While the majority of the oils were non-irritating to mildly irritating, Crambe Abyssinica Seed Oil was an ocular irritant and Linum Usitatissimum (Linseed) Seed Oil was moderately irritating. Available ocular irritation studies are summarized in Table 9.

<u>Human</u>

In clinical ocular irritation studies, Linum Usitatissimum (Linseed) Oil and Ribes Nigrum (Black Currant) Seed Oil did not produce adverse reactions, and were considered safe for contact lens wearers. These studies are also summarized in Table 9.

CLINICAL USE

Clinical Trials/Case Studies

Various case studies have been summarized for a number of the oils included in this report. Since various effects were reported for different oils, please refer to Table 10 for this information.

SUMMARY

The report addresses the safety of Plant-Derived Fatty Acid Oils. These oils, which are derived from vegetable and fruit plants, are composed of mono-, di-, and, primarily, triglycerides, free fatty acids and other minor components, including natural antioxidants and fat-soluble vitamins. The percentage of chemical constituents and nutritional content of individual oil types is dependent on region where the oil plant is grown, individual cultivars, and plant genetics. Oils used in cosmetics are likely produced in the same manner as those used in the food industry. Oils may be expressed through mechanical or solvent extraction. The oils may undergo further refining, such as neutralizing, bleaching, and deodorizing, to remove pigments, odors, unsaponifiable materials, and other undesirables.

Individuals who have food allergies to a plant protein rarely exhibit allergic reactions when exposed to refined oils of the same plant. Data evaluation by the CIR Expert Panel regarding method of manufacture indicates that protein constituents do not partition into the refined oils. The CIR Expert Panel also has found a general lack of clinical effects for fatty acid oils that they have already reviewed; however, other researchers have raised concerns about the presence of residual proteins in oils, such as peanut and soy.

Glycidol fatty acid esters are possible impurities in refined vegetable oils. While the amount of glycidol that may be present with glycidol fatty acid esters is not known, the IARC has noted that glycidol is probably carcinogenic to humans and that glycidol fatty acid esters are not classifiable as to carcinogenicity in humans. Peanuts and soy may contain aflatoxins, metabolic products of certain molds that are carcinogenic to humans.

Of the oils described in this report, Butyrospermum Parkii (Shea) Butter has the most reported uses in cosmetic and personal care products with a total of 1950 and is used at a maximum concentration of 60%. Oils are used in a wide variety of cosmetic products, including use in hair spray and other aerosolized products. None of the oils, or the related counterparts, described in this report were restricted from use in the European Union.

Anacardium Occidentale (Cashew) Seed Oil was not a tumor promoter in a DMBA skin test system.

The safety focus of use of these oils as cosmetic ingredients is on the potential for irritation and sensitization. Undiluted, technical grade, Arachis Hypogaea (Peanut) Oil was moderately irritating to rabbits and guinea pig skin, and 5% aq. solutions of a bar soap containing 13% sodium cocoate had irritation scores of 1.6-4.0/8 in animal studies. However, the remaining animal and clinical irritation and/or sensitization studies conducted on a large number of the oils included in this report, primarily in formulation, did not report any significant irritation or sensitization reactions, indicating that refined oils derived from plants are not dermal irritants or sensitizers.

The phototoxic potential of Butyrospermum Parkii (Shea) Butter, Elaeis Guineensis (Palm) Oil, Oryza Sativa (Rice) Bran and (Rice) Germ Oil was evaluated in animal studies, and the phototoxic potential of Cocos Nucifera (Coconut) Oil, Sodium Cocoate, Prunus Amygdalus Dulcis (Sweet) Almond Oil, and Oryza Sativa (Rice) Bran Oil was examined clinically. None of these ingredients were phototoxic.

The comedogenicity of Corylus Avellana (Hazel) Seed Oil was evaluated using rabbits, and a slight difference in the number and size of the pilosebaceous follicles and a slight excess of sebum and a dilation of the follicles was observed. In clinical

testing with an eye mask containing 0.2% Ribes Nigrum (Black Currant) Seed Oil (undiluted), the formulation was non-comedogenic.

The ocular irritation potential of a number of the oils, mostly in formulation, was evaluated in testing using animals or alternative assays. The majority of the test results did not report significant ocular irritation. A lotion containing 1.5% Elaeis Guineensis (Palm) Oil was moderately irritating to rabbit eyes, and a mascara containing 9.4% Linum Usitatissimum (Linseed) Seed Oil was moderately irritating in an alternative assay.

In human testing, a mascara containing 9.4% Linum Usitatissimum (Linseed) Seed Oil did not produce ocular irritation or adverse effects in contact lenses wearers or subjects with sensitive eyes. An eye mask containing 0.2% Ribes Nigrum (Black Currant) Seed Oil (undiluted) was considered ophthalmologist tested and safe for contact lens wearers.

DISCUSSION

Plant-derived fatty acid oils, which are the glyceryl esters of fatty acid (triglycerides) normally found in plants, including those which have been hydrogenated to reduce or eliminate unsaturation, were reviewed by the CIR Expert Panel. Upon review of these ingredients, the Panel expressed concern regarding pesticide residues and heavy metals that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities in the ingredient before blending into cosmetic formulation.

Additionally, the Panel considered the safety of glycidol and glycidol fatty acid esters in refined vegetable oils. While the Panel recognizes that these impurities may be carcinogenic, absorption through the skin would be very low and likely does not pose the same hazard as through ingestion. Nonetheless, suppliers should take steps to eliminate or reduce the presence of glycidol and glycidol fatty acid esters in plant-based fatty acid oils that are used in cosmetic products. Aflatoxins, potent carcinogens, may be present in moldy nuts and coconut copra, but are not found in oils expressed from these nuts and copra. The Panel adopted the USDA designation of \leq 15 ppb as corresponding to "negative" aflatoxin content.

Some of the fatty acid oils are used in formulations that can be inhaled. The potential adverse effects of inhaled aerosols depend on the specific chemical species, the concentration and the duration of the exposure and their site of deposition within the respiratory system. In practice, aerosols should have at least 99% of their particle diameters in the $10 - 110 \mu m$ range and the mean particle diameter in a typical aerosol spray has been reported as ~38 μm . Particles with an aerodynamic diameter of $\leq 10\mu m$ are respirable. In absence of inhalation toxicity data, the panel determined that plant-derived fatty acid oils can be used safely in hair sprays, because the product particle size is not respirable.

The relationship between food allergies and exposure to refined oils was discussed by the Panel. Individuals who have food allergies to a plant protein rarely elicit allergic reactions when exposed to refined oils of the same plant. The Panel has found a general lack of clinical effects for plant-derived fatty acid oils already reviewed.

The Expert Panel discussed the fact that arachidonic acid, a cosmetic ingredient with a CIR conclusion of insufficient safety, is part of the fatty acid composition of <u>Lycium Barbarum Seed Oil</u>, Oryza Sativa (Rice) Germ Oil, and Sclerocarya Birrea Seed Oil. The Panel was of the opinion that the concentration of use of these ingredients was sufficiently low, as would be the amount of free arachidonic acid, as to not warrant concern.

Fatty acid composition data were available for the majority of the oils included in this review, and the Panel agreed that the composition data, in combination with the available data on method of manufacture, impurities, safety test data, a long history of safe use in foods, and an absence of adverse reactions in clinical experience, was a sufficient basis for determining safety.

However, composition data, specifically fatty acid profiles, were not available for all of the plant-derived fatty acid oils, and as such, the Expert Panel could not make a determination of safety on those oils. The oils for which the data were insufficient are:

Fragaria Chiloensis (Strawberry Seed Oil Fragaria Vesca (Strawberry) Seed Oil Fragaria Virginiana (Strawberry) Seed Oil

The Expert Panel did note that vegetable oil is a blend of a number of different oils, and a specific composition of vegetable oil was not available. The Expert Panel determined that the safety of vegetable oil as used in cosmetic formulations has been established, providing that the blend contains oils for which the fatty acid composition is known.

CONCLUSION

The CIR Expert Panel concluded that 241 of the 244 plant-derived fatty acid oils included in this review are safe in the present practices of use and concentration described in this safety assessment. Were the ingredients not in current use (as indicated by *) to be used in the future, the expectation is that they would be used in product categories and concentrations comparable to others in these groups. The ingredients found safe are:

Actinidia Chinensis (Kiwi) Seed Oil Adansonia Digitata Oil Adansonia Digitata Seed Oil* Aleurites Moluccanus Bakoly Seed Oil* Aleurities Moluccana Seed Oil Amaranthus Hypochondriacus Seed Oil* Anacardium Occidentale (Cashew) Seed Oil Arachis Hypogaea (Peanut) Oil Arctium Lappa Seed Oil* Argania Spinosa Kernel Oil Astrocarvum Murumuru Seed Butter Avena Sativa (Oat) Kernel Oil Babassu Acid* Bassia Butyracea Seed Butter* Bassia Latifolia Seed Butter Bertholletia Excelsa Seed Oil Borago Officinalis Seed Oil Brassica Campestris (Rapeseed) Oil Unsaponifiables* Brassica Campestris (Rapeseed) Seed Oil Brassica Napus Seed Oil* Brassica Oleracea Acephala Seed Oil* Brassica Oleracea Italica (Broccoli) Seed Oil Butyrospermum Parkii (Shea) Butter Butyrospermum Parkii (Shea) Butter Unsaponifiables Butyrospermum Parkii (Shea) Oil Camelina Sativa Seed Oil Camellia Japonica Seed Oil Camellia Kissi Seed Oil Camellia Oleifera Seed Oil Camellia Sinensis Seed Oil Canarium Indicum Seed Oil* Canola Oil Canola Oil Unsaponifiables Carica Papaya Seed Oil Carthamus Tinctorius (Safflower) Seed Oil Carva Illinoensis (Pecan) Seed Oil* Carvocar Brasiliense Fruit Oil Chenopodium Quinoa Seed Oil Citrullus Lanatus (Watermelon) Seed Oil Citrus Aurantifolia (Lime) Seed Oil* Citrus Aurantifolia (Lime) Seed Oil Unsaponifiables* Citrus Aurantium Dulcis (Orange) Seed Oil*

Citrus Aurantium Dulcis (Orange) Seed Oil Unsaponifiables* Citrus Grandis (Grapefruit) Seed Oil* Citrus Grandis (Grapefruit) Seed Oil Unsaponifiables* Citrus Limon (Lemon) Seed Oil* Citrus Paradisi (Grapefruit) Seed Oil Coconut Acid Cocos Nucifera (Coconut) Oil Cocos Nucifera (Coconut) Seed Butter* Coix Lacryma-Jobi (Job's Tears) Seed Oil* Corn Acid* Corvlus Americana (Hazel) Seed Oil Corvlus Avellana (Hazel) Seed Oil Cottonseed Acid* Crambe Abyssinica Seed Oil Cucumis Sativus (Cucumber) Seed Oil Cucurbita Pepo (Pumpkin) Seed Oil Cynara Cardunculus Seed Oil* Elaeis (Palm) Fruit Oil* Elaeis Guineensis (Palm) Butter* Elaeis Guineensis (Palm) Kernel Oil Elaeis Guineensis (Palm) Oil Elaeis Oleifera Kernel Oil Euterpe Oleracea Fruit Oil Fragaria Ananassa (Strawberry) Seed Oil* Garcinia Indica Seed Butter Gevuina Avellana Seed Oil Gevuina Avellana Oil Glycine Soja (Soybean) Oil Glycine Soja (Soybean) Oil Unsaponifiables Gossypium Herbaceum (Cotton) Seed Oil Guizotia Abyssinica Seed Oil* Helianthus Annuus (Sunflower) Seed Oil Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables Hippophae Rhamnoides Fruit Oil Hippophae Rhamnoides Oil Hippophae Rhamnoides Seed Oil* Hydrogenated Adansonia Digitata Seed Oil* Hydrogenated Apricot Kernel Oil Hydrogenated Apricot Kernel Oil Unsaponifiables* Hydrogenated Argania Spinosa Kernel Oil* Hydrogenated Avocado Oil Hydrogenated Black Currant Seed Oil*

Hydrogenated Camelina Sativa Seed Oil* Hydrogenated Camellia Oleifera Seed Oil Hydrogenated Canola Oil Hydrogenated Coconut Acid Hydrogenated Coconut Oil Hydrogenated Cottonseed Oil Hydrogenated Cranberry Seed Oil* Hydrogenated Evening Primrose Oil Hydrogenated Grapefruit Seed Oil* Hydrogenated Grapefruit Seed Oil Unsaponifiables* Hydrogenated Grapeseed Oil Hydrogenated Hazelnut Oil* Hydrogenated Kukui Nut Oil* Hydrogenated Lime Seed Oil* Hydrogenated Lime Seed Oil Unsaponifiables* Hydrogenated Macadamia Seed Oil* Hydrogenated Meadowfoam Seed Oil* Hydrogenated Olive Oil Hydrogenated Olive Oil Unsaponifiables Hydrogenated Orange Seed Oil* Hydrogenated Orange Seed Oil Unsaponifiables* Hydrogenated Palm Acid* Hydrogenated Palm Kernel Oil Hydrogenated Palm Oil Hydrogenated Passiflora Edulis Seed Oil* Hydrogenated Peach Kernel Oil* Hydrogenated Peanut Oil Hydrogenated Pistachio Seed Oil* Hydrogenated Pumpkin Seed Oil* Hydrogenated Punica Granatum Seed Oil* Hydrogenated Rapeseed Oil* Hydrogenated Raspberry Seed Oil Hydrogenated Rice Bran Oil* Hydrogenated Rosa Canina Fruit Oil* Hydrogenated Safflower Seed Oil* Hydrogenated Sesame Seed Oil* Hydrogenated Shea Butter Hydrogenated Soybean Oil Hydrogenated Sunflower Seed Oil Hydrogenated Sweet Almond Oil Hydrogenated Sweet Almond Oil Unsaponifiables* Hydrogenated Vegetable Oil Hydrogenated Wheat Germ Oil* Hydrogenated Wheat Germ Oil Unsaponifiables* Irvingia Gabonensis Kernel Butter Juglans Regia (Walnut) Seed Oil Limnanthes Alba (Meadowfoam) Seed Oil Linseed Acid Linum Usitatissimum (Linseed) Seed Oil Luffa Cylindrica Seed Oil Lupinus Albus Oil Unsaponifiables* Lupinus Albus Seed Oil Lycium Barbarum Seed Oil Macadamia Integrifolia Seed Oil Macadamia Ternifolia Seed Oil Magnesium Cocoate Mangifera Indica (Mango) Seed Butter Mangifera Indica (Mango) Seed Oil Morinda Citrifolia Seed Oil* Moringa Oleifera Seed Oil Moringa Pterygosperma Seed Oil Oenothera Biennis (Evening Primrose) Oil Olea Europaea (Olive) Husk Oil* Olea Europaea (Olive) Oil Unsaponifiables Olea Europaea (Olive) Fruit Oil Olive Acid*

Orbignya Cohune Seed Oil Orbignya Oleifera Seed Oil Orbignya Speciosa Kernel Oil Oryza Sativa (Rice) Bran Oil Oryza Sativa (Rice) Germ Oil Oryza Sativa (Rice) Seed Oil* Palm Acid Palm Kernel Acid Passiflora Edulis Seed Oil Peanut Acid* Perilla Ocymoides Seed Oil Persea Gratissima (Avocado) Butter Persea Gratissima (Avocado) Oil Persea Gratissima (Avocado) Oil Unsaponifiables Pistacia Vera Seed Oil Plukenetia Volubilis Seed Oil Potassium Babassuate* Potassium Cocoate Potassium Cornate* Potassium Hydrogenated Cocoate* Potassium Hydrogenated Palmate* Potassium Olivate Potassium Palm Kernelate Potassium Palmate Potassium Peanutate Potassium Rapeseedate* Potassium Safflowerate* Potassium Sovate* Prunus Amygdalus Dulcis (Sweet Almond) Oil Prunus Amygdalus Dulcis (Sweet Almond) Oil Unsaponifiables* Prunus Armeniaca (Apricot) Kernel Oil Prunus Armeniaca (Apricot) Kernel Oil Unsaponifiables* Prunus Avium (Sweet Cherry) Seed Oil Prunus Domestica Seed Oil Prunus Persica (Peach) Kernel Oil Punica Granatum Seed Oil Pyrus Malus (Apple) Seed Oil Rapeseed Acid* Ribes Nigrum (Black Currant) Seed Oil Ribes Rubrum (Currant) Seed Oil* Rice Bran Acid* Rosa Canina Fruit Oil Rubus Chamaemorus Seed Oil Rubus Idaeus (Raspberry) Seed Oil Safflower Acid* Schinziophyton Rautanenii Kernel Oil Sclerocarya Birrea Seed Oil Sesamum Indicum (Sesame) Oil Unsaponifiables Sesamum Indicum (Sesame) Seed Butter* Sesamum Indicum (Sesame) Seed Oil Silybum Marianum Seed Oil [Thistle] Sodium Astrocaryum Murumuruate Sodium Avocadoate Sodium Babassuate Sodium Cocoa Butterate* Sodium Cocoate Sodium Grapeseedate Sodium Hydrogenated Cocoate* Sodium Hydrogenated Palmate* Sodium Macadamiaseedate* Sodium Mangoseedate Sodium Olivate Sodium Palm Kernelate Sodium Palmate Sodium Peanutate* Sodium Rapeseedate*

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Sodium Safflowerate* Sodium Sesameseedate Sodium Soyate* Sodium Sweet Almondate Sodium Theobroma Grandiflorum Seedate* Solanum Lycopersicum (Tomato) Fruit Oil Solanum Lycopersicum (Tomato) Seed Oil Soy Acid* Sunflower Seed Acid* Theobroma Cacao (Cocoa) Seed Butter Theobroma Grandiflorum Seed Butter Torreya Nucifera Seed Oil* Triticum Aestivum (Wheat) Germ Oil* Triticum Vulgare (Wheat) Germ Oil Triticum Vulgare (Wheat) Germ Oil Unsaponifiables* Vaccinium Corymbosum (Blueberry) Seed Oil* Vaccinium Macrocarpon (Cranberry) Seed Oil Vaccinium Myrtillus Seed Oil Vaccinium Vitis-Idaea Seed Oil Vegetable (Olus) Oil Vitis Vinifera (Grape) Seed Oil Wheat Germ Acid Zea Mays (Corn) Germ Oil Zea Mays (Corn) Oil Zea Mays (Corn) Oil Unsaponifiables

The data are insufficient to make a determination that the following 3 ingredients are safe under the intended

conditions of use:

Fragaria Chiloensis (Strawberry Seed Oil* Fragaria Vesca (Strawberry) Seed Oil* Fragaria Virginiana (Strawberry) Seed Oil*

FIGURES AND TABLES



-OCR, -OCR', and -OCR" may be the same or different fatty acid radicals.

Figure 1. General structure of fats and oils (Reference^4)



Figure 2. Basic oil refinement flowchart (Reference.⁶)

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Table 1. Plant-derived fatty acid oils.

Actinidia Chinensis (Kiwi) Seed Oil Adansonia Digitata Oil [Baobab] Adansonia Digitata Seed Oil Hydrogenated Adansonia Digitata Seed Oil Aleurities Moluccana Seed Oil [Kukui] (CAS No. 8015-80-3) Hydrogenated Kukui Nut Oil Aleurites Moluccanus Bakoly Seed Oil Amaranthus Hypochondriacus Seed Oil [Amaranth] Anacardium Occidentale (Cashew) Seed Oil (CAS No. 8007-24-7) Arachis Hypogaea (Peanut) Oil (CAS No. 8002-03-7)^a Hydrogenated Peanut Oil (CAS No. 68425-36-5) Potassium Peanutate Sodium Peanutate Peanut Acid (CAS No. 91051-35-3) Arctium Lappa Seed Oil [Burdock] Argania Spinosa Kernel Oil [Argan] Hydrogenated Argania Spinosa Kernel Oil Astrocaryum Murumuru Seed Butter [Murumuru] Sodium Astrocaryum Murumuruate Avena Sativa (Oat) Kernel Oil Bassia Butyracea Seed Butter Bassia Latifolia Seed Butter [Mahwa] Bertholletia Excelsa Seed Oil [Brazil] Borago Officinalis Seed Oil [Borage] (CAS No. 225234-12-8) Brassica Campestris (Rapeseed) Seed Oil Brassica Campestris (Rapeseed) Oil Unsaponifiables Hydrogenated Rapeseed Oil Rapeseed Acid Potassium Rapeseedate Sodium Rapeseedate Brassica Napus Seed Oil [Rapeseed] Brassica Oleracea Acephala Seed Oil [Kale] Brassica Oleracea Italica (Broccoli) Seed Oil Butyrospermum Parkii (Shea) Oil Butyrospermum Parkii (Shea) Butter (CAS No. 68920-03-6;194043-92-0) Butyrospermum Parkii (Shea) Butter Unsaponifiables (CAS No. 194043-92-0: 225234-14-0) Hydrogenated Shea Butter Camelina Sativa Seed Oil [False Flax] Hydrogenated Camelina Sativa Seed Oil Camellia Japonica Seed Oil Camellia Kissi Seed Oil [Tea] Camellia Oleifera Seed Oil [Tea Seed] Hydrogenated Camellia Oleifera Seed Oil Camellia Sinensis Seed Oil Canarium Indicum Seed Oil [Galip] Canola Oil Canola Oil Unsaponifiables Hydrogenated Canola Oil Carica Papaya Seed Oil [Papaya] Carthamus Tinctorius (Safflower) Seed Oil Hydrogenated Safflower Seed Oil Potassium Safflowerate Sodium Safflowerate Safflower Acid Carya Illinoensis (Pecan) Seed Oil Caryocar Brasiliense Fruit Oil [Pequi] Chenopodium Quinoa Seed Oil [Quinoa] Citrullus Lanatus (Watermelon) Seed Oil Citrus Aurantifolia (Lime) Seed Oil Citrus Aurantifolia (Lime) Seed Oil Unsaponifiables Hydrogenated Lime Seed Oil Hydrogenated Lime Seed Oil Unsaponifiables Citrus Aurantium Dulcis (Orange) Seed Oil Citrus Aurantium Dulcis (Orange) Seed Oil Unsaponifiables Hydrogenated Orange Seed Oil Hydrogenated Orange Seed Oil Unsaponifiables Juglans Regia (Walnut) Seed Oil (CAS No. 8024-09-7) Limnanthes Alba (Meadowfoam) Seed Oil (CAS No. 153065-40-8) Hydrogenated Meadowfoam Seed Oil Linum Usitatissimum (Linseed) Seed Oil (CAS No. 8001-26-1)

Citrus Grandis (Grapefruit) Seed Oil Citrus Grandis (Grapefruit) Seed Oil Unsaponifiables Hydrogenated Grapefruit Seed Oil Hydrogenated Grapefruit Seed Oil Unsaponifiables Citrus Paradisi (Grapefruit) Seed Oil Citrus Limon (Lemon) Seed Oil (CAS No. 85085-28-5) Cocos Nucifera (Coconut) Oil (CAS No. 8001-31-8) Hydrogenated Coconut Oil (CAS No. 84836-98-6) Cocos Nucifera (Coconut) Seed Butter Magnesium Cocoate Potassium Cocoate (CAS No. 61789-30-8) Potassium Hydrogenated Cocoate Sodium Cocoate (CAS No. 61789-31-9) Sodium Hydrogenated Cocoate Coconut Acid (CAS No. 61788-47-4) Hydrogenated Coconut Acid (CAS No. 68938-15-8) Coix Lacryma-Jobi (Job's Tears) Seed Oil Corylus Americana (Hazel) Seed Oil Hydrogenated Hazelnut Oil Corvlus Avellana (Hazel) Seed Oil Crambe Abyssinica Seed Oil [Abyssinian Mustard] Cucumis Sativus (Cucumber) Seed Oil (CAS No. 70955-25-8) Cucurbita Pepo (Pumpkin) Seed Oil (CAS No. 8016-49-7) Hydrogenated Pumpkin Seed Oil Cynara Cardunculus Seed Oil [Artichoke] (CAS No. 923029-60-1) Elaeis Guineensis (Palm) Oil (CAS No. 8002-75-3) Elaeis Guineensis (Palm) Kernel Oil (CAS No. 8023-79-8) Hydrogenated Palm Kernel Oil (CAS No. 68990-82-9; 84540-04-5) Elaeis (Palm) Fruit Oil Hydrogenated Palm Oil (CAS No. 8033-29-2; 68514-74-9) Elaeis Guineensis (Palm) Butter (CAS No. 8002-75-3) Palm Kernel Acid Potassium Palm Kernelate Potassium Palmate Potassium Hydrogenated Palmate Sodium Palm Kernelate (CAS No. 61789-89-7) Sodium Palmate (CAS No. 61790-79-2) Sodium Hydrogenated Palmate Palm Acid Hydrogenated Palm Acid Elaeis Oleifera Kernel Oil Euterpe Oleracea Fruit Oil [Acai] Fragaria Ananassa (Strawberry) Seed Oil Fragaria Chiloensis (Strawberry) Seed Oil Fragaria Vesca (Strawberry) Seed Oil Fragaria Virginiana (Strawberry) Seed Oil Garcinia Indica Seed Butter [Kokum] Gevuina Avellana Oil [Chilean Hazel] Gevuina Avellana Seed Oil Glycine Soja (Soybean) Oil (CAS No. 8001-22-7) Glycine Soja (Soybean) Oil Unsaponifiables (CAS No. 91770-67-1) Hydrogenated Soybean Oil (CAS No. 8016-70-4) Soy Acid (CAS No. 68308-53-2) Potassium Soyate Sodium Soyate Gossypium Herbaceum (Cotton) Seed Oil (CAS No. 8001-29-4) Hydrogenated Cottonseed Oil (CAS No. 68334-00-9) Cottonseed Acid (CAS No. 68308-51-0) Guizotia Abyssinica Seed Oil [Ramtil/Niger] Helianthus Annuus (Sunflower) Seed Oil (CAS No. 8001-21-6) Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables Hydrogenated Sunflower Seed Oil Sunflower Seed Acid (CAS No. 84625-38-7) Hippophae Rhamnoides Oil [Sea-Buckthorn] Hippophae Rhamnoides Fruit Oil [Sea-Buckthorn] Hippophae Rhamnoides Seed Oil [Sea-Buckthorn] Irvingia Gabonensis Kernel Butter [Dika] (CAS No. 192230-28-7) Linseed Acid (CAS No. 68424-45-3) Luffa Cylindrica Seed Oil [Luffa] Lupinus Albus Seed Oil [White Lupine] Lupinus Albus Oil Unsaponifiables

Lycium Barbarum Seed Oil [Goji Berry] Macadamia Integrifolia Seed Oil Hydrogenated Macadamia Seed Oil Macadamia Ternifolia Seed Oil (CAS No. 128497-20-1 or 129811-19-4) Sodium Macadamiaseedate Mangifera Indica (Mango) Seed Oil Mangifera Indica (Mango) Seed Butter Sodium Mangoseedate Morinda Citrifolia Seed Oil [Noni] Moringa Oleifera Seed Oil [Ben/Moringa] Moringa Pterygosperma Seed Oil Oenothera Biennis (Evening Primrose) Oil Hydrogenated Evening Primrose Oil Olea Europaea (Olive) Fruit Oil (CAS No. 8001-25-0) Olea Europaea (Olive) Oil Unsaponifiables (CAS No. 156798-12-8) Hydrogenated Olive Oil Hydrogenated Olive Oil Unsaponifiables Potassium Olivate (CAS No. 68154-77-8) Sodium Olivate (CAS No. 64789-88-6) Olea Europaea (Olive) Husk Oil Olive Acid (CAS No. 92044-96-7) Orbignya Cohune Seed Oil [Cohune] Orbignya Oleifera Seed Oil [Babassu] (CAS No. 91078-92-1) Potassium Babassuate Sodium Babassuate Babassu Acid Orbignya Speciosa Kernel Oil Oryza Sativa (Rice) Bran Oil (CAS No. 68553-81-1; 84696-37-7) Hydrogenated Rice Bran Oil Oryza Sativa (Rice) Germ Oil Oryza Sativa (Rice) Seed Oil Rice Bran Acid (CAS No. 93165-33-4) Passiflora Edulis Seed Oil [Passion Fruit] (CAS No. 87676-26-1) Hydrogenated Passiflora Edulis Seed Oil Perilla Ocymoides Seed Oil [Perilla] Persea Gratissima (Avocado) Oil (CAS No. 8024-32-6) Persea Gratissima (Avocado) Oil Unsaponifiables (CAS No. 91770-40-0) Hydrogenated Avocado Oil Persea Gratissima (Avocado) Butter Sodium Avocadoate Pistacia Vera Seed Oil [Pistachio] (CAS No. 90082-81-8; 129871-01-8) Hydrogenated Pistachio Seed Oil Plukenetia Volubilis Seed Oil [Sacha Inchi] Prunus Amygdalus Dulcis (Sweet Almond) Oil (CAS No. 8007-69-0; 90320-37-9) Prunus Amygdalus Dulcis (Sweet Almond) Oil Unsaponifiables Hydrogenated Sweet Almond Oil Hydrogenated Sweet Almond Oil Unsaponifiables Sodium Sweet Almondate Prunus Armeniaca (Apricot) Kernel Oil (CAS No. 72869-69-3) Prunus Armeniaca (Apricot) Kernel Oil Unsaponifiables Hydrogenated Apricot Kernel Oil

^a Previously reviewed ingredients are in *bold and italics*.

Hydrogenated Apricot Kernel Oil Unsaponifiables Prunus Avium (Sweet Cherry) Seed Oil Prunus Domestica Seed Oil [Prune/Plum] Prunus Persica (Peach) Kernel Oil (CAS No. 8002-78-6; 8023-98-1) Hydrogenated Peach Kernel Oil Punica Granatum Seed Oil [Pomegranate] Hydrogenated Punica Granatum Seed Oil Pyrus Malus (Apple) Seed Oil Ribes Nigrum (Black Currant) Seed Oil (CAS No. 97676-19-2) Hydrogenated Black Currant Seed Oil Ribes Rubrum (Currant) Seed Oil Rosa Canina Fruit Oil [Dog Rose] Hydrogenated Rosa Canina Fruit Oil Rubus Chamaemorus Seed Oil [Cloudberry] Rubus Idaeus (Raspberry) Seed Oil Hydrogenated Raspberry Seed Oil Schinziophyton Rautanenii Kernel Oil [Mongongo] Sclerocarya Birrea Seed Oil [Marula] Sesamum Indicum (Sesame) Seed Oil (CAS No. 8008-74-0) Sesamum Indicum (Sesame) Oil Unsaponifiables Hydrogenated Sesame Seed Oil Sesamum Indicum (Sesame) Seed Butter Sodium Sesameseedate Silvbum Marianum Seed Oil [Thistle] Solanum Lycopersicum (Tomato) Fruit Oil Solanum Lycopersicum (Tomato) Seed Oil Theobroma Cacao (Cocoa) Seed Butter (CAS No. 8002-31-1) Sodium Cocoa Butterate Theobroma Grandiflorum Seed Butter [Cupuacu] (CAS No. 394236-97-6) Sodium Theobroma Grandiflorum Seedate Torreya Nucifera Seed Oil [Kaya] Triticum Vulgare (Wheat) Germ Oil (CAS No. 8006-95-9; 68917-73-7) Triticum Aestivum (Wheat) Germ Oil Triticum Vulgare (Wheat) Germ Oil Unsaponifiables Hydrogenated Wheat Germ Oil Unsaponifiables Hydrogenated Wheat Germ Oil Wheat Germ Acid (CAS No. 68938-32-9) Vaccinium Corymbosum (Blueberry) Seed Oil Vaccinium Macrocarpon (Cranberry) Seed Oil Hydrogenated Cranberry Seed Oil Vaccinium Myrtillus Seed Oil [Bilberry] (CAS No. 1161921-09-0) Vaccinium Vitis-Idaea Seed Oil [Ligonberry], Vegetable (Olus) Oil Hydrogenated Vegetable Oil Vitis Vinifera (Grape) Seed Oil (CAS No. 8024-22-4) Hydrogenated Grapeseed Oil Sodium Grapeseedate Zea Mays (Corn) Oil (CAS No. 8001-30-7) Zea Mays (Corn) Oil Unsaponifiables Zea Mays (Corn) Germ Oil Potassium Cornate (CAS No. 61789-23-9)

Corn Acid (CAS No. 68308-50-9)

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| Table 2. Previously reviewed oil and fatty acid ingredients. | | |
|---|---|-------------------|
| Ingredients | Publication Date | Conclusion |
| Oil Ingredients | | |
| Arachis Hypogaea (Peanut) Oil (CAS No. 8002-03-7) | | |
| Hydrogenated Peanut Oil (CAS No. 68425-36-5) | IJT 20(S2):65-77, 2001 | Safe |
| Peanut Acid (CAS No. 91051-35-3) | | |
| | | |
| Carthamus Tinctorius (Safflower) Seed Oil (CAS No. 8001-23-8) | JAC 1 4(5):1/1-197, 1985; Re-reviewed, not reopened IJT 25(2):1-89, 2006 | Safe |
| Cocos Nucifera (Coconut) Oil (CAS No. 8001-31-8) | | |
| Coconut Acid (CAS No. 61788-47-4) | | |
| Hydrogenated Coconut Acid (CAS No. 68938-15-8) | | |
| Hydrogenated Coconut Oil (CAS No. 84836-98-6) | | |
| Magnesium Cocoate | JACT 5(3):103-121, 1986; CIR Final Report, 2008 | Safe |
| Potassium Cocoate (CAS No. 61789-30-8) | | |
| Potassium Hydrogenated Cocoate | | |
| Sodium Cocoate (CAS No. 61789-31-9) | | |
| Sodium Hydrogenated Cocoate | | |
| Corvlus Americana (Hazel) Seed Oil | | |
| Corylus Avellana (Hazel) Seed Oil | IJT 20 (S1):15-20, 2001 | Insufficient data |
| Elaeis Guineensis (Palm) Oil (CAS No. 8002-75-3) | | |
| Elaeis Guineensis (Palm) Kernel Oil (CAS No. 8023-79-8) | | |
| Hydrogenated Palm Oil (CAS No. 8033-29-2: 68514-74-9) | IJT 19(S2):7-28, 2000 | Safe |
| Hydrogenated Palm Kernel Oil (CAS No. 68990-82-9: 84540-04-5) | | |
| Gossynium Herbaceum (Cotton) Seed Oil (CAS No. 8001-29-4) | | |
| Cottonseed Acid (CAS No. 68308-51-0) | UT 20(S2):21-29, 2001 | Safe |
| Hydrogenated Cottonseed Oil (CAS No. 68334-00-9) | | |
| Orvza Sativa (Rice) Bran Oil (CAS No. 68553-81-1: 84696-37-7) | | |
| Oryza Sativa (Rice) Germ Oil | UT 25(S2):91-120, 2006 | Safe |
| Rice Bran Acid (CAS No. 93165-33-4) | | |
| | JACT 2(5):85-99, 1983; Re-reviewed, not reopened IJT | |
| Prunus Amygdaius Duicis (Sweet Almond) Oli (CAS No. 8007-69-0) | 24 (S1):1-102, 2005 | Safe |
| Sesamum Indicum (Sesame) Seed Oil (CAS No. 8008-74-0) | | |
| Hydrogenated Sesame Seed Oil | JACT 12(3):261-277, 1993; | Safe |
| Sesamum Indicum (Sesame) Oil Unsaponifiables | Amended Final Report, 2009 | Sale |
| Sodium Sesameseedate | | |
| Zea Mays (Corn) Oil (CAS No. 8001-30-7) | | |
| Zea Mays (Corn) Germ Oil | | |
| Zea Mays (Corn) Oil Unsaponifiables | Final Report, 2008 | Safe |
| Corn Acid (CAS No. 68308-50-9) | | |
| Potassium Cornate (CAS No. 61789-23-9) | | |
| | IEPT 4(4):93-103 1980: | |
| Persea Gratissima (Avocado) Oil (CAS No. 8024-32-6) | Re-reviewed, not reopened IJT 22(1):1-35, 2003 | Safe |
| | JEPT 4(4):33-45, 1980: | |
| Triticum Vulgare (Wheat) Germ Oil (CAS No. 8006-95-9; 68917-73-7) | Re-reviewed, not reopened IJT 22(1):1-35, 2003 | Safe |
| Fatty Acids | | |
| Arachidonic Acid (CAS No. 506-32-1) | JACT 12 (5):481-559, 1993 | Insufficient data |
| Hydroxystearic Acid (CAS No. 106-14-9) | IJT 18(S1):1-10, 1999 | Safe |
| Lauric Acid (CAS No. 143-07-7) | | |
| Myristic Acid (CAS No. 544-63-8) | LACT 6(2),221 401 1007. | |
| Oleic Acid (CAS No. 112-80-1) | JAC1 0(5):521-401, 1987; Re-reviewed not reopened IIT 25(2):1-89 2006 | Safe |
| Palmitic Acid (CAS No. 57-10-3) | 10 1010 week, not 100 period 13 1 25(2).1 07, 2000 | |
| Stearic Acid (CAS No. 57-11-4) | | |

| Table 2. Previously reviewed oil and fatty acid ingredients. | | |
|--|-------------------------|------------|
| Ingredients | Publication Date | Conclusion |
| Glyceryl Triesters | | |
| Trilaurin | | |
| Triarachidin | | |
| Tribehenin | | |
| Tricaprin | | |
| Tricaprylin | | |
| Trierucin | | |
| Triheptanoin | | |
| Triheptylundecanoin | | |
| Triisononanoin | | |
| Triisopalmitin | | |
| Triisostearin | | |
| Trilinolein | IJT 20 (S4):61-94, 2001 | Safe |
| Trimyristin | | |
| Trioctanoin | | |
| Triolein | | |
| Tripalmitin | | |
| Tripalmitolein | | |
| Triricinolein | | |
| Tristearin | | |
| Triundecanoin | | |
| Glyceryl Triacetyl Hydroxystearate | | |
| Glyceryl Triacetyl Ricinoleate | | |
| Glyceryl Stearate Diacetate | | |

| Table 3. Chemical properties | for plant-derived fatty ac | cid oils. | | | | | |
|--|---|---|--|--|--|--|---|
| Properties and Constituents ^a | Actinidia Chinensis (Kiwi) Seed Oil ⁶⁸ | Adansonia Digitata Oil ^{60,70} | Aleurites Moluccana Seed Oil [Kukui] ⁷¹⁻⁷⁴ | Anacardium Occidentale (Cashew) Seed Oil ⁷⁵ | Arachis Hypogaea (Peanut) Oil ^{6,71,76-79} | Argania Spinosa Kernel Oil ^{80,81} | Astrocaryum Murumuru Seed Butter ^{6,82} |
| Appearance Specific gravity | | Pale yellow | Clear yellow liquid 0.920-0.930 (20°C) | | Light yellow 0.912-0.920 (20°C) | Yellow 0.908-0.918 (20∘C) | Pale brown waxy solid at room temperature 0.890-0.910 (25°C) |
| Refractive index Iodine value | | 65-95 | 1.470-1.480 (20∘C) 130-175 | | 1.46-1.475 (20∘C) 74-107 | 95 | 15 max |
| Saponification value | | 190-210 | 185-210 | | 180-208 | | 270-350 |
| Peroxide value (meq/kg) Melting point (°C) | 44.37 | 5.0-10 | 5.0 max | 0.22 | 0.39, 5.0 max | 10.0 max | 20.0 max 25-37 |
| Unsaponifiable matter (%) | | | 0.3 - 1 | | ≤1.0 | | |
| Free fatty acids (%) Titer (°C) Acid value | 1.2 | 2.0 max as oleic acid | 0.1-4 | | 0.2-2.08 26-32 0.5 | 3-4 | 12.56 as oleic acid |
| Properties and Constituents | Avena Sativa (Oat) Kernel Oil ⁸³ | Bertholletia Excelsa Seed Oil ^{75,84} | Borago Officinalis Seed Oil ^{85,86} | Brassica Campestris (Rapeseed) Seed Oil ⁶ | Hydrogenated Rapeseed Oil ⁷ | Rapeseed Acid ⁸⁷ | Canola Oil ⁷ |
| Appearance | Yellow | | Clear, pale yellow- golden | | White waxy solid | | Light yellow oil |
| Specific gravity | 0.914-0.932 (25°C) | 1.473 | 0.918-0.928 (20°C) | | | | |
| Refractive index Iodine value Saponification value | 1.469-1.471 (25°C) 176-186 | 0.914 (20∘C) 74.2 192.4 | 1.474-1.479 (20∘C) 130-155 184-194 | 81-112 168-192 | 4 max | 119-120 g/100 g | 1.465-1.467 (40°C) 110-126 |
| Peroxide value (meq/kg) Melting point (°C) | 0.6-1.1 | 0.16 | 10.0 max | | 2.0 max | | 10 max |
| Unsaponifiable matter (%) | 3.7-4.3 | | | 0.5 - 2 | | | 1.5 max |
| Free fatty acids (%) Titer (°C) | 0.1-0.3 | | | Н | 2.0 max as oleic acid | | 0.1% max as oleic acid |
| Acid value ^a Shading identifies previously 1 | reviewed ingredients, wi | th gray shading for ingredients | 1.0 max s with safe and red shading | g for ingredients with insu- | fficient data conclusions. | 197-200 mg KOH/g | |

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| Table 3. Chemical proper | ties for plant-derived fatty a | acid oils (continued). | | | | | |
|--|--|---|--|--|---|--|--|
| Properties and Constituents ^a | Brassica Oleracea Acephala Seed Oil ⁸⁸ | Brassica Oleracea Italica (Broccoli) Seed Oil ⁸⁹ | Butyrospermum Parkii (Shea) Butter ^{6,71,90-93} | Butyrospermum Parkii (Shea) Oil ⁷ | Camellia Oleifera Seed Oil ^{94,95} | Canarium Indicum Oil ^{96,97} | Carica Papaya Seed Oil ^{98,99} |
| | = | | = - - | = - 4 | Clear, pale yellow or | - | = - 4 |
| Appearance Specific gravity | Yellow 0 9010 (20°C) | Golden 0 910-0 918 (200-01) | Urey, tallow-like 0 018 /15₀C) | Pale yellow | water white | Cream to golden | Pale yellow |
| Refractive index | 1.4741 (23°C) | 1.465-1.475 (20°C) | 1.468 (25°C) | | | 1.45-1.47 | |
| Iodine value | 61.2 | 90-120 | 45-77 | 28 - 43 | 80-94 | | 65-100 |
| Saponification value | 123.06 | | 165-190 | 185-195 | 188-196 | | |
| Peroxide value (mea/kg) | | | 5.0 max | < 10 | 10.0 max | < 20 | 10.0 max |
| Melting point (°C) | | | 32-46; 28-42 (slip) | | | 2 1 | |
| Unsaponifiable matter (%) | 1.6 | | 3-13 | <1.5 | 1.5 max | | |
| | | | | | | | |
| Free fatty acids (%) Titer (°C) | | | 1.0 max as oleic acid 49-54 | ≤ 0.1 as oleic acid | | 0.2 | 0.8-3 |
| Acid value | 2.1 | 1.5 | 1.5 | | 1.0 max | <u></u> < 10 | |
| Properties and Constituents | Carthamus Tinctorius (Safflower) Seed Oil ⁷ | Carya Illinoensis (Pecan) Seed Oil ^{71,7584} | Caryocar Brasiliense Fruit Oil [Pequil ^{87,100} | Citrullus Lanatus (Watermelon) Seed Oil ^{6,101} | Citrus Aurantifolia (Lime) Seed Oil ^{102,103} | Citrus Aurantium Dulcis (Orange) Seed Oil ^{104,105} | Citrus Paradisi (Grapefruit) Seed Oil ^{106,107} |
| Appearance | Light yellow oil | | Yellow ¹⁰⁰ | Pale to golden yellow liquid | Clear yellow | Clear, light yellow | Clear yellow |
| Specific gravity | | 0.924 (25°C) | | 0.8930-0.9166 | | 0.910-0.920 (20°C) | |
| Refractive index | | 1.472 | 001 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 1.4668 | | 1.466-1.475 (20°C) | |
| Iodine value | 135-150 | 100 - 105 | $48.65-74.80^{100}$ $50-70 g/100 g^{87}$ | 113-123 | | 90-110 | 80-125 |
| Saponification value | | 190 | 190-210 mg KOH/g | 193-195 | | 185-200 | |
| Peroxide value (meq/kg) | 10 max | 0.15 | $0.99-5.22^{100} \le 20^{87}$ | ≤5.0 | 5.0 max | 5-10 | 5-10 |
| Melting point (°C) Unsaponifiable matter (%) | 1.5 max | 0.35-40 | | | | | |
| Free fatty acids (%) | 0.1 max as oleic acid | | 0.98-2.85 (mg KOH/g) | < 5.0 as oleic acid | | 0.5 as oleic acid | |
| Titer (°C) | | | 0 | | | | |
| Acid value | | | 10 mg KOH/g max°' | | 1.0 max | 0.8 max | 1.0 max |

| Frequencies tendenciesControlling Regis (Constrained Constrained (Constrained)Constrained (| Table 3. Chemical proper | ties for plant-derived fatty a | acid oils (continued). | | | | | |
|---|--|---|--|---|---|--|--|--|
| Mathematication control betwein die outper numer betwein die 0.977-000 6-01Mathematication outper numer 0.977-000 6-01Mathematication outper numer 0.977-000 6-01Mathematication outper numer 0.977-000 0.971-000Mathematication outper numer 0.977-000 0.971-000Mathematication outper numer 0.977-000 0.971-000Mathematication 0.971-000 0.950-000Mathematication 0.971-000 0.950-000Mathematication 0.971-000 0.950-000Mathematication 0.971-00 | Properties and Constituents ^a | Cocos Nucifera (Coconut) Oil ^{6,7,108} | Cucurbita Pepo (Pumpkin) Seed Oil ^{109,110} | Elaeis Guineensis (Palm) Oil ^{6,7} | Elaeis Guineensis (Palm) Kernel Oil ^{6,7} | Fragaria Ananassa (Strawberry) Seed Oil ^{6,111,112} | Garcinia Indica Seed Butter [Kokum] ¹¹³⁻¹¹⁵ | Glycine Soja (Soybean) Oil ^{6,7} |
| Strength framework burners in the solution of the solution state of the solution state | Appearance | White to light yellow- tan | Dark green | Pale yellow to deep orange in color | Nearly colorless | Light golden/yellow to yellow | | Light amber oil |
| of the educe of the order of the | Specific gravity Refractive index | 0.917 - 0.919 (25°/15.5°C) 1 448 - 1 450 (40°C) | | 0.921-0.925 (40∘C) 1 453-1 458 (40∘C) | | 0.93-0.95 | 1 4565-1 4575 (40°C) | |
| Sepantification value convolution to work of to work | lodine value | (2-0+) 0CF.1 - 0FF.1 | 110-330 | ()-0-1-1-0-(| 14-33 | | (2004) C/CFTT-COCFT 30-50 | 120.9-151.4 |
| Provide value (works) ≤ 10 ≤ 10 ≤ 13 ≤ 13 ≤ 13 ≤ 13 ≤ 13 ≥ 13 ≥ 10 ≥ 10 ≥ 10 ≥ 10 ≥ 13 $= 13$ | Saponification value | 248-265 | 174-197 | 195-205 | 245-255 | | 185-195 | |
| | Peroxide value (meq/kg) Melting point (°C) | ≤ 10 22 - 26 | 5.0 max | 10 max 25-50 | 10 max 25-30 | < 15 | 37-43; 27 (slip) | 10 max |
| Free farty acids (%) The farty acids (%) 2007% as lattic acid The farty acids (%) | Unsaponifiable matter (%) | ≤0.5 | 1.5 | 0.2-0.8 | 1.5 max | | 1.5 max; 18-20; 32- 40 | 0.3-0.6 |
| Matrix relationIs max is maxIs max is maxFright relationHizofis dysinicsHizofis dysinicsHizofis dollHimophateHipophateHipophateFright relationHicofis dysinicsGizofis dysysinicsHizofis dollSeed Olt****Riamoldes FruitRiamoldes FruitRiamolde | Free fatty acids (%) Titor 600 | $\leq 0.1\%$ as oleic acid; $\leq 0.07\%$ as lauric acid 20.07% as $20.07%$ | 1.5 as oleic acid | 0.1 max as oleic acid; 0.09 as palmitic acid | 0.1 max as oleic acid; 0.07 max as lauric acid | | 0.1-1 | 0.05-0.7 |
| Properties and ConstituentsGosspitue Seed Off*Guizotia Abysinica ImportantHead Seed Off* ImportantHippophace Seed Off*Hippophace ImportantHippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace Andia*Hippophace | Acid value | 40 - 24 | | | | 18 max | | |
| AppearanceDark red-brown of butk red-brown ofPale yellow with a bluish tittLight amber oilOrange-redOrange-redOrange-redSpecific gravity $3 + 1 + 1 = 1 = 1 = 1 = 1 = 1 = 1 = 1 = 1$ | Properties and Constituents | Gossypium Herbaceum (Cotton) Seed Oil ^{6,7} | Guizotia Abyssinica Seed Oil ⁶ | Hazel Seed Oil* ^{76,116-} 118 | Helianthus Annuus (Sunflower) Seed Oif ^{6,7} | Sunflower Seed Acid ⁸⁷ | Hippophae Rhamnoides Fruit Oil ¹¹⁹ | Hippophae Rhamnoides Seed Oil ¹²⁰⁻¹²² |
| Specific gravity $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.910-0.928)$ $(0.90-0.955)$ $(0.90-0.955)$ $(0.90-0.955)$ $(0.90-0.956)$ <th>Appearance</th> <th>Dark red-brown oil</th> <th>Pale yellow with a bluish tint</th> <th></th> <th>Light amber oil</th> <th></th> <th>Orange-red</th> <th>Orange</th> | Appearance | Dark red-brown oil | Pale yellow with a bluish tint | | Light amber oil | | Orange-red | Orange |
| Refractive index lodine value $1.467-1.471$ $1.467-1.471$ $1.467-1.471$ $1.467-1.471$ $1.467-1.471$ $1.467-1.472$ $1.467-1.472$ $1.456-1.432$ $1.456-1.432$ $1.4650-1.4826$ Reindine value $90-113$ $126-139$ $83-100$ $183-100$ $188-194$ $1.25-140$ $1.145-100$ $1.84-210$ Saponification value $10 max$ $10 max$ $10 max$ $0.43; 100 max$ $1.88-194$ $1.25-140 g/100 g$ $1.84-210$ Peroxide value $10 max$ $0.43; 100 max$ $0.43; 100 max$ $0.43; 100 max$ $0.188-194$ $1.25-140 g/100 g$ $1.84-210$ Metting point (\circ C) $10 max$ $0.43; 100 max$ $0.43; 100 max$ $0.43; 100 max$ $0.10 max$ $0.10 max$ $0.10 max$ Netting point (\circ C) 0.51 $0.43; 0.0 max$ $0.43; 0.0 max$ $0.3-0.5$ $0.3-0.5$ $1.0 max$ Metting point (\circ C) $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ $0.3-0.5$ $1.0 max$ Neide value $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ $0.3-0.5$ $1.0 max$ Meting point (\circ C) $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ $0.3-0.5$ $1.0 max$ Meting point (\circ C) $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ so loic acid $0.1 max$ $0.1 max$ $0.1 max$ Meting point (\circ C) $0.1 max$ $0.2 max$ | Specific gravity | | 0.910-0.928 | 0.912-0.917 (15.5°C); 0.905-0.925 (20°C) | 0.894-0.899 (60°C) | | 06.0 | 0.890-0.955 (20∘C) |
| Peroxide value (meq/kg) $10 \max$ $0.43; 10.0 \max$ $10 \max$ $5.10 \max$ $5.10 \max$ Melting point (\circ C) $0.3 \min$ $0.33; 10.0 \max$ $0.33; 10.0 \max$ $0.10 \max$ $0.10 \max$ $0.10 \max$ Melting point (\circ C) $1.5 \max$ $0.5-1$ 2.10 $0.3-0.5$ 1.0 Unsaponifiable matter (\circ) $1.5 \max$ $0.5-1$ $2.0 \max$ 1.0 There fatty acids (\diamond) $0.1 \max$ as oleic acid $0.1 \max$ as oleic acid $2.0 \max$; $1.8 \min$ Titler (\circ C) $0.1 \max$ as oleic acid $0.1 \max$ as oleic acid $2.0 \max$; $1.8 \max$ Acid value $0.5 - 1$ $0.5 - 1$ $0.1 \max$ as oleic acid $0.1 \max$ | Refractive index Iodine value Saponification value | 90-113 180-198 | 1.467-1.471 126-139 180-195 | 1.467-1.474 (20∘C) 83-100 180-200 | 1.4597-1.4745 (25°C) 128-144 188-194 | 125-140 g/100 g | | 1.4650-1.4825 (20°C) 130-200 184-210 |
| Unsaporifiable matter (%)1.5 max $0.5-1$ ≤ 1.0 $0.3-0.5$ 1.0 (%) $1.5 \max$ $0.5-1$ ≤ 1.0 $0.3-0.5$ 1.0 Free fatty acids (%) $0.1 \max$ as oleic acid $0.4-3$ $0.2 \max$ as oleic acid $0.1 \max$ as oleic acid $2.0 \max$; $1.8 \ln$ Titer (°C)Acid value $0.5 - 5$ $1.25-140 \mathrm{mg} \mathrm{KOH/g}$ $18 \mathrm{max}$ 15 | Peroxide value (meq/kg) Melting point (°C) | 10 max | | 0.43; 10.0 max | 10 max 0 | | 10 max | 5-10 max |
| Free fatty acids (%)0.1 max as oleic acid0.4-30.2 max as oleic acid0.1 max as oleic acid2.0 max; 18 nTiter (\circ C) \sim | Unsaponifiable matter (%) | 1.5 max | 0.5-1 | ≤ 1.0 | 0.3-0.5 | | | 1.0 |
| Acid value ≤ 0.5 125-140 mg KOH/g 18 max 15 | Free fatty acids (%) Titer (°C) | 0.1 max as oleic acid | 0.4-3 | 0.2 max as oleic acid | 0.1 max as oleic acid | | | 2.0 max; 18 max |
| *Information mainly on Corylus Avellena. | Acid value *Information mainly (| on Corylus Avellena. | | ≤ 0.5 | | 125-140 mg KOH/g | 18 max | 15 |

| Table 3. Chemical propertie | es for plant-derived fatty acid | oils (continued). | | | | | |
|---|---|---|--|--|--|---|---|
| Properties and Constituents ^a | Irvingia Gabonenesis Kernel Butter ¹²³ | Juglans Regia (Walnut) Seed Oil ^{71,76,84} | Linum Usitatissimum (Linseed) Seed Oil ⁶ | Macadamia Nut Oil ^{76,84,124-126} | Mangifera Indica (Mango) Seed Oil ⁶ | Moringa Oleifera Seed Oil ¹²⁷⁻¹²⁹ | Oenothera Biennis (Evening Primrose) Oil ^{130,131} |
| Appearance | | | | Pale to golden yellow | Pale yellow to ivory cream color | | Light yellow |
| Specific gravity | | 0.917 (25°C) | 0.927-0.931 (20°C) | 0.911-0.918 (20°C) | 0.91 | 0.908 (20°C); 0.8933 (24°C) | 0.920-0.930 (20∘C) |
| Refractive index | | 1.475 (25°C) | 1.4786-1.4815 | 1.466-1.470 (20∘C) | 1.456 | 1.4566 (40∘C) | 1.475-1.480 (20∘C) |
| Iodine value | | 150 - 162 | 170-204 | 62-82 | 32-93 | 66.47 | 145-165 |
| Saponification value | | 190 - 197 | 189-196 | 190-200 | 190-195 | 164.27; 192 | 180-195 |
| Peroxide value (meq/kg) Melting point (°C) | | 0.37 | 0 | 0.36; 10.0 max | 34-43 | 0.45; 10.0 18.93 | 10.0 max |
| Unsaponifiable matter (%) | 0.13 | 0.5 | 0.5-1.5 | 1.5 | 0.8-2.9 | 0.58 | |
| Free fatty acids (%) | 0.30 | 0.2 - 2.5 | S | 0.5 max; 1.0 max as oleic acid | | 2.55 as oleic acid | |
| Titer (°C) Acid value | | | | Т | | | 1-2 |
| Properties and Constituents | Olea Europaea (Olive) Fruit Oil ⁶ | Olea Europaea(Olive) Husk Oil ¹³² | Olive Acid ⁸⁷ | Oryza Sativa (Rice) Bran Oil ^{133,134} | Oryza Sativa (Rice) Bran Oil ^{133,134} | Passiflora Edulis Seed Oil [Passion Fruit] | Persea Gratissima (Avocado) Oil ⁶ |
| Appearance | Almost colorless to yellow, greenish, or brown in color | | | Light golden yellow | Light golden yellow | Golden-orange | |
| Specific gravity | 0.914-0.918 | | | 0.916-0.922 (15.5°C) | 0.916-0.922 (15.5°C) | 0.917 (20∘C) | 0.910-0.916 |
| Refractive index Iodine value | 1.469-1.484 64-88; refined 75-94 | | 85-91 g/100 g | 1.470-1.473 (20∘C) 92-115 | 1.470-1.473 (20∘C) 92-115 | 1.468-1.473 (20°C) 119.9-129.29 ¹³⁵ | 1.461-1.465 71-95 |
| Saponification value | 185-212; refined 184- 186 | | | 180-195 | 180-195 | 176-187.4 | 177-198 |
| Peroxide value (meq/kg) Melting point (°C) | 20 max (refined) | 14.33 | | 10.0 max | 10.0 max | 1.37-2.23 | |
| Unsaponifiable matter (%) | 0.6-1.2; 1.5 max refined | | | | | 0.9-2.86 | |
| Free fatty acids (%) Titer (60) | 0.6-1.4; 0.3 max refined | | | 1.0 as oleic acid | 1.0 as oleic acid | | |
| Acid value | | | 190-201 mg KOG/g | | | 2.11-2.36 | |

| Table 3. Chemical properti | ies for plant-derived fatty acid oi | ils (continued). | | | | |
|---|---|--|---|---|--|---|
| Properties and Constituents ^a | Pistacia Vera Seed Oil ⁷⁵ | Plukenetia Volubilis Seed Oil ¹³⁶ | Prunus Amygdalus (Sweet Almond) Oil ^{6,71,76,137-139} | Prunus Armeniaca (Apricot) Kernel Oil | Prunus Avium (Sweet Cherry) Seed Oil ^{140,141} | Prunus Domestica Seed Oil ^{142,143} |
| Appearance Specific gravity Refractive index Iodine value | | Y ellow-amber 0.90-0.93 (20°C) 1.478-1.481 (20°C) 180-200 | Colorless to pale yellow liquid 0.911-0.920 (20°C) 1.467-1.473 (20°C) 93 - 106 | 0.923 ⁶ 1.4672-1.4722 ⁶ 81-123 ⁶ | Clear light yellow 0.905-0.925 (20°C) 1.463-1.480 (20°C) 90-115 | 801-06 |
| Saponification value | | 180-210 | 183 - 197 | 1916 | 105-135 | |
| Peroxide value (meq/kg) Melting point (°C) Unsaponifiable matter | 0.22 | 0-15 | 0.19 | | 10.0 max | 10.0 max |
| (%) | | | 0.4-1.0 | 0.4-1.4 | | |
| Free fatty acids (%) Titer (60) | | | 1.0 max | 0-6 ¹⁴⁴ | 0.5% max | 2.0 max as oleic acid |
| Acid value | | 0-2 | 0.5 |) | 1.0 max | |
| Droperties and Constituents | Prunus Persica (Peach) Kernel Oil ^{6,145} | Punica Granatum Seed Oil ^{146,147} | Pyrus Malus (Apple) Seed Oil ¹⁴⁸ | Ribes Nigrum (Black Currant) Seed Oil ¹⁴⁹⁻¹⁵¹ | Ribes Rubrum (Currant) Seed Oil ¹⁵² | Rubus Chamaemorus Seed Oil ¹⁵³ |
| Appearance Abpearance | Pale yellow (refined) | Golden to dark yellow | | Pale yellow or slightly greenish | Pale yellow or slightly greenish | Yellow-red |
| 4 Specific gravity | 0.910-0.920 (20°C) refined | 0.935 (15.5°C) | 0.902-0.903 (25°C) | 0.92 | 0.92 | 0.92 |
| Refractive index Iodine value Saponification value | 90-115 (refined) | 190-230 | 1.465-1.466 (40°C) 94.14-101.15 179.01-197.25 | 145-185 | | |
| Peroxide value (meq/kg) Melting point (°C) Unsaponifiable matter (%) | 5.0 max (refined) | 10.0 max | 2.43-2.52 | 1-10 | 10 max | 10 max |
| Free fatty acids (%) Titer (°C) | | 1.4; 5.0 max as oleic acid | | 0.2 | | |
| Acid value | | | 4.036-4.323 | 3; 18 max | 18 max | 18 max |

| | л | | | | | |
|---|--|--|--|--|---|--|
| Properties and Constituents ^a | Rubus Idaeus (Raspberry) Seed Oil ¹⁵⁴ | Schinziophyton Rautanenii Kernel Oil ¹⁵⁷ | Sclerocarya Birrea Seed Oil [Marula] ¹⁵⁸ | Solanum Lycopersicum (Tomato) Seed Oil ¹⁵⁹ | Theobroma Cacao (Cocoa) Seed Butter ⁶ | Vaccinium Corymbosum (Blueberry) Seed Oil ^{68,160,161} |
| Appearance | Yellow or vellow-red | Light vellow | | Clear golden yellow to darker red | | Green with yellow tint or dark green /brown |
| Specific gravity | 0.92 | | | 0.9135-0.9357 | 0.950-0.998 | 0 |
| Refractive index | | 1.4830 | 1.46 | 1.4577-1.4771 | 1.453-1.458 | |
| Iodine value | 175-195 | | 100.25 | 105-130.5 | 35-40 | 155-175 |
| Saponification value | 180-200 | | 162.70 | 156-194.9 | 190-200 | |
| Peroxide value (meq/kg) | 5.0 max; 10 max | 10 mg/kg | 4.58 | | | 20-24.62 |
| Melting point (°C) | | | 26-28 | | 33.5 | |
| Unsaponifiable matter (%) | | | 3.06 | | | |
| Free fatty acids (%) | 1.5 max as oleic acid | | | | | 0.67: 2.0 as oleic acid |
| d mainter (∘C) | | | | | | |
| Acid value | 18 max | | 33.70 | | | |
| र्ने जूम operties and a Constituents | Vaccinium Macrocarpon (Cranberry) Seed Oif ^{6,68,162-165} | Vaccinium Myrtillus Seed Oil ¹⁶⁶ | Vaccinium Vitis-Idaea Seed Oil ¹⁶⁷ | Vitis Vinifera (Grape) Seed Oil ⁶ | Zea Mays (Corn) Oil ^{168,169} | |
| 25 Appearance | Pale yellow to greenish; light green | Pale yellow to greenish | Pale yellow | | Clear, bright golden yellow | |
| Specific gravity | 0.923 | 0.93 | 0.92 | 0.91-0.93 | 0.920-0.928 (15.5°C) | |
| Refractive index Iodine value Saponification value | 140-180 170-200 | | | 1.470-1.476 125-143 176-206 | 1.472-1.476 (20∘C) 103-128 185-195 | |
| Peroxide value (meq/kg) Melting point (°C) Unsaponifiable matter (%) | < 15; 10 max | 10 max | 10 max | | 10.0 max | |
| Free fatty acids (%) Titer (°C) | 0.7; 1.0 as oleic acid | | | | | |
| Acid value | 2.0 max; 18 max | 18 max | 18 max | | 0.2 max | |

| | Actinidia Chinensis (Kiwi) Seed | Adansonia Digitata Oil | Aleurites Moluccana Seed | Amaranthus Hypochondriacus Seed Oil | Anacardium Occidentale (Cashew) Seed | Arachis Hypogaea (Peanut) | Arctium Lappa | Argania Spinosa Kernel Oil | Astrocaryum Murumuru Seed Butter | Avena Sativa (Oat) Kernel |
|--------------------------------|--|---------------------------|---------------------------------|---|--|---------------------------------|---|-------------------------------|--|--------------------------------|
| Fatty Acids ^a | Oil ⁶⁸ | [Baobab] ^{69,70} | Oil [Kukui] ^{71,73,74} | [Amaranth] ¹⁷⁰ |) Oil ⁷⁵ | Oil ^{6,77,78} | Seed Oil ^{171[°]} | [Argan] ^{80,81} | [Murumuru] ⁸² | Óil ^{83,172} |
| Caproic (C6) | | | | | | | | | | |
| Caprylic (C8) Canrie (C10) | | | | | | | | | 1.85 1.85 | |
| Capite (C10) | 0.02 | | | | | | | | 00'T | |
| Lauric (C12) Mvristic (C14) | 0.03 | | | | 0.07 | | 0.01 | | 47.46 26 | 0 2-0 3 |
| Myristoleic | | | | | 5 | | | | 9 | |
| (C14:1) Palmitic (C16) | 5.96 | 18-30 | 5-8 | 19 - 20 | 6.6 | 5-16 | 7.27 | 10-15 | 6.28 | 13.9-18.82 |
| Palmitoleic | | - | | | | | 0.01 | | | |
| (C16:1) Heptadecanoic | | | 6.0 | | 0.4 | | | | | 0.1-0.4 |
| (C17:0) | 1 00 | 0 | | | 0.1 | | 22.67 | | | |
| Stearic (C18) | 5.09 1.1.6 | 20.40 | 0.1-6.7 | 3 | 8.7 | 1-6.5 | 0C.26 1C.03 | 5-6.5 | 2.65 | 0.8-2.79 |
| Oleic (C18:1) | 14.0 | 50-40 | 10-35 | 22 - 26 | 57.2 | 33.3-76 | 17.00 | 45-55 | 12.56 | 31.4-51.26 |
| Linoleic (C18:2) | 17.55 | 24-34 | 35-50 | 46 - 50 | 20.8 | 8-47.5 | 3.18 | 28-36 | 2.87 | 22.8-43.1 |
| Indenic | 57.4 | 1-3 | 07 70 | | Ċ | 200 | | | | 1 6 7 7 0 |
| (Total) | 0.34 | | 15 | | | 0.17-3 | 0.22 | | | 1.2-10.0 |
| R cosenoic | | | | | | | 0.33 | | | |
| (G20:1) Ecosadienoic | | | 1 | | 0.3 | 0.33-3 | | | | 0.5-1 |
| (C20:2) | | | | | | | | | | |
| Afachidonic (C20:4) | | | | | | | | | | |
| Behenic (C22) | | | | | 0.4 | 1-5 | | | | |
| Erucic (C22:1) | | | | | 0.3 | 0.5 | | | | |
| Docosadienoic (C22:2) | | | | | | | | | | |
| Docosahexaenoic | | | | | | | | | | |
| Lignoceric (C24) | | | | | | 0.2-3 | 0.49 | | | |
| | | | | | | 1 | heptadecenoic=0.02; | | | |
| | | | | | | | nonadecadienoic acid=2.99; | | | Arachidic (C20) + |
| | | | | | | | heneicosanoic acid =1.07; dicosanoic | | | Eicosadienoic (C20:2)=0.1-0.3; |
| Others | | | | | | < C16:0 = 0.4 | acid=0.43 | | | C18:1, n-11=0.9- 1.3 |

| a - - | Bassia Butyracea | Bassia Latifolia Seed Butter | Bertholletia Excelsa Seed Oil | Borago Officinalis Seed | Brassica Campestris (Rapeseed) Seed | | Brassica Napus Seed Oil | Hydrogenated | 2.0 |
|---|------------------|---------------------------------|----------------------------------|--|---|---|----------------------------|--------------|---|
| Caproic (C6) Caproic (C6) Caprylic (C8) Convio (C10) | Seeu Duncr | [MIAIIWA] | DIAZII | OII DUTAGe | 5 | Kapeseeu Actu | [vapeseeu] | Kapeseeu Oli | |
| Capita (C12) Lauric (C12) Myristic (C14) | | | 0.06 | | | ≤0.5 | | < 1.0 | <0.2 |
| Myristoleic (C14:1) | | | | | | | | | |
| Palmitic (C16) | 60.8 | 23.7-24.7 | 13.5 | 9-13 | 1.5 - 3 | °% | 2 | 3-5.0 | <6.0 |
| Palmitoleic (C16:1) | | | 0.3 | | | Q | | | <1.0 |
| Heptadecanoic (C17:0) | | | 0.2 | | | | | | |
| Stearic (C18) | 3.2 | 19.3-29.9 | 11.8 | 3-5 | 0.7 - 1.3 | Ø, | 1 | 38-42 | <2.5 |
| Oleic (C18:1) | 30.9 | 36.3-43.3 | 29.1 | 10-22 | 12.1 - 57.4 | 54-70 | 21 | - | >50 |
| Linoleic (C18:2) | 4.9 | 11.6-15.8 | 42.8 | 33-46 | 11.4 - 22.1 | 18-24 | 20 | < 1.0 | <40.0 |
| LINOIENIC (C18:3) | | | 0.2 | 18-25 | 8.3 - 12.5 | 5-10 | 2 | | <14 |
| Arachidic (C20) | | | 0.5 | | | 9 | 1 | 8-10.0 | <1.0 |
| Elcosenoic (C20:1) Eicosodianaio | | | 0.2 | 2-6 | 5.6 - 3.1 | | | < 1.0 | <2.0 |
| Elcosadienoic (C20:2) | | | | | | | | | |
| Arachidonic (C20:4) | | | | | | | | | |
| Behenic (C22) | | | 0.1 | | | | | 42-50 | <0.5 |
| Erucic (C22:1) Docosadienoic | | | 0.3 | 1-3.5 | 1 - 58.6 | | 53 | < 1.0 | <2.0 |
| (C22:2) Docosahexaenoic (C77-6) | | | | | | | | | |
| Lignoceric (C24) | | | | | | | 2 | 1-2.0 | <0.2 |
| Others | | | | α -Linolenic (C18:3) = 0.4%; γ -Linolenic = 1- 3.5% | | <c14 =="" li="" ≤0.5;<=""> >C18:3 = ≤5; >C20 = ≤6 </c14> | | | <cl4 <0.1;<br="" =="">C24:1 = <0.2</cl4> |

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| | | Duccies | | | | | | Comollio | |
|---|--|--|--------------------------------|--------------------------------|-----------------------------|---------------------------|------------------------|---------------------------|-------------------------|
| | Brassica Oleracea Acephala Seed Oil | Di assica Oleracea Italica (Broccoli) Seed | Butyrospermum Parkii (Shea) | Butyrospermum Parkii (Shea) | Camelina Sativa Seed Oil | Camellia Japonica Seed | Camellia Kissi Seed | Oleifera Seed Oil [Tea | Camellia Sinensis |
| Fatty Acids ^a | [Kale] ⁸⁸ | Oil | Oil | Butter ^{6,90-92} | [False Flax] ¹⁷⁴ | Oil ¹⁷⁵ | Oil | Seed] ^{94,95} | Seed Oil ¹⁷⁵ |
| Caproic (C6) | | | | | | | | | |
| Caprylic (C8) | | | | | | | | | |
| Capric (C10) | | | | | | | | | |
| Lauric (C12) | | | | | | | | | |
| Myristic (C14) | | | | 0.5 | | | | | |
| Myristoleic (C14:1) | | | | | | | | | |
| Palmitic (C16) | 4.4 | 0-5 | 3.8-4.1 | 3-9 | 7.8 | 7.9 | | 6.1-15 | 8-10 |
| Palmitoleic (C16:1) Heptadecanoic (C17:0) | | | | | | 0.16 | | | |
| Stearic (C18) | 0.7 | 0-5 | 41.2-56.8 | 30-50 | 2.96 | 2.46 | | 0.8-2 | 1.5-3.5 |
| Oleic (C18:1) | 11.3 | 10-20 | 34.0-46.9 | 38-50 | 16.77 | 84.99 | 80 | 72-87 | 78-86 |
| Linoleic (C18:2) | 12.6 | 10-20 | 3.7-6.5 | 3-8 | 23.08 | 3.76 | | 5.3-14.3 | 7-10 |
| Linolenic (C18:3) | 10.2 | 5-10 | | 0.5 max | 31.2 | | | | 0.2-0.8 |
| Arachidic (C20) | 8.2 | | 1-2 | 2.5-3 | | 0.49 | | | |
| Eicosenoic (C20:1) Eicosadienoic (C20:2) | 0.4 | 5-10 | | | 11.99 | | | | |
| Arachidonic (C20:4) | | | | | | | | | |
| Behenic (C22) | | | | | | | | | |
| Erucic (C22:1) | 51.8 | 40-50 | | | 2.8 | | | | |
| Docosadienoic | | | | | | | | | |
| Docosahexaenoic | | | | | | | | | |
| (C22:6) | | | | | | | | | |
| Lignoceric (C24) | | | | | | | | | |
| | | | | | | | | | |
| Others | | | | | 3.4 | | | | |

| Table 4. Total fatty aci | d composition of pla | nt-derived fatty acid o | ils (%) (continued). | | | | | | |
|--------------------------|-------------------------|---------------------------|---|-----------------------------------|-------------------------------|------------------------------------|-----------------------------------|---------------------------------------|--|
| - - - | Canarium Indicum Oil | Carica Papaya Seed Oil | Carthamus Tinctorius (Safflower) Seed | Carya Illinoensis (Pecan) Seed | Caryocar Brasiliense Fruit | Chenopodiu m Quinoa Seed Oil | Citrullus Lanatus (Watermelon) | Citrus Aurantifolia (Lime) Seed | Citrus Aurantium Dulcis (Orange) |
| Fatty Acids " | [Galip] | Papaya 2007 | 0il ^{22,170} | Oil (1) | Oil [Pequi] """" | Quinoa] | Seed Oil ¹⁰¹ | 01/10/10 | Seed Oil The Seed |
| Caproic (C6) | | | | | | | | | |
| Caprylic (C8) | | | | | | | | | |
| Capric (C10) | | | | | | | | | |
| Lauric (C12) | 2 | | | | | | | | |
| Myristic (C14) | ≤ 2 | | | Trace | 0.5 | 0.2 | | | |
| Myristoleic (C14:1) | | | | | | | | | |
| Palmitic (C16) | 28-38 | 8-18 | 2 | 3-4.3 | 34.4-44.3 | 9.9 - 11 | 8.0 - 13.0 | 20-30 | 14-22 |
| Palmitoleic | | | | | | | | | |
| (C16:1) | 2 | 2 | | 0.1 | 1.3 | 0.1 | < 1.0 | | |
| Heptadecanoic (C17:0) | 6 | | | 0.1 | | | | | |
| Stearic (C18) | 10-20 | 2-6 | | 1.8-2 | 0.66-1.8 | 0.7 - 0.8 | 8.0 - 12.0 | 3-8 | 2-6 |
| Oleic (C18:1) | 30-40 | 60-77 | 26 | 40.6-79 | 54.55-57.4 | 22 - 50.2 | 15.0 - 30.0 | 20-38 | 26-35 |
| Linoleic (C18:2) | 12-22 | 3-25 | 68 | 16-50.3 | 0.84-2.8 | 1.2 - 56 | 55.0 - 65.0 | 30-45 | 35-45 |
| Linolenic (C18:3) | | 0.8 | Trace | 0.7 | 0.18-1.0 | 0.7 - 7 | < 1.0 | 5-15 | 2-6 |
| Arachidic (C20) | | | Trace | Trace | | 0.7 | < 1.0 | 2 | 0.5 |
| Eicosenoic (C20:1) | | 2 | | 1.2 | | | < 1.0 | | |
| Eicosadienoic (C20:2) | | | | | | | | | |
| Arachidonic (C20:4) | | | | | | | | | |
| Behenic (C22) | | | | 0.2 | | | < 1.0 | | |
| Erucic (C22:1) | | | | 0.3 | | | | | |
| Docosacienoic (C22:2) | | | | | | | | | |
| Docosahexaenoic | | | | | | | | | |
| (C22:0) | | | | | | | < 2.0 | | |
| Lignoceric (C24) | | | | | | | | | |
| | | α -Linolenic | | | | | | | |
| Others | Others = < 2 | (C18:3) = 2% | | | | | < 1.0 | | |
| | I | | | | | | | | |

| | Citrus | | | | | Corvins | Corvins | Crambe | Cucumis | Cucurhita |
|------------------------------|--|--|--|---|--|---|---|---|--|--|
| Fatty Acids ^a | Grandis (Grapefruit) Seed Oil ^{106,107} | Citrus Limon (Lemon) Seed Oil ¹⁷⁸ | Citrus Paradisi (Seed) Oil ¹⁷⁹ | Cocos Nucifera (Coconut) Oil ³³ | Coix Lacryma- Jobi (Job's Tears) Seed Oil ¹⁸⁰ | Americana (Hazel) Seed Oil ¹⁷³ | Avellana (Hazel) Seed Oil ^{12,116-118} | Abyssinica Seed Oil [Abyssinian Mustard] ^{173,181} | Sativus (Cucumber) Seed Oil ¹⁸² | Pepo (Pumpkin) Seed Oil ^{109,110} |
| Caproic (C6) | | | | 0-1 | | | | | | |
| Caprylic (C8) | | | | 5-9 | | | | | | |
| Capric (C10) | | | | 6-10 | | | | <0.01-0.11 | | |
| Lauric (C12) | 1.5 | | 2.95 | 44-52 | | | | <0.01-0.14 | | |
| Myristic (C14) | 1 | | 1.01 | 13-19 | | | ≤0.2 | <0.01-0.43 | | |
| Myristoleic (C14:1) | | | | | | | | <0.01-0.09 | | |
| Palmitic (C16) | 18-30 | 18.8 | 36.25 | 8-11 | 16.0 | 6 | 4-9 | 0.81-5.55 | 9-13 | 10-16 |
| Palmitoleic | | | | | | | | | | |
| (C16:1) Hentedecencie | | | | 0-1 | | | 0.2-1 | <0.01-0.77 | | |
| (C17:0) | | 0.08 | | | | | ≤0.1 | | | |
| Stearic (C18) | 2-8 | 3.5 | 5.95 | 1-3 | trace | 3 | 1-6 | 0.6-10.42 | 6-9 | 3-7 |
| Oleic (C18:1) | 20-38 | 30.1 | 18.34 | 5-8 | 53 | 76 | 66-85 | 12.8-23.13 | 14-20 | 18-38 |
| Linoleic (C18:2) | 30-48 | 33.4 | 29.26 | Trace-2.5 | 30.5 | 15 | 7-25 | 9.08-15.86 | 60-68 | 40-62 |
| E Linolenic (C18:3) | 2-6 | 13.5 | 3.58 | | trace | | ≤0.6 | 3.27-9.43 | $\overline{\nabla}$ | 1 |
| a Arachidic (C20) | | 0.3 | 0.38 | | | | ≤0.5 | <0.01-1.19 | | |
| Eicosenoic | | 20.0 | 0.84 | | | | -0 E | | | |
| A (C20:1) A Eicosadienoic | | c0.0 | | | | | C.U <u>></u> | 0-10:0> | | |
| 60 (C20:2) | | | | | | | | <0.01-0.21 | | |
| 8 Arachidonic 0 (C20:4) | | | | | | | | <0.01 | | |
| Behenic (C22) | | 0.08 | | | | | ≤0.3 | <0.01-2.59 | | |
| Erucic (C22:1) | | | | | | | Trace-0.01 | 48.86-60 | | |
| Docosadienoic (C22:2) | | | | | | | | | | |
| Docosahexaenoic | | | | | | | | -0.01 1.34 | | |
| (C22:0) Lignoceric (C24) | | 0.2 | | | | | 0.01 | <0.01-1.85 | | |
| | | | C12:1=1.44 | | | | 1 | | | |
| | | | | | | | | C20:3 = <0.01- | | |
| Others | | C23:0 = <0.01; C26:0 = 0.01 | | | | | $C17:1 = \le 0.1$ | 0.19; C20:5 = <0.01-1.91 | | |
| | | | | | | | | | | |

| | Cynara Cardunculus | Elacis | Elaeis Guineensis | Elaeis | | Fragaria Ananassa | Garcinia Indica | Gevuina Avellana | |
|----------------------------|--|--|------------------------------------|---------------------------------------|---|--|---|--|--|
| Fatty Acids ^a | Seed Oil [Artichoke] ¹⁸³ | Guineensis (Palm) Oil ²⁶ | (Palm) Kernel Oil ²⁶ | Oleifera Kernel Oil ¹⁸⁴ | Euterpe Oleracea Fruit Oil [Acai] ¹⁸⁵ | (Strawberry) Seed Oil ^{68,111,112} | Seed Butter [Kokum] ^{g,123,186} | Oil [Chilean Hazel] ^{j,187} | Glycine Soja (Soybean) Oil ⁶ |
| Caproic (C6) | | | 0.3 | 0.1 | | | | | |
| Caprylic (C8) | | | 4.4 | 0.9 | | | | | |
| Capric (C10) | | | 3.7 | 0.8 | | | | | |
| Lauric (C12) | | 0.2 | 48.3 | 29.3 | | | | | |
| Myristic (C14) | | 1.1 | 15.6 | 25.7 | | 0.05 | | | |
| Myristoleic (C14:1) | | | | | | | | | |
| Palmitic (C16) | 12 | 44 | 7.8 | 10.1 | 22 | 4.32 | 2-8 | 1.9 | |
| Palmitoleic | | 0.1 | | | ¢ | | | 7 66 | |
| Heptadecanoic (C17:0) | | | | | 1 | | | | |
| Stearic (C18) | £ | 4.5 | 2 | 1.8 | 2 | 1.68 | 50-67.4 | 0.5 | |
| Oleic (C18:1) | 25 | 39.2 | 15.1 | 26.4 | 60 | 10-20 | 27-42 | 39.4 | 11.5 - 60.0 |
| Linoleic (C18:2) | 60 | 10.1 | 2.7 | 4.5 | 12 | 28.5 - 50 | 0.5-2 | 5.6 | 0000 |
| Linolenic (C18:3) | | 0.4 | | | Trace | 25-40 | | 0.1 | 2.9 - 12.1 |
| Arachidic (C20) | | 0.4 | | | 2.5 | 0.71 | 0.7 | 1.4 | |
| Eicosenoic (C20:1) | | | | | | | | 3.1 | |
| Elcosadienoic (C20:2) | | | | | | | | | |
| Arachidonic (C20:4) | | | | | | | | | |
| Behenic (C22) | | | | | | | | 2.2 | |
| Erucic (C22:1) | | | | | | | | | |
| Docosadienoic (C22:2) | | | | | | | | | |
| Docosahexaenoic | | | | | | | | | |
| (C22:6) 1 ian and (C34) | | | | | | | | 0 S | |
| | | | | | | | | $C18:1\Delta 12 = 6.2;$ | |
| | | | | | | | | $C20:1\Delta 15 = 6.6; ;$ $C22.1\Delta 17 = 7.9.$ | |
| Others | | | 0.2 | 0.4 | | 5.5 - 8.5 | | $C22:1\Delta 19 = 1.6$ | |

| - - - - | Gossypium Herbaceum | Guizotia Abyssinica Seed | Helianthus Annuus (Sunflower) | Sunflower Seed | Hippophae Rhamnoides Fruit | Hippophae Rhamnoides Seed | Irvingia Gabonenesis Kernel | Juglans Regia (Walnut) Seed | Limnanthes Alba (Meadowfoam) |
|--|---------------------------------|-----------------------------|-------------------------------------|----------------|--|---------------------------------|-----------------------------------|--------------------------------|---------------------------------|
| Fatty Acids ^a Caproic (C6) | (Cotton) Seed Oil ²⁷ | Oil Ramtil/Niger | Seed Oil | Acid"' | 0il:13,100 | 0il 1211124100 | Butter ^{123,123} | 01 | Seed Oil [®] |
| Caprylic (C8) | | | | | | | | | |
| Capric (C10) | | | | | | | | | |
| Lauric (C12) | | | | | | | 35-51.1 | | |
| Myristic (C14) | 2 | | | Ø | 0.4-0.6 | | 36.8-58 | | |
| Myristoleic (C14:1) | | | | | 0.2 | | | | |
| Palmitic (C16) | 21 | 5.0-13 | 5.0 - 7.2 | 6-11 | 24-42 | 5-11.3 | 3.9-5 | 3-7 | |
| Palmitoleic | | | | | CF FC | 7 | | | |
| Heptadecanoic | | | | | 7 | r F | | | |
| Stearic (C18) | Trace | 2.0-11 | 2.0 - 6.5 | 3-7 | 0.9-2.1 | 2-5 | 0.4-0.7 | 0.5-3 | |
| Oleic (C18:1) | 30 | 6.0-40 | 14.7 - 37.2 | 19-31 | 3-30 | 11-30 | 0.6-2.7 | 9-30 | |
| Linoleic (C18:2) | 45 | 45-77 | 51.5 - 73.5 | 57-66 | | 28-45 | 09.0 | 57-76 | |
| Linolenic (C18:3) | | | Trace - 0.3 | Vı | 1.7-6.8 | 24.9-38 | 1.3 | 2-16 | |
| Arachidic (C20) | Trace | | 0.3 - 1 | ۲¢ | | | | | |
| Eicosenoic (C20:1) Eicosadienoic | | | | | | | | | 52 - 77 |
| (C20:2) | | | | | | | | | |
| Arachidonic (C20:4) | | | | | | | | | |
| Behenic (C22) | | | | | | | | | |
| Erucic (C22:1) Decessionaie | | | | | | | | | 8.0 - 29 |
| (C22:2) | | | | | | | | | 7.0 - 20 |
| Docosahexaenoic (C22:6) | | | | | | | | | |
| Lignoceric (C24) | | 2 max | | | | | | | |
| | | | | | | Vakccenic C18:1(n-7) = | | | |
| | | | | | Vakcenic C18:1(n- | 3.2; α- Linoleic | | | |
| | | | | | $7) = 7.3 - 7.5; \alpha - 1 = 1000 = 1000 = 1000 = 1000 = 1000 = 1000 = 1000 = 1000 = 1000 = 1000 = 100000 = 100000 = 10000 = 100000 = 100000 = 100000 = 100000 = 1000000 = 100000 = 1000000 = 100000 = 1000000 = 100000000$ | C18:2 = 34.1; Others - 2 | | | |
| Others | | | | >C20 = <3 | 4.1-5.5 | u – cipino max | | | |

| | Linum Usitatissimum (Linseed) Seed | Luffa Cylindrica | Lupinus Albus | Lycium Barbarum Seed | Macadamia Integrifolia | Mangifera Indica (Mango) | Morinda Citrifolia Seed | Moringa Oleifera Seed Oil [Ben/Moringa] ^{127,12} | Oenothera Biennis (Eve- ning Primrose) | Olea Europaea |
|-------------------------------|--|-------------------------|-------------------------|---------------------------|---------------------------------|-----------------------------|----------------------------|---|--|--------------------------|
| Fatty Acids ^a | Oil ⁶ | Seed Oil ¹⁹⁰ | Seed Oil ¹⁹¹ | Oil ¹⁹² | Seed Oil ^{b,2,124-126} | Seed Oil ^{c,6} | Oil ¹⁹³ | 8,194 | Oil ^{130,131} | (Olive) Oil ⁶ |
| Caproic (C6) | | | | | | | 1 12 | | | |
| Caprylic (C8) Canric (C10) | | | | | | | Ę | | | |
| Lauric (C12) | | | | | 0.1-1.4 | | | | | |
| Myristic (C14) | | 0.1 | | | 0.7-1.5 | | | Trace | | Trace |
| Myristoleic (C14:1) | | | | | | | | | | |
| Palmitic (C16) | 5.5 | 12.2 | 14.44-21.57 | | 6-12 | 5-8 | 9.0 | 5-9.3 | 4-10 | 7.5 - 20 |
| Palmitoleic (C16:1) | | 0.1 | 0.36-1.03 | | 12-25 | | 0.12 | 1.5-3 | | 0.3 - 3.5 |
| Heptadecanoic (C17:0) | | | | | | | 0.13 | | | |
| Stearic (C18) | 3.5 | 0.1 | 1.37-3.91 | 3 | 0.5-8 | 33-48 | 4.07 | 3-8 | 2-4 | 0.5 - 3.5 |
| Oleic (C18:1) | 1.9.1 | 19.6 | 42.78-52.87 | 19.1 | 50-67 | 35-50 | 17.45 | 65-80 | 5-12 | 53 - 86 |
| Linoleic (C18:2) | 15.3 | 59.7 | 9.20-17.23 | 68.3 | 1.5-5 | 4.0-8 | 59.45 | 1.5-5 | 60-85 | 3.5 - 20 |
| Linolenic (C18:3) | 57 | | 4.81-9.02 | 2.8 | 0.5-1.9 | | 0.27 | 1-1.5 | | 0 - 1.5 |
| Arachidic (C20) | | | 1.61-2.30 | | 1.5-5 | 1-7 | 0.51 | 2-5 | | Trace |
| Eicosenoic (C20:1) | | | 3.86-5.30 | | 1.5-3.1 | | 0.2 | 2.5-4 | | |
| Eicosadienoic (C20:2) | | | | | | | | | | |
| Arachidonic (C20:4) | | | | 0.68 | | | | | | |
| Behenic (C22) | | | 4.75-5.99 | | 0.3-1 | | | 8-8.6 | | Trace |
| Erucic (C22:1) | | | 0.51-1.47 | | 1 | | | ю | | |
| Docosadienoic (C22:2) | | | | | | | | | | |
| Docosahexaenoic | | | | | | | | | | |
| (C22:6) | | | | | | | | I | | |
| Lignoceric (C24) | | | | | | | | Trace | | Trace |
| | | | | | | | | | α-Linolenic | |
| ā | | | | | | | | | $\gamma-\text{Linolenic} = 7-$ | |
| Uthers | | | | | | | | | 1 / ./0 | |

| | Olea Europaea (Olive) Husk | | Orbignya Cohune Seed | Orbignya Oleifera Seed Oil | Orhignva Speciosa | Orvza Safiva | Orvza Sativa | Passiflora Edulis Seed Oil IPassion | Perilla Ocymoides |
|-----------------------------|-------------------------------|--------------------------|---------------------------|-------------------------------|---------------------------|--------------------------------|---------------------------------|--|---------------------------------|
| Fatty Acids ^a | Oil ¹³² | Olive Acid ⁸⁷ | Oil [Cohune] ⁶ | [Babassu] ⁶ | Kernel Oil ¹⁹⁵ | (Rice) Bran Oil ¹³⁴ | (Rice) Germ Oil ²⁸ | Fruit] ¹³⁵ | Seed Oil [Perilla] ⁶ |
| Caproic (C6) | | | | | | | | | |
| Caprylic (C8) | | | 7.5 | 4 to 8 | 2-10 | | | | |
| Capric (C10) | | | 6.5 | 4 to 8 | 2-12 | | | | |
| Lauric (C12) | | | 46.5 | 44 - 47 | 35-50 | | | | |
| Myristic (C14) | | ≤1.0 | 16 | 15 - 20 | 12-25 | | 6.92 ²⁸ | 0.03 | |
| Myristoleic (C14:1) | | | | | | | | | |
| Palmitic (C16) | 14.96 | 9-15 | 9.5 | 6 to 9 | 4-15 | 14 | 9.28 | 8.57 | |
| Palmitoleic | | | | | | | 96 | | |
| (C16:1) Hentadecanoic | 2.18 | 75 | | | | | 4.41 | 0.23 | |
| (C17:0) | | ≤0.5 | | | | | | | |
| Stearic (C18) | 1 | 2-5 | 3 | 3 to 5 | 1-7 | 2 | 7.9128 | 1.66 | |
| Oleic (C18:1) | 64.08 | 69-78 | 10 | 10 to 12 | 5-20 | 45 | 17.81 ²⁸ | 16.25 | 14-23 |
| Linoleic (C18:2) | 16.09 | 8-14 | 1 | 1 to 3 | \heartsuit | 34 | 16.22 ²⁸ | 72.69 | 16 |
| The Transferring (C18:3) | 0.71 | ≤3.5 | | | | 1 | 15.56 ²⁸ | 0.26 | 63-70 |
| u Arachidic (C20) | | | | | | | 3.08 ²⁸ | | |
| Eicosenoic | | | | | | | | | |
| S Eicosadienoic | | | | | | | | | |
| ed (C20:2) | | | | | | | | | |
| 6 Arachidonic | | | | | | | 5.48 ²⁸ | | |
| Behenic (C22) | | | | | | | | | |
| Erucic (C22:1) | | | | | | | | | |
| Docosadienoic | | | | | | | | | |
| (C22:2) Dococa hevaenoic | | | | | | | | | |
| (C22:6) | | | | | | | | | |
| Lignoceric (C24) | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Others | | | | | | | Aracmidonurienoic $= 5.21^{28}$ | Eatty acids $= 0.31$ | |
| | | | | | | | | | |

| Fatty Acids ^a | Persea Gratissima (Avocado) Oil ⁶ | Pistacia Vera Seed Oil [Pistachio] ⁷⁵ | Plukenetia Volubilis Seed Oil [Sacha Inchi] ¹⁹⁶ | Prunus Amygdalus (Sweet Almond) Oil ^{6,71,137-139,197} | Prunus Armeniaca (Apricot) Kernel Oil ¹⁴⁴ | Prunus Avium (Sweet) Cherry Seed Oil ^{d,140,141} | Prunus Domestica Seed Oil [Prune/Plum] ^{142,143} | Prunus Persica (Peach) Kernel Oil ¹⁴⁵ |
|-------------------------------|--|---|--|--|--|---|---|--|
| Caproic (C6) Canrylic (C8) | | | | | | | | |
| Capric (C10) | | | | | | | | |
| Lauric (C12) | | | | | | | | |
| Myristic (C14) | | 0.09 | 0.02 | 1 | | | | |
| Myristoleic (C14:1) | | | | | | | | |
| Palmitic (C16) | 13-17 | 7.4 | 4.72 | 4-9 | 4.6-6 | 4-10 | 4-9 | 2.0 - 7 |
| Palmitoleic (C16:1) | 3 - 5.1 | 0.7 | 0.04 | 0.8 | 1-2 | | 1 | |
| Heptadecanoic (C17:0) | | | 0.12 | 0.2 | | | | |
| Stearic (C18) | | 0.0 | 3.33 | 2-3 | 0.5-1.2 | 1-4 | 3 | 0.5 - 3.5 |
| Oleic (C18:1) | 67-72 | 58.2 | 10.46 | 62-86 | 58-65.7 (total 18:1) | 23-55 | 60-80 | 55 - 70 |
| | | | | | 29-33 | | | |
| Linoleic (C18:2) | 10 to 12 | 30.3 | 37.64 | 20-30 | 28.5 (undef. 18:2) | 30-55 | 15-25 | 22 - 33 |
| Linolenic (C18:3) | | 0.4 | 48.96 | 0.4 | 05-1.0 (undef 18:3) | 13 | 1 | ≤ 1 |
| Arachidic (C20) | | 0.6 | 0.09 | 0.2 | 0.2 | 2 | | |
| Eicosenoic (C20:1) | | 0.6 | 0.3 | 0.3 | | | | |
| Eicosadienoic | | | | | | | | |
| Arachidonic | | | | | | | | |
| (C20:4) | | | | | | | | |
| Behenic (C22) | | 0.3 | | 0.2 | | | | |
| Erucic (C22:1) | | 0.6 | | 0.1 | | | | |
| Docosadienoic | | | | | | | | |
| Docosa hexa enoic | | | | | | | | |
| (C22:6) | | | | | | | | |
| Lignoceric (C24) | | | | | | | | |
|) | | | | | | | | |
| | | | C17:1 = 0.06; | | | | | |
| Others | | | gamma C18:3 = 0.24;Others = 0.02 | <c16:0 0.1<="" =="" th=""><th>Oleic/Linoleic = 90- 93%</th><th>Eleostearic (C18:3 conj) = 10%</th><th></th><th></th></c16:0> | Oleic/Linoleic = 90- 93% | Eleostearic (C18:3 conj) = 10% | | |

| | Punica Granatum | | Kibes Nigrum (Black | Ribes Rubrum | Rosa Canina | Rubus | Kubus Idaeus (Raspberry) | Schinziophyton |
|--------------------------|--|--|---|--|---|--|------------------------------------|---|
| Fatty Acids ^a | Seed Oil [Pomegranate] ^{146,147} | Pyrus Malus (Apple) Seed Oil ¹⁴⁸ | Currant) Seed Oil ¹⁴⁹⁻¹⁵¹ | (Currant) Seed Oil ^{152,198} | Seed Oil [Dog Rose] ^{178,199} | Chamaemorus Seed Oil ¹⁵³ | Seed Oil ^{68,154-} 156 | Rautanenii Kernel Oil ¹⁵⁷ |
| Caproic (C6) | | | | | | | | |
| Caprylic (C8) | | | | | | | | |
| Capric (C10) | | | | | | | | |
| Lauric (C12) | | | | | | | | |
| Myristic (C14) | | | | | 0.11-0.21 | | 0.07 | |
| Myristoleic (C14:1) | | | | | | | | |
| Palmitic (C16) | 1-10 | 6.51-6.60 | 6-10 | 4.6-4.8 | 1.71-4.6 | | 2-2.43 | 8 |
| Palmitoleic (C16:1) | | 0-0.05 | | | 0.24-1.01 | | | |
| Heptadecanoic (C17:0) | | | | | 0.04 | | | |
| Stearic (C18) | 1-5 | 1.75-1.96 | 1-4 | 2-3 | 1.69-2.47 | | 0.9-1 | 6 |
| Oleic (C18:1) | 3-12 | 37.49-38.55 | 9-16 | 17.1-17.8 | 14.71-21.7 | 13-19 | 8-13 | 15 |
| Linoleic (C18:2) | 2-12 | 50.70-51.40 | 40-54 | 36-48 | 47.9-54.41 | 40-52 | 47-63 | 37 |
| Linolenic (C18:3) | | 0.19-0.30 | 11-18 | 15-30 | 16.42-21.8 | 27-38 | 25-40 | 25 |
| Arachidic (C20) | | 1.49-1.54 | 1 | | 1.0-2.61 | | 0.37 | |
| Eicosenoic (C20:1) | | 0.51-0.56 | ŝ | | 0.3 | | | |
| Eicosadienoic (C20:2) | | | | | 0.07 | | | |
| Arachidonic (C20:4) | | | | | | | | |
| Behenic (C22) | | 0-0.40 | 1 | | 0.1 - 0.64 | | | |
| Erucic (C22:1) | | | 1 | | | | | |
| Docosadienoic (C22:2) | | | | | | | | |
| Docosahexaenoic (C22:6) | | | | | | | | |
| Lignoceric (C24) | | | | | 0.04 | | | |
| | | | C18:3 (n-6) = | C18:1n-/=0.5- 0.6; C18:3n-6= | | | | |
| | Punicic (C18:3conj) = 60-80; Other | | 11-18 C18:4 (n-3) = | 5.6-12; C18:4n-3 = 2-5; Others = | C17:1 = 0.01; C21:0= 0.01, | | | |
| Others | C18:3 conj = 18% | | 2-5 | 0-0.3 | C23:0 = 0.03 | | | |

| | 0-1- <i>1</i> -0 | 5 | | | | | | |
|--|-----------------------------------|-------------------------------------|------------------------------|---|--|---------------------------------|--|---------------------------|
| | Scierocarya Birrea Seed Oil | Sesamum Indicum (Sesame) Seed | Silybum Marianum Seed | Solatium Lycopersicum (Tomato) Seed | Solatium Lycopersicum (Tomato) Fruit | Theobroma Cacao (Cocoa) Seed | Licoprolita Grandiflorum Seed Butter | Torreya Nucifera Seed |
| Fatty Acids ^a | [Marula] ^{158,200} | Oil ^{25,55} | Oil [Thistle] ²⁰¹ | Oil ¹⁵⁹ | Oil* ²⁰² | Butter ⁶ | [Cupuacu] ²⁰³ | Oil [Kaya] ²⁰⁴ |
| Caproic (C6) Caprylic (C8) | 1.41 | | | | | | | |
| Capric (C10) | | | | | | | | |
| Lauric (C12) | | | | Trace-0.3 | | | | |
| Myristic (C14) | 2.12 | <0.5 | | 1.5-2.3 | | | Trace | Trace |
| Myristoleic (C14:1) | | | | Trace | | | | |
| Palmitic (C16) | 9-12; 22.56 | 7.0 - 12.0 | 9.4 | 16.9-23.4 | 47 | 24-29 | 7.2 | 6.03 |
| Palmitoleic (C16:1) Heptadecanoic | 0.05 - 0.15 | <0.5 | | 3.3-6.8 | | | 0.1 | Trace |
| (C17:0) | | | | | | | 0.2 | Trace |
| Stearic (C18) | 5-8; 50.76 | 3.5 - 6.0 | 6.6 | 4.0-9.5 | 3 | 34-36 | 30.8 | 2.51 |
| Oleic (C18:1) | 4.13; 70 - 78 | 35 - 50 | 21.3 | 18.3-29.7 | 30 | 30-40 | 43.9 | 30.35 |
| Linoleic (C18:2) | 4.0 - 7.0 | 35 - 50 | 53.3 | 37.6-42.8 | 12 | 2.4 | 4.6 | 51.26 |
| Linolenic (C18:3) | 0.1 - 0.6 | <1.0 | trace | Trace-0.7 | | | Trace | 0.23 |
| Arachidic (C20) | 0.3 - 0.7 | <1.0 | 3.8 | 0.8-1.3 | | | 11 | |
| Eicosenoic (C20:1) | 0.1 - 0.5 | <0.5 | 0.5 | | | | | 0.28 |
| Eicosadienoic (C20:2) | | | | | | | | 0.98 |
| Arachidonic (C20:4) | 8.46 | | | | | | | |
| Behenic (C22) | 5.14 | <0.5 | 2.4 | Trace-0.7 | | | | |
| Erucic (C22:1) | 0.1 - 0.5 | | | | | | | |
| Docosadienoic (C22:2) Docosahexaenoic | | | | | | | | |
| (C22:6) | | | | | | | | |
| Lignoceric (C24) | 4.13 | | 0.7 | | | | | C18-1 A11 = |
| | | | | | | | | 0.57; C18:3 |
| | | | | | | | | $\Delta 5,9,12 = 0.08;$ |
| | | | | | | | | 0.79; C20:3 |
| | , | Trace of | | | | | | $\Delta 5, 11, 14 =$ |
| Others | Butyric = 0.35% | components below C14 | | | Other ($C14 + C20$) = 8 | | | 0.08; Uthers = 0.24 |
| | | | | | | | | |

| | | Vaccinium | Vaccinium | Vaccinium | | | | |
|---|-----------------------------------|--------------------------------|---|-------------------------------|------------------------------------|-------------------------------|---------------------------|---------------------------|
| | Triticum Vulgare (Wheat) Germ | Corymbosum (Blueberry) Seed | Macrocarpon (Cranberry) Seed | Myrtillus Seed Oil | Vaccinium Vitis- Idaea Seed Oil | Vitis Vinifera | Zea Mays (Corn) | Zea Mays (Corn) |
| Fatty Acids ^a | Oil ^{30,52} | Oil ^{68,160,161} | Oil ^{68,162-165} | [Bilberry] ^{166,205} | [Lingonberry] ^{167,205} | (Grape) Seed Oil ⁶ | Oil ^{53,168,169} | Oil ^{53,168,169} |
| Caproic (C6) Caprvlic (C8) | | | | | | | | |
| Capric (C10) | | | | | | | | |
| Lauric (C12) | | 0.02 | 0.14 | | | | | |
| Myristic (C14) Myristolaio (C14-1) | | 0.09 | 0.08 | 2.2-2.5 | 1.6-2.6 | | 0.1 - 1.7 | 0.1 - 1.7 |
| Palmitic (C16) | 11.0 - 16 | 3-8 | 4-6 | 4.8-7.4 | 4.4-6.7 | 7-9.5 | 8-16.5 | 8-16.5 |
| Palmitoleic (C16:1) Heptadecanoic (C17:0) | | | | | | | 0.2 - 1.6 | 0.2 - 1.6 |
| Stearic (C18) | 1.0 - 6 | 0.5-3.5 | 1-1.25 | 2.2-2.5 | 1.2-1.9 | 3.5-5.5 | 0-4.5 | 0-4.5 |
| Oleic (C18:1) | 8.0 - 30 | 15-25 | 15-25.3 | 17.4-23 | 10-25 | 14-44 | 19 - 49 | 19 - 49 |
| Linoleic (C18:2) | 44 - 65 | 35-45 | 32-42 | 35-47.5 | 30-46.8 | 46-74 | 34-66 | 34-66 |
| Linolenic (C18:3) | 4.0 - 10 | 22-38 | 30-40 | 23.1-40 | 25.2-55 | | 0-2 | 0-2 |
| Arachidic (C20) | | 0.25 | 0.07 | | | | 1 | 1 |
| Eicosenoic (C20:1) | | | | | | | 1 | 1 |
| Eicosadienoic (C20:2) | | | | | | | | |
| Arachidonic (C20:4) | | | | | | | | |
| Behenic (C22) Erucic (C22:1) | | | | | | | | |
| Docosadienoic (C22:2) | | | | | | | | |
| Docosahexaenoic (C22:6) | | | | | | | | |
| Lignoceric (C24) | | | | | | | | |
| | | | | | | | | |
| Othors | 0 - 1.2 C20-22 Saturated acids | | α -Linolenic (C18.3) = 34.35% | | | | | |
| Outers | Datatativa avius | | $0/cc + c - (c \cdot o t - c)$ | | | | | |
| | | | | | | | | |

ternifolia are synonyms; information is being reported under the more common name. c As mango kernel fat. d As cherry kernel oil. e As Bassia Latifolia seed fat or madhuca indica seed fat. f As caryocar Brasiliense pulp oil. e As garcinia indica seed fat. h As bassia butyracea seed fat. I As Hippophae pulp oil. ^bMacadamia integrifolia and macadamia "Shading identifies previously reviewed ingredients, with gray shading for ingredients with safe and red shading for ingredients with insufficient data conclusions.

Table 4. Total fatty acid composition of plant-derived fatty acid oils (%) (continued).

| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|---------------------------|---------------------|----------------------------|---------------------|---------------------------|---------------------|---------------------------|-----------------------|------------------------------|---------------------|---------------------------|---------------------|---------------------------|
| | Actinidia C Se | Chinensis (Kiwi) ed Oil | Adansonia | Digitata Oil | Aleurities N | 1oluccana Seed Oil | Anacardiuı (Cashev | n Occidentale v) Seed Oil | Argania Spir | osa Kernel Oil | Astrocaryu Seed | um Murumuru d Butter |
| Totals* | 7 | 0.1 | 9 | 0.01 | 141 | 0.00001-5 | 10 | 0.002-1 | 100 | 0.001-10 | 192 | 0.001-7 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 5 | NR | 4 | 0.01 | 28 | 0.00002-5 | 6 | 0.04-I | 87 | 0.001-10 | 121 | 0.001-7 |
| Rinse-Off | 2 | 0.1 | 2 | NR | 54 | 0.00001-3 | Ι | 0.002 | 13 | 0.001-2 | 21 | 0.001-0.2 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | NR | 9 | 0.0001-0.005 | NR | NR | 11 | 0.1-1 | 21 | 0.06-0.5 |
| Possible Ingestion | 1 | NR | NR | 0.01 | 1 | 0.01 | NR | NR | 6 | 0.1-1 | 22 | 1-7 |
| Inhalation | 1 | NR | NR | NR | 15 | 0.1 | NR | NR | NR | 0.01 | NR | NR |
| Dermal Contact | S | NR | 5 | 0.01 | 76 | 0.00001-5 | 6 | 0.002-1 | 88 | 0.001-10 | 178 | 0.001-7 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | 0.001 | NR | NR |
| Hair - Non-Coloring | 2 | 0.1 | 1 | NR | 58 | 0.00002-0.1 | 1 | NR | 8 | 0.01-1 | 11 | 0.001-0.2 |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | NR | NR | NR | 0.07-0.1 | С | NR |
| A Nail | NR | NR | NR | NR | 4 | NR | NR | NR | 2 | 0.001-01 | NR | NR |
| B Mucous Membrane | NR | NR | NR | NR | 5 | 0.00001-0.4 | NR | NR | 2 | 0.001-2 | С | NR |
| Bath Products | NR | NR | NR | NR | 9 | 0.01-0.3 | NR | NR | 1 | 0.05 | NR | NR |
| S Baby Products | NR | NR | 1 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Pa | | | | | | | | | | | | |
| ge 89 | Sodium , | Astrocaryum | Avena Sativa | a (Oat) Kernel | Bassia L | atifolia Seed | Bertholletis | t Excelsa Seed | Dounce Office | Coord Oil | Brassica | t Campestris |
| | INTA | | | | a | uner | | 10 | DUIAGO UIIN | CILIAILS SECU OIL | (Napese | |
| Totals | NR | 0.002-0.005 | 43 | 0.01-3 | 22 | 0.001-2 | 55 | 0.0003-0.5 | 180 | 0.001-1 | 27 | 0.007-17 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | NR | 0.002 | 37 | 0.1-3 | 17 | 0.001-0.05 | 18 | 0.0003-0.5 | 160 | 0.001-1 | 23 | 0.007-17 |
| Rins e-Off | NR | 0.002-0.005 | 6 | 0.001-0.1 | 5 | 0.001-2 | 37 | 0.01-0.2 | 20 | 0.001-0.01 | 4 | 0. I-I |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | 0.2 | 4 | 0.01 | 1 | NR | 7 | 0.001-0.5 | 2 | NR |
| Possible Ingestion | NR | NR | NR | 2 | NR | NR | NR | NR | NR | 0.01 | 1 | 6 |
| Inhalation | NR | NR | NR | NR | NR | NR | 1 | NR | 3 | 0.1 | NR | NR |
| Dermal Contact | NR | 0.002-0.005 | 41 | 0.001-3 | 22 | 00.01-2 | 29 | 0.0003-0.5 | 168 | 0.001-1 | 27 | 0.007-17 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | 7 | 0.1 | NR | 0.001-0.5 | 12 | 0.03-0.2 | 10 | NR | NR | 0.1 |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | 14 | NR | NR | NR | NR | NR |
| Nail | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Mucous Membrane | NR | 0.002 | 2 | 0.01-0.1 | 5 | NR | 7 | 0.01 | 4 | 0.001-0.01 | 1 | NR |
| Bath Products | NR | NR | 1 | NR | NR | NR | б | NR | 1 | NR | NR | NR |
| Baby Products | NR | NR | 9 | 0.1 | NR | NR | NR | NR | 3 | NR | NR | NR |

| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|----------------------|---------------------|---------------------------|-----------------------|--------------------------------|---------------------|---------------------------|---------------------|---------------------------|--------------------------------|-----------------------------------|---------------------|---------------------------|
| | Hydrogena | tted Rapeseed Oil | Brassica O (Brocco | leracea Italica i) Seed Oil | Butyrospe (Sh | ermum Parkii ea) Oil | Butyrospe (Shea | rmum Parkii) Butter | Butyrosper (Shea) Unsapo | mum Parkii Butter nifiables | Hydrogenat | ed Shea Butter |
| Totals | - | 0.3-4 | NR | 0.001-3 | 22 | 0.01-15 | 1950 | 0.0005-60 | 38 | 0.06-3 | 4 | - |
| Duration of Use | | | | | | | | | | | | Ι |
| Leave-On | NR | 0.3-4 | NR | s | 16 | 0.01-15 | 1680 | 0.001-60 | 35 | 0.06-3 | 2 | I |
| Rinse-Off | Ι | NR | NR | 0.001-0.5 | 22 | 0.6-1 | 270 | 0.0005-30 | ŝ | NR | 2 | Ι |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | 2 | NR | NR | 1 | NR | 108 | 0.1-8 | L | 0.2-0.7 | NR | NR |
| Possible Ingestion | NR | NR | NR | NR | NR | 15 | 128 | 0.5-26 | 2 | 3-Jan | NR | NR |
| Inhalation | NR | NR | NR | NR | NR | NR | 17 | 0.001-3 | NR | NR | NR | NR |
| Dermal Contact | 1 | 0.3-4 | NR | NR | 22 | 0.6-15 | 1724 | 0.001-45 | 33 | 0.06-3 | 4 | 1 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | 7 | 1 | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | NR | NR | NR | NR | 210 | 0.0005-3 | 5 | 2 | NR | NR |
| , Hair - Coloring | NR | NR | NR | 0.001-3 | NR | NR | 4 | NR | NR | NR | NR | NR |
| Nail | NR | NR | NR | NR | NR | 0.01-1 | 7 | 0.01-60 | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | NR | NR | 3 | 0.6 | 101 | 0.003-5 | NR | NR | NR | NR |
| Bath Products | NR | NR | NR | NR | 3 | 1 | 13 | 1 | NR | NR | 2 | NR |
| Baby Products | NR | NR | NR | NR | NR | NR | 24 | 0.01-5 | NR | NR | NR | NR |
| | | | | | | | | | | | | |
| | Camelina S | ativa Seed Oil | Camellia Jan | onica Seed Oil | Camellia 1 | Kissi Seed Oil | Camellia Ol | eifera Seed Oil | Hydrogena Oleifera | ted Camellia Seed Oil | Camellia Si | nensis Seed Oil |
| Totals | 76 | 0.002-1 | NR | 0.01-0.2 | 47 | 0.1-10 | 25 | 0.003-3 | ļ | NR | 12 | 0.1 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 61 | 0.002-1 | NR | 0.01-0.2 | 34 | 0.1-10 | 23 | 0.003-3 | Ι | NR | 8 | 0.1 |
| Rinse-Off | 15 | Ι | NR | 0.1 | 13 | 0.1-3 | 2 | 0.01-0.1 | NR | NR | 4 | 0.1 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | 0.05 | NR | 0.01 | 4 | 0.1 | NR | 2 | NR | NR | NR | NR |
| Possible Ingestion | 34 | 0.05-0.5 | NR | 0.1 | 1 | 0.1 | ю | ю | NR | NR | 1 | 0.1 |
| Inhalation | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Dermal Contact | 47 | 0.002-1 | NR | 0.01-0.2 | 36 | 0.1-10 | 23 | 0.003-3 | 1 | NR | 10 | 0.1 |
| Deodorant (Underarm) | NR | NR | NR | 0.01 | NR | NR | NR | NR | NR | NR | NR | 0.1 |
| Hair - Non-Coloring | 29 | 1 | NR | 0.1 | 11 | 0.1-1 | 2 | 2 | NR | NR | 2 | 0.1 |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Nail | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | NR | 0.1 | - | 0.1 | NR | 0.01-0.1 | NR | NR | 2 | 0.1 |
| Bath Products | NR | NR | NR | NR | 1 | 0.3 | NR | 0.05 | NR | NR | NR | NR |
| Baby Products | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |

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| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|----------------------|----------------------|-----------------------------|------------------------|-------------------------------|---------------------|---------------------------|---------------------|-----------------------------|---------------------|---------------------------|---------------------|---------------------------|
| | Can | ola Oil | Canola Oil I | Unsaponifiables | Hydrogenat | ted Canola Oil | Carica Pa | paya Seed Oil | Caryocar Br | asiliense Fruit Dil | Chenopodiu | m Quinoa Seed Oil |
| Totals | 132 | 0.0002-73 | NR | 0.001 | 3 | NR | NR | 0.1 | 31 | 0.0005-0.2 | 1 | 0.3 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 112 | 0.002-73 | NR | NR | 2 | NR | NR | 0.1 | 29 | 0.0005-2 | Ι | NR |
| Rinse-Off | 20 | 0.02-33 | NR | 0.0001 | Ι | NR | NR | NR | 2 | NR | NR | 0.3 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 3 | 0.002-0.03 | NR | NR | NR | NR | NR | NR | 12 | NR | NR | NR |
| Possible Ingestion | 62 | 0.3-70 | NR | NR | NR | NR | NR | NR | 12 | 0.2 | NR | NR |
| Inhalation | 1 | 0.0002-17 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Dermal Contact | 113 | 0.0002-73 | NR | NR | ю | NR | NR | 0.1 | 30 | 0.0005-0.2 | NR | NR |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | 19 | 0.006-24 | NR | 0.001 | NR | NR | NR | NR | 1 | NR | 1 | NR |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | 0.3 |
| Nail | NR | 5 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| 7 Mucous Membrane | 2 | 0.02-1 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Bath Products | 1 | 1-33 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Baby Products | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| | | | | | | | | | | | | |
| Deco | Citrullı (Waterme | us Lanatus Ion) Seed Oil | Citrullu (Watermelo | is Vulgaris nn) Seed Oil** | Citrus Lin See | non (Lemon) ed Oil | Citrus | : Paradisi uit) Seed Oil | Crambe Ab | yssinica Seed Dil | Cucumis Sati See | vus (Cucumber) ed Oil |
| Totals | 1 | 2 | s | NR | 6 | 9 | NR | 0.01-20 | 9 | NR | 6 | NR |
| Duration of Use | - | | | | | | | | | | | |
| Leave-On | Ι | 2 | З | NR | 5 | 5 | NR | 0.08-20 | 5 | NR | 5 | NR |
| Rinse-Off | NR | NR | 2 | NR | Ι | Ι | NR | 0.01-1 | Ι | NR | Ι | NR |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | NR | NR | 1 | NR | NR | NR | NR | 1 | NR |
| Possible Ingestion | NR | NR | NR | NR | NR | NR | NR | 5 | NR | NR | NR | NR |
| Inhalation | NR | NR | NR | NR | NR | NR | NR | 2 | NR | NR | NR | NR |
| Dermal Contact | 1 | 2 | 5 | NR | 9 | 5 | NR | 2-5 | 9 | NR | 5 | NR |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | NR | NR | NR | 1 | NR | 0.01-20 | NR | NR | 1 | NR |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | NR | 6 | NR | NR | NR | NR |
| Nail | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | 1 | NR | 1 | NR | NR | NR | 1 | NR | NR | NR |
| Bath Products | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Baby Products | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |

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| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|----------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|
| | Cucurbita Po See | epo (Pumpkin) d Oil | Palm Ko | ernel Acid | Potassium I | Palm Kernelate | Potassiu | m Palmate | Sodium Pa | lm Kernelate | Sodiur | n Palmate |
| Totals | 18 | 0.003 - 0.1 | 72 | 0.2-12 | 7 | 0.3-30 | S | 0.3-3 | 194 | 12-44 | 212 | 3-68 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 17 | 0.003-0.1 | 3 | NR | NR | NR | NR | NR | 01 | NR | 2 | NR |
| Rinse-Off | Ι | NR | 69 | 0.2-12 | 7 | 0.3-30 | 5 | 0.3-3 | 184 | 12-44 | 205 | 3-68 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 1 | 0.003 | NR | NR |
| Possible Ingestion | NR | NR |
| Inhalation | 1 | NR | NR | NR | NR | NR | NR | NR | 1 | NR | 1 | NR |
| Dermal Contact | 18 | 0.003-0.1 | 71 | 0.2-12 | 7 | 0.3-30 | 5 | 0.3-3 | 194 | 12-44 | 212 | 3-68 |
| Deodorant (Underarm) | NR | NR |
| Hair - Non-Coloring | 1 | NR | 1 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Coloring | NR | NR |
| Nail | NR | NR |
| 1 Mucous Membrane | NR | NR | 64 | 0.2-3 | 1 | 0.3-30 | 7 | 0.3-3 | 173 | 16-44 | 189 | 3-68 |
| Bath Products | NR | NR | NR | NR | NR | NR | NR | NR | e. | NR | 1 | NR |
| Baby Products | NR | NR | NR | NR | NR | NR | NR | NR | 4 | NR | 3 | NR |
| | | | | | | | | | | | | |
| | Paln | n Acid | Elaeis Oleife | era Kernel Oil | Euterpe Ole | eracea Fruit Oil | Garcinia Bı | Indica Seed utter | Gevuina A | Avellana Oil | Glycine Soj | a (Soybean) Oil |
| Totals | 33 | 1-17 | 5 | NR | 29 | 0.00001-0.5 | 30 | 0.1-2 | S | 0.002-0.2 | 912 | 0.0002-95 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | Ι | NR | NR | NR | 61 | 0.00001-0.5 | 27 | 0.1-2 | 5 | 0.04 - 0.2 | 718 | 0.0005-95 |
| Rinse-Off | 32 | 1-17 | 5 | NR | 10 | 0.05 | 3 | NR | NR | 0.002-0.01 | 194 | 0.0002-95 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | NR | 2 | 0.5 | 1 | NR | NR | NR | 53 | 0.04-2 |
| Possible Ingestion | NR | NR | NR | NR | 1 | 0.002 | б | 0.1-2 | NR | NR | 103 | 0.6-4 |
| Inhalation | 1 | NR | NR | NR | 1 | NR | NR | NR | NR | NR | 9 | 0.03-0.5 |
| Dermal Contact | 33 | 1-17 | NR | NR | 14 | 0.00001-0.5 | 30 | 0.1-2 | 4 | 0.002-0.2 | 800 | 0.0005-93 |
| Deodorant (Underarm) | NR | NR | NR | 0.01-0.5 |
| Hair - Non-Coloring | NR | NR | 2 | NR | 15 | NR | NR | NR | NR | NR | 67 | 0.0002-95 |
| Hair - Coloring | NR | NR | б | NR | NR | NR | NR | NR | NR | NR | 5 | NR |
| Nail | NR | NR | 9 | 0.02-95 |
| Mucous Membrane | 31 | 1-4 | NR | NR | ę | NR | 1 | NR | NR | NR | 70 | 0.01-52 |
| Bath Products | NR | NR | 19 | 0.1-78 |
| Baby Products | NR | NR | 21 | 2 |

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| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|----------------------|-----------------------|-------------------------------|---------------------|---------------------------|----------------------|----------------------------|-------------------------------|---|---------------------|----------------------------|---------------------|---------------------------|
| | Glycine Soji Unsap | a (Soybean) Oil onifiables | Hydrogenate | ed Soybean Oil | Helianth (Sunflow | nus Annuus er) Seed Oil | Heliant† (Sunflow Unsap | us Annuus er) Seed Oil onifiables | Hydrogena | ted Sunflower Oil | Hippophae I | Rhamnoides Oil |
| Totals | 12 | 0.0001-0.2 | 36 | 0.001-42 | 1414 | 0.000007-96 | 10 | 0.005-2 | NR | 6-35 | 15 | 0.2-0.7 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 12 | 0.0001-0.2 | 33 | 0.001-39 | 1054 | 0.0002-96 | 01 | 0.005-2 | NR | 6-35 | 01 | 0.2-0.7 |
| Rinse-Off | NR | NR | з | 0.05-42 | 360 | 0.000007-92 | NR | 0.002 | NR | 15-35 | 5 | 0.2 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | 4 | 0.03-7 | 64 | 0.0005-19 | 2 | 0.02 | NR | 7 | NR | NR |
| Possible Ingestion | NR | NR | ю | 0.1-39 | 260 | 0.08-41 | NR | NR | NR | 9 | NR | NR |
| Inhalation | NR | NR | NR | NR | б | 0.0002-85 | NR | NR | NR | NR | NR | NR |
| Dermal Contact | 12 | 0.0001-0.2 | 34 | 0.01-39 | 707 | 0.0002-96 | 10 | 0.005-2 | NR | 6-35 | 1 | 0.2-0.7 |
| Deodorant (Underarm) | NR | NR | NR | NR | 1 | 0.0003-4 | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | 1 | 0.1 | 179 | 0.000007-92 | NR | NR | NR | NR | 9 | NR |
| Hair - Coloring | NR | NR | NR | NR | 85 | 0.03-35 | NR | NR | NR | 15-35 | NR | NR |
| , Nail | NR | NR | NR | 0.001-25 | 8 | 0.05-30 | NR | NR | NR | NR | 8 | NR |
| Mucous Membrane | NR | NR | NR | 0.05-6 | 52 | 0.0003-4 | NR | 0.002 | NR | NR | 1 | 0.2 |
| Bath Products | NR | NR | NR | 5-42 | 11 | 0.005-75 | NR | NR | NR | NR | NR | NR |
| Baby Products | NR | NR | NR | NR | 18 | 0.2 | NR | NR | NR | NR | NR | NR |
| | - | | | - | | | _ | | | | - | |
| | Hippophae Fri | e Rhamnoides uit Oil | Irvingia Gab Bı | onensis Kernel utter | Juglans Ro See | egia (Walnut) ed Oil | Limnaı (Meadowfi | nthes Alba aam) Seed Oil | Linum Us (Linsee | itatissimum 1) Seed Oil | Linse | eed Acid |
| Totals | 7 | 0.004-2 | 109 | 0.003 - 0.4 | 15 | 0.00003-0.2 | 316 | 0.002-74 | 102 | 0.001-10 | 3 | NR |
| Duration of Use | - | | | | | | | | | | | |
| Leave-On | 2 | 0.004-2 | 601 | 0.003 - 0.4 | 12 | 0.01-0.2 | 225 | 0.002-74 | 52 | 0.002-10 | 3 | NR |
| Rinse-Off | NR | NR | NR | NR | 3 | 0.00003-0.1 | 91 | 0.01-2 | 50 | 0.001-0.4 | NR | NR |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 1 | NR | 2 | NR | 1 | NR | 30 | 0.1-20 | 3 | 0.01 | NR | NR |
| Possible Ingestion | NR | NR | 64 | 0.003-0.3 | NR | NR | 67 | 0.6-26 | NR | 0.01 | NR | NR |
| Inhalation | NR | NR | NR | NR | NR | NR | 1 | 0.1-3 | 3 | NR | NR | NR |
| Dermal Contact | 9 | 2 | 108 | 0.003-0.4 | 15 | 0.003-0.2 | 211 | 0.002-74 | 58 | 0.003-4 | 3 | NR |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | 0.05-0.1 | NR | NR |
| Hair - Non-Coloring | NR | NR | 1 | NR | NR | 0.00003-0.1 | 47 | 0.1-1 | 42 | 0.001-0.1 | NR | NR |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | 46 | 0.2-2 | NR | NR | NR | NR |
| Nail | 1 | 0.004 | NR | NR | NR | NR | NR | 0.5 | 2 | 0.002-0.05 | NR | NR |
| Mucous Membrane | NR | NR | NR | NR | NR | NR | 4 | 0.001-0.6 | 5 | 0.003-0.4 | NR | NR |
| Bath Products | NR | NR | NR | NR | 2 | NR | 2 | 0.5-0.9 | 1 | 0.02-0.2 | NR | NR |
| Baby Products | NR | NR | NR | NR | NR | NR | 1 | NR | 2 | NR | 1 | NR |

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| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|-------------------------------|
| | Luffa Cylin | drica Seed Oil | Lupinus A | Ibus Seed Oil | Lycium Ba | rbarum Seed Oil | Macadami Se | ia Integrifolia ed Oil | Macadamia 7 | Ternifolia Seed Oil | Macadan | iia Nut Oil** |
| Totals | 21 | 0.01 | | NR | 2 | NR | 41 | 0.00006-5 | 533 | 0.0003-30 | 208 | NS |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 21 | NR | Ι | NR | 2 | NR | 25 | 0.00006-5 | 482 | 0.001-30 | 161 | NS |
| Rinse-Off | NR | 0.01 | NR | NR | NR | NR | 16 | 0.006-3 | 51 | 0.0003-10 | 17 | NS |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 1 | NR | NR | NR | 1 | NR | 3 | 0.1 | 16 | 0.1-15 | 22 | NS |
| Possible Ingestion | 6 | NR | NR | NR | 1 | NR | 4 | 1 | 33 | 0.1-30 | 11 | NS |
| Inhalation | NR | NR | NR | NR | NR | NR | NR | 0.5 | 12 | 0.007-16 | 7 | NS |
| Dermal Contact | 21 | 0.01 | 1 | NR | 2 | NR | 36 | 0.00006-5 | 493 | 0.001-30 | 170 | NS |
| Deodorant (Underarm) | NR | NR | NR | NS |
| Hair - Non-Coloring | NR | NR | NR | NR | NR | NR | 12 | 0.01-0.03 | 33 | 0.0003-16 | 6 | NS |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | NR | NR | e | 0.02 | NR | NS |
| Nail | NR | NR | NR | NR | NR | NR | NR | 3 | 1 | 0.001-0.5 | NR | NS |
| h Mucous Membrane | NR | 0.01 | NR | NR | NR | NR | 10 | 2 | 12 | 0.02-10 | NR | NS |
| Bath Products | NR | NR | NR | NR | NR | NR | 1 | 0.5 | 2 | 1-10 | 1 | NS |
| Baby Products | NR | NR | NR | RN | NR | NR | NR | NR | 4 | NR | NR | NS |
| | | | | | | | | | | | | |
| Deco | Mangifera I See | Indica (Mango) ed Oil | Mangifera I Seed | ndica (Mango) Butter | Sodium M | angoseedate | Moringa Ol | eifera Seed Oil | Moringa Pt See | terygosperma d Oil | Oenothera B Prim | iiennis (Evening rose) Oil |
| Totals | 72 | 0.003-6 | 175 | 0.0005-3 | 1 | nR | NR | 0.001 | 15 | 0.003-3 | 150 | 0.00002-58 |
| Duration of Use | - | | | | | | | | | | - | |
| Leave-On | 64 | 0.003-6 | 134 | 0.01-5 | NR | NR | NR | 0.001 | 13 | 0.004-3 | 113 | 0.00002-58 |
| Rinse-Off | 8 | 0.05-0.2 | 41 | 0.0005-0.5 | Ι | NR | NR | NR | 2 | 0.003 | 37 | 0.002-0.2 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 13 | 5 | 9 | 0.02 | NR | NR | NR | NR | 4 | ę | 4 | 0.00002-0.5 |
| Possible Ingestion | 7 | 0.03-6 | 25 | 1-5 | NR | NR | NR | NR | 1 | NR | 14 | 0.1-15 |
| Inhalation | 1 | NR | 7 | 0.02 | NR | NR | NR | NR | NR | NR | 2 | NR |
| Dermal Contact | 60 | 0.003-6 | 147 | 0.0005-5 | 1 | NR | NR | 0.001 | 11 | 0.003-3 | 109 | 0.00002-58 |
| Deodorant (Underarm) | NR | NR | NR | 0.2 |
| Hair - Non-Coloring | 12 | 0.05-0.2 | 12 | 0.02-0.5 | NR | NR | NR | NR | 1 | 0.02 | 37 | 0.05-0.1 |
| Hair - Coloring | NR | 0.05 | 16 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Nail | NR | NR | NR | 0.5 | NR | NR | NR | NR | NR | NR | 4 | 0.001-3 |
| Mucous Membrane | 2 | 0.1 | 10 | 0.0005-0.5 | 1 | NR | NR | NR | NR | 0.003 | 4 | 0.1-0.2 |
| Bath Products | NR | NR | 1 | NR | NR | NR | NR | NR | NR | NR | 2 | 0.2 |
| Baby Products | NR | NR | б | NR | NR | NR | NR | NR | NR | NR | б | NR |

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| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|----------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|-------------------------------|---------------------|---------------------------|-------------------------|----------------------------|---------------------|---------------------------|
| | Hydrogen Prim | ated Evening rose Oil | Olea Euro Fru | paea (Olive) iit Oil | Olea Europ Unsap | aea (Olive) Oil onifiables | Hydrogens | ted Olive Oil | Hydrogena Unsapo | ted Olive Oil mifiables | Potassi | um Olivate |
| Totals | 14 | NR | 915 | 0.0005-100 | 77 | 0.0001-3 | 50 | 0.0005-12 | 2 | 0.05-5 | 3 | NR |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 14 | NR | 219 | 0.001-100 | 68 | 0.0001-3 | 36 | 0.1-12 | 2 | 0.05-5 | NR | NR |
| Rinse-Off | NR | NR | 298 | 0.0005-94 | 9 | 0.04-0.3 | 14 | 0.0005-0.1 | NR | NR | 3 | NR |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 1 | NR | 26 | 0.004-17 | 12 | 0.02-0.4 | 13 | 0.1-3 | NR | 0.3-2 | NR | NR |
| Possible Ingestion | NR | NR | 26 | 0.7-26 | 1 | 0.08 | 7 | 0.1-12 | NR | NR | NR | NR |
| Inhalation | NR | NR | 9 | 0.2-5 | NR | С | NR | NR | NR | NR | NR | NR |
| Dermal Contact | 14 | NR | 711 | 0.0005-100 | 67 | 0.0001-3 | 34 | 0.0005-12 | 2 | 0.05-5 | б | NR |
| Deodorant (Underarm) | NR | NR | ŝ | 0.02-0.1 | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | 190 | 0.006-94 | 9 | 0.02-0.3 | 11 | 0.01-0.1 | NR | NR | NR | NR |
| Hair - Coloring | NR | NR | NR | 0.2-0.5 | NR | NR | NR | NR | NR | NR | NR | NR |
| Nail | NR | NR | 5 | 1-40 | NR | NR | NR | NR | NR | NR | NR | NR |
| 7 Mucous Membrane | NR | NR | 121 | 0.0005-3 | 4 | NR | 1 | 0.0005 | NR | NR | 1 | NR |
| Bath Products | NR | NR | 14 | 0.9-17 | NR | NR | NR | NR | NR | NR | NR | NR |
| Baby Products | NR | NR | 6 | 0.2 | NR | 0.04 | NR | 0.4 | NR | NR | NR | NR |
| | - | | | - | | - | | | - | | - | |
| | Sodiur | n Olivate | Orbignya Co | ohune Seed Oil | Orbignya O | leifera Seed Oil | Sodium | Babassuate | Orbignya S _I | oeciosa Kernel Dil | Passiflora I | dulis Seed Oil |
| Totals | 16 | 4-18 | 1 | NR | 161 | 0.0009-27 | NR | 8 | 8 | 0.5-0.9 | 62 | 0.0007-3 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 5 | NR | NR | NR | 118 | 0.0009-4 | NR | NR | Ι | 0.9 | 53 | 0.003-5 |
| Rinse-Off | 11 | 4-18 | I | NR | 43 | 0.01-27 | NR | 8 | 7 | 0.5 | 9 | 0.0007-0.005 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | NR | 7 | 0.5-0.6 | NR | NR | NR | NR | б | 0.8 |
| Possible Ingestion | NR | NR | NR | NR | 57 | 0.001-2 | NR | NR | NR | NR | 14 | 0.6-3 |
| Inhalation | NR | NR | NR | NR | 5 | 0.02-2 | NR | NR | NR | NR | б | NR |
| Dermal Contact | 16 | 4-18 | NR | NR | 110 | 0.0009-27 | NR | 8 | NR | NR | 49 | 0.003-3 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | 0.003 |
| Hair - Non-Coloring | NR | NR | 1 | NR | 43 | 0.02-2 | NR | NR | 5 | 0.5-0.9 | 10 | 0.007-0.5 |
| Hair - Coloring | NR | NR | NR | NR | 8 | NR | NR | NR | 3 | NR | ŝ | NR |
| Nail | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Mucous Membrane | 6 | 4-18 | NR | NR | 5 | 27 | NR | 8 | NR | NR | 1 | NR |
| Bath Products | NR | NR | NR | NR | 2 | 0.01-0.1 | NR | NR | NR | NR | NR | 0.01-0.05 |
| Baby Products | 1 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |

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| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|----------------------|---------------------|---------------------------|------------------------------|-------------------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|----------------------------|
| | Perilla Ocvn | noides Seed Oil | Persea ((Avoc. Unsapo | Gratissima ado) Oil mifiables | Hvdrogenate | ed Avocado Oil | Persea (Avoca | Gratissima do) Butter | Sodium | Avocadoate | Pistacia V | /era Seed Oil |
| Totals | 7 | NR | 63 | 0.2-6 | 11 | 0.5 | 15 | NR | 1 | NR | 158 | 0.003-1 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 5 | NR | 57 | 0.5-6 | 6 | NR | 15 | NR | NR | NR | 107 | 0.08-0.2 |
| Rinse-Off | 7 | NR | 9 | 0.2 | 2 | 0.5 | NR | NR | I | NR | 51 | 0.003-1 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 2 | NR | 6 | 0.5 | NR | NR | NR | NR | NR | NR | 7 | NR |
| Possible Ingestion | NR | NR | 2 | 3 | 2 | NR | 11 | NR | NR | NR | 9 | NR |
| Inhalation | NR | NR | 4 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Dermal Contact | S | NR | 56 | 0.2-3 | 8 | NR | 15 | NR | 1 | NR | 133 | 0.003-0.2 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | 2 | NR | 2 | 9 | ę | 0.5 | NR | NR | NR | NR | 16 | 0.05-1 |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| , Nail | NR | NR | ŝ | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | NR | NR | NR | NR | NR | NR | 1 | NR | 19 | NR |
| Bath Products | NR | NR | 4 | NR | NR | NR | NR | NR | NR | NR | 8 | NR |
| Baby Products | NR | NR | 1 | NR | NR | NR | NR | NR | NR | NR | 3 | NR |
| | | | | | | · | | | | | | |
| | Plukenetia | Volubilis Seed Oil | Hydrogei Almo | nated Sweet | Sodium Swe | eet Almondate | Prunus (Apricot | Armeniaca) Kernel Oil | Hydrogen Ker | ated Apricot nel Oil | Prunus A Cherry | vium (Sweet v) Seed Oil |
| Totals | 13 | 0.05-0.6 | 21 | 0.5 | 4 | 15 | 885 | 0.00001-89 | 2 | NR | 2 | 0.01 - 0.02 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 12 | 0.05-0.6 | 13 | 0.5 | 4 | NR | 677 | 0.0001-40 | 2 | NR | NR | NR |
| Rinse-Off | Ι | NR | 8 | 0.5 | NR | 15 | 139 | 0.00001-89 | NR | NR | 2 | 0.01-0.02 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | 1 | NR | NR | NR | NR | NR | 25 | 0.002-18 | NR | NR | NR | NR |
| Possible Ingestion | ю | 0.6 | 1 | NR | NR | NR | 38 | 0.001-5 | NR | NR | NR | NR |
| Inhalation | NR | NR | NR | NR | NR | NR | 5 | 0.0009-1 | NR | NR | NR | NR |
| Dermal Contact | 13 | 0.6 | 15 | 0.5 | 4 | 15 | 486 | 0.00001-18 | 2 | NR | 7 | 0.01-0.02 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | 1 | 0.003-0.1 | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | 9 | 0.5 | NR | NR | 78 | 0.0001-89 | NR | NR | NR | NR |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | 10 | 0.1 | NR | NR | NR | NR |
| Nail | NR | 0.05 | NR | NR | NR | NR | 10 | 0.002-40 | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | 1 | NR | NR | 15 | 24 | 0.01-9 | NR | NR | 2 | 0.01-0.02 |
| Bath Products | NR | NR | 1 | NR | NR | NR | 8 | 4 | NR | NR | NR | NR |
| Baby Products | NR | NR | NR | NR | NR | NR | 7 | NR | NR | NR | NR | NR |

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| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
|----------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|---------------------|---------------------------|----------------------|---------------------------|----------------------|----------------------------|
| | Prunus Don | nestica Seed Oil | Prunus Per Keri | sica (Peach) iel Oil | Punica Gran | latum Seed Oil | Pyrus Malus (| (Apple) Seed Jil | Ribes Nig Currant | rum (Black) Seed Oil | Rosa Can | ina Fruit Oil |
| Totals | NR | 0.04 | 22 | 0.003-22 | 46 | 0.001-1 | ~ | NR | 53 | 0.000001-0.3 | 121 | 0.001-19 |
| Duration of Use | | | | | | - | | | | | | |
| Leave-On | NR | NR | 16 | 0.05-22 | 44 | 0.001-1 | 8 | NR | 45 | 0.000001-0.3 | 901 | 0.001-19 |
| Rinse-Off | NR | 0.04 | 6 | 0.003-6 | 7 | 0.001-0.1 | NR | NR | 8 | 0.05 | 15 | 0.001-0.5 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | NR | 2 | NR | NR | NR | 2 | 0.08 | 17 | 0.1-0.5 |
| Possible Ingestion | NR | NR | NR | 0.04-22 | 30 | 1 | 1 | NR | 7 | 0.03-0.1 | 7 | 0.001-2 |
| Inhalation | NR | NR | NR | 2 | NR | NR | NR | NR | NR | NR | 1 | NR |
| Dermal Contact | NR | 0.04 | 18 | 0.003-22 | 46 | 0.001-1 | 8 | NR | 43 | 0.000001-0.3 | 109 | 0.008-19 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | 4 | NR | NR | NR | NR | NR | 5 | NR | 6 | 0.001-0.5 |
| Hair - Coloring | NR | NR | NR | 0.1 | NR | 0.1 | NR | NR | NR | NR | NR | NR |
| Nail | NR | NR | NR | NR | NR | 0.001 | NR | NR | 5 | 0.2 | 1 | 0.1-2 |
| Mucous Membrane | NR | NR | 1 | NR | 2 | 0.001 | NR | NR | 2 | NR | ю | 0.001 |
| Bath Products | NR | NR | 1 | 0.1-1 | NR | NR | NR | NR | NR | NR | 1 | 0.5 |
| Baby Products | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| ok F | | | | | | | | | | | | |
| Page 9 | Rubus Chai | naemorus Seed Oil | Rubus Idaeu See | s (Raspberry) d Oil | Schinziophy Keri | ton Rautanenii nel Oil | Sclerocary: (| ı Birrea Seed Dil | Silybum Ma | arianum Seed Dil | Solanum I (Tomato | ycopersicum) Fruit Oil |
| ≺ Totals | 3 | 0.1 | 10 | 0.1-5 | 9 | NR | 29 | 1 | NR | 0.5 | NR | 0.01-1 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | з | 0.1 | 8 | 0.1-5 | 4 | NR | 23 | Ι | NR | 0.5 | NR | 0.001-1 |
| Rinse-Off | NR | NR | 2 | NR | 2 | NR | 6 | Ι | NR | NR | NR | NR |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | 0.01 |
| Possible Ingestion | NR | NR | 1 | NR | NR | NR | 9 | NR | NR | NR | NR | 0.001 |
| Inhalation | NR | NR | NR | NR | NR | NR | 2 | NR | NR | NR | NR | NR |
| Dermal Contact | ю | 0.1 | 8 | 0.1-5 | б | NR | 23 | 1 | NR | 0.5 | NR | 0.001-1 |
| Deodorant (Underarm) | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | NR | NR | ю | NR | 9 | 1 | NR | NR | NR | NR |
| Hair - Coloring | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Nail | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | 2 | NR | NR | NR | 2 | NR | NR | NR | NR | NR |
| Bath Products | NR | NR | 1 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Bahy Products | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |

| | _ | | | | | | | | | | | |
|---------------------------|---------------------|------------------------------|------------------------|------------------------------|---------------------|---------------------------|---------------------------|----------------------------------|---------------------|---------------------------|-----------------------|--------------------------------|
| | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) | No. of Uses 2010 | Conc of Use (2010) (%) |
| | Solanum (Tomat | Lycopersicum to) Seed Oil | Theobroma Seed | Cacao (Cocoa) I Butter | Theobroma Seed | Grandiflorum Butter | Triticum Vı Germ Oil U | llgare (Wheat) nsaponifiables | Wheat | Germ Acid | Vaccinium (Cranbei | l Macrocarpon rry) Seed Oil |
| Totals | - | NR | 442 | 0.000002-37 | 153 | 0.00005-7 | 17 | 0.2 | 16 | NR | 21 | 0.002-2 |
| Duration of Use | - | | | | | | | | | | | |
| Leave-On | Ι | NR | 367 | 0.000002-37 | 611 | 0.00005-7 | 17 | 0.2 | ŝ | NR | 18 | 0.002-2 |
| Rinse-Off | NR | NR | 75 | 0.0001-2 | 34 | 0.001-1 | NR | NR | 13 | NR | ŝ | 0.003-0.1 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | 11 | 0.0002-9 | 21 | 0.1-2 | 1 | NR | NR | NR | 2 | NR |
| Possible Ingestion | NR | NR | 33 | 37 | 49 | 7 | NR | NR | NR | NR | NR | 0.3 |
| Inhalation | NR | NR | 2 | 0.4 | NR | NR | NR | NR | NR | NR | NR | NR |
| Dermal Contact | 1 | NR | 417 | 0.000002-37 | 141 | 0.00005-7 | 17 | 0.2 | NR | NR | 17 | 0.002-2 |
| Deodorant (Underarm) | NR | NR | NR | 0.001-1 | NR | 0.1 | NR | NR | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | 24 | 0.01-2 | 6 | 0.001-1 | NR | NR | 16 | NR | 4 | 0.01-0.1 |
| Hair - Coloring | NR | NR | NR | 0.1 | б | NR | NR | NR | NR | NR | NR | NR |
| H Nail | NR | NR | NR | 0.1-1 | NR | NR | NR | NR | NR | NR | NR | NR |
| B Mucous Membrane | NR | NR | 35 | 0.02-2 | 19 | 0.05-0.1 | NR | NR | NR | NR | 1 | 0.003-0.1 |
| Bath Products | NR | NR | 4 | 0.1-1 | 4 | NR | NR | NR | NR | NR | NR | NR |
| S Baby Products | NR | NR | 8 | 0.01 | NR | NR | NR | NR | NR | NR | NR | NR |
| k Pa | | | | | | | | | | | | |
| age 98 | Vaccinium | Myrtillus Seed Oil | Vacciniuı (Cranberr | n Oxycoccos y) Seed Oil** | Vacciniun See | n Vitis-Idaea ed Oil | Vegetabl | e (Olus) Oil | Hydrogena | ıted Vegetable Oil | Vitis Vinife | ra (Grape) Seed Oil |
| Totals | 33 | 0.01 - 0.1 | 4 | NS | 6 | NR | 165 | 0.0005-31 | 457 | 0.0004-60 | 465 | 0.001-43 |
| Duration of Use | | | | | | | | | | | | |
| Leave-On | 32 | 0.01-0.12 | ŝ | NS | 9 | NR | 135 | 0.0005-11 | 439 | 0.0005-60 | 368 | 0.001-41 |
| Rinse-Off | Ι | NR | Ι | NS | NR | NR | 30 | 0.002-31 | 18 | 0.0004-8 | 97 | 0.001-43 |
| Exposure Type | | | | | | | | | | | | |
| Eye Area | NR | NR | NR | NS | NR | NR | 11 | 0.01-11 | 102 | 0.008-49 | 14 | 0.01-5 |
| Possible Ingestion | 29 | 0.01 | NR | NS | NR | NR | 74 | 0.03-11 | 216 | 0.8-60 | 34 | 0.03-7 |
| Inhalation | NR | NR | NR | NS | NR | NR | 1 | 0.0005-0.02 | 1 | ю | 9 | 0.001-7 |
| Dermal Contact | 33 | 0.01-0.1 | 4 | NS | 1 | NR | 143 | 0.0005-31 | 450 | 0.005-60 | 401 | 0.001-41 |
| Deodorant (Underarm) | NR | NR | NR | NS | NR | NR | NR | 1 | NR | NR | NR | 0.001-0.2 |
| Hair - Non-Coloring | NR | NR | NR | NS | NR | NR | 7 | 0.02-2 | 2 | 0.0005-0.09 | 46 | 0.01-0.3 |
| Hair - Coloring | NR | NR | NR | NS | NR | NR | 18 | 1 | NR | 0.0004-1 | 10 | 43 |
| Nail | NR | NR | NR | NS | 8 | NR | 1 | 2 | 1 | 0.2 | 8 | 0.001-35 |
| Mucous Membrane | NR | NR | NR | NS | NR | NR | 1 | 0.03-2 | 2 | 2-4 | 21 | 0.001-7 |
| Bath Products | NR | NR | NR | NS | NR | NR | 2 | 0.002-0.02 | NR | 0.5 | 8 | 0.01-2 |
| Bahy Products | NR | NR | NR | SN | NR | NR | | 1 | NR | NR | 5 | NR |

| Hydrogenated Grapeseed Sodium Grapese Totals 7 0.3-0.5 4 1 | |
|--|--|
| Totals 7 0.3-0.5 4 1 | |
| | R States and States |
| Duration of Use | |
| Leave-On 4 0.3-0.5 4 | R |
| Rinse-Off 3 0.5 NR | IR |
| Exposure Type | |
| Eye Area NR NR NR | R |
| Possible Ingestion 1 0.5 NR 1 | R |
| Inhalation NR NR NR I | R |
| Dermal Contact 5 0.5 NR 1 | R |
| Deodorant (Underarm) NR NR NR I | X |
| Hair - Non-Coloring 1 NR 4 | X |
| Hair - Coloring NR NR NR I | K |
| Nail 1 0.3 NR | |
| Ward Mucous Membrane 1 NR NR | R |
| Bath Products NR NR NR I | R |
| Baby Products NR NR NR NR | R |

| | fo # | ^c Uses | Conc. o | f Use (%) | # of | Uses | Conc. of | Use (%) | # of I | Ises | Conc. of Us | e (%) | fo # | Uses | Conc. of | Use (%) |
|---------------------------|------|-------------------|--------------------|-----------|------|-----------|--------------|---------|--------|------------|--------------------|----------|------|----------|-----------------|---------|
| | A | vrachis Hyp | ogaea (Peanu | t) Oil | | Hydrogena | ted Peanut O | li | Cartha | nus Tincto | rius (Safflower) ! | Seed Oil | | Cocos Nu | icifera (Coconu | t) Oil |
| data year | 1998 | 2010 | 1984 | 2010 | 1998 | 2010 | 1998 | 2010 | 2002 | 2010 | 2003 | 2010 | 2007 | 2010 | 2008 | 2010 |
| ÷ | Ş | ì | mostly ≤25; >50 | | ç | \$ | 1 | 1 | | | | Ç | ě | | | |
| Totals* | 77 | 74 | (1 use) | 0.0001-30 | 61 | 12 | ** | 2-2 | 142 | 508 | 0.00005-84 | SZ | 626 | 867 | 0.0001-80 | SZ |
| Duration of Use | | | | | | | | | | | | | | | | |
| Leave-On | 14 | 59 | * * | 0.0001-1 | 19 | 12 | * | 2-5 | 114 | 402 | 0.00005-84 | NS | 243 | 409 | 0.005-80 | NS |
| Rinse Off | 8 | 15 | * * | 0.0002-30 | NR | NR | * | NR | 28 | 106 | 0.001-72 | NS | 383 | 389 | 0.0001-16 | NS |
| Exposure Type | | | | | | | | | | | | | | | | NS |
| Eye Area | NR | 4 | * * | NR | NR | NR | * * | NR | 5 | 15 | 1-6 | NS | L | 25 | 0.01-80 | NS |
| Possible Ingestion | С | NR | * * | NR | NR | NR | * * | 2 | 18 | 83 | 0.1-60 | NS | 19 | 4 | 0.2-51 | NS |
| Inhalation | NR | 2 | * * | NR | NR | NR | * * | NR | ю | 5 | 5 | NS | 7 | 10 | 0.01-26 | NS |
| Dermal Contact | 19 | 53 | * * | 0.0001-1 | 19 | 12 | * * | 2-5 | 113 | 395 | 0.001-72 | NS | 380 | 548 | 0.005-80 | NS |
| Deodorant (underarm) | NR | NR | * | NR | NR | NR | * * | NR | NR | NR | NR | NS | NR | NR | 0.1-16 | NS |
| Hair - Non-Coloring | б | 21 | * * | 25-30 | NR | NR | * * | NR | 28 | 79 | 0.00005-27 | NS | 67 | 176 | 0.0001-13 | NS |
| Hair-Coloring | NR | NR | * * | NR | NR | NR | * * | NR | NR | 20 | 1 | NS | 145 | 69 | NR | NS |
| hail | NR | NR | * * | NR | NR | NR | * * | NR | 1 | 32 | 84 | NS | 2 | 5 | 0.005-2 | NS |
| Mucous Membrane | 4 | 2 | * * | NR | NR | NR | * * | NR | NR | 31 | NR | NS | 12 | 161 | 0.0005-16 | NS |
| Bath Products | NR | NR | * * | NR | NR | NR | * * | NR | NR | ŝ | 7 | NS | 141 | 15 | 0.004-23 | NS |
| Saby Products | NR | NR | ** | NR | NR | NR | ** | NR | NR | 9 | 10 | NS | 12 | 15 | 0.010-0.3 | NS |
| k Page | | | | | | | | | | | | | | | | |
| : 10 | | Hydrogen | ited Coconut | Oil | | Magnesi | um Cocoate | | | Potass | ium Cocoate | | | So | dium Cocoate | |
| data year | 2007 | 2010 | 2008 | 2010 | 2007 | 2010 | 2008 | 2010 | 2007 | 2010 | 2008 | 2010 | 2007 | 2010 | 2008 | 2010 |
| Totals | 62 | 105 | 0.001-50 | NS | 11 | 6 | NR | NS | 24 | 40 | 0.003-40 | NS | 230 | 340 | 1-52 | NS |
| Duration of Use | | | | | | | | | | | | | | | | |
| Leave-On | 55 | 29 | 0.001-50 | NS | NR | NR | NR | SN | 4 | NR | 28 | NS | 12 | 16 | NR | NS |
| Rinse-Off | 7 | 26 | 0.001-38 | NS | 11 | 9 | NR | NS | 20 | 40 | 0.03-40 | NS | 218 | 324 | I-52 | NS |
| Exposure Type | | | | | - | | | | | | | | | | | |
| Eye Area | 6 | 7 | 0.2-22 | NS | NR | NR | NR | NS | NR | NR | NR | NS | NR | NR | NR | NS |
| Possible Ingestion | 9 | 10 | 0.7-29 | NS | NR | NR | NR | NS | NR | NR | NR | NS | NR | NR | NR | NS |
| Inhalation | NR | NR | 0.3 | NS | NR | NR | NR | NS | NR | NR | NR | NS | 1 | NR | NR | NS |
| Dermal Contact | з | 102 | 0.001-25 | NS | 11 | 6 | NR | NS | 22 | 38 | 0.3-40 | NS | 175 | 269 | 1-52 | NS |
| Deodorant (underarm) | NR | NR | NR | NS | NR | NR | NR | NS | NR | NR | NR | NS | NR | NR | NR | NS |
| Hair - Non-Coloring | ŝ | ŝ | 0.001-2 | NS | NR | NR | NR | NS | 2 | 2 | 15 | NS | 55 | 71 | 2 | NS |
| Hair-Coloring | NR | NR | 0.5-0.6 | NS | NR | NR | NR | NS | NR | NR | 0.003 | NS | NR | NR | NR | NS |
| Nail | NR | NR | 0.8-25 | NS | NR | NR | NR | NS | NR | NR | NR | NS | NR | NR | NR | NS |
| Mucous Membrane | NR | 18 | 1-17 | NS | NR | NR | NR | NS | NR | 8 | 0.3 | NS | 1 | 238 | 1-2 | NS |
| Bath Products | 1 | NR | 0.5-39 | NS | NR | NR | NR | NS | 11 | NR | 0.3-40 | NS | 149 | Э | 1-52 | NS |
| Baby Products | 1 | - | 2-50 | NS | NR | NR | NR | NS | NR | NR | NR | NS | 2 | 5 | NR | NS |

Table 5b. Current and historical frequency and concentration of use according to duration and type of exposure - previously reviewed ingredients

| | fo # | f Uses | Conc. of | f Use (%) | # of | Uses | Conc. of | r Use (%) | # of i | Uses | Conc. of L | Ise (%) | # of e | Uses | Conc. ç | f Use (%) |
|----------------------|------|--------------|---------------|------------|------|--------------|---------------|-----------|-------------|--------------|----------------|---------|------------|-------------|---------------|-----------|
| | | Coce | onut Acid | | 1 | Hydrogenate | ed Coconut A | Acid | Cor | ylus Americi | ana (Hazel) Se | ed Oil | C | orylus Avel | llana (Hazel) | Seed Oil |
| data year | 2007 | 2010 | 2008 | 2010 | 2007 | 2010 | 2008 | 2010 | $1998^{\#}$ | 2010 | 1998 | 2010 | $1998^{#}$ | 2010 | 1997 | 2010 |
| Totals | 142 | 141 | 0.03-14 | NS | NR | NR | 6-10 | NS | # | 10 | ** | NR | 85 | 150 | ≤100 | 0.005-98 |
| Duration of Use | | | | | | | | | | | | | | | | |
| Leave-On | 18 | 17 | NR | SN | NR | NR | 9 | SN | # | 9 | * * | NR | 74 | 131 | * * | 0.005-98 |
| Rinse Off | 124 | 124 | 0.03-14 | NS | NR | NR | 10 | NS | # | Ι | * * | NR | 11 | 61 | * * | 0.005-5 |
| Exposure Type | | | | SN | | | | NS | | | | | | | | |
| Eye Area | 1 | 1 | NR | NS | NR | NR | NR | NS | # | NR | * * | NR | 2 | 6 | * * | 0.1 |
| Possible Ingestion | NR | NR | NR | NS | NR | NR | NR | NS | # | NR | * * | NR | NR | NR | * * | 14 |
| Inhalation | NR | NR | NR | NS | NR | NR | NR | NS | # | NR | * * | NR | NR | 7 | * * | NR |
| Dermal Contact | 140 | 140 | 0.04-14 | NS | NR | NR | 6-10 | NS | # | 10 | * * | NR | 83 | 147 | * * | 0.005-98 |
| Deodorant (underarm) | NR | NR | NR | NS | NR | NR | NR | NS | # | NR | * * | NR | NR | NR | * * | NR |
| Hair - Non-Coloring | 2 | 1 | 0.03-0.3 | NS | NR | NR | NR | NS | # | NR | * * | NR | 1 | 7 | * * | NR |
| Hair-Coloring | NR | NR | NR | NS | NR | NR | NR | NS | # | NR | * * | NR | NR | NR | * * | NR |
| Nail | NR | NR | NR | NS | NR | NR | NR | NS | # | NR | * * | NR | 1 | 1 | * * | NR |
| Mucous Membrane | 1 | 101 | 0.04-2 | NS | NR | NR | NR | NS | # | 1 | * * | NR | 4 | 1 | * * | NR |
| Bath Products | 93 | NR | 0.04 - 14 | NS | NR | NR | NR | NS | # | NR | * * | NR | 7 | 7 | * * | NR |
| Baby Products | 1 | - | NR | NS | NR | NR | NR | NS | # | NR | * * | NR | NR | 1 | * * | NR |
| el Book | | | | | | | | | | | | | | | | |
| : Pa | | Elaeis Guine | eensis (Palm) | Oil | Elae | is Guineensi | is (Palm) Kei | rnel Oil | B | lydrogenatec | 1 Palm Kernel | Oil | | Hydrog | enated Palm | Oil |
| alata year | 1997 | 2010 | 1997 | 2010 | 1997 | 2010 | 1997 | 2010 | 1997 | 2010 | 1997 | 2010 | 1997 | 2010 | 1997 | 2010 |
| ਰੋ otals | 36 | 272 | ** | 0.002 - 48 | 11 | 77 | ** | 0.05-23 | 29 | 47 | * * | 0.4-13 | 13 | 152 | ** | 0.2-30 |
| Duration of Use | | | | | | | | | | | | | | | | |
| Leave-On | 28 | 171 | * | 0.008-13 | 9 | 09 | * * | 0.8-3 | 27 | 45 | * | 0.4-13 | 13 | 134 | * * | 0.2-30 |
| Rinse-Off | 8 | 101 | * * | 0.002-48 | 2 | 17 | * * | 0.05-23 | 2 | 2 | * * | 0.6-2 | NR | 18 | * * | 2 |
| Exposure Type | | | | | | | | | | | | | | | | |
| Eye Area | NR | 12 | * * | 0.04-2 | NR | 10 | * * | 0.8 | 5 | 2 | * | 2-10 | 1 | 61 | * * | 0.2-30 |
| Possible Ingestion | NR | 11 | * * | 2 | NR | 9 | * * | NR | 2 | 5 | * | 3-13 | 3 | 12 | * | 2-30 |
| Inhalation | 1 | 3 | * | NR | NR | NR | * | NR | NR | 1 | * * | NR | NR | NR | * * | 1 |
| Dermal Contact | 36 | 229 | * * | 0.002-48 | 11 | 71 | * * | 0.05-2 | 24 | 47 | * | 0.4-13 | 12 | 123 | * * | 0.4-30 |
| Deodorant (underarm) | NR | NR | * * | NR | NR | NR | * | NR | NR | NR | * | NR | NR | NR | * * | NR |
| Hair - Non-Coloring | NR | 43 | * * | 2-34 | NR | 9 | * * | 0.9-23 | NR | NR | * | NR | NR | NR | * * | NR |
| Hair-Coloring | NR | NR | * * | NR | NR | NR | * * | NR | NR | NR | * | NR | NR | NR | * * | NR |
| Nail | NR | NR | * * | NR | NR | NR | * | 3 | NR | NR | * | NR | NR | NR | * * | NR |
| Mucous Membrane | 7 | 68 | * | 0.002-48 | NR | 10 | * | 0.05 | 2 | 7 | * | 0.9-2 | NR | 17 | * * | 2 |
| Bath Products | NR | NR | * | NR | NR | 1 | * * | NR | NR | NR | * | NR | NR | NR | * | NR |
| Baby Products | 1 | 7 | * * | NR | NR | NR | * * | NR | NR | NR | * * | NR | NR | NR | * * | NR |

Table 5b. Current and historical frequency and concentration of use according to duration and type of exposure - previously reviewed ingredients (continued)

| Table 5b. Current and hi | storical freq | uency and co | pincentration o | t use according | to duratio | n and type o | I exposure - p | sreviously revie | ewed ingred | ients (conu | (pənu | | | | | |
|--------------------------|---------------|-----------------|-----------------|-----------------|------------|--------------|----------------|------------------|-------------|---------------------|-------------------|---------------|------|------------|------------------|-------------|
| | # of | Uses | Conc. oj | f Use (%) | # of | Uses | Conc. of | . Use (%) | # of l | Ises | Conc. of U | lse (%) | # of | Uses | Conc. o | f Use (%) |
| | Gossy | ium Herba | ceum (Cotton |) Seed Oil | F | Iydrogenati | ed Cottonseec | l Oil | | <u> Dryza Sativ</u> | 'a (Rice) Bran C | li | | Oryza Sa | ttiva (Rice) Ger | rm Oil |
| data year | 1998 | 2010 | 1998 | 2010 | 1998 | 2010 | 1998 | 2010 | 2002 | 2010 | 2000-2003 | 2010 | 2002 | 2010 | 2000- 2003 | 2010 |
| Totals | 4 | 83 | | 0.004-32 | 272 | 362 | ** | 0.001-24 | 39 | 371 | 0.1-39 | 0.0003- 78 | 9 | 34 | 0.1 | 0.003-3 |
| Duration of Use | | | | | | | | | | | | | | | | |
| Leave-On | 1 | 68 | | 0.08-32 | 272 | 358 | * | 0.001-24 | 32 | 267 | 0.1-8 | 0.0003- 78 | 5 | 29 | 0.1 | 0.003-3 |
| Rinse Off | ŝ | 15 | * * | 0.004-29 | NR | 4 | * * | 0.01-0.1 | ~ ~ | 104 | 0.2-39 | 0.005-6 | , I | <i>ب</i> ا | NR | 0.003-3 |
| Exposure Type | | | | | | | | | | | | | | | | |
| Eye Area | NR | 4 | | 0.1-11 | 116 | 155 | * | 0.5-24 | NR | 5 | 0.1-1 | 0.5-0.8 | NR | 2 | NR | 0.01-1 |
| Possible Ingestion | NR | 6 | * * | 0.2-1 | 151 | NR | * * | 8-12 | NR | 17 | 0.1-1 | 0.1-8 | NR | 4 | NR | 0.1-3 |
| Inhalation | NR | 12 | * | 0.2 | NR | NR | * * | NR | NR | 11 | NR | 0.1 | NR | NR | NR | NR |
| Dermal Contact | 4 | 78 | * * | 0.004-29 | 156 | 356 | * | 0.001-24 | 36 | 321 | 0.1-39 | -couu.u | 9 | 32 | 0.1 | 0.003-3 |
| Deodorant (underarm) | NR | 1 | * * | 0.2 | NR | NR | * | NR | NR | NR | NR | 0.5 | NR | NR | NR | 0.003 |
| Hair - Non-Coloring | NR | 2 | * | NR | NR | 4 | * | 0.01-0.1 | 3 | 42 | 0.3 | 0.005-0.5 | NR | NR | NR | NR |
| Hair-Coloring | NR | NR | * | NR | NR | NR | * * | NR | NR | NR | NR | 0.3 | NR | NR | NR | NR |
| ail o | NR | 1 | * * | 0.5-32 | NR | NR | * * | NR | 2 | 5 | NR | 0.02-78 | NR | NR | NR | NR |
| Mucous Membrane | NR | 7 | * * | 0.004-0.01 | NR | NR | * * | NR | NR | 48 | 1 | 0.0006-6 | NR | 1 | NR | 0.003-0.005 |
| Bath Products | NR | NR | * * | NR | NR | NR | * * | NR | 1 | 17 | 1-39 | 0.2 | NR | 1 | NR | 0.5 |
| Baby Products | NR | NR | * | NR | NR | 8 | * | NR | NR | - | NR | NR | NR | NR | NR | NR |
| Page 1 | ě | Control Control | hoon. A' ami | i C C | Prunus | Amygdalus | s Dulcis (Swee | st Almond) | C.c.o.D | Ladio. | (Comon) (Comon) | 101 | 02 | Sesamum | Indicum (Sesa | me) Oil |
| S data vear | 2001 | 2010 | 2001 | 2010 | 2002 | 2010 | 2002 | 2010 | 2009 | 2010 | 2008 | 2010 | 2009 | 2010 | 2008 | 2010 |
| Totals | 188 | 883 | 0.001-23 | 0.0001-98 | 375 | 1127 | 0.004-76 | 0.0001-77 | 402 | 480 | 0.0001-73 | SN | و | 17 | 0.01-0.03 | SN |
| Duration of Use | | | | | | | | | | | | | | | | |
| Leave-On | 40 | 657 | 0.001-23 | 0.0005-98 | 302 | 162 | 0.004-76 | 0.001-77 | 313 | 374 | 0.0001-73 | SN | NR | 17 | 0.01-0.03 | SN |
| Rinse-Off | 148 | 226 | 0.1-5 | 0.0001-15 | 73 | 336 | 0.01-2 | 0.0001-43 | 89 | 106 | 0.001-68 | NS | NR | NR | NR | NS |
| Exposure Type | | | | _ | | | | | | | | | | | | |
| Eye Area | 8 | 24 | 0.1-3 | 0.05-2 | 9 | 28 | 0.4 | 0.1-22 | 11 | 14 | 0.0008-10 | NS | NR | NR | 0.01 | NS |
| Possible Ingestion | 29 | 60 | 0.7-21 | 0.05-26 | Э | 55 | 0.5 | 0.1-19 | 57 | 52 | 0.1-16 | NS | NR | 11 | 0.03 | NS |
| Inhalation | 2 | 11 | 0.02-3 | 0.01-8 | б | 18 | 1-3 | 0.5-39 | 5 | 5 | 2 | NS | NR | NR | NR | NS |
| Dermal Contact | 165 | 685 | 0.001-23 | 0.000598 | 323 | 986 | 0.04-11 | 0.001-46 | 346 | 414 | 0.0008-73 | NS | 9 | 17 | 0.01-0.03 | NS |
| Deodorant (underarm) | NR | NR | NR | 0.1 | NR | 7 | 0.004 | 0.02-1 | NR | NR | NR | NS | NR | NR | NR | NS |
| Hair - Non-Coloring | 11 | 189 | 0.002-3 | 0.0001-41 | 46 | 116 | 0.3-3 | 0.001-19 | 50 | 59 | $0.0001 - 30^{a}$ | NS | NR | NR | NR | NS |
| Hair-Coloring | 8 | NR | NR | 0.3 | 7 | 7 | 0.1 | 0.02 | NR | NR | $0.03-0.8^{b}$ | NS | NR | NR | NR | NS |
| Nail | 4 | 7 | 0.4-19 | 0.001-34 | 4 | 13 | 1-76 | 0.001-77 | 9 | L | ≤1-10 | NS | NR | NR | NR | NS |
| Mucous Membrane | NR | 43 | 0.1-5 | 0.002-3 | 19 | 93 | 0.5 | <0.1-23 | 4 | 28 | NR | NS | NR | NR | NR | NS |
| Bath Products | 5 | 25 | 0.1-5 | 0.6-6 | 10 | 41 | 0.01-0.1 | 0.1-43 | 27 | S | 0.09-68 | NS | NR | NR | NR | NS |
| Baby Products | NR | 6 | NR | NR | 7 | 14 | NR | 2-3 | 1 | б | 9 | NS | NR | NR | NR | NS |

| | # <i>of</i> (| Uses | Conc. of | Use (%) | # <i>of</i> | Uses | Conc. of U. | se (%) | # of t | Ises | Conc. of Us | e (%) | # of t | Jses | Conc. of | Use (%) |
|----------------------|---------------|-----------|-----------------|---------------|-------------|------------|-------------------|--------|--------|-------------|-----------------------|-------|--------|---------|---------------|---------|
| | Tritic | cum Vulga | re (Wheat) Ge | rm Oil | | Zea May | ys (Corn) Oil | | Zea I | Mays (Corn) | Oil Unsaponifi | ables | | Zea May | s (Corn) Gern | Oil |
| data year | 2001 | 2010 | 2001 | 2010 | 2007 | 2010 | 2006 | 2010 | 2007 | 2010 | 2006 | 2010 | 2007 | 2010 | 2006 | 2010 |
| Totols | 303 | 277 | 0.0002- | 90 1000 0 | 100 | 200 | 0.0003- | SIN . | ٢ | - | QN | NC | 27 | 53 | 1 J JE | NC |
| Duration of Use | 2002 | 140 | 01 | 07-1000-0 | | 000 | t, | | - | - | ALC: N | | 5 | 8 | 07-7-0 | |
| Dummin of Case | | | | | | | | | | | | | | | | |
| nD-awe-On | 80 | 373 | 0.00002- 18 | 0 0001-28 | 241 | 361 | 0.00003- 14 | SN | ý | 1 | NR | SN | 2.5 | 34 | 3-25 | SN |
| Rinse Off | 223 | 154 | 0.00002-5 | 0.001-2 | 257 | 237 | 0.001-0.07 | SN | · - | NR | NR | SN | 12 | 61 | 0.2-3 | SN |
| Exposure Type | | | | | | | | | | | | | | | | |
| - | | | | | 0 | | 0.0008- | C, | f | Ę | ţ | ç | Ę | Ę | Ę | 5 |
| Eye Area | 6 | 12 | 0.00004-3 | 0.0001-0.5 | 39 | 35 | 0.2 | NZ | NK | NK | NK | S | NK | NK | NK | SS |
| Possible Ingestion | 33 | 29 | 0.1-3 | 0.3-5 | 29 | 30 | 0.003-10 | NS | NR | NR | NR | NS | NR | NR | NR | NS |
| Inhalation | 5 | ٢ | 0.0002- 0.01 | 0.0001-0.0005 | - | - | 0.001-0.1 | NS | NR | NR | NR | NS | NR | NR | NR | NS |
| | | | 0.00002- | | | | 0.00003- | | | | | | | | | |
| Dermal Contact | 220 | 360 | 18 | 0.0005-23 | 276 | 371 | 14 | NS | 7 | 1 | NR | NS | 31 | 50 | 3-25 | NS |
| Deodorant (underarm) | NR | NR | 0.02 | NR | 1 | 4 | NR | NS | NR | NR | NR | NS | NR | NR | NR | NS |
| nel | | | | | | | 0.0001- | | | | | | | | | |
| Hair - Non-Coloring | 63 | 142 | 0.0001-2 | 0.0001-<1 | 38 | 40 | 0.02 | NS | NR | NR | NR | NS | 4 | ŝ | 0.2 | NS |
| k P | 5 | Ű¢ | 10 | | 107 | 107 | 0.004- | NIC | aN | CIV CIV | an | NIC | đ | av | đN | NIC |
| | 71. | 07 | 1.0 | 0.01-U.2 | 107 | 01 0 | 0.00/ | | | NN . | | CN1 | | | | CN CN |
| | 4 | 7 | 0.1-4 | 0.1-28 | Ι | τ η | 0.001-5 0.004- | SN | NK | NK | NK | SN | NK | NK | NK | Z |
| Mucous Membrane | ŝ | 22 | 0.02-1 | 0.01-0.5 | 7 | 2 | 0.01 | NS | NR | NR | NR | NS | 4 | ŝ | ŝ | NS |
| | - | ć | C 100 0 | ц С | Ę | e, | 0.001- | L | Ę | | Ĥ | NIC. | , | - | EX. | J. |
| Bath Products | - | 7 | 0.001-2 | c.0 | NK | NK | 0.01 | N | NK | NK | NK | NZ | 'n | 4 | NK | SN |
| Baby Products | 1 | 6 | 0.5 | NR | 8 | 8 | 0.004 | NS | NR | NR | NR | NS | 2 | 4 | NR | NS |

*Note - Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types my not equal the sum of total uses.

NR - not reported to the VCRP or the Council

NS - not surveyed; ingredients that were recently reviewed will not be resurveyed

** concentration of use data were not given in the original report

- was not distinguished whether C. Americana or C. Avellana was reported; arbitrarily reported under C. Avellana (Hazel) Seed Oil for this table ^a 15% after dilution.

^b 0.4 after dilution.

Table 5c. Ingredients with no reported use concentrations or uses.

Adansonia Digitata Seed Oil Aleurites Moluccanus Bakoly Seed Oil Amaranthus Hypochondriacus Seed Oil Arctium Lappa Seed Oil Babassu Acid Bassia Butyracea Seed Butter Brassica Campestris (Rapeseed) Oil Unsaponifiables Brassica Napus Seed Oil Brassica Oleracea Acephala Seed Oil Canarium Indicum Seed Oil Carya Illinoensis (Pecan) Seed Oil Citrus Aurantifolia (Lime) Seed Oil Citrus Aurantifolia (Lime) Seed Oil Unsaponifiables Citrus Aurantium Dulcis (Orange) Seed Oil Citrus Aurantium Dulcis (Orange) Seed Oil Unsaponifiables Citrus Grandis (Grapefruit) Seed Oil Citrus Grandis (Grapefruit) Seed Oil Unsaponifiables Cocos Nucifera (Coconut) Seed Butter Coix Lacryma-Jobi (Job's Tears) Seed Oil Corn Acid Cottonseed Acid Cynara Cardunculus Seed Oil Elaeis (Palm) Fruit Oil Elaeis Guineensis (Palm) Butter Fragaria Ananassa (Strawberry) Seed Oil Fragaria Chiloensis (Strawberry) Seed Oil Fragaria Vesca (Strawberry) Seed Oil Fragaria Virginiana (Strawberry) Seed Oil Guizotia Abyssinica Seed Oil Hippophae Rhamnoides Seed Oil Hydrogenated Adansonia Digitata Seed Oil Hydrogenated Apricot Kernel Oil Unsaponifiables Hydrogenated Argania Spinosa Kernel Oil Hydrogenated Black Currant Seed Oil Hydrogenated Camelina Sativa Seed Oil Hydrogenated Cranberry Seed Oil Hydrogenated Grapefruit Seed Oil Hydrogenated Grapefruit Seed Oil Unsaponifiables Hydrogenated Hazelnut Oil Hydrogenated Kukui Nut Oil Hydrogenated Lime Seed Oil Hydrogenated Lime Seed Oil Unsaponifiables Hydrogenated Macadamia Seed Oil Hydrogenated Meadowfoam Seed Oil Hydrogenated Orange Seed Oil Hydrogenated Orange Seed Oil Unsaponifiables Hydrogenated Palm Acid Hydrogenated Passiflora Edulis Seed Oil Hydrogenated Peach Kernel Oil

Hydrogenated Pistachio Seed Oil Hydrogenated Pumpkin Seed Oil Hydrogenated Punica Granatum Seed Oil Hydrogenated Raspberry Seed Oil Hydrogenated Rice Bran Oil Hydrogenated Rosa Canina Fruit Oil Hydrogenated Safflower Seed Oil Hydrogenated Sesame Seed Oil Hydrogenated Sweet Almond Oil Unsaponifiables Hydrogenated Wheat Germ Oil Hydrogenated Wheat Germ Oil Unsaponifiables Lupinus Albus Oil Unsaponifiables Morinda Citrifolia Seed Oil Olea Europaea (Olive) Husk Oil Olive Acid Oryza Sativa (Rice) Seed Oil Peanut Acid Potassium Babassuate Potassium Cornate Potassium Hydrogenated Cocoate Potassium Hydrogenated Palmate Potassium Peanutate Potassium Rapeseedate Potassium Safflowerate Potassium Soyate Prunus Amygdalus Dulcis (Sweet Almond) Oil Unsaponifiables Prunus Armeniaca (Apricot) Kernel Oil Unsaponifiables Rapeseed Acid Ribes Rubrum (Currant) Seed Oil Rice Bran Acid Safflower Acid Sesamum Indicum (Sesame) Seed Butter Sodium Cocoa Butterate Sodium Hydrogenated Cocoate Sodium Hydrogenated Palmate Sodium Macadamiaseedate Sodium Peanutate Sodium Rapeseedate Sodium Safflowerate Sodium Sesameseedate Sodium Soyate Sodium Theobroma Grandiflorum Seedate Soy Acid Sunflower Seed Acid Torreya Nucifera Seed Oil Triticum Aestivum (Wheat) Germ Oil Triticum Vulgare (Wheat) Germ Oil Unsaponifiables Vaccinium Corymbosum (Blueberry) Seed Oil

| Table 6. Examples of non-cosmetic uses of oils. | |
|---|---|
| Oil | Use ^{6,114,206-211} |
| Aleurities Moluccana Seed Oil [Kukui] | wood preservative, varnishes, paint oil, illumination, soap making, waterproofing paper, rubber substitute, insulating material |
| Anacardium Occidentale (Cashew) Seed Oil | folk remedies |
| Arachis Hypogaea (Peanut) Oil | pharmaceutical, soap making, lubricants, emulsions for insect control, diesel engine fuel |
| Brassica Napus Seed Oil [Rapeseed]/Canola Oil | rubber additive · lubricants · fat liquoring of leather · varnishes and lacquers · textile chemicals · detergent additives · plasticizers · weed control · medicinal procedures |
| Butyrospermum Parkii (Shea) Oil | illumination |
| Camelina Sativa Seed Oil [False Flax] | drying oil · manufacturing of varnishes and paints |
| Citrullus Lanatus (Watermelon) Seed Oil | illumination |
| Cocos Nucifera (Coconut) Oil | lubricants, hydraulic fluid, paints, synthetic rubber, plastics, illumination |
| Elaeis Guineensis (Palm) Oil | crayon and candle manufacturing \cdot tin plate industry |
| Elaeis Guineensis (Palm) Kernel Oil | detergent production · pharmaceutical · crayon and candle manufacturing · tin plate industry |
| Garcinia Indica Seed Butter [Kokum] | candle and soap making, sizing of cotton yarn, pharmaceutical |
| Guizotia Abyssinica Seed Oil [Niger/Ramtil] | paint · lubricant · pharmaceutical |
| Helianthus Annuus (Sunflower) Seed Oil | manufacturing of lacquers, copolymers, polyester films, modified resins, plasticizers, alkyld resins, other similar products |
| Juglans Regia (Walnut) Seed Oil | paints, soap making |
| Linum Usitatissimum (Linseed) Seed Oil | manufacturing of linoleum, cloth oil, printing and lithographic inks, core oils, linings, packings, oil-modified alkyd resins, caulking compounds, putties, leather-finishing compounds, lubricants, greases, polishes, pyrotechnic compositions · pigment binder in petrochemicals · concrete protector · stabilizer/plasticizer for vinyl plastics · industrial stains · jute textiles · drying oil in paints and varnishes |
| Mangifera Indica (Mango) Seed Butter | substitute for cocoa butter |
| Olea Europaea (Olive) Fruit Oil | textile industry · pharmaceutical |
| Orbignya Cohune Seed Oil | manufacturing of soaps, candles, and nightlights \cdot cotton dyeing \cdot ointment base \cdot substitute for cocoa butter in food |
| Perilla Ocymoides Seed Oil [Perilla] | substitute for linseed oil in the manufacture of paints, varnishes, linoleum, oilclothes, and printing inks |
| Prunus Amygdalus Dulcis (Sweet Almond) Oil | pharmaceutical, energy source |
| Prunus Armeniaca (Apricot) Kernel Oil | pharmaceutical |
| Theobroma Cacao (Cocoa) Seed Butter | pharmaceutical |
| Vitis Vinifera (Grape) Seed Oil | substitute for linseed oil in the manufacture of paints, and varnishes |
| | |

| Table 7. Dermal effects - Non-Hu | nan studies | | | | |
|---|--|---|---|--|-----------|
| Ingredient | Concentration | Animals | Procedure | Results | Reference |
| Adansonia Digitata (Baobab) Oil | 100% | | Adansonia Digitata Seed Oil MatTek EpiDerm MTT viability assay; 100 μl of test material for 1-24 h | classified as non-irritating | 212 |
| Undiluted technical grade Arachis l the test site was occluded. Howeve | Iypogaea (Peanut) r, in a 48 h occlusi | Oil was moderately irritat ve patch test using miniatu | Arachis Hypogaea (Peanut) Oil ing to rabbits and guinea pig skin and mildly irritating to r irre swine, technical grade Arachis Hypogaea (Peanut) Oil | at skin following exposure; there was no indication that was not irritating | 17 |
| Arachis Hypogaea (Peanut) Oil | | Hartley and/or Hima- layan guinea pigs | Single drops of a store-bought peanut oil were applied to clipped skin on the backs of 4 guinea pigs. Applications were made at 2-6 wk intervals, for a total of 7 applications over a 3-mo period. It appears that the test sites were not covered. The test sites were scored 24 h after application. Well-defined erythema was considered a positive reaction. | None of the animals had a positive reaction following the initial application. Two animals had positive reac- tions following application at wks 6 and 12, while one animal had a positive reaction following dosing at wk 12 only | 1 |
| | | | Butyrospermum Parkii (Shea) Butter | | |
| Butyrospermum Parkii (Shea) Butter | not specified | 3 male New Zealand White (NZW) rabbits | 0.5 ml applied to the shaved dorso-lumbar region | very slight erythema with or without edema was observed in 2 rabbits: resolved by day 3 or 4 | 213 |
| Butter Butter | induction: 75% challenge: 20 and 50% | 10 female albino Hart- ley/Dunkin guinea pigs | mixed in contrast of the provided and the provided adjuvant (FCA) during induction | no evidence of delayed hypersensitivity | 214 |
| Undiluted Carthamus Tinctorius (S. guinea pigs. | tfflower) Seed Oil | was minimally irritating ir | Carthamus Tinctorius (Safflower) Oil a repeat open patch test using rabbits and was not a prim | ary irritant or sensitizer in a maximization study using | 32 |
| Undiluted Cocos Nucifera (Coconu study. | t) Oil was non- irri | ating to rabbit skin. In gu | Cocos Nucifera (Coconut) Oil inea pigs, undiluted Cocos Nucifera (Coconut) Oil was no | t a sensitizer in a Magnusson-Kligman maximization | 33 |
| Undiluted hydrogenated coconut oi | was non-irritating | to rabbit skin. In guinea J | Hydrogenated Coconut Oil pigs, undiluted hydrogenated coconut oil was not a sensiti | zer in a Buehler test. | 33 |
| Undiluted coconut acid was minima | lly irritating to rab | bit skin. | Coconut Acid | | 33 |
| In single-insult occlusive patch test | s of a 5% aq. soluti | on of a bar soap containin | Sodium Cocoate g 13% sodium cocoate, scores of 1.6-4.0/8.0 were reported | | 33 |
| Crambe Abyssinica Seed Oil | undiluted | | Crambe Abyssinica Seed Oil dermal irritation study; details not provided | not a dermal irritant | 215 |
| Undiluted Elacis Guineensis (Paln | Oil was practical | ly non- to minimally irrita | Elacis Guineensis (Palm) Oil ting to rabbit skin. Elacis Guineensis (Palm) Oil, 5%, was | : non-allergenic in a maximization study. | 26 |
| Cosmetic formulations containing 3 | .4-8.97% hydroger | nated cottonseed oil were r | Gossypium Herbaceum (Cotton) Seed Oil not irritating to rabbit skin. | | 27 |
| Hippophae Rhamnoides Seed Oil | | albino rabbits, number not specified | Hippophae Rhamnoides Seed Oil 0.5 ml applied under an occlusive patch for 4 h | no irritation | 216 |
| I appre 7. Definite creets – NOI-Frantian survices Ingredient Concentration | Animals | Procedure | Results | Reference |
|--|--|---|--|-----------|
| Olea Europaca (Olive) Fruit Oil | 12 Harley and/or Him- alayan guinea pigs 22 guinea pigs sensi- tive to the 10-yr-old USP olive oil 8 sensitized and 4 non- sensitized guinea pigs | Olea Europaea (Olive) Fruit Oil Single drops of a USP-grade olive oil that had been stored in its original metal container for 10 yrs were applied to a clipped area on the backs of 12 guinea pigs. (The composition of the oil was not determin- ed.) Applications were made at 2-6 wk intervals over a period of 5 mos. Four guinea pigs were treated similarly using store-bought virgin olive oil. cross-reactivity to store-bought olive oil, another store-bought olive oil (not specified as virgin olive oil), corn oil, and peantu oil was determined. The 5 oils were applied simultaneously to the backs of the guinea pigs single drops of the unsaponifiable fraction of the 10- yr-old oil were applied | None of the animals had a positive reaction following the initial application of either oil. With 10-yr-old olive oil, 11/12 of the animals had a positive reaction at some point. Some, but not all, of these guinea pigs re- acted consistently following the first positive reaction; 2 animals had only 1 positive reaction; 2 guinea pigs in this group died by wk 16. In the group dosed with virgin olive oil, 1 animal had a positive reaction at wk 2 and 1 animals reacted to the virgin olive oil, and 18 reacted to the other store-bought olive oil. (Overlap of these animals was not complete.) Cross-reactivity to corn or peanut oil was not observed. All of the sensitized animals reacted to the unsaponifi- able fraction, while the non-sensitized animals did not. | 217 |
| Undiluted Oryza Sativa (Rice) Bran Oil was not irritat Sativa (Rice) Bran Oil were used at challenge. An Or Undiluted hydrolyzed rice protein was also not irritati Oryza Sativa (Rice) Germ Oil was not a primary derm | ing to rabbits, and in a gui yza Sativa (Rice) Bran Oi g or sensitizing. al irritant. | Oryza Sativa (Rice) Bran Oil nea pig maximization study, no reactions were observed //Oryza Sativa (Rice) Germ Oil mixture, concentrations Oryza Sativa (Rice) Germ Oil | hen 5% was used at induction and 25% and 50% Oryza ot stated, did not cause a contact allergy response. | 28 28 |
| Undiluted Prunus Amygdalus Dulcis (Sweet Almond) rabbits using occlusive patches. Undiluted Prunus An Almond) Oil were minimally irritating (PIIs = 0.28 an In a 60-day cumulative irritation test, 10 and 100% Pr (Sweet Almond) Oil produced mean maximum irritati 0.66. Results indicated that, when applied to the skin nonirritating. A maximization assay was used to determine the sensi Amygdalus Dulcis (Sweet Almond) Oil, the dose-rang induction injection of 100% Prunus Amygdalus Dulcis petrolatum applied topically under occlusion for 24 h. Undiluted Prunus Amygdalus Dulcis (Sweet Almond) abraded dorsal skin of each animal. Twenty-three hou Amygdalus Dulcis (Sweet Almond) Oil ranged from 0 | Oil and two moisturizer for tygdalus Dulcis (Sweet Al 10.72, respectively). Inuus Amygdalus Dulcis (S nn indices (MMIIs) rangin over a long period of time, tizing potential of Prunus. e phase of the experiment (Sweet Almond) Oil was Prunus Amygdalus Dulcii oil was tested for irritanci to 0.18 (maximum score- to 0.18 (maximum score- | Prunus Amygdalus Dulcis (Sweet Almond) Oil ormulations, each containing 25% Prunus Amygdalus Du mond) Oil was nonirritating (PII = 0/4). The formulation weet Almond) Oil was applied to rabbits. When tested in g from 0.34 to 1.34 (maximum score = 8). At a concentr Prunus Amygdalus Dulcis (Sweet Almond) Oil is slight Amygdalus Dulcis (Sweet Almond) Oil. using guinea pit used a single dermal application of 5%, 10%, or 100% P applied occlusively for 48 h 1 wk later, challenge was w s (Sweet Almond) Oil was non-sensitizing. | cis (Sweet Almond) Oil, were tested for skin irritancy in containing 25% Prunus Amygdalus Dulcis (Sweet 7 separate trials, 100% Prunus Amygdalus Dulcis tion of 10%, MMIIs for this ingredient ranged from 0- rirritating; whereas, at 10% it is practically Intradermal induction used concentrations of 5% mus Amygdalus Dulcis (Sweet Almond) Oil, a booster h 5% Prunus Amygdalus Dulcis (Sweet Almond) Oil in applied under occlusion to the clipped intact and tritation Indices (PIIs) for seven test samples of Prunus ing to skin. | 218 |
| Undiluted Sesamum Indicum (Sesame) Seed Oil was r | on- or minimally irritating | Sesamum Indicum (Sesame) Seed Oil 5 to rabbit skin. | | 55 |
| Triticum Vulgare (Wheat) Germ Oil, undiluted and at | 2% in formulation, was no | Triticum Vulgare (Wheat) Germ Oil on- to mildly irritating, and undiluted Triticum Vulgare (V | heat) Germ Oil was not sensitizing to guinea pigs. | 30 |

| Table 7. Dermal effects - Non-F | Iuman studies | | | | |
|---|---|---|---|---|-----------|
| Ingredient | Concentration | Animals | Procedure | Results | Reference |
| corn oil, store-bought | | 6 Hartley and/or Himalayan guinea pigs | Zea Mays (Corn) Oil sensitization study, details not specified | 0 of the animals had a positive reaction following the initial application; 2 animals had positive reactions following application at wks 4 and 6, while 1 animal had a positive reaction following application at wk 12 | 217 |
| | | | | | |
| | | | PHOTOTOXICITY | | |
| Butyrospermum Parkii (Shea) Butter | 10 and 20% in acetone | 10 Pirbright white guinea pigs | Butyrospermum Parkii (Shea) Butter animals were treated with test compound, then irradiated with UV-B light for 80 seconds followed by UV-A light for 80 min | not phototoxic | 219 |
| | | | Elaeis Guineensis (Palm) Oil | | |
| A facial lotion containing 1.5% | Elaeis Guineensis (Pa | ulm) Oil was not phototoxic | c in the phototoxicity yeast assay. | | 26 |
| Undiluted Oryza Sativa (Rice) Br | an Oil, ≤75%,, was n | ot phototoxic or photosens | Oryza Sativa (Rice) Bran Oil itizing. | | 28 |
| Oryza Sativa (Rice) Germ Oil, ≦7 | 5%, was not phototo | xic or photosensitizing. | Oryza Sativa (Rice) Germ Oil | | 28 |
| | | | | | |
| | | | COMEDOGENICITY | | |
| A comedogenicity study was con- application site. A "slight differe upon microscopic examination of | ducted in which 0.1 n nce in the number and the treated areas | al of Corylus Avellana (Ha | Corylus Avellana (Hazel) Seed Oil zel) Seed Oil (pH 6) was applied to the pinna of the ear of follicles" was noted via magnifying glass. A "slight exc | of albino rabbits. No local irritation was noted at the ess of sebum and a dilation of the follicles" was noted | 41 |

| Table 8. Dermal effects – Human studies | | | | |
|---|---|---|--|-----------|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 0.01% Adansonia Digitata Seed Oil in a lip product | 106 | Adansonia Digitata Seed Oil HRIPT with 0.2 g test material, semi-occluded | not a dermal irritant or sensitizer | 220 |
| 100% Adansonia Digitata Seed Oil | 107 | HRIPT with 0.02-0.05 ml test material, semi-occluded | not a dermal irritant or sensitizer | 221 |
| | | Aleurites Moluccana Seed Oil | | |
| 0.005% Aleurites Moluccana Seed Oil in scalp conditioner/hair wax | 104 | HRIPT; occlusive; applied neat | not a dermal irritant or sensitizer | 222 |
| ~3% in a skin cleanser | 110 | modified HRIPT; semi-occlusive; 10% dilution in distilled water | not a dermal irritant or sensitizer | 223 |
| | | Arachis Hypogaea (Peanut) Oil | | |
| dermatologic product containing 0.01% fluocinolone and refined Arachis Hypogaea (Peanut) Oil | peanut-sensitive subjects; 8 children, 6 adults | skin prick test with peanut extracts, a soln, of 50% glycerin (negative control), a solution of 1.8 mg/ml histamine phosphate in 50% glycerin (positive control), the complete test product, vehicle only (without fluocinolone), and refined Arachis Hypogaea (Peanut) Oil | I child had a trace positive reaction | 224 |
| | | patch test with product, vehicle only, and refined Arachis Hypogaea (Peanut) Oil | no reactions | |
| | | Argania Spinosa Kernel Oil | | |
| 5% Argania Spinosa Kernel Oil in a face serum | 108 | primary cutaneous irritation | no primary irritation | 225 |
| 5% Argania Spinosa Kernel Oil in a face serum | 108 | HRIPT; occlusive; applied neat | not an irritant or a sensitizer | 225 |
| 10% Argania Spinosa Kernel Oil in a skin salve | 209 | HRIPT; occlusive applied neat | not a sensitizer | 226 |
| 10% Argania Spinosa Kernel Oil in a skin salve | 51 | 4-wk use test; applied to lips, hands/nails, elbows, knees, feet/heels | did not elicit significant dermal irritation or dryness; 2 subjects had level 1 (mild, very slight erythema on the lips, and 5 had level 1 erythema on the elbows, lips, or knees; 15 subjects reported subjective irritation | 227 |
| 1% Astrocaryum Murumuru Seed Butter in a lipstick | 79 | Astrocaryum Murumuru HRIPT with 150 mg test material, semi-occluded | not a dermal irritant or sensitizer | 228 |
| 4% Astrocaryum Murumuru Seed Butter in a lipstick | 108 | HRIPT, occluded | not a dermal irritant or sensitizer | 229 |
| 4% Astrocaryum Murumuru Seed Butter in a lipstick | 108 | HRIPT, occluded | not a dermal irritant or sensitizer | 230 |
| 4% Astrocaryum Murumuru Seed Butter in a lipstick | 108 | HRIPT, occluded | not a dermal irritant or sensitizer | 231 |
| 4% Astrocaryum Murumuru Seed Butter in a lipstick | 106 | HRIPT, occluded | not a dermal irritant or sensitizer | 232 |
| 4% Astrocaryum Murumuru Seed Butter in a lipstick | 106 | HRIPT, occluded | not a dermal irritant or sensitizer | 233 |
| 4% Astrocaryum Murumuru Seed Butter in a lipstick | 108 | HRIPT, occluded | not a dermal irritant or sensitizer | 234 |
| | | | | |

| Table 8 . Dermal effects – Human studies | | | | |
|--|--|--|---|--|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| | | Avena Sativa (Oat) Kernel Oil | | |
| 3% Avena Sativa (Oat) Kernel Oil in a body and hand formulation | 100 | HRIPT with 0.2 ml, occluded | not a dermal irritant or sensitizer | 235 |
| | | Bassia Latifolia Seed Butter | | |
| 2% Bassia Latifolia Seed Butter in a body scrub | 110 | HRIPT with 1% aq. solution of the formulation, semi- occluded | not a dermal irritant or sensitizer | 236 |
| | | Borago Officinalis Seed Oil | | |
| 1% Borago Officinalis Seed Oil in a body and hand formulation | 213 | HRIPT with 0.2 g, occluded | not a dermal irritant or sensitizer | 237 |
| 2% Borago Officinalis Seed Oil in a face serum | 108 | primary cutaneous irritation | no primary irritation | 225 |
| 2% Borago Officinalis Seed Oil in a face serum | 108 | HRIPT; occlusive; applied neat | not an irritant or a sensitizer | 225 |
| | B | trassica Campestris (Rapeseed) Oil | 1 1 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | |
| 5% Hydrogenated Rapeseed Oil in a baby oil | 105 | HRIPT with 0.2 ml, semi-occluded | not a dermal irritant or sensitizer | 238 |
| | Brass | ica Oleracea Italica (Broccoli) Seed Oil | | |
| 0.5% Brassica Oleracea Italica (Broccoli) Seed Oil in a hair conditioner | 102 | HRIPT with 150 μl of test material, 10% dilution, semi-occluded | not a dermal irritant or sensitizer | 239 |
| | B | utyrospermum Parkii (Shea) Butter | | |
| Butyrospermum Parkii (Shea) Butter and fractions of | 21 | single applications to normal skin and sodium lauryl | normal skin: barely perceptible ery- | 240 |
| unsaponifiable lipids from Butyrospermum Parkii (Shea) | | sulfate (SLS)-irritated skin; right volar forearm was | thema observed in a "small" number of | |
| the unsaponifiable fraction was obtained from a supprist, | | chambers for 48 h; the left volar forearm was treated | subjects at 24 if arter treatment with shea butter; no irritation to the shea un- | |
| temperature crystallization of the supplied sample | | with 50 µl of 14% aq. SLS for 7 h, rinsed, dried, and then treated with 50 µl of each test material for 17 h. | saponifiable fraction; no sig. difference in CBF or TEMI | |
| | | cutaneous blood flow (CBF) and transeptdermal water | SLS-treated skin: 2 subjects had a | |
| | | loss (TEWL) were measured | slight- and moderate reaction to the un- saponifiable fraction; no sig. difference | |
| 0.1% Butyrospermum Parkii (Shea) Butter in a scalp conditioner | 114 | primary cutaneous irritation; formulation diluted to 1% | no primary irritation | 241 |
| 2% Butyrospermum Parkii (Shea) Butter in a cream | 119 | primary cutaneous irritation | no primary irritation | 242 |
| 0.1% Butyrospermum Parkii (Shea) Butter in a scalp conditioner | 110 | HRIPT; occlusive; formulation diluted to 1% | not a dermal irritant or sensitizer | 241 |
| 2% Butyrospermum Parkii (Shea) Butter in a cream | 118 (irritation)/ 116 (sensitization) | HRIPT; occlusive | not a dermal irritant or sensitizer | 242 |
| 4% Butyrospermum Parkii (Shea) Butter in a face cream | 51 | HRIPT with 20 µl test material, occluded | not a dermal irritant or sensitizer | 243 |
| 4% Butyrospermum Parkii (Shea) Butter in an eye cream | 108 | HRIPT with 20 µl test material, occluded | not a dermal irritant or sensitizer | 244 |
| 23.5% Butyrospermum Parkii (Shea) Butter in a lip gloss | 104 | HRIPT | not a dermal irritant or sensitizer | 245 |
| 23.7% Butyrospermum Parkii (Shea) Butter in a lip gloss | 104 | HRIPT | irritation on induction days 5-9 in one subject; no sensitization | 246 |

| Table 8. Dermal effects – Human studies | | | | |
|---|------------------------------------|--|--|-----------|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 24.1% Butyrospermum Parkii (Shea) Butter in a lip wax | 113 | HRIPT | not a dermal irritant or sensitizer | 247 |
| 24.1% Butyrospermum Parkii (Shea) Butter in a lip wax | 2 runs | Episkin | average viability 67.3% - no irritation potential | 248 |
| 24.7% Butyrospermum Parkii (Shea) Butter in a lip gloss | 40 | 28-day use study, 2-6 times /day | 1 subject with desquamation | 249 |
| 45% Butyrospermum Parkii (Shea) Butter in a body/hand massage | 109ª | HRIPT | not a dermal irritant or sensitizer | 250 |
| 45% Butyrospermum Parkii (Shea) Butter in a body/hand massage | 109 ^a | HRIPT | not a dermal irritant or sensitizer | 251 |
| 45% Butyrospermum Parkii (Shea) Butter in a body/hand massage | 109 ^a | HRIPT | not a dermal irritant or sensitizer | 252 |
| 45% Butyrospermum Parkii (Shea) Butter in a body/hand massage | 109 ^a | HRIPT | not a dermal irritant or sensitizer | 253 |
| 45% Butyrospermum Parkii (Shea) Butter in a body/hand massage | 31 | 2-week use study, 2 time per day | no erythema, edema, or dryness | 254 |
| 60% Butyrospermum Parkii (Shea) Butter in a cuticle cream | 111 | HRIPT | not a dermal irritant or sensitizer | 255 |
| · · · · · · · · · · · · · · · · · · · | | Camelina Sativa Seed Oil | | |
| 0.25% Camelina Sativa Seed Oil in a body powder | 204 | HRIPT with 0.1 g, semi-occluded | not a dermal sensitizer | 256 |
| 7% Camelina Sativa Seed Oil in an oil treatment | 103 | HRIPT with 200 µl test material, semi-occluded | Grade 1 (mild erythema) reactions in 4 subjects for 1 or 2 patches in the induc- tion phase, grade 1 (mild erythema in different subjects at the 48 h challenge reading. Study concluded test material was not a dermal irritant or sensitizer. | 257 |
| 0.0985% Camellia Sinensis Seed Oil in a lipstick | 108 | Camellia Sinensis Seed Oil HRIPT with 0.2 g, occluded | not a dermal irritant or sensitizer | 258 |
| 0.0985% Camellia Sinensis Seed Oil in a lipstick | 108 | HRIPT with 0.2 g, occluded | not a dermal irritant or sensitizer | 259 |
| 74.7% Canola Oil in a body oil | 101 | Canola Oil HRIPT with 150 µl test material, semi-occluded | not a dermal irritant or sensitizer | 260 |
| Cosmetic formulations containing 3-5% Carthamus Tinctor. repeated insult patch tests | Ca rius (Safflower) Seed Oil we | urthamus Tinctorius (Safflower) Oil are not irritating to humans in occlusive patch tests and | were not primary irritants or sensitizers in | 32 |

| Table 8. Dermal effects – Human studies | | | | |
|---|---------------------------|--|--|--|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 5% Carthamus Tinctorius (Safflower) Seed Oil in a cleansing oil rinse-off | 214 | HRIPT with 0.2 ml of a 10% v/v aqueous solution, semi-occluded | 3 subjects had a " γ " reaction following a patch during the induction and 1 subject had definite erythema with no edema or damage to the epidermis (+D) following the 7^{th} patch. No reactions were observed at a new test site. No other reactions were observed. Study concluded test material was not a dermal sensitizer. | 261 |
| 30% Carthamus Tinctorius (Safflower) Seed Oil in a massage oil | 107 | HRIPT with 0.2 ml test material, semi-occluded | 1 subject had slight erythema follow- ing the 7^{th} patch that did not reoccur, no other reactions observed. Not a dermal irritant or sensitizer. | 262 |
| | | Caryocar Brasiliense Fruit Oil | | |
| 0.1% Caryocar Brasiliense Fruit Oil in a lipstick | 100 | HRIPT with 200 mg test material, semi-occluded | not a dermal irritant or sensitizer | 263 |
| | | Chenopodium Quinoa Seed Oil | | |
| 1% Chenopodium Quinoa Seed Oil in a UV SPF cream | 105 | HRIPT with 0.02 ml test material, occluded | "An acceptable level of irritation" was observed in the induction phase con- sisting of grade 1 (mild erythema) in 39 subjects, with one additional subject exhibiting a grade 2 (moderate ery- thema) reaction. No evidence of skin sensitization was observed. | 264 |
| 1% Chenopodium Quinoa Seed Oil in a UV SPF cream | 102 | HRIPT with 0.02 ml test material, occluded | "An acceptable level of irritation" was observed in the induction phase, with 54% of the subjects exhibiting a grade 1 (mild erythema) reaction and 3% of the subjects exhibiting a grade 2 (mod- erate erythema) reaction. One subject had a strong reaction to the 3^{rd} in- duction patch and discontinued the induction was to other materials tested at the same time, it could not be determined if the test material was the causative agent. No evidence of skin sensitization was observed in the remaining subjects. | 265 |
| | Cit | rullus Lanatus (Watermelon) Seed Oil | | |
| 2% Citrullus Lanatus (Watermelon) Seed Oil in a facial oil | 105 | HRIPT, semi-occluded | not a dermal irritant or sensitizer | 266 |
| | | | | |

| Table 8. Dermal effects – Human studies | | | | |
|---|---|--|---|-----------|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| | | Cocos Nucifera (Coconut) Fruit Oil | | |
| An RIPT was performed using 103 subjects with a tanning b containing 13% Cocos Nucifera (Coconut) Oil produced ve chamber test with a 8% aq. solution; the soap produced no subjects | butter containing 2.5% Co 2ry mild irritation when tes unusual irritation respons | cos Nucifera (Coconut) Oil no erythematous reactions w ited as a 1% aq. solution on 106 subjects, and it was min 'e in a 2-wk normal use test; undiluted Cocos Nucifera ((| ere seen at challenge; A bar soap mally to mildly irritating in a soap oconut) Oil was not an allergen in 12 | 43 |
| 0.15% Cocos Nucifera (Coconut) Oil in a scalp conditioner/hair wax | 104 | HRIPT; occlusive; applied neat | not a dermal irritant or sensitizer | 222 |
| 31% Cocos Nucifera (Coconut) Oil in a lip balm | 222 | HRIPT with 0.2 g test material, occluded | 2 subjects had low-level, transient (\pm) reactions during the induction, no other reactions were observed. Study concluded that test material was not a dermal sensitizer. | 267 |
| | | Hydrogenated Coconut Oil | | |
| Four lipstick formulations containing 10% hydrogenated co indication of sensitization on retests performed 14 d later | ocomut oil were tested with | a single 48-h application on 204 fémales; there was no | vidence of primary irritation and no | 43 |
| | | Potassium Cocoate | | |
| In a test using 40 healthy subjects and 480 patients with act | tive skin disease, 5% aq. p | otassium cocoate produced 5 positive responses | | 43 |
| | | Corylus Avellana (Hazel Seed) Oil | | |
| A patch testing reference book by de Groot noted that the p reader, de Groot reported that an unpublished (and at the ti contact allergy who had been patch tested with 30% Hazel 3 | ublished literature does nu time, ongoing) study found Seed Oil in petrolatum | ot contain recommended test concentrations concerning , no irritant reaction in 1 to 20 patients suffering from or | tazel Seed Oil. To serve as a guide to the uspected to suffer from cosmetic product | 41 |
| 1% Corylus Avellana (Hazel) Seed Oil in a moisturizing cream | 25 | Amended Draize patch test, 10% standard concentration | Non-irritating | 268 |
| 1% Corylus Avellana (Hazel) Seed Oil in a moisturizing cream | 32 | 60 day clinical study | "Fairly good acceptability" | 269 |
| 5% Corylus Avellana (Hazel) Seed Oil in a massage oil | 107 | HRIPT with 0.2 ml test material, semi-occluded | 1 subject had slight erythema follow- ing the 7^{th} patch that did not reoccur, no other reactions observed. Not a dermal irritant or sensitizer. | 262 |
| | | Crambe Abyssinica Seed Oil | | |
| 5% Crambe Abyssinica Seed Oil in a face and neck product | 54 | HRIPT; semi-occluded, undiluted | not a dermal irritant or sensitizer | 270 |
| 100% Crambe Abyssinica Seed Oil in an unspecified product | 107 | HRIPT; undiluted | not a dermal irritant or sensitizer | 215 |
| | | Elaeis Guineensis (Palm) Oil | | |
| Elaeis Guineensis (Palm) Oil, 15% in petrolatum or cosmet Bar soap flakes, tested at dilutions that contained $\leq 2.13\% p$ | tic formulations containing palm kernel oil, were not i | z 1.0-2.0%, was not an irritant or sensitizer in clinical st irritating or sensitizing | dies | 26 |
| 15.7% Sodium Palm Kernelate in a soap | 42 | 28-day use test | good acceptability for use | 271 |
| 61.6% Sodium Palmate in a soap | 42 | 28-day use test | good acceptability for use | 271 |
| | | | | |

| Table 8. Dermal effects - Human studies | | | | |
|--|---|--|---|-----------|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 0.5% Euterpe Oleracea Fruit Oil in an eye treatment | 104 | Euterpe Oleracea Fruit Oil HRIPT with 150 µl test material, semi-occluded | not a dermal irritant or sensitizer | 272 |
| 0.19% Glycine Soja (Soybean) Unsaponifiables in a face and neek product | 50 | Glycine Soja (Soybean) Oil HRIPT, occluded | not a dermal irritant or sensitizer | 273 |
| 39% Hydrogenated Soybean Oil in a lipstick | 108 | HRIPT, occluded | not a dermal irritant or sensitizer | 274 |
| 0.286.00% Graninin Indian Saad Dutter in a hadu and hand | 101 | Garcinia Indica Seed Butter | not a conscitizon: invitation was | 275 |
| 0.3869% Garcinia Indica Seed Butter in a body and nand product | 101 | HKIP1, 0.2 g applied, occlusive | not a sensitizer; irritation was observed in one subject | |
| Patients that were hypersensitive to cottonseed proteins wer | Goss re not sensitive to cottonsee | <pre>sypium Herbaceum (Cotton) Seed Oil doil in a skin prick test</pre> | | 27 |
| 3.6% Hydrogenated Cottonseed Oil in a lip balm | 222 | HRIPT with 0.2 g test material, occluded | 2 subjects had low-level, transient (\pm) reactions during the induction, no other reactions were observed. Study concluded that test material was not a dermal sensitizer. | 267 |
| | | Hydrogenated Cottonseed Oil | | |
| In a clinical patch test, the irritation potential of a cosmetic, ed cottonseed oil was acceptably low in a use study. Cosmet | formulation containing 3.4 tic formulations containing | 1% hydrogenated cottonseed oil was mildly low, and the 10.6-20.86% hydrogenated cottonseed oil were not irrit | severity of reaction to 10.4% hydrogenat- ating or sensitizing. | 27 |
| | Heli | anthus Annuus (Sunflower) Seed Oil | | |
| 6% Helianthus Annuus (Sunflower) Seed Oil in a skin cream | 108 | primary cutaneous irritation | no primary irritation | 276 |
| 20% Helianthus Annuus (Sunflower) Seed Oil in a face serum | 108 | primary cutaneous irritation | no primary irritation | 225 |
| 0.264% Helianthus Annuus (Sunflower) Seed Oil in a cream | 57 | HRIPT; Finn chambers, applied neat | not a dermal irritant or sensitizer | 277 |
| 6% Helianthus Annuus (Sunflower) Seed Oil in a skin cream | 106 | HRIPT, occlusive | not a dermal irritant or sensitizer | 276 |
| 20% Helianthus Annuus (Sunflower) Seed Oil in a face serum | 108 | HRIPT; occlusive; applied neat | not an irritant or a sensitizer | 225 |
| 1% Helianthus Annuus (Sunflower) Seed Oil in a soap | 42 | 28-day use test | good acceptability for use | 271 |
| 39.8% Helianthus Annuus (Sunflower) Seed Oil in a massage oil | 107 | HRIPT with 0.2 ml test material, semi-occluded | 1 subject had slight erythema follow- ing the 7^{th} patch that did not reoccur, no other reactions observed. Not a dermal irritant or sensitizer. | 262 |
| | Helianthus | Annuus (Sunflower) Seed Oil Unsaponifiables | | |
| 2% Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables in a night product | 100 | HRIPT, semi-occluded | not a dermal irritant or sensitizer | 273 |
| | | | | |

| Table 8. Dermal effects – Human studies | | | | |
|---|--------------------|--|---|-----------|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 2% Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables in a face and neck product | 100 | HRIPT, semi-occluded | not a dermal irritant or sensitizer | 273 |
| | | Hippophae Rhamnoides Seed Oil | | |
| 5% Hippophae Rhannoides Seed Oil | 10 | cutaneous local tolerance test, 0.02 ml single 48 h occlusive application | not an irritant; average irritation score of 0 | 278 |
| | | Irvingia Gabonensis Kernel Butter | | |
| 0.31% Irvingia Gabonensis Kernel Butter in a face and neck product | 52 | HRIPT, occluded | not a dermal irritant or sensitizer | 273 |
| | Lim | nanthes Alba (Meadowfoam) Seed Oil | | |
| 71.3% Linnanthes Alba (Meadowfoam) Seed Oil in a facial repair product | 109 | HRIPT, semi-occluded | 7 subjects had <u>+</u> on the first day of the induction only, no other reactions. Not a dermal irritant or sensitizer. | 279 |
| | Lin | um Usitatissimum (Linseed) Seed Oil | | |
| 9.4% Linum Usitatissimum (Linseed) Seed Oil in mascara | 105 | HRIPT with 0.2 g test material, semi-occluded | not a dermal irritant or sensitizer | 280 |
| | | Luffa Cylindrica Seed Oil | · · · · · · · · · · · · · · · · · · · | |
| 0.01% Luffa Cylindrica Seed Oil in a body wash | 102 | HRIPT; 0.2 ml of a 1% dilution using distilled water was applied to a 1" x 1" pad applied with a semi- occlusive patch | not a dermal irritant or sensitizer | 281 |
| | | Macadamia Ternifolia Seed Oil | | |
| 0.5% Macadamia Ternifolia Seed Oil in a cleansing oil rinse-off | 214 | HRIPT with 0.2 ml of a 10% v/v aqueous solution, semi-occluded | 3 subjects had a "?" reaction following a patch during the induction and 1 subject had definite erythema with no edema or damage to the epidermis (+D) following the 7^{th} patch. No | 261 |
| | | | site. No other reactions were observed. Study concluded test material was not a dermal sensitizer. | |
| 30% Macadamia Ternifolia Seed Oil in a body and hand product | 55 | HRIPT; semi-occluded, undiluted | not a dermal irritant or sensitizer | 270 |
| | | Mangifera Indica (Mango) Seed Oil | | |
| 2% Mangifera Indica (Mango) Seed Oil in a lipstick | 100 | HRIPT with 150 µl test material, semi-occluded | not a dermal irritant or sensitizer | 282 |
| 3.87% Mangifera Indica (Mango) Seed Oil in an eyeliner | 102 | HRIPT with 0.2 g of test material, semi-occluded | not a dermal irritant or sensitizer | 283 |
| | M | angifera Indica (Mango) Seed Butter | | |
| 1% Mangifera Indica (Mango) Seed Butter in a facial lotion | 100 | HRIPT with 200 µl test material, semi-occluded | not a dermal irritant or sensitizer | 284 |
| 9% Mangifera Indica (Mango) Seed Butter in a body product | 102 | HRIPT with 0.2 g, semi-occluded | not a sensitizer | 285 |

| Table 8. Dermal effects – Human studies | | | | |
|--|--------------------|--|--|-----------|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 0.01% Moringa Oleifera Seed Oil in a cleansing oil rinse- off | 214 | Moringa Oleifera Seed Oil HRIPT with 0.2 ml of a 10% v/v aqueous solution, semi-occluded | 3 subjects had a "?" reaction following a patch during the induction and 1 subject had definite erythema with no edema or damage to the epidermis (+D) following the 7^{th} patch. No reactions were observed at a new test site. No other reactions were observed. Study concluded test material was not a dermal sensitizer. | 261 |
| 3% Moringa Pterygosperma Seed Oil in an eye treatment | 104 | Moringa Pterygosperma Seed Oil HRIPT with 150 µl test material, semi-occluded | not a dermal irritant or sensitizer | 286 |
| | Oei | oothera Biennis (Evening Primrose) Oil | | |
| 1.99% Oenothera Biennis (Evening Primrose) Oil in a foundation | 600 | HRIPT, occluded | not a dermal irritant or sensitizer | 287 |
| | | Olea Europaea (Olive) Fruit Oil | | |
| 0.7% Olea Europaea (Olive) Fruit Oil in a scalp conditioner | 114 | primary cutaneous irritation; formulation diluted to 1% | no primary irritation | 241 |
| 0.1595% Olea Europaea (Olive) Fruit Oil in a scalp conditioner/hair wax | 104 | HRIPT; occlusive; applied neat | not a dermal irritant or sensitizer | 222 |
| 0.7% Olea Europaea (Olive) Fruit Oil in a scalp conditioner | 110 | HRIPT; occlusive; formulation diluted to 1% | not a dermal irritant or sensitizer | 241 |
| 1.6% Olea Europaea (Olive) Fruit Oil in a body lotion | 110 | HRIPT with 0.02 ml test material , occluded | I subject had slight erythema following the 7^{th} patch that did not reoccur, no other reactions observed. Not a dermal irritant or sensitizer. | 288 |
| 10% Olea Europaea (Olive) Fruit Oil in a skin salve | 209 | HRIPT; occlusive applied neat | not a sensitizer | 226 |
| 22% Olea Europaea (Olive) Fruit Oil in a body moisturizer | 105 | HRIPT, semi-occluded | not a dermal irritant or sensitizer | 289 |
| 58.7% Olea Europaea (Olive) Fruit Oil in a conditioning hair oil | 102 | HRIPT with 0.2 ml, semi-occluded | not a dermal irritant or sensitizer | 290 |
| 69.6% Olea Europaea (Olive) Fruit Oil in a foundation | 209 | HRIPT with 200 µl test material, occluded | not a dermal irritant or sensitizer | 291 |
| 10% Olea Europaea (Olive) Oil in a skin salve | 51 | 4-wk use test; applied to lips, hands/nails, elbows, knees, feet/heels | did not elicit significant dermal irritation or dryness; 2 subjects had level 1(mild, very slight erythema on the lips, and 5 had level 1 erythema on the elbows, lips, or knees; 15 subjects reported subjective irritation | 227 |
| 2.5% Olea Europaea (Olive) Oil Unsaponfiables in a bath body mist | 0le | a Europaea (Olive) Oil Unsaponfiables HRIPT with 150 µl test material, semi-occluded | not a dermal irritant or sensitizer | 292 |

| Table 8. Dermal effects – Human studies | | | | |
|---|---|---|---|-----------|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| | | Hydrogenated Olive Oil | | |
| 12% Hydrogenated Olive Oil in a lipstick | 108 | HRIPT, occluded | not a dermal irritant or sensitizer | 274 |
| | Hyd | lrogenated Olive Oil Unsaponifiables | | |
| 2% Hydrogenated Olive Oil Unsaponifiables in a face and neck product | 50 | HRIPT, occluded | not a dermal irritant or sensitizer | 273 |
| | Hyd | rogenated Olive Oil Unsaponifiables | | |
| 5% Hydrogenated Olive Oil Unsaponifiables in a skin cleansing product | 57 | HRIPT, semi-occluded, 10% dilution of product | not a dermal irritant or sensitizer | 273 |
| | | Sodium Olivate | | |
| 17.64% Sodium Olivate in a body bar soap | 107 | HRIPT, semi-occluded | not a dermal irritant or sensitizer | 293 |
| 3.79% Orbignya Oleifera Seed Oil in a cream cleanser | 104 | Orbignya Oleifera Seed Oil HRIPT with 0.2 ml of a 10% dilution of formulation, semi-occluded | not a dermal irritant or sensitizer | 294 |
| | | Orbignya Speciosa Kernel Oil | | |
| 0.4125% Orbignya Speciosa Kernel Oil in a hair conditioner | 104 | modified HRIPT; semi-occlusive; 10% dilution in distilled water | not a dermal irritant or sensitizer | 295 |
| | | Oryza Sativa (Rice) Bran Oil | | |
| Rice is generally regarded as hypoallergenic, although some c Oryza Sativa (Rice) Bran Oil were not irritating or sensitizing. | case studies of allergic re Hydrolyzed rice proi | actions to raw rice have been reported. In clinical testing ein was not irritating to human subjects. | s, formulations containing 1.04-8.0% | 28 |
| | | Persea Gratissima (Avocado) Oil | | |
| Persea Gratissima (Avocado) Oil was not an irritant or sensiti. (Avocado) Oil or in patch tests using 100% Persea Gratissimc | izer when human subject a (Avocado) Oil. | s were patch tested with cosmetic formulations containin | g up to 10.7% Persea Gratissima | 31 |
| 0.2% Persea Gratissima (Avocado) Oil in a scalp conditioner | 114 | primary cutaneous irritation; formulation diluted to 1% | no primary irritation | 241 |
| 0.2% Persea Gratissima (Avocado) Oil in a scalp conditioner | 110 | HRIPT; occlusive; formulation diluted to 1% | not a dermal irritant or sensitizer | 241 |
| 10% Persea Gratissima (Avocado) Oil in a skin salve | 51 | 4-wk use test; applied to lips, hands/nails, elbows, knees, feet/heels | did not elicit significant dermal irritation or dryness; 2 subjects had level 1(mild, very slight erythema on the lips, and 5 had level 1 erythema on the elbows, lips, or knees; 15 subjects reported subjective irritation | 227 |
| | | Plukenetia Volubilis Seed Oil | | |
| 0.51% Plukenetia Volubilis Seed Oil in a lipstick | 108 | HRIPT; occlusive; applied neat | not an irritant or a sensitizer | 296 |
| | Prunu | s Amygdalus Dulcis (Sweet Almond) Oil | | |
| Undiluted Prunus Amygdalus Dulcis (Sweet Almond) Oil was 1 | non-irritating in a single | e insult patch test with 101 subjects, and it was non-irritat | ing and non-sensitizing in an HRIPT | 218 |
| using 52 subjects. Cosmetic formulations containing 0.1-25% day Cumulative Irritancy Assay, a moisturizer containing 25% | were practically non-irr Prunus Amvedalus Dul | itating and non-sensitizing in HRIPTs performed with 69 cis (Sweet Almond) Oil had a total irritancy score of 14/6 | 06 subjects. In the Lanman-Maibach 21- 30 | |

| Table 8. Dermal effects – Human studies | | | | |
|--|--------------------|--|--|---|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 7% Prunus Amygdalus Dulcis (Sweet Almond) Oil in an oil treatment | 103 | HRIPT with 200 µl test material, semi-occluded | Grade 1 (mild erythema) reactions in 4 subjects for 1 or 2 patches in the induc- tion phase, grade 1 (mild erythema in different subjects at the 48 h challenge reading. Study concluded test material was not a dermal irritant or sensitizer. | 257 |
| 10% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a face serum | 108 | primary cutaneous irritation | no primary irritation | 225 |
| 10% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a face serum | 108 | HRIPT; occlusive; applied neat | not an irritant or a sensitizer | 225 |
| 10% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a skin salve | 209 | HRIPT; occlusive applied neat | not a sensitizer | 226 |
| 10% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a skin salve | 51 | 4-wk use test; applied to lips, hands/nails, elbows, knees, feet/heels | did not elicit significant dermal irrita- tion or dryness; 2 subjects had level 1 (mild, very slight crythema on the lips, and 5 had level 1 erythema on the elbows, lips, or knees; 15 subjects re- ported subjective irritation | 227 |
| 15% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a massage oil | 107 | HRIPT with 0.2 ml test material, semi-occluded | I subject had slight erythema follow- ing the 7^{th} patch that did not reoccur, no other reactions observed. Not a dermal irritant or sensitizer. | 262 |
| 25% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a lip balm | 222 | HRIPT with 0.2 g test material, occluded | 2 subjects had low-level, transient (\pm) reactions during the induction, no other reactions were observed. Study concluded that test material was not a dermal sensitizer. | 267 |
| ~31% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a facial oil | 108 | modified HRIPT; semi-occlusive; applied neat | not a dermal irritant or sensitizer | 297 |
| 45.25% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a facial oil | 109 | HRIPT; semi-occlusive; applied neat | not a dermal irritant or sensitizer | 298 |
| 46% Prunus Amygdalus Dulcis (Sweet Almond) Oil in a cuticle softener | 106 | modified Draize assay with an induction phase (3x/wk for 10 applications) and a challenge phase, applied neat, occlusive | not a dermal irritant or sensitizer | 299 |
| | Pru | nus Armeniaca (Apricot) Kernel Oil | | |
| 2% Prunus Armeniaca (Apricot) Kernel Oil in a face cream | 51 | HRIPT with 20 µl test material, occluded | not a dermal irritant or sensitizer | 243 |
| 2% Prunus Armeniaca (Apricot) Kernel Oil in an eye cream | 108 | HRIPT with 20 µl test material, occluded | not a dermal irritant or sensitizer | 244 |
| 2.5% Prunus Armeniaca (Apricot) Kernel Oil in a cream | 119 | primary cutaneous irritation | no primary irritation | 242 |
| 19.749% Prunus Armeniaca (Apricot) Kernel Oil in a face serum | 108 | primary cutaneous irritation | no primary irritation | 225 |
| 0.005% Prunus Armeniaca (Apricot) Kernel Oil in a scalp conditioner/hair wax | 104 | HRIPT; occlusive; applied neat | not a dermal irritant or sensitizer | 222 |
| 1% Prunus Armeniaca (Apricot) Kernel Oil in a cream | 57 | HRIPT; Finn chambers, applied neat | not a dermal irritant or sensitizer | 277 |
| | | 99 | | |

| Table 8. Dermal effects – Human studies | | | | |
|---|--|--|---|---|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 2.5% Prunus Armeniaca (Apricot) Kernel Oil in a cream | 118 (irritation)/ 116 (sensitization) | HRIPT; occlusive | not a dermal irritant or a sensitizer | 242 |
| 19.749% Prunus Armeniaca (Apricot) Kernel Oil in a face serum | 108 | HRIPT; occlusive; applied neat | not an irritant or a sensitizer | 225 |
| | | Prunus Domestica Seed Oil | | |
| 0.04% Prunus Domestica Seed Oil in a preshave lotion | 105 | HRIPT with 0.2 ml, occluded | not a sensitizer | 300 |
| | | Prunus Persica (Peach) Kernel Oil | | |
| 24% Prunus Persica (Peach) Kernel Oil in a lip balm | 222 | HRIPT with 0.2 g test material, occluded | 2 subjects had low-level, transient (\pm) reactions during the induction, no other reactions were observed. Study concluded that test material was not a dermal sensitizer. | 267 |
| | R | ibes Nigrum (Black Currant) Seed Oil | | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 |
| 0.1% Ribes Nigrum (Black Currant) Oil in a scalp conditioner | 114 | primary cutaneous irritation; diluted to 1% | no primary irritation | 241 |
| 0.25% Ribes Nigrum (Black Currant) Oil in a cream | 119 | primary cutaneous irritation | no primary irritation | 242 |
| 0.1% Ribes Nigrum (Black Currant) Oil in a scalp conditioner | 110 | HRIPT; occlusive; diluted to 1% | not a dermal irritant or sensitizer | 241 |
| 0.2% Ribes Nigrum (Black Currant) Seed Oil is an eye mask | 228 | HRIPT, occluded | 4 subjects had "?" or "+" reaction during induction that were not considered clinically relevant, no other reactions observed. Not sensitizing | 301 |
| 0.2% Ribes Nigrum (Black Currant) Oil in a skin cream | 106 | HRIPT, occlusive | not a dermal irritant or sensitizer | 276 |
| 0.25% Ribes Nigrum (Black Currant) Oil in a cream | 118 (irritation)/ 116 (sensitization) | HRIPT; occlusive | not a dermal irritant or a sensitizer | 242 |
| 0.2% Ribes Nigrum (Black Currant) Seed Oil is an eye mask | 195 | 4-week safety in-use study | No adverse reactions reported. Product considered suitable for sensitive skin. | 302 |
| | | Rosa Canina Fruit Oil | | |
| 0.39% Rosa Canina Fruit Oil in a skin cream | 108 | primary cutaneous irritation | no primary irritation | 276 |
| 0.39% Rosa Canina Fruit Oil in a skin cream | 106 | HRIPT, occlusive | not a dermal irritant or sensitizer | 276 |
| | | Rubus Chamaemorus Seed Oil | | |
| 2.5% Rubus Chamaemorus Seed Oil in product | 10 | Single occlusive patch test for 48 h with 25 μ l | not an irritant | 303 |
| 5% Rubus Idaeus (Raspberry) Seed Oil in a face and neck product | 102 | Rubus Idaeus (Raspberry) Seed Oil HRIPT, occluded | not a dermal irritant or sensitizer | 273 |
| | | | | |

| Table 8. Dermal effects – Human studies | | | | |
|--|--|---|--|-----------|
| Ingredient and Concentration Subje | cts Completed | Method | Results | Reference |
| | Set | amum Indicum (Sesame) Seed Oil | | |
| In clinical testing, undiluted Sesamum Indicum (Sesame) Seed Oil wa essentially non-irritating. Prophetic patch testing with formulations contact allergy to Sesamum Indicum (Sesame) Seed Oil were patch te | s not irritating. C containing 10-119 ssted, and most ha | osmetic formulations containing 8-14, 3% Sesamum Indic 6 Sesamum Indicum (Sesame) Seed Oil were not irritating 1 positive reactions to sesamol, sesamin, and sesamolin. | um (Sesame) Seed Oil were non- to 5 with or without UV light. Patients with | 55 |
| 25% Sesamum Indicum (Sesame) Seed Oil in a face serum | 108 | primary cutaneous irritation | no primary irritation | 225 |
| 8% Sesamum Indicum (Sesame) Seed Oil in a skin salve | 209 | HRIPT; occlusive applied neat | not a sensitizer | 226 |
| 25% Sesamum Indicum (Sesame) Seed Oil in a face serum | 108 | HRIPT; occlusive; applied neat | not an irritant or a sensitizer | 225 |
| 8% Sesamum Indicum (Sesame) Seed Oil in a skin salve | 51 | 4-wk use test; applied to lips, hands/nails, elbows, knees, feet/heels | did not elicit significant dermal irritation or dryness; 2 subjects had level 1 (mild, very slight erythema on the lips, and 5 had level 1 erythema on the elbows, lips, or knees; 15 subjects reported subjective irritation | 227 |
| | Solan | um Lycopersicum (Tomato) Seed Oil | | |
| 0.0023% Solanum Lycopersicum (Tomato) Seed Oil in a cream cleanser | 104 | HRIPT with 0.2 ml of a 10% dilution of the formulation, semi-occluded | not a dermal irritant or sensitizer | 304 |
| | The | obroma Cacao (Cocoa) Seed Butter | | |
| 50.1% Theobroma Cacao (Cocoa) Seed Butter in a lip balm | 106 | HRIPT with 150 µl test material, semi-occluded | not a dermal irritant or sensitizer | 305 |
| | Theo | broma Grandiflorum Seed Butter ³⁰⁶ | | |
| 5% Theobroma Grandiflorum Seed Butter in a lip balm | 106 | HRIPT with 150 µl test material, semi-occluded | not a dermal irritant or sensitizer | 307 |
| | T | iticum Vulgare (Wheat) Germ Oil | | |
| In clinical testing, Triticum Vulgare (Wheat) Germ Oil was not an irr | itant or a sensitize | Ŀ. | | 30 |
| 0.005% Triticum Vulgare (Wheat) Germ Oil in a scalp conditioner/hair wax | 104 | HRIPT; occlusive; applied neat | not a dermal irritant or sensitizer | 222 |
| | Vaccini | um Macrocarpon (Cranberry) Seed Oil | | |
| 0.04% Vaccinium Macrocarpon (Cranberry) Seed Oil in a face and neck product | 53 | HRIPT, occluded | not a dermal irritant or sensitizer | 273 |
| | | Vaccinium Myrtillus Seed Oil | | |
| ~1% Vaccinium Myrtillus Seed Oil in a facial oil | 116 | modified HRIPT; semi-occlusive; volatilized | not a dermal irritant or sensitizer | 306 |
| | | Vaccinium Vitis-Idaea Seed Oil | | |
| 5% Vaccinium Vitis-Idaea Seed Oil in product | 10 | Single occlusive patch test of 48 h with 0.02 ml | not an irritant | 308 |
| | | Vegetable Oil | | : |
| 4% Vegetable Oil in a foundation | 115 | HRIPT, semi-occluded | 1 subject had ± on the first day of the induction only, no other reactions. Not a dermal irritant or sensitizer. | 309 |
| 4% Vegetable Oil in a lipstick | 106 | HRIPT with 0.2 g. occluded | not a dermal irritant or sensitizer | 310 |

| Table 8. Dermal effects – Human studies | | | | |
|---|--|--|---|---|
| Ingredient and Concentration | Subjects Completed | Method | Results | Reference |
| 11% Vegetable Oil in an eye shadow | 106 | HRIPT, semi-occluded | not a dermal irritant or sensitizer | 311 |
| 39% Vitis Vinifera (Grape)Seed Oil in a preshave lotion | 105 | Vitis Vinifera (Grape) Seed Oil HRIPT with 0.2 ml, occluded | not a sensitizer | 300 |
| 90% Vitis Vinifera (Grape) Seed Oil in a fragranced oil | 105 | HRIPT; semi-occluded; applied neat | not a dermal irritant or sensitizer | 312 |
| 0.5% Hydrogenated Grapeseed Oil in a lip product | 53 | HRIPT; semi-occluded | not a dermal irritant or sensitizer | 313 |
| | | Zea Mays (Corn) Germ Oil | | |
| 20% Zea Mays (Corn) Germ Oil in a cleansing oil rinse- off | 214 | HRIPT with 0.2 ml of a 10% v/v aqueous solution, semi-occluded | 3 subjects had a " γ " reaction following a patch during the induction and 1 sub- ject had definite erythema with no edema or damage to the epidermis (+D) following the 7^{th} patch. No reac- tions were observed at a new test site. No other reactions were observed. Study concluded test material was not a dermal sensitizer. | 261 |
| | | | | |
| | PHOTO | OTOXICITY/PHOTOSENSITIZATION | | |
| | | Cocos Nucifera (Coconut) Oil | | |
| Bar soaps made with 13% Cocos Nucifera (Coconut) Oil, tes on 52 panelists, did not produce any evidence of photosensit | sted as a 3% aqueous solu tization. | ttion, tested using 10 subjects, and a similar soap, prepar | ed as 1 or 3% aqueous solutions, tested | 33 |
| | | Sodium Cocoate | | |
| Bar soaps 13% sodium cocoate, prepared as a 3% aqueous s | solution, tested using 10 s | ubjects did not produce any evidence of photosensitizati | Jn. | 33 |
| | Prunu | s Amygdalus Dulcis (Sweet Almond) Oil | | |
| Formulations containing 0.1% - 2.0% Prunus Amygdalus Du the test subjects. | ulcis (Sweet Almond) Oil, | tested for photosensitization in a total of 764 subjects, dic | l not manifest photosensitivity in any of | 218 |
| | | Oryza Sativa (Rice) Bran Oil | | - - - - - - - - - - - - - - - - - - - |
| Formulations containing 1.04% Oryza Sativa (Rice) Bran Oi | iil were not photosensitizin | ß | | 28 |
| | | | | |
| | | COMEDOGENICITY | | |
| | Rih | oes Nigrum (Black Currant) Seed Oil | | |
| 0.2% Ribes Nigrum (Black Currant) Seed Oil in an eye mask formulation | 6 | applied undiluted; occlusive | avg. score of 0.00 comedones/cm ² ; non-comedogenic | 314 |

mask formulation ^aSame 109 panelists tested these 4 formulations hat differed only in color and fragrance.

| Table 9 . Ocular irritation – Non-Human | and Human | | | | |
|--|---|--|--|--|--|
| Ingredient | Concentration | Test Group | Procedure | Results | Reference |
| | | | NON-HUMAN | | |
| baobab oil | 100% | V | Adansonia Digitata Seed Oil MatTek EpiOcular MTT viability assay; 100 µl of test material for 16- 256 min | non-irritating | 212 |
| | | A | leurites Moluccana Seed Oil | | |
| Aleurites Moluccana oil | | | Draize test | not an ocular irritant | 315 |
| Aleurites Moluccana oil | | | in vitro conjunctival cell assay | not cytotoxic | 315 |
| Aleurites Moluccana oil | | | ocular burn treatment efficacy test | no adverse effects | 316 |
| | | Butyr | ospermum Parkii (Shea) Butter | | |
| Butyrospermum Parkii (Shea) Butter | undiluted | 3 male Kleinrussen Chbb:HM rabbits | 0.1 ml instilled into the conjunctival sac of one eye for 24 h | not irritating; mild conjunctival reactions | 317 |
| iiO (massa), andin iN accord Postelit all | internet internet | C | ocos Nucifera (Coconut) Oil | | |
| Undiluted Cocos Nucifera (Coconut) Uil, | l, instilled into rabbit | eyes without rinsing, pro | oduced minimal eye irritation | | 33 |
| Undiluted hydrogenated coconut oil proa formulations containing 10% hydrogenat | duced mild irritation i ted coconut oil both p |] in one study, minimal irr voduced slight conjuncti | Hydrogenated Coconut Oil itation in another, negligible or minimal witis. | irritation in eight additional tests. Two lipstick | 33 |
| Undiluted coconut acid produced mild ir | rtitation in rabbit eyes | s in two studies and mini | Coconut Acid <i>mal irritation in a third.</i> | | 33 |
| | | C | Trambe Abyssinica Seed Oil | | |
| Crambe Abyssinica Seed Oil | undiluted | | details not provided | an ocular irritant, but not corrosive | 215 |
| Undiluted Elaeis Guineensis (Palm) Oil c one lotion containing 1.5% Elaeis Guinec | and cosmetic lotions (ensis (Palm) Oil was | E and creams containing I moderately irritating. | laeis Guineensis (Palm) Oil .5-2.0%6 Elaeis Guineensis (Palm) Oil w | ere minimally irritating to the eyes of rabbits, while | 26 |
| | | | Hydrogenated Palm Oil | | |
| Hydrogenated palm oil suppositories wei | re mildly irritating to | rabbit eyes. | | | 26 |
| Fragaria Ananassa (Strawberry) Seed Oil | 5-50% in a lipophilic solvent | Fragari | a Ananassa (Strawberry) Seed Oil neutral red release test | IC ₃₀ >50%; negligible cytotoxicity | 318 |
| Cosmetic formulations containing 3.4-12 | 2.3% hydrogenated co | H ottonseed oil were mildly | ydrogenated Cottonseed Oil <i>i</i> irritating to the eyes of rabbits | | 27 |
| | | Hip | pophae Rhamnoides Seed Oil | | |
| Hippophae Rhamnoides Seed Oil | 5-50% in a lipophilic solvent | | neutral red release test | IC ₅₀ >50%; negligible cytotoxicity | 319 |
| mascara containino 9 4% I inum | diluted at 0-50% | Linum | Usitatissimum (Linseed) Seed Oil neutral red release test | NR.~>50%- eliehtly exterioxic | č |
| Usitatissimum (Linseed) Oil | in mineral oil | | | | 320 |
| | | | 70 | | |

| Table 9. Ocular irritation – Non-Human a | ınd Human | | | | |
|--|---|--|--|--|-----------|
| Ingredient | Concentration | Test Group | Procedure | Results | Reference |
| mascara containing 9.4% Linum | 67.1% solution in | | hen's egg test-chorioallantoic | moderately irritating | 320 |
| Usutaussimum (Linseed) Oli mascara containing 9.4% Linum Usitatissimum (Linseed) Oil | mineral oil 66.9% solution in mineral oil | | memorane assay (HEL-CAM) reconstituted epithelial culture assay | slightly cytotoxic | 320 |
| | | Ole | a Europaea (Olive) Fruit Oil | | |
| Olea Europaea (Olive) Fruit Oil, "high purity" | undiluted | rabbits; number not specified | Draize test | not irritating | 315 |
| Olea Europaea (Olive) Fruit Oil, "high purity" | | 4 | in vitro study using human conjunc- tival epithelial cells | did not induce cellular necrosis or apoptosis | 315 |
| | | Ō | ryza Sativa (Rice) Bran Oil | | |
| A mixture of Oryza Sativa (Rice) Bran Oi was considered minimally irritating. | l and Oryza Sativa (R | ice) Germ Oil, concentr | ations not stated, were not irritating to r | abbit eyes. Undiluted Oryza Sativa (Rice) Bran Oil | 28 |
| | | O | yza Sativa (Rice) Germ Oil | | |
| Oryza Sativa (Rice) Germ Oil, concentral | ion not stated, was no | ot a primary irritant. | | | 28 |
| | | Prunus An | nygdalus Dulcis (Sweet Almond) Oil | | |
| The ocular irritation potential of undilute Almond) Oil were evaluated using rabbits taining up to 25% Prunus Amygdalus Duu irritation, which cleared by the third day. | d Prunus Amygdalus : Undiluted Prunus / cis (Sweet Almond) C of observation. | Dulcis (Sweet Almond) (Amygdalus Dulcis (Swee Dil were nonirritating to | Oil and cosmetic formulations containin, 1 Almond) Oil was practically nonirritat minimally irritating. In most instances, | g up to 25% Prunus Amygdalus Dulcis (Sweet ing or minimally irritating, and formulations con- reactions that occurred were limited to conjunctival | 218 |
| | | Ribes N | igrum (Black Currant) Seed Oil | | |
| eye mask containing 0.2% Black Ribes (Black Currant) Seed Oil | 50% dilution | | HET-CAM assay | practically no irritation | 321 |
| | | Ru | bus Chamaemorus Seed Oil | | |
| product containing 2.5% Rubus Chamaemorus Seed Oil | | | neutral red release assay | negligible cytotoxicity; product was considered well tolerated | 322 |
| Undiluted Sesamum Indicum (Sesame) Se ocular irritant. | ed Oil was non- to mi | Sesar inimally irritating to rab | ne Indicum (Sesame) Seed Oil bit eyes, and a lipstick containing 10-11 | % Sesamum Indicum (Sesame) Seed Oil was not an | 55 |
| | | Tritic | um Vulgare (Wheat) Germ Oil | | |
| Undiluted Triticum Vulgare (Wheat) Ger | n Oil was, at most, a | minimal ocular irritant, | and 2% in a water emulsion was not irr | itating. | 30 |
| | | Vac | ccinium Vitis-Idaea Seed Oil | | |
| Vaccinium Vitis-Idaea Seed Oil | 5-50% in a lipophilic solvent | | neutral red release test | IC ₅₀ > 50%; negligible cytotoxicity | 323 |
| | · · · · · · · · · · · · · · · · · · · | | Zea Mays (Corn) Oil | | |
| Zea Mays (Corn) Oil, "high purity" | undiluted | rabbits, number not specified | Draize test | not irritating | 315 |
| Zea Mays (Corn) Oil, "high purity" | | | in vitro study using human conjunc- tival epithelial cells | did not induce necrosis or apoptosis | 315 |
| | | | | | |

| I AUTE 7. UVUIAT ITTIAUUII – INOII-ITUIIIAII AIIU ITUI | uman | | | | |
|---|------------|--------------------|-------------------------------------|---|-----------|
| Ingredient Conc | centration | Test Group | Procedure | Results | Reference |
| | | | HUMAN STUDIES | | |
| | | Linum (| Jsitatissimum (Linseed) Seed Oil | | |
| 9.4% Linum Usitatissimum (Linseed) | | 33 female subjects | 4 wk study; 16 wore contact lenses, | no subjective irritation and no adverse reports; | 324 |
| Seed Oil in a mascara | | | 17 had "sensitive" eyes | clinically safe for use by contact lens-wearers | |
| | | Ribes N | igrum (Black Currant) Seed Oil | | |
| 0.2% Ribes Nigrum (Black Currant) undil Seed Oil | luted | 52 subjects | 4-wk in-use study | no adverse reactions; safe for contact-lens wearers | 325 |

| Table 10. Clinical Trials/Case Stud | dies Patients/Condition | Effort/Observation | Dafaranca | |
|--|--|---|-----------|--|
| Ingreutent | Aleur | rites Moluccana Seed Oil | Kelerence | |
| Aleurites Moluccana oil | 15; mild, stable plaque psoriasis | efficacy study "just enough (oil) to moisten the plaque" was applied 3 x daily for 12 wks; no side effects or adverse events were reported. | 326 | |
| | Anacardium | o Occidentale (Cashew) Seed Oil | | |
| Anacardium Occidentale (Cashew) Seed Oil | 37-year-old male resin researcher | presentation of bullae on his right leg after dropping pure oil from a bottle on his right thigh; skin was thoroughly washed immediately; erythema developed 10 days after exposure Patch testing was performed with cashew nut oil 3% alcohol, cashew nut oil 0.3% alcohol, cashew nut oil 0.03% alcohol, and urushiol 0.01% petrolatum.; a "+" reaction was reported on day 2 and "++" reactions on days 3 and 4 to the 3% dilution; a "+" reactions to the 0.3% dilution and urushiol was reported on days 2-4; a "?+" reaction was observed on days 2 and 3 and a "+" reaction was observed on day 4 to the 0.03% dilution | 327 | |
| | Сосо | s Nucifera (Coconut) Oil | 22 | |
| Cocos Nucifera (Coconut) Oil did n | ot produce adverse effects in seve | eral therapeutic studies | | |
| | Gly | cine Soja (Soybean) Oil | | |
| Glycine Soja (Soybean) Oil | 7; history of immediate hyper- sensitivity reaction after the ingestion of soybeans | a double-blind crossover study; the patients were first skin tested by the puncture method with a crude whole soybean extract, a partially hydrogenated oil, a non-hydrogenated oil, and a cold-pressed soybean oil; olive oil from a retailer was used as a negative control. Since all 7 patients had negative skin tests to the oils and positive reactions to the crude soybean extract, they were challenged orally with capsules of each of the oils in random order on 4 separate days. None of the patients reacted to the oral challenges; the researchers remarked that while a reaction to the cold-pressed soybean oil did not occur in this study, cold-pressed oils may contain soybean protein and should be avoided | 67 | |
| soy oil proteins | 4; known allergy to soybean | Sera was used to examine the allergenicity; neither the IgE nor the IgG ₄ in the sera reacted to protein in the soy oil | 23 | |
| | Heliantl | hus Annuus (Sunflower) Oil | 10 | |
| refined and cold-pressed sunflower oils | patients had anaphylactic reactions following ingestion of sunflower seeds | no reactions were seen upon oral or open challenge with refined or cold-pressed sunflower oils, both of which were shown to contain detectable amounts of protein. | 18 | |
| | 1 woman; desensitized to mugwort (of the Compositae family) pollen for a yr, then had an anaphylactic reaction to sunflower (also of the Compositae family) seeds | a delayed positive reaction to sunflower oil in a skin prick test was discovered; prick test results with 10 control subjects were negative. In an oral challenge test, a delayed reaction was again observed, with symptoms occurring 2.25-8 h after administration. | 328 | |
| | Γ | Macadamia Seed Oil | | |
| Macadamia Seed Oil in a lipstick (species description or concentra- tion were not reported) | 28-year-old woman; chelitis | Chelitis case reported after lipstick use; patient was patch tested with ingredients contained in the lipstick, Positive reactions to diisostearyl malate and Macadamia Seed Oil were reported; the condition . improved after discontinuing use of lipsticks containing these 2 ingredients | 329 | |
| | Olea H | Europaea (Olive) Fruit Oil | 220.227 | |
| Throughout the literature, it is stated that sensitization to Olea Europaea (Olive) Fruit Oil is considered rare. Case reports have been de- scribed, however, and generally involved patients with venous eczema, some type of dermatitis or lesion, or an occupational exposure. Patch testing with Olea Europaea (Olive) Fruit Oil produced positive reactions in most of these cases, and these results were usually regarded as allergenic. The concentrations of Olea Europaea (Olive) Fruit Oil tested were not always given, but when stated, test concentrations giving positive results, ranged from 30-100%. When the constituents of olive oil were tested as well, the results of that testing were negative | | | | |
| Whether the reactions to olive oil w cluded that olive oil presented as a w | ere contact sensitization or irritat weak irritant rather than a contact | ion were investigated using open and occlusive testing. It was con- sensitizer in the few case studies observed. | 338 | |
| | Persea | Gratissima (Avocado) Oil | | |
| Persea Gratissima (Avocado) Oil | 1 female; dermatitis around the eyes and earlobes | Patch testing with her sunscreen resulted in positive results. In subsequent patch testing of the individual ingredients, a positive reaction to undiluted oil, but not to the active ingredient, was observed; 20 controls subjects were used, and reactions to Persea Gratissima (Avocado) Oil were not seen | 339 | |

| Ingredient | Patients/Condition | Effect/Observation | Reference |
|---|---------------------------|--|-----------|
| | Se | esamum Indicum (Sesame) Seed Oil | |
| Sesamum Indicum (Sesame) Seed Oil in an ointment | female | Pruritic erythema, papules, and vesicles appeared after application of the ointment; patch testing was performed with the ointment and with the individual ingredients, including undiluted Sesamum Indicum (Sesame) Seed Oil Both the ointment and Sesamum Indicum (Sesame) Seed Oil pro- duced positive reactions on days 2, 3, 4, and 1; the other components did not cause a reaction Results were negative in patch testing of Sesamum Indicum (Sesame) Seed Oil using 20 healthy subjects. | 340 |

REFERENCES

- Gottschalck TE and Bailey JE. International Cosmetic Ingredient Dictionary and Handbook. 2010. 13th:Washington, DC: Personal Care Products Council.
- Center for New Crops & Plant Products.Macadamia integrifolia Maiden & Betche and Macadamia tetraphylla L. Johnson. 1-7-1998. <u>http://www.hort.purdue.edu/newcrop/duke_energy/Macadamia.html</u>. Accessed 5-20-2010.
- 3. Storey, WB. The Ternifolia group of Macadamia species. Pacific Science. 1965;19:507-514.
- Gottschalck TE and Bailey JE. International Cosmetic Ingredient Dictionary and Handbook. 2008. 12th:(3):Washington, DC: CTFA.
- 5. Miraliakbari, H and Shahidi, F. Oxidative stability of tree nut oils. J Agric Food Chem. 2008;56:4751-4759.
- Salunkhe, DK, Chavan, JK, Adsule, RN, and Kadam, SS. World Oilseeds: Chemistry, Technology, and Utilization. New York: Van Nostrand Reinhold, 1992.
- 7. US Pharmacopeia. 2008-2009 Food Chemicals Codex. 6th ed. Baltimore: United Book Press, Inc., 2008.
- 8. Personal Care Products Council. Description of Vegetable Oil. Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on November 9, 2010. 1 page.
- 9. Bailey's Industrial Oil & Fat Products. John Wiley & Sons., 1996.
- John L. Seaton & Co, Ltd. Oil seed processing. Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 11. Davrieux, F, Allal, F, Piombo, G, Kelly, B, Okulo, JB, Thiam, M, Diallo, OB, and Bouvet, JM. Near infrared spectroscopy for high-throughput characaterization shea tree (Vitellaria paradoxa) nut fat profiles. *J Agric Food Chem*. 2010.
- 12. Oliveira, I, Sousa, A, Morais, JA, Ferreira, ICFR, Bento, A, Estevinho, L, and Perira, JA. Chemical composition, and antioxidant and antimicrobial activities of three hazelnut (Corylus avellana L.) cultivars. *Food Chem Toxicol.* 2008;46:1801-1807.
- Holcapek, M, Jandera, P, Zderadicka, P, and Hruba, L. Characterization of triacylglycerol and diacylglycerol composition of plant oils using high-performance liquid chromatography-atmospheric pressure chemical ionization mass spectrometry. *J Chromatogr A*. 2003;1010:195-215.
- Saraiva, SA, Cabral, EC, Eberlin, MN, and Catharino, RR. Amazonian vegetable oils and fats: Fast typification and quality control via triacylglycerol (TAG) profiles from dry matrix-assisted laser desorption/ionization timeof-flight (MALDI-TOF) mass spectrometry fingerprinting. J Agric Food Chem. 2009;57:4030-4034.
- 15. Teuber, SS, Brown, RL, and Haapanen, LAD. Allergenicity of gourmet nut oils processed by different methods. *J* Allergy Clin Immunol. 1997;99:(4):502-507.
- Crevel, R. W., Kerkhoff, M. A., and Koning, M. M. Allergenicity of refined vegetable oils. *Food Chem Toxicol*. 2000;38:(4):385-393.
- Andersen, F.A. (ed). Final report on the safety assessment of peanut (arachis hypogaea) oil, hydrogenated peanut oil, peanut acid, peanut glycerides, and peanut (arachis hypogaea) flour. *Int J Toxicol*. 2001;20:(Suppl 2):65-77.
- Halsey, A. B., Martin, M. E., Ruff, M. E., Jacobs, F. O., and Jacobs, R. L. Sunflower oil is not allergenic to sunflower seed-sensitive patients. *J Allergy Clin Immunol*. 1986;78:408-410.

- Zitouni, N., Errahali, Y., Metche, M., Kanny, G., Moneret-Vautrin, D. A., Nicolas, J. P., and Fremont, S. Influence of refining steps on trace allergenic protein content in sunflower oil. *J Allergy Clin Immunol*. 2000;106:(5):962-967.
- 20. Olszewski, A, Pons, L, Moutété, F, Aimone-Gastin, I, Kanny, G, Moneret-Vautrin, DA, and Gueant, JL. Isolation and characterization of proteic allergens in refined peanut oil. *Clin Exp Allergy*. 1998;28:850-859.
- Ramazzotti, M., Mulinacci, N., Pazzagli, L., Moriondo, M., Manao, G., Vincieri, F. F., and Degl'Innocenti, D. Analytic investigations on protein content in refined seed oils: implications in food allergy. *Food Chem Toxicol.* 2008;46:(11):3383-3388.
- 22. Porras, O., Carlsson, B., Fallstrom, S. P., and Hanson, L. A. Detection of soy protein in soy lecithin margarine and, occasionally, soy oil. *Int Archs Allergy Appl Immunol*. 1985;78:30-32.
- Awazuhara, H., Kawai, H., Baba, M., Matsui, T., and Komiyama, A. Antigenicity of the proteins in soy lecithin and soy oil in soybean allergy. *Clin Exp Allergy*. 1998;28:1559-1564.
- 24. Paschke, A, Zunker K, Wigotzki M, and Steinhart H. Determination of the IgE-binding activity of soy lecithin and refined and non-refined soybean oils. *J Chromatogr B*. 2001;(756):249-254.
- 25. Andersen, F.A. (ed). Final report on the safety assessment of sesame oil. J Am coll Toxicol. 1993;12:(3):261-277.
- 26. Andersen, F.A.(ed). Final report on the safety assessment of Elaeis guineensis (palm) oil, Elaeis guineensis (palm) kernel oil, hydrogenated palm oil and hydrogenated palm kernel oil. *Int J Toxicol*. 2000;19:(Suppl 2):7-28.
- Andersen, F.A.(ed). Final report on the safety assessment of hydrogenated cottonseed oil cottonseed (Gossypium) oil, cottonseed acid, cottonseed glyceride, and hydrogenated cottonseed glyceride. *Int J Toxicol*. 2001;20:(Suppl 2):21-29.
- 28. Andersen, F.A.(ed). Amended final report on the safety assessment of Oryza sativa (rice) bran oil, Oryza sativa (rice)germ oil, rice bran acid, Oryza sative (rice)bran wax, hydrogenated rice bran wax, Oryza sativa (rice) bran extract, Oryza sativa (rice) extract, Oryza sative (rice) germ powder, Oryza sative (rice) starch, Oryza sativa (rice) bran, hydrolyzed rice bran extract, hydrolyzed rice bran protein, hydrolyzed rice extract. and hydrolyzed rice proten. *Int J Toxicol.* 2006;25:(Suppl 2):91-120.
- 29. Cosmetic Ingredient Review. Final report of the Cosmetic Ingredient Review Expert Panel. Amended safety assessment of cocos nucifera (coconut) oil, coconut acid, hydrogenated coconut acid, hydrogenated coconut oil, ammonium cocomonoglyceride sulfate, butylene glycol cocoate, carprylic/capric/coco glycerides, cocoglycerides, coconut alcohol, coconut oil decyl esters, decyl cocoate, ethylhexyl cocoate, hydrogenated coco-glycerides, isodecyl cocoate, lauryl cocoate, magnesium cocoate, methyl cocoate, octyldodecyl cocoate, pentaerythrityl cocoate, potassium cocoate, potassium hydrogenated cocoate, sodium cocoate, sodium cocoate, sodium cocoate, sodium cocoate, sodium cocoate, adn tridecyl cocoate. *Available from CIR*. 2008.
- 30. Elder, R.L.(ed.). Final report on the safety assessment for wheat germ oil. JEPT. 1980;4:(4):33-45.
- 31. Elder, R.L.(ed.). Final report of the safety assessment for avocado oil. JEPT. 1980;4:(4):93-103.
- 32. Elder, R.L.(ed.). Final report on the safety assessment of safflower oil. J Am coll Toxicol. 1985;4:(5):171-197.
- 33. Burnett, CL, Cosmetic Ingredient Review Expert Panel, and Andersen, FA. Final Report of the Cosmetic Ingredient Review Expert Panel. Amended Safety Assessment of Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Oil, Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Alcohol, Coconut Oil Decyl Esters, Decyl Cocoate, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate, Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl Cocoate. Available from CIR. 2008.

- European Medicines Agency (EMEA). Working party on herbal medicinal products. Final position paper on the allergenic potency of herbal medicinal products containing soya or peanut protein. EMEA/HMPWP/37/04. <u>http://www.ema.europa.eu/pdfs/human/hmpc/003704en.pdf</u>. 6-11-2004.
- 35. Pease, R. W. Webster's Medical Desk Dictionary. 1986. Springfield, MA: Merriam-Webster, Inc.
- 36. Budavari, S. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 1989. 10th:Rahway, NJ: Merck and Co.
- 37. Wood, G. E. Aflatoxins in domestic and imported foods and feeds. J Assoc Anal Chem. 1989;72:543-548.
- 38. IARC. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans. 1976. (10):51-72. Lyon, France: IARC.
- IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans. Overall evaluations of carcinogenicity: An updating of IARC Monographs volumes 1 to 42. 1987. (Supplement 7):83-87. Lyon, France: IARC.
- 40. National Archives and Records Administration.Code of Federal Regulations. 4-5-2010. http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200607.
- 41. Andersen, FA. Final Report on the Safety Assessment of Corylus Avellana (Hazel) Seed Oil, Corylus Americana (Hazel) Seed Oil, Corylus Avellana (Hazel) Seed Extract, Corylus Americana (Hazel) Seed Extract, Corylus Rostrata (Hazel) Seed Extract, Corylus Avellana (Hazel) Leaf Extract, Corylus Americana (Hazel) Leaf Extract, and Corylus Rostrata (Hazel) Leaf Extract. *IJT*. 2001;20:(S1):15-20.
- 42. Andersen, FA. Final Report on the Safety Assessment of Corylus Avellana (Hazel) Seed Oil, Corylus Americana (Hazel) Seed Oil, Corylus Avellana (Hazel) Seed Extract, Corylus Americana (Hazel) Seed Extract, Corylus Rostrata (Hazel) Seed Extract, Corylus Avellana (Hazel) Leaf Extract, Corylus Americana (Hazel) Leaf Extract, and Corylus Rostrata (Hazel) Leaf Extract. *IJT*. 2001;20:(S1):15-20.
- 43. Burnett, CL, Cosmetic Ingredient Review Expert Panel, and Andersen, FA. Final Report of the Cosmetic Ingredient Review Expert Panel. Amended Safety Assessment of Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Oil, Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Alcohol, Coconut Oil Decyl Esters, Decyl Cocoate, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate, Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl Cocoate. Available from CIR. 2008.
- Weisshauer R. Fatty acid esters of 3-MCPD: overview of occurences in different types of foods. Chemisches und Veterinaruntersuchungsaut (CUUA). 2009. <u>http://www.ilsi.org/Europe/Documents/E2009MCPD-7.pdf</u>.
- 45. Federal Institute for Risk Assessment. Initial evaluation of the assessment of levels of glycidol fatty acid esters detected in refined vegetable fats--B&R opinion no. 007/2009. 2009. http://www.bfr.bund.de./cm/245/initial_evaluation_of_the_assessment_of glycidol_fatty_acid_esters.pdf. Date Accessed 3-10-2009.
- 46. IARC. Epoxides. 1976. IARC Monographs:(11):125-209.
- 47. IARC. Glycidol. 2000. IARC Monographs:(77):469-486.
- 48. Food and Drug Administration (FDA). Frequency of use of cosmetic ingredients. FDA database. 5-4-2010.
- 49. Personal Care Products Council. Concentration of use Plant Oils. March 2010 Survey. Unpublished data submitted by the Council (27 pp). 5-13-2010.

- 50. Personal Care Products Council. Concentration of use Plant Oils. Updated May 2010 survey. Unpublished data submitted by the Council (10 pp). 7-21-2010.
- 51. Personal Care Products Council. Updated Concentration of Use Plant Oils August 2010 Survey. 11-8-2010. Unpublished data submitted by the Personal Care Products Council on Nov. 8, 2010. (12 pp).
- Andersen, FA. Annual Review of Cosmetic Ingredient Safety Assessments 2001/2002. IJT. 2003;22:(Suppl. 1):1-35.
- 53. Diamante, CD, Andersen, FA, and Cosmetic Ingredient Review Expert Panel. Safety Assessment of Zea Mays (Corn) Oil, et al. 2008.
- 54. Elder, RL. Final Report of the Safety Assessment for Wheat Germ Oil. JEPT. 1980;4:(4):33-45.
- 55. Johnson, WJ, Andersen, FA, and Cosmetic Ingredient Review Expert Panel. Amended Safety Assessment of Sesamum Indicum (Sesame) Seed Oil, Hydrogenated Sesame Seed Oil, Sesamm Indicum (Sesame) Oil Unsaponifiables, and Sodium Sesameseedate. 2009.
- Personal Care Products Council. Concentration of use surveys. 2010. Unpublished data submitted by the Council on May 13 and July 12.
- 57. Personal Care Products Council. Updated concentration of use information plant oils. 1-20-2011. Unpublished data submitted by the Council (16 pp).
- 58. Personal Care Products Council. Updated Concentration of Use Butyrospermum Parkii (Shea) Butter, et al. Unpublished data. 7-26-2010.
- 59. James, A. C., Stahlhofen, W, Rudolf, G, Kobrich, R, Briant, J. K., Egan, M. J., Nixon, W, and Birchall, A. Annexe D. Deposition of inhaled particles. *Annals of the ICRP*. 1994;24:(1-3):231-2.
- 60. Oberdorster, G, Oberdorster, E, and Oberdorster, J. Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles. *Environmental Health Perspectives*. 2005;113:(7):823-839.
- 61. Bower, D. 1999. Unpublished information on hair spray particle sizes provided at the September 9, 1999 CIR Expert Panel meeting.
- 62. Johnson, M. A. The Influence of Particle Size. Spray Technology and Marketing. 2004; November: 24-27.
- European Union. 1976, Council Directive 1976/768/EEC of 27 July 1976 on the Approximation of the Laws of the Member States Relating to Cosmetic Products, as amended through Commission Directive 2008/42/EC. 2008. Internet site accessed March 24, 2010.
- 64. American Soybean Association.Soy Stats 2010 World Vegetable Oil Consumption 2009. 2010. http://www.soystats.com/2010/Default-frames.htm. Accessed 4-14-2010.
- Singh, B, Kale, RK, and Rao, AR. Modulation of antioxidant potential in liver of mice by kernel oil of cashew nut (Anacardium occidentale) and its lack of tumour promoting ability in DMBA induced skin papillomagenesis. *Indian J Exp Biol.* 2004;42:373-377.
- 66. de Groot AC. Adverse Reactions to Cosmetics. Port Washington, NY: Scholium International, Inc, 1988.
- 67. Bush, R. K., Taylor, S. L., Nordlee, J. A., and Busse, W. W. Soybean oil is not allergenic to soybean-sensitive individuals. *J Allergy Clin Immunol*. 1985;76:(2 PART 1):242-245.
- 68. Van Hoed V, De Clercq N, Echim C, Andjelkovic M, Leber E, Dewettinck K, and Verhe R. Berry seeds: A source of specialty oils with high content of bioactives and nutritional value. *J Food Lipids*. 2009;16:33-49.

- 69. John L. Seaton & Co, Ltd. Seatons Baobab Oil data sheet. Unpublished data. 2005. John L. Seaton & Co, Lted.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- John L. Seaton & Co, Ltd. Seatons Refined Baobab Oil specifications. Unpublished data. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 71. Swern, D (ed). Bailey's Industrial Oil and Fat Products. 4th ed. John Wiley & Sons, Inc., 1979.
- 72. Center for New Crops & Plant Products.Aleurites moluccana (L.) Willd. 1997. <u>http://www.hort.purdue.edu/newcrop/duke_energy/Aleurites_moluccana.html</u>. Accessed 5-20-2010.
- 73. John L. Seaton & Co., Ltd. Seatons Kukui Nut Oil. 2006. John L. Seaton & Co. Limited.
- 74. John L. Seaton & Co., Ltd. Seatons Refined Kukui Nut Oil Specification. 2006. John L. Seaton & Co. Limited.
- Ryan, E, Galvin, K, O'Connor, TP, Maguire, AR, and O'Brien, NM. Fatty acid profile, tocopherol, squalene and phytosterol content of brazil, pecan, pine, pistachio and cashew nuts. *Int J Food Sci Nutr*. 2006;57:(3/4):219-228.
- Maguire, LS, O'Sullivan, SM, Galvin, K, O'Connor, TP, and O'Brien, NM. Fatty acid profile, tocopherol, squalene and phytosterol content of walnuts, almonds, peanuts, hazelnuts and the macadamia nut. *Int J Food Sci Nutr*. 2004;55:(3):171-178.
- 77. John L. Seaton & Co., Ltd. Arachis Oil BP/EP Specification. 2010. John L. Seaton & Co. Limited.
- 78. John L. Seaton & Co., Ltd. Seatons Arachis Oil. 2005. John L. Season & Co.Limited.
- 79. Henry Lamotte Oils. Product Specification: Groundnut Oil, Refined. Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 1 page.
- John L. Seaton & Co, Ltd. Seatons Argan Oil data sheet. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- John L. Seaton & Co, Ltd. Seatons Virgin Argan Oil specifications. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 82. Natural Sourcing.Murumuru Butter Specifications. 2008. http://www.naturalsourcing.com/spec/SPEC_Murumuru_Butter.pdf. Accessed 1-27-2010.
- Ozcan MM, Ozkan G, and Topal A. Characteristics of grains and oils of four different oats (Avena sativa L.) cultivars growing in Turkey. Int J Food Sci Nutr. 2006;57:(5/6):345-352.
- 84. Moodley, R, Kindness, A, and Jonnalagadda, SB. Elemental composition and chemical characteristics of five edible nuts (almond, Brazil, pecan, macadamia and walnut) consumed in Southern Africa. *J Environ Sci Health B*. 2007;42:585-591.
- John L. Seaton & Co, Ltd. Seatons Borage Oil data sheet. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- John L. Seaton & Co, Ltd. Seatons Refined Borage Oil specifications. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- Croda, Inc. Specification and composition of Rapeseed Acid, Sunflower Seed Acid, Olive Acid, and Caryocar Brasiliense Fruit Oil. 2010. Unpublished data submitted by the Council on Dec. 9, 2010. (2 pp).
- Kaul VK, Banerjee A, and Nigam SS. Chemical investigation of the seeds of Brassica oleracea Var. Acephala. J Am Oil Chem Soc. 1980;57:(7):199-201.

- 89. Wilshire Technologies.Product Specifications: Broccoli Seed Oil, Pressed, Organic Production. 2009. <u>http://www.wilshiretechnologies.com/master_pdf/Broccoli%20Seed%20Oil,%20Pressed,%20Organic%20</u> <u>Production,%20CAS%20N_A.pdf</u>. Accessed 10-13-2010.
- 90. John L. Seaton & Co., Ltd. Seatons Refined Shea Nut Butter Specification. 2009. John L. Seaton & Co. Limited.
- 91. John L. Seaton & Co., Ltd. Seatons Shea Nut Butter. 2005. John L. Seaton & Co., Limited.
- 92. Henry Lamotte Oils. Product Specification: Shea Butter, Solid. Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 1 page.
- Cognis Care Chemicals. Data profile on Cetiol SB45 (Butyrospermum Parkii (Shea) Butter). Unpublished data.
 2010. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 4 pages.
- John L. Seaton & Co, Ltd. Seatons Camellia Seed Oil data sheet. 2007. John L. Seaton & Co, Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 95. John L. Seaton & Co, Ltd. Seatons Camellia Seed Oil specifications. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 96. Australian Government, Department of Health and Ageing, Therapeutic Goods Administration.CMEC 48 Complementary Medicines Evaluation Committee. Extracted Ratified Minutes of the 48th Meeting. 10-15-2004. <u>http://www.tga.gov.au/docs/pdf/cmec/cmeemi48.pdf</u>. Accessed 10-20-2010.
- 97. Australian Government, Department of Health and Ageing, Therapeutic Goods Administration. Therapeutic Goods Administration Draft Compositional Guideline for Canarium Indicum Oil. 2004.
- John L. Seaton & Co, Ltd. Seatons Papaya Seed Oil data sheet. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 99. John L. Seaton & Co, Ltd. Seatons Refined Papaya Seed Oil specification. 2010. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 100. Mariano RGB, Couri S, and Freitas SP. Enzymatic technology to improve oil extractions from *Caryocar brasiliense* camb. (pequi) pulp. *Rev.Bras.Frutic*. 2009;31:(3):637-643.
- 101. Natural Sourcing.Watermelon Seed Oil Specifications. 2009. http://www.naturalsourcing.com/spec/SPEC Watermelon Seed Oil.pdf.
- 102. John L. Seaton & Co, Ltd. Seatons Lime Seed Oil data sheet. 2007. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 103. John L. Seaton & Co, Ltd. Seatons Refined Lime Seed Oil specifications. 2007. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 104. John L. Seaton & Co, Ltd. Seatons Orange Seed Oil data sheet. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 105. John L. Seaton & Co, Ltd. Seatons Refined Orange Seed Oil specifications. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 106. John L. Seaton & Co, Ltd. Seatons Grapefruit Seed Oil data sheet. 2007. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 107. John L. Seaton & Co, Ltd. Seatons Refined Grapefruit Seed Oil specifications. 2010. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 108. Swern, D (ed). Bailey's Industrial Oil and Fat Products. 4th ed. John Wiley & Sons, Inc., 1979.

- 109. John L. Seaton & Co, Ltd. Seatons Pumpkin Seed Oil data sheet. 2007. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 110. John L. Seaton & Co, Ltd. Seatons Pressed Pumpkin Seed Oil specifications. 2006. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 111. Natural Sourcing.Strawberry Seed Oil Specifications. 2008. http://www.naturalsourcing.com/spec/SPEC_Strawberry_Seed_Oil.pdf. Accessed 1-28-2010.
- 112. Aromtech. Product specification, No. LT04.015.1 SUMMER VITA Strawberry Seed Oil (Fragaria Ananassa Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 113. Panhwar F.Non-traditional oilseeds and oils. 2005. <u>http://www.chemlin.de/publications/documents/non%20traditional%20oilseeds%20and%20oils.pdf</u>. Accessed 10-19-2010.
- 114. Carlisle International Corp. Kokam Butter. 2010. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 2 pages.
- 115. John L. Seaton & Co, Ltd. Seatons Kokum Butter data sheet. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on July 19, 2010. 1 page.
- 116. John L. Seaton & Co., Ltd. Seatons Hazelnut Oil. 2005. John L. Seaton & Co. Limited.
- 117. John L. Seaton & Co., Ltd. Seatons Refined Hazelnut Oil Specification. 2010. John L. Seaton & Co. Limited.
- 118. A.A. Fratellin Parodi s.r.l. Technical data sheet Corylus Avellana (Hazel) Seed Oil. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on November 22, 2010. 1 page.
- Aromtech. Product specification, No. LT04.004.1 SHAJIO Sea Buckthorn Berry Oil (Hippophae Rhammnoides Fruit Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 120. John L. Seaton & Co, Ltd. Seatons Cold Pressed Seabuckthorn Oil specifications. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by ther Personal Care Products Council on July 19, 2010. 1 page.
- 121. John L. Seaton & Co, Ltd. Seatons Seabuckthorn Oil data sheet. 2007. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on July 19, 2010. 1 page.
- 122. Aromtech. Product specification, No. LT04.003.1 SHAJIO Sea Buckthorn Seed Oil (Hippophae Rhammnoides Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 123. Laboratoires Serobiologiques. Fatty acids composition IRVINOL SL 9890: Composition of Irvingia Gabonenesis Kernel Butter. Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on Novmeber 24, 2010. 1 page.
- 124. John L. Seaton & Co., Ltd. Seatons Macadamia Nut Oil. 2005. John L. Seaton & Co. Limited.
- John L. Seaton & Co., Ltd. Seatons Refined Macadamia Nut Oil Specification. 2010. John L. Seaton & Co. Limited.
- 126. Henry Lamotte Oils. Product Specificationi: Macadamia Nut Oil, Refined. Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 2 pages.
- 127. John L. Seaton & Co, Ltd. Seatons Moringa Oil data sheet. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.

- 128. John L. Seaton & Co, Ltd. Seatons Refined Moringa Oil specification. 2006. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- Banerji R, Bajpai A, and Verma SC. Oil and fatty acid diversity in genetically variable clones of Moringa oleifera from India. J Oleo Sci. 2009;58:(1):9-16.
- John L. Seaton & Co, Ltd. Seatons Evening Primrose Oil data sheet. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 131. John L. Seaton & Co, Ltd. Seatons Refined Evening Primose Oil specification. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- Bouaziz M, Fki I, Jemai H, Ayadi M, and Sayadi S. Effect of storage on refined and husk olive oils composition: Stabilization by addition of natural antioxidants from Chemlali olive leaves. *Food Chemistry*. 2008;108:253-262.
- 133. John L. Seaton & Co, Ltd. Seatons Refined Rice Bran Oil specifications. 2009. John L. Seaton & Co, Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 134. John L. Seaton & Co, Ltd. Seatons Rice Bran Oil data sheet. 2005. John L. Seaton & Co, Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- Liu S, Yang F, Li J, Zhang C, Ji H, and Hong P. Physical and chemical analysis of Passiflora seeds and seed oil from China. *Int J Food Sci Nutr.* 2008;59:(7-8):706-715.
- 3QP. INCA Omega Oil Specifications (Plukenetia Volubilis Seed Oil). Unpublished data. 2007. Unpublished data submitted by the Personal Care Products Council on November 3, 2010. 1 page.
- John L. Seaton & Co., Ltd. Seatons Refined Sweet Almond Oil Cosmetic Blend Specification. 2009. John L. Seaton & Co. Limited.
- 138. John L. Seaton & Co., Ltd. Seatons Sweet Almond Oil. 2005. John L. Seaton & Co. Limited.
- Henry Lamotte Oils. Product Specification: Almond Oil, Refined. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 2 pages.
- 140. John L. Seaton & Co, Ltd. Seatons Cherry Kernel Oil data sheet. 2005. John L. Seaton & Co. Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 141. John L. Seaton & Co, Ltd. Seatons Refined Cherry Kernel Oil specifications. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 142. John L. Seaton & Co, Ltd. Seatons Plum Oil data sheet. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 143. John L. Seaton & Co, Ltd. Seatons Virgin Plum Oil specification. 2010. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 144. Physical and Chemical Characteristics of Oils, Fats, and Waxes. 2nd ed. Champaign, IL: AOCS Press, 2006.
- 145. Northstar Lipids.Product Specification. 2010. <u>http://www.northstarlipids.co.uk/files/peach-kernel-oil.pdf</u>. Accessed 1-28-2010.
- John L. Seaton & Co, Ltd. Seatons Cold Pressed Pomegranate Seed Oil specifications. 2009. John L. Seaton & Co., Ltd.
- 147. John L. Seaton & Co, Ltd. Seatons Pomegranante Seed Oil data sheet. 2006. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on July 19, 2010. 1 page.

- 148. Tian HL, Zhan P, and Li KX. Analysis of components and study on antioxidant and antimicrobial activities of oil in apple seeds. *Int J Food Sci Nutr*. 2010;61:(4):395-403.
- 149. John L. Seaton & Co, Ltd. Seatons Blackcurrant Seed Oil specification. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 150. John L. Seaton & Co, Ltd. Seatons Refined Blackcurrant Seed Oil specification. 2010. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 151. Aromtech. Product specification, No. LT04.002.1 EFADUO Blackcurrant Seed Oil (RIbes Nigrum (Black Currant) Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 152. Aromtech. Preliminary product specification, No. LT04.018.1 EFARUBY Redcurrant Seed Oil (Ribes Rubrum (Currant) Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 153. Aromtech. Product specification, No. LT04.006.1 Sun Essence Cloudberry Seed Oil (Rubus Chamaemorus Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 154. John L. Seaton & Co, Ltd. Seatons Red Raspberry Seed Oil data sheet. 2007. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 155. John L. Seaton & Co, Ltd. Seatons Refined Red Raspberry Seed Oil specification. 2006. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 156. Aromtech. Product specification, No. LT04.013.1 RED GAMMA Raspberry Seed Oil (Rubus Idaeus (Raspberry) Seed Oil. Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 157. Juliani HR, Koroch AR, Simon JE, and Wamulwange C.Mungongo cold pressed oil (*Schinziophyton rautanenii*): A new natural product with potential cosmetic applications. 2010. <u>http://www.actahort.org/books/756/756_43.htm</u>. Accessed 12-15-2010.
- 158. Ogbobe O. Physico-chemical composition and characterisation of the seed and seed oil of *Sclerocarya birrea*. *Plant Foods for Human Nutrition*. 1992;42:201-206.
- 159. Cantarelli PR, Regitano-d'Arce MAB, and Palma ER. Physicochemical characteristics and fatty acid composition of tomato seed oils from processing wastes. *Sci.agric.(Piracicaba, Braz.).* 1993;50:(1):117-120.
- John L. Seaton & Co, Ltd. Seatons Blueberry Seed Oil data sheet. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on July 19, 2010. 1 page.
- 161. John L. Seaton & Co, Ltd. Seatons Cold Pressed Blueberry Seed Oil specifications. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on July 19, 2010. 1 page.
- 162. Natural Sourcing.Cranberry Seed Oil Specifications. 2008. http://www.naturalsourcing.com/spec/SPEC_Cranberry_Seed_Oil.pdf. Accessed 1-28-2010.
- 163. John L. Seaton & Co, Ltd. Seatons Cranberry Seed Oil data sheet. 2005. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 164. John L. Seaton & Co, Ltd. Seatons Refined Cranberry Seed Oil specification. 2008. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.

- Aromtech. Product specification, No. LT04.012.1 RED TOCOL Cranberry Seed Oil (Vaccinium Macrocarpon (Cranberry) Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- 166. Aromtech. Product Specification No. LT04.008.1. Blue Tocol Bilberry Seed Oil (Vaccinium Myrtillus Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on October 15, 2010. 1 page.
- Aromtech. Product specification, No. LT04.011.1 RED ALFA Lingonberry Seed Oil (Vaccinium Vitis-Idaea Seed Oil). Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 1 page.
- John L. Seaton & Co, Ltd. Seatons Maize Oil data sheet. 2007. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- John L. Seaton & Co, Ltd. Seatons Refined Maize Oil specifications. 2009. John L. Seaton & Co., Ltd.Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 1 page.
- 170. Aroma Plus, Dr. Hoffmann Ingredients Corp.Amaranth Oil Data Sheet. 2010. http://www.aromaplus.de/1Amaranth%20oil.htm. Accessed 1-25-2010.
- 171. Wang C, Zhang X, Li F, and Cheng C. Analysis of fatty acid in *Arctium lapp L. seed oil by GC MS. J Plant Resources and Environment.* 2002;11:(4):58-59.
- 172. Leonova S, Shelenga T, Hamberg M, Konarev AV, Loskutov I, and Carolsson AS. Analysis of oil composition in cultivars and wild species of oat (*Avena* sp.). *J Agric Food Chem*. 2008;56:7983-7991.
- 173. O'Lenick AJ, Steinberg DC, Klein K, and LaVay C. Oils of Nature. Carol Stream, IL: Allured Publishing Corp., 2008.
- 174. Putnam, DH, Budin, JT, Field, LA, and Breene, WM.Camelina: A promising low-input oilseed. 9-11-1997. http://www.hort.purdue.edu/newcrop/proceedings1993/v2-314.html. Accessed 1-26-2010.
- 175. Personal Care Products Council. Composition of Camellia Seed Oils. Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on October 27, 2010. 1 page.
- Andersen, FA. Annual Review of Cosmetic Ingredient Safety Assessments-2004/2005. *IJT*. 2006;25:(Suppl. 2):1-89.
- 177. Koziol, MJ.Quinoa: A Potential New Oil Crop. 1997. Accessed 1-26-2010.
- 178. Lisa M, Holcapek M, and Bohac M. Statistical evaluation of triacylglycerol composition in plantoils based on highperformance liquid chromatography-atmospheric pressure chemical ionization mass spectrometry data. J Agric Food Chem. 2009;57:6888-6898.
- 179. Waheed A, Mahmud S, Saleem M, and Ahmad T. Fatty acid composition of neutral lipid: Classes of citrus seed oil. J Saudi Chem Soc. 2009;13:269-272.
- Burkill HM.Entry for Coix lacryma-jobi Linn. [family Poaceae]. From, 'The useful plants of west rropical Africa, Vol. 2. 1985. <u>http://plants.jstor.org/upwta/2_430</u>. Accessed 1-13-2011.
- 181. Elementis Specialties. Crambe Abyssinica Seed Oil fatty acid profiles. Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on November 5, 2010. 1 page.
- 182. Natural Sourcing.Cucumber Seed Oil. 2010. http://www.naturalsourcing.com/downloads/NS info cucumberseedoil.pdf. Accessed 1-28-2010.

- BDpedia.Plant Oils Used for Bio-diesel. 2006. <u>http://www.bdpedia.com/biodiesel/plant_oils/plant_oils.html</u>. Accessed 1-25-2010.
- 184. Tan BK and Berger KG. Characteristics of kernel oils from *Elaeis oleifera*, F1 hybrids and back-cross with Elaeis guineensis. *J Sci Food Agric*. 1982;33:204-208.
- 185. Enlightened Products Co.Analytical Study on Life Dynamics Acai Part 1. 2010. <u>http://www.enlightenedproductsco.com/Pages/acai/aslda1.html</u>. Accessed 1-25-2010.
- Laboratoires Serobiologiques. Fatty acid composition of IRWINOL LS 9890 (Irvingia Gabonensis Kernel Butter).
 2010. Unpublished data submitted by the Council on Dec. 7, 2010. (1 p).
- 187. Bertoli C, Fay LB, Stancanelli M, Gumy D, and Lambelet P. Characterization of Chilean hazelnut (*Gevuina avellana* Mol) seed oil. *JAOCS*. 1998;75:(8):1037-1040.
- Kaminskas A, Briedis V, Budrioniene R, Hendrixson V, Petraitis R, and Kucinskiene Z. Fatty acid composition of sea buckthorn (*Hippophae rhamnoides* L.) pulp oil of Lithuanian origin stored at different temperatures. *Biologija*. 2006;2:39-41.
- 189. Center for New Crops & Plant Products.Juglans regia L. 1-7-1998. <u>http://www.hort.purdue.edu/newcrop/duke_energy/Juglans_regia.html</u>. Accessed 5-20-2010.
- 190. Personal Care Products Council. Fatty acid composition on Luffa Cylindrica Seed Oil. 12-7-2010. Unpublished data submitted by the Council on Dec. 7, 2010. (1 p).
- 191. Boschin G, D'Agostina A, Annicchiarico P, and Arnoldi A. The fatty acid composition of the oil from Lupinus albus cv. Luxe as affected by environmental and agricultural factors. *Eur Food Res Technol*. 2007;225:769-776.
- 192. Personal Care Products Council. Composition of Lycium Barbarum Seed Oil. 1-18-2011. Unpublished data submitted by the Council. (1 p).
- 193. West BJ, Jensen CJ, and Westendorf J. A new vegetable oil from noni (*Morinda citrofolia*) seeds. Int J Food Sci Technol. 2008;43:1988-1992.
- 194. Center for New Crops & Plant Products.Moringa oleifera Lam. 1-7-1998. http://www.hort.purdue.edu/newcrop/duke_energy/Moringa_oleifera.html. Accessed 1-25-2010.
- 195. Personal Care Products Council. Composition of Orbignya Speciosa Kernel Oil. 1-10-2011. Unpublished data submitted by the Council. (1 p).
- 196. Cobiosa Industrias Asociads SL. Inform analitico S1026 (Plukenetia Volubilis Seed Oil). Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on November 3, 2010. 1 page.
- 197. Center for New Crops & Plant Products.Prunus dulcis (Mill.) D.A. Webb. 1998. http://www.hort.purdue.edu/newcrop/duke_energy/Prunus_dulcis.html. Accessed 5-20-2010.
- 198. Johansson A, Laine T, Linna MM, and Kallio H. Variability in oil content and fatty acid composition in wild northern currants. *Eur Food Res Technol*. 2000;211:277-283.
- 199. Ozcan M. Nutrient composition of rose (Rosa canina L.) seed and oils. J Med Food. 2002;5:(3):137-140.
- 200. Marula Natural Products.Marula Natural Products: Technical Info Oil. 2010. http://www.marula.org.za/techoil.htm. Accessed 1-26-2010.
- El-Mallah MH, El-Shami M, and Hassanein MM. Detailed stdies on some lipids of *Silybum marianum* (L.) seed oil. *Grasas y Aceites*. 2003;54:(4):397-402.

- 202. Carotech Berhad. Composition of Maxopene 6% (Solanum Lycopersicum (Tomato) Fruit Oil and Elaeis Guineensis (Palm) Oil). Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on November 24, 2010. 1 page.
- 203. Natural Sourcing.Cupuacu Butter. 2009.

http://www.naturalsourcing.com/product.asp?product_id=vegbuttercupuacu&cat=AmazonianOils. Accessed 1-27-2010.

- 204. Takagi T and Itabashi Y. *cis*-5-Olefinic unusual faty acids in seed lipids of gymnospernae and their distribution in triacylglycerols. *Lipids*. 1982;17:(10):716-723.
- 205. Yang B, Koponen J, Tahvonen R, and Kallio H. Plant sterols in seeds of two species of Vaccinium (V. myrtillus and V. vitis-idaea) naturally distributed in Finland. *Eur Food Res Technol*. 2003;216:34-38.
- 206. Center for New Crops & Plant Products.Aleurites moluccana (L.) Willd. 1997. http://www.hort.purdue.edu/newcrop/duke_energy/Aleurites_moluccana.html. Accessed 5-20-2010.
- 207. Center for New Crops & Plant Products.Anacardium occidentale L. 12-22-1997. http://www.hort.purdue.edu/newcrop/duke_energy/Anacardium_occidentale.html. Accessed 5-20-2010.
- 208. Center for New Crops & Plant Products.Arachis hypogaea L. 1997. http://www.hort.purdue.edu/newcrop/duke_energy/Arachis_hypogaea.html. Accessed 5-20-2010.
- 209. Center for New Crops & Plant Products.Cocos nucifera L. 1996. <u>http://www.hort.purdue.edu/newcrop/duke_energy/Cocos_nucifera.html</u>. Accessed 5-20-2010.
- 210. Center for New Crops & Plant Products.Juglans regia L. 1-7-1998. http://www.hort.purdue.edu/newcrop/duke_energy/Juglans_regia.html. Accessed 5-20-2010.
- 211. Center for New Crops & Plant Products.Prunus dulcis (Mill.) D.A. Webb. 1998. http://www.hort.purdue.edu/newcrop/duke_energy/Prunus_dulcis.html. Accessed 5-20-2010.
- 212. MB Research Laboratories. MatTek EpiOcular MTT Viability Assay of Baobab Oil. MB Research Project #: MB 08-17549.19. Unpublished data. 2008. MB Research Laboratories.Unpublished data submitted by the Personal Care Products Council on May 18, 2010. 12 pages.
- 213. Huntingdon Research Centre Ltd. Irritant effects on rabbit skin of Cetiol SB 45 (Butyrospermum Parkii (Shea) Butter). 8552D/AOL 11/SE/2. Unpublished data. 1985. Unpublished data submited by the Personal Care Products Council on August 9, 2010. 6 pages.
- 214. Huntingdon Research Centre Ltd. Delayed contact hypersensitivity in the guinea pig with Cetiol SB 45 (Butyrospermum Parkii (Shea) Butter). 85711D/AOL 12/SS/2. Unpublished data. 1985. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 10 pages.
- 215. Elementis Specialties. Toxicity dossier for Fancor Abyssinian Oil (Crambe Abyssinica Seed Oil). Unpublished data. 2010. Unpublished data submitted by the Personal Care Products Council on November 5, 2010. 2 pages.
- 216. Upadhyay NK, Kumar R, Mandotra SK, Meena RN, Siddiqui MS, Sawhney RC, and Gupta A. Safety and healing efficacy of Sea buckthorn (*Hippophae rhmnoides* L.) seed oil on burn wounds in rats. *Food Chem Toxicol*. 2009;47:1146-1153.
- 217. Grover, R. W. Experimental contact sensitization of guinea pigs to vegetable oils. J Allergy. 1962;33:(5):402-405.
- 218. Elder, RL. Final Report on the Safety Assessment of Sweet Almond Oil and Almond Meal. JACT. 1983;2:(5):85-99.
- IBR Forschungs GmbH. Phototoxicity test with "Cetiol SB 45" (Butyrospermum Parkii (Shea) Butter) in guinea pigs. Project no: 10-05-1511-90. Unpublished data. 1990. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 19 pages.

- 220. Consumer Product Testing Co. Repeated insult patch test of a lip product containing 0.01% Adansonia Digitata Seed Oil. Experiment reference number: C08-1131.02. Unpublished data. 4-29-2008. Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 13 pages.
- 221. BioScreen Testing Services, Inc. Human subject repeat insult patch test skin irritation/sensitization evaluation of Phytoterra Organic Baobab Oil. SCS Study No.: 08-042. 2009. BioScreen Testing Services, Inc.Unpublished data submitted by the Personal Care Products Council on May 18, 2010. 10 pages.
- 222. Clinical Research Laboratories, Inc. Repeated insult patch test of product 8454 SA (scalp conditioner containing 0.1595% Olea Europea (Olive) Fruit Oil, 0.005% Prunus Armeniaca (Apricot) Kernel Oil, 0.005% Simmondsia Chinensis (Jojoba) Seed Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, 0.005% Aleurites Moluccana Seed Oil, 0.15% Cocos Nucifera (Coconut) Oil and 0.005% Triticum Vulgare (Wheat) Germ Oil). 12-5-2005. Unpublished data submitted by the Council on Aug 11, 2010. 15 pages.
- Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a skin cleanser containing 2.9944% Aleurites Moluccana Seed Oil on skin. 4-9-2007. Unpublished data submitted by the Council on Dec. 9, 2010. 11 pages.
- 224. Yunginger, JW and Calobrisi, SD. Investigation of the allergenicity of a refined peanut oil-containing topical dermatologic agent in persons who are sensitive to peanuts. *Cutis*. 2001;68:(2):153-155.
- 225. Institut D'Expertise Clinique. Sensitisation and cutaneous compatibility study of a face serum containing 25% Sesamum Indicum (Sesame) Seed Oil, 20% Helianthus Annuus (Sunflower) Seed Oil, 19.749% Prunus Armeniaca (Apricot) Kernel Oil, 15% Simmondsia Chinensis (Jojoba) Seed Oil, 10% Prunus Amygdalus Dulcis (Sweet Almond) Oil, 5% Argania Spinosa Kernel Oil and 2% Borago Officinalis Seed Oil. Report N°B072004RD1 Version 1. 2010. Unpublished data submitted by the Council on August 11, 2010. 60 pages.
- 226. TKL Research. Repeated insult patch test study of formula no. 685392 5 (skin salve containing 10% Prunus Amygdalus Dulcis (Sweet Almond) Oil, 10% Persea Gratissima (Avocado) Oil, 10% Olea Europaea (Olive) Fruit Oil, 8% Sesamum Indicum (Sesame) Seed Oil and 10% Argania Spinosa Kernel Oil). Study No. DT024310. 10-1-2007. Unpublished data submitted by the Council on Aug 11, 2010. 48 pages.
- 227. Harrison Research Laboratories, Inc. Use test under the supervision of a dermatologist of formula no. 685392 5 (skin salve containing 10% Prunus Amygdalus Dulcis (Sweet Almond) Oil, 10% Persea Gratissima (Avocado) Oil, 10% Olea Europaea (Olive) Fruit Oil, 8% Sesamum Indicum (Sesame) Seed Oil and 10% Argania Spinosa Kernel Oil). Study no. DT02417. 8-16-2007. Unpublished data submitted by the Council on Aug 11, 2010. 28 pages.
- 228. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of lipstick (containing 1% Astrocaryum Murumuru Seed Butter) on human skin. Unpublished data. 9-30-2002. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council. 11 pages.
- 229. Clinical Research Laboratories, Inc. Repeated insult patch test on a lipstick formulation containing 4% Astrocaryum Murumura Seed Butter. CRL study no.: CRL69608-4. Unpublished data. 8-1-2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 230. Clinical Research Laboratories, Inc. Repeated insult patch test on a lipstick formulation containing 4% Astrocaryum Murumura Seed Butter. CRL study no.: CRL69608-5. Unpublished data. 8-1-2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 231. Clinical Research Laboratories, Inc. Repeated insult patch test on a lipstick formulation containing 4% Astrocaryum Murumura Seed Butter. CRL study no.: CRL69608-6. Unpublished data. 8-1-2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 232. Clinical Research Laboratories, Inc. Repeated insult patch test on a lipstick formulation containing 4% Astrocaryum Murumura Seed Butter. CRL study no.: CRL109108-1. Unpublished data. 11-11-2008.

- 233. Clinical Research Laboratories, Inc. Repeated insult patch test on a lipstick formulation containing 4% Astrocaryum Murumura Seed Butter. CRL study no.: CRL109108-2. Unpublished data. 8-1-2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 234. Clinical Research Laboratories, Inc. Repeated insult patch test on a lipstick formulation containing 4% Astrocaryum Murumura Seed Butter. CRL study no.: CRL114608-6. Unpublished data. 11-21-2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 235. RCTS, Inc. Clinical safety evaluation. Human repeated insult patch test with a body and hand formulation containing 3% Avena Sativa (Oat) Kernel Oil. RCTS study no.: 1712 &1714. Unpublished data. 9-8-2004. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 10 pages.
- 236. Clinical Research Laboratories, Inc. Repeated insult patch test on pre-tan scrub containing 2% Bassia Latifolia Seed Butter. CRL Study No. CRL 123305-2. 1-20-2006. Unpublished data sumbitted by the Personal Care Products Council on October 20, 2010. (13 pp).
- 237. TKL Research. Repeated insult patch test on a body and hand formulation containing 1% Borago Officinalis Seed Oil. TKL study o.: DS103107/103507. 6-22-2007. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 30 pages.
- 238. Consumer Product Testing Co. Repeated insult patch test of a baby oil containing 5% hydrogenated rapeseed oil. Unpublished data. 1999. Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 13 pages.
- Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a hair conditioner (containing 0.5% Brassica Oleracea Italica (Broccoli) Seed Oil) on human skin. Unpublished data. 11-11-2008. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 1, 2010. 12 pages.
- 240. Loden, M and Andersson, AC. Effect of topically applied lipids on surfactant-irritated skin. *Br J Dermatol.* 1996;134:215-220.
- 241. Institut D'Expertise Clinique. Sensitisation and cutaneous compatibility study of product 408991 02 (scalp conditioner containing 0.1% Butyrospermum Parkii (Shea) Butter, 0.7% Olea Europaea (Olive) Fruit Oil, 0.1% Ribes Nigrum (Black Currant) Oil and 0.2% Persea Gratissima (Avocado) Oil). Report No. B050427RD9. 6-23-2005. Unpublished data submitted by the Council on Aug 11, 2010. 48 pages.
- 242. Institut D'Expertise Clinique. Sensitisation and cutaneous compatibility study of product 609464 18 (cream for very dry skin containing 2% Butyrospennum Parkii (Shea) Butter, 2.5% Prunus Armeniaca (Apricot) Kernel Oil and 0.25% Ribes Nigrum (Black Currant) Oil). Report No. B041713RD6. 4-12-2005. Unpublished data submitted by the Council on Aug 11, 2010. 48 pages.
- 243. EVIC Romania. Human repeat insult patch test with challenge for Formula No. 695315 1 (face cream containing 4% Butyrospermum Parkii (Shea) Butter and 2% Prunus Armeniaca (Apricot) Kernel Oil). DT037120. Unpublished data. 2010.
- 244. EVIC Romania. Human repeat insult patch test with challenge for Formula No. 695069 12 (eye cream containing 2% Prunus Armeniaca (Apricot) Kernel Oil and 4% Butryospermum Parkii (Shea) Butter. DT035575. Unpublished data. 2010.
- 245. Product Investigations, Inc. Human repeat insult patch test formula no. 838003 (lip gloss containing 23.08089% Butyrospermum Parkii (Shea) Butter). Study no. PIIS08002. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 19 pages.
- 246. TKL Reseach. Human repeat insult patch test on formula no. 838002 (lip gloss containing 23.7057% Butyrospermum Parkii (Shea) Butter. TKL study report no. DS103608-4. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 43 pages.

- 247. TKL Reseach. Human repeat insult patch test on formulat no. 754842 (lip wax containing 24.08768% Butyrospermum Parkii (Shea) Butter). TKL study report no. DS108007-9. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 42 pages.
- 248. EPISKIN-SNC. Cytotoxicity study on reconstructed human epidermis formula 754842 (lip wax containing 24.08768% Butyrospermum Parkii (Shea) Butter. Study no. 07-EPITOL-323. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 11 pages.
- 249. Groupe Dermscan. Use test under the supervision of a dermatologist of formula #755195 (lip gloss containing 24.73792% Butyrospermum Parkii (Shea) Butter). Study no. 08E5382. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 36 pages.
- 250. Clinical Research Laboratories, Inc. Repeated insult patch test on a body and hand product containing 45% Butyrospermum Parkii (Shea) Butter. CRL study number CRL106504-1. Unpublished data. 2004. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 13 pages.
- 251. Clinical Research Laboratories, Inc. Repeated insult patch test on a body and hand product containing 45% Butyrospermum Parkii (Shea) Butter. CRL study number CRL106504-2. Unpublished data. 2004. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 13 pages.
- 252. Clinical Research Laboratories, Inc. Repeated insult patch test on a body and hand product containing 45% Butyrospermum Parkii (Shea) Butter. CRL study number CRL106504-3. Unpublished data. 2004. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 13 pages.
- 253. Clinical Research Laboratories, Inc. Repeated insult patch test on a body and hand product containing 45% Butyrospermum Parkii (Shea) Butter. CRL study number CRL106504-4. Unpublished data. 2004. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 13 pages.
- 254. Clinical Research Laboratories, Inc. Two week "dermatologist tested" safety in-use study of a body and hand product containing 45% Butyrospermum Parkii (Shea) Butter. Clinical study number CRL106604. Unpublished data. 2004. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 11 pages.
- 255. Clinical Research Laboratories, Inc. Repeated insult patch test of a cuticle softener containing 60% Butyrospermum Parkii (Shea) Butter. Clinical study number CRL29904. Unpublished data. 2004. Unpublished data submitted by the Personal Care Products Council on August 19, 2010. 14 pages.
- 256. Harrison Research Laboratories, Inc. Final report repeated insult patch test of a body powder containing 0.2499% Camelina Sativa Seed Oil. Report 00-125. Unpublished data. 2000. Harrison Research Laboratories, Inc.Unpublished data submitted by the Personal Care Products Council on August 11, 2010. 14 pages.
- 257. TKL Research. Human repeat insult patch test with challenge of formula no. 1082018 B (oil treatment containing 7% Prunus Amygdalus Dulcis (Sweet Almond) Oil and 7% Camelina Sativa Seed Oil). TKL Study Report No. DS108609-2. Unpublished data. 2009.
- 258. Consumer Product Testing Co. Repeated insult patch test on a lipstick containing 0.0985% Camellia Sinensis Seed Oil. Ref. No.: C08-5394.07. 2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 259. Consumer Product Testing Co. Repeated insult parch test of a lipstick containing 0.0985% Camellia Sinensis Seed OII. Ref. No. C08-5394.08. 2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 260. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a body oil (containing 74.7% Canola Oil) on human skin. Unpublished data. 2005. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 13 pages.
- 261. TKL Research. Repeated insult patch test of formula no. 999105 2 (cleansing oil rinse-off containing 20% Zea Mays (Corn) Germ Oil, 5% Carthamus Tinctorius (Safflower) Seed Oil, 1% Simmondsia Chinensis (Jojoba) Seed

Oil, 0.5% Macadamia Ternifolia Seed Oil, and 0.01% Moringa Oleifera Seed Oil). TKL Study Report No. DT036977. Unpublished data. 2010.

- 262. Institut D'Expertise Clinque. Sensitisation and cutaneous compatibility study of a massage oil containing 39.8% Helianthus Annuus (Sunflower) Seed Oil, 30% Carthamus Tinctorius (Safflower) Seed Oil, 15% Prunus Amygdalus Dulcis (Sweet Almond) Oil, 10% Simmondsia Chinensis (Jojoba) Seed Oil, and 5% Corylus Avellana (Hazel) Seed Oil. Report no. B080442RD6. Unpublished data. 2008.
- 263. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a lipstick (containing 0.1% Caryocar Brasilienses Fruit Oil) on human skin. Unpublished data. 2009. Products Investigations, Inc.Unpublished data submitted by the Personl Care Products Council on June 1, 2010. 12 pages.
- 264. I S Consultancy Limited. Human repeat insult patch test of a UV SPF cream containing 1% Chemopodium Quinoa Seed Oil. Report no. 06601 final. Unpublished data. 2003. I S Consultancy Limited.Unpublished data submitted by the Personal Care Products Council on August 11, 2010. 24 pages.
- 265. I S Consultancy Limited. Human repeat insult patch test of a UV SPF cream containing 1% Chenopodium Quinoa Seed Oil. Report no. 06427 final. Unpublished data. 2002. I S Consultancy Limited.Unpublished data submitted by the Personal Care Products Council on August 11, 2010. 30 pages.
- 266. Clinical Research Laboratories, Inc. Repeated insult patch test of a facial oil containing 2% Citrullus Lanatus (Watermelono) Seed Oil. Unpublished data. 2009. Clinical Research Laboratories, Inc.
- 267. Harrison Research Laboratories, Inc. Final report repeated insult patch test of product 674976 1 (lip balm containing 31% Cocos Nucifera (Coconut) Oil, 25% Prunus Amygdalus Dulcis (Sweet Almond) Oil, 24% Prunus Persica (Peach) Kernel Oil, and 3.6% Hydrogenated Cottonseed Oil). HRL Panel #07-127. Unpublished data. 2007.
- 268. Biobasic Europe. Summary: Evaluation of the irritation potential of cosmetic formula (moisturizing cream containing 1% Corylus Avellana (Hazel) Seed Oil) by the amended Draize patch test. Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 22, 2010. 1 page.
- 269. Biobasic Europe. Summary: Evaluation of the anti-wrinkle potential of a cosmetic formula (moisturizing cream containing 1% Corylus Avellana (Hazel) Seed Oil) through a 60 day clinical study. Unpublished data. 2009. Unpublished data submitted by the Personal Care Products Council on November 22, 2010. 1 page.
- 270. Personal Care Products Council. Summaries of HRIPT studies of a product containing Crambe Abysinnica Seed Oil and a product containing Macadamia Ternifolia Seed Oil. Unpublished data. 2010.
- 271. EVIC France. Checking in human of the acceptability of a cosmetic product after application under normal conditions of use subjective assessment of its cosmetic acceptability (soap containing 6 1.6% Sodium Palmate, 15.7% Sodium Palm Kernelate and 1% Helianthus Annuus (Sunflower) Seed Oil). Study reference: DT034521. 12-17-2009. Unpublished data submitted by the Council on Aug 11, 2010. 36 pages.
- 272. Product Investigations, Inc. Determination of the irritating and senstizing propensities of an eye treatment (containing 0.5% Euterpe Oleracea Fruit Oil) on human skin. Unpublished data. 2007. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 1, 2010. 12 pages.
- 273. Personal Care Products Council. Summaries of HRIPT studies of products containing plant oils. Unpublished data.
 6-1-2010. Unpublished data submitted by the Personal Care Products Council. 2 pages.
- 274. Clinical Research Laboratories, Inc. Repeated insult patch test on a lipstick containing 39% Hydrogenated Soybean Oil and 12% Hydrogenated Olive Oil. CRL study no.: CRL128208-13. Unpublished data. 12-24-2008. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 275. TKL Reseach. Repeated insult patch test on a body and hand product containing 0.3869% Garcinia Indica Seed Butter. TKL Study No. DS101005-14. 3-23-2005. Unpublished data submitted by the Personal Care Products Council on October 20, 2010. (19 pp).
- 276. Institut D'Expertise Clinique. Sensitisation and cutaneous compatibility study of product 781528 19 (skin cream containing 6% Helianthus Annuus (Sunflower) Seed Oil, 0.39% Rosa Canina Fruit Oil and 0.2% Ribes Nigrum (Black Currant) Oil). Report No. B100171RD5. 5-14-2010. Unpublished data submitted by the Council on Aug 11, 2010. 62 pages.
- 277. EVIC Portgual. Human repeat insult patch test with challenge of formula 591559 20A (face cream for dry skin containing 3% Butyrospermum Parkii (Shea) Butter, 1% Prunus Armeniaca (Apricot) Kernel Oil and 0.264% Helianthus Annuus (Sunflower) Seed Oil). Study reference DT020375. 11-21-2006. Unpublished data submitted by the Council on Aug 11, 2010. 22 pages.
- 278. Aromtech. Evaluation of the cutaneous tolerance of a cosmetic product (Hippophae Rhammnoides Seed Oil) after a single application under occlusive patch during 48 hours. 12-28-2005. Unpublished data submitted by the Council on Nov. 24, 2010. (13 pp).
- 279. Clinical Research Laboratories, Inc. Repeated insult patch test of a facial repair product containing 71.3% Limnanthes Alba (Meadowfoam) Seed Oil. Unpublished data. 2005. Clinical Research Laboratories, Inc.Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 14 pages.
- 280. Consumer Product Testing Co. Repeated insult patch test on a mascara containing Linum Usitatissiumum (Linseed) Seed Oil at 9.4%. Experiment reference number: C08-3409.02. Unpublished data. 9-10-2008. Unpublished data submitted by the Personal Care Products Council. 13 pages.
- 281. Consumer Product Testing Co. Repeated insult patch test of a body wash containing 0.01% Luffa Cylindrica Seed Oil. Experiment Ref. No. C05-0189.03. 2005. Unpublished data submitted by the Personal Care Products Council on October 20, 2010. (13 pp).
- 282. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of lipstick (containing 2% Mangifera Indica (Mango) Seed Oil) on human skin. Unpublished data. 2003. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 13 pages.
- 283. Consumer Product Testing Co. Repeated insult patch test protocol of an eyeliner containing 3.87% Mangifera Indica (Mango) Seed Oil. Unpublished data. 2004. Consumer Product Testing Co.Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 13 pages.
- 284. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a facial lotion containing 1% Mangifera Indica (Mango) Seed Butter on human skin. Unpublished data. 2009. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 1, 2010. 12 pages.
- 285. TKL Research. Repeated insult patch test of a body product containing 9% Mangifera Indican (Mango) Seed Butter. Unpublished data. 2001. Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 18 pages.
- 286. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of an eye treatment containing 3% Moringa Pterygosperm Seed Oil on human skin. Unpublished data. 2007. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 1, 2010. 12 pages.
- 287. Orentreich Research Corporation. Predictive patch test study of a foundation containing 1.99% Oenothera Biennis (Evening Primrose) Oil. Unpublished data. 2007. Unpublished data submitted by the Personal Care Products Council. 27 pages.
- 288. Institut D'Expertise Clinque. Sensitisation and cutaneous compatibility study of a body lotion containing 1.6% Olea Europaea (Olive) Fruit Oil. Report no. B041222RD2. Unpublished data. 2004.
- 289. Clinical Research Laboratories, Inc. Repeated insult patch test on a body moisturizer containing 22% Olea Europaea (Olive) Fruit Oil. Unpublished data. 2007. Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 13 pages.

- 290. Consumer Product Testing Co. Repeated insult patch test on a conditioning hair oil containing 58.70% Olea Europaea (Olive) Fruit Oil. Unpublished data. 2003. Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 13 pages.
- 291. Product Investigations, Inc. Human repeat insult patch test summary formula No. 852069 (foundation containing 69.6% Olea Europaea (Olive) Fruit Oil). Report no. 25675. Unpublished data. 2009. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on August 11, 2010. 20 pages.
- 292. Product Investigations, Inc. Determination of the irritating and sensitizing propensities on human skin for a frgranced body mist containing 2.5% Olea Europaea (Olive) Oil Unsaponifiables. Unpublished data. 2007. Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 12 pages.
- 293. Clinical Research Laboratories, Inc. Repeated insult patch test of a body bar soap containing 17.64% sodium olivate. Unpublished data. 2008. Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 13 pages.
- 294. Consumer Product Testing Co. Repeated insult patch test of a cream cleanser containing 3.79% Orbignya Oleifera Seed Oil. Unpublished data. 2006. Consumer Product Testing Co.Unpublished data submitted by the Personal Care Products Council on June 1, 2010. 13 pages.
- 295. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a hair conditioner (containing 0.4125% Orbingnya Speciosa Kernel Oil) on human skin. 2007.
- 296. Consumer Product Testing Co. Repeated insult patch test of a lipstick containing 0.509847% Plukentia Volubilis Seed Oil. Experiment reference number: C08-5394.06. Unpublished data. 2008. Consumer Product Testing Co.
- 297. Clinical Research Laboratories, Inc. Repeated insult patch test of a facial oil containing 30.9938% Prunus Amygdalus Dulcis (Sweet Almond) Oil. 3-8-2006. Unpublished data submitted by the Council on Dec 9, 2010. 12 pages.
- 298. Consumer Product Testing Co. Repeated insult patch test of a facial oil containing 45.2% Prunus Amygdalus Dulcis (Sweet Almond) Oil. 2007.
- 299. International Research SErvices, Inc. A study to assess the skin sensitization potential of cuticle softener (containing 46% Prunus Amygdalus Dulcis (Sweet Almond) Oil) when applied to the skin of 100 heatly human subjects in a shared panel assay. 7-9-2003. Unpublished data submitted by the Personal Care Products Council on October 20, 2010. (11 pp).
- 300. TKL Research. Repeated insult patch test of a preshave lotion containing 39% Vitis Vinifera (Grape) Seed Oil and 0.04% Prunus Domestica Seed Oil. TKL Study No: DS109206-3. Unpublished data. 2-15-2007. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 17 pages.
- TKL Reseach. HRIPT of an eye mask containing 0.2% Ribes Nigrum (Black Currant) Seed Oil. RIPT 07-7331-036. Unpublished data (summary). 2007.
- 302. Q Research. 4-week use study of an eye mask containing 0.2% Ribes Nigrum (Black Currant) Seed Oil. Use 07-7331-056. Unpublished data (summary). 2007. Unpublished data submitted by the Personal Care Products Council on May 27, 2010. 1 page.
- 303. Eurofins. Assessment of skin tolerance of a cosmetic product after single application under occlusive dressing for 48 hours: Patch test method SUN ESSENCE Cloudberry Seed Oil (Rubus Chamaemorus Seed Oil). Unpublished data. 2007. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 15 pages.
- 304. Consumer Product Testing Co. Repeated insult patch test of a cream cleanser containing 0.0023% Solanum Lycopersicum (Tomato) Seed Oil. Unpublished data. 2006. Consumer Product Testing, Co.Unpublished data submitted by the Personal Care Products Council on June 1, 2010. 13 pages.

- 305. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a lip balm (containing 50.1% Theobroma Cacao (Cocoa) Seed Butter) on human skin. Unpublished data. 2006. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 1, 2010. 13 pages.
- 306. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a facial oil containing 0.998% Vaccinium Myrtillus Seed Oil on human skin. 6-1-2009. Unpublished data submitted by the Council on Dec 9, 2010. 11 pages.
- 307. Product Investigations, Inc. Determination of the irritating and sensitizing propensities of a lip balm (containing 5% Theobroma Grandiflorum Seed Butter) on human skin. Unpublished data. 2008. Product Investigations, Inc.Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 12 pages.
- 308. Eurofins. Evaluation of the cutaneous tolerance of a cosmetic product after a single application under occlusive patch during 48 hours RED ALFA Lingonberry Seed Oil (Vaccinium Vitis-Idaea Seed Oil). Unpublished data. 2005. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 14 pages.
- 309. Clinical Research Laboratories, Inc. Repeated insult patch test of a foundation containing 4% Vegetable Oil. Unpublished data. 2005. Clinical Research Laboratories, Inc.Unpublished data submitted by the Personal Care Products Council on June 2, 2010. 14 pages.
- Consumer Product Testing Co. Exclusive repeated insult patchtest on a lipstick containing 4% vegetable oil. Ref. No. C07-0193.12. Unpublished data. 2007. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 311. Clinical Research Laboratories, Inc. Repeated insult patch test of an eye shadow containing 11% vegetable oil. CRL study number: CRL14606-4. Unpublished data. 3-30-2006. Unpublished data submitted by the Personal Care Products Council on June 30, 2010. 13 pages.
- 312. Clinical Research Laboratories, Inc. Repeated insult patch test of product 1061119 (fragranced oil containing 90% Vitis Vinifera (Grape) Seed Oil). Study No. CRL65209. 11-3-2009. Unpublished data submitted by the Council on August 11, 2010. 13 pages.
- 313. Clinical Research Laboratories, Inc. Repeated insult patch test of a lip product containing 0.5% hydrogenated grapeseed oil. CRL study number: CRL88908-5. Unpublished data. 9-8-2008. Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 10 pages.
- 314. Ivy Labs (KGL). Comedogenicity study of an eye mak containing 0.2% Ribes Nigrum (Black Currant) Seed Oil. Comedo 07-7331-039. Unpublished data (summary). 2007. Unpublished data submitted by the Personal Care Products Council on May 27, 2010. 1 page.
- 315. Said, T., Dutot, M., Christon, R., Beaudeux, J. L., Martin, C., Warnet, J.-M., and Rat, P. Benefits and side effects of different vegetable oil vectors on apoptosis, oxidative stress, and P2X7 cell death receptor activation. *Invest Ophthalmol Vis.Sci.* 2007;48:5000-5006.
- 316. Said, T., Dutot, M., Labbe, A., Warnet, J.-M., and Rat, P. Ocular burn: Rinsing and healing with ionic marine solutions and vegetable oils. *Ophthalmologica*. 2009;223:52-59.
- 317. Henkel KgaA. Cetiol SB 45/Sheabutter acute eye irritation report. File no. TBD900604. Unpublished data. 1990. Unpublished data submitted by the Personal Care Products Council on August 9, 2010. 11 pages.
- Eurofins. Ocular irritation potential of Fragaria Ananassa (Strawberry) Seed Oil Neutral Red release test. 12-16-2005. Unpublished data submitted by the Council on Nov. 24, 2010. (1 p).
- Eurofins. Ocular irritation potential of Hippophae Rhammnoides Seed Oil Neutral red release test. 12-16-2005. Unpublished data submitted by the Council on Nov. 24, 2010. (1 p).

- 320. Cell Toxicology Laboratory. Assessment of the eye irritaing potential of a cosmetic product through alternative methods to the Draize test. Report reference: CTOX/08059. Unpublished data. 9-11-2008. Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 26 pages.
- 321. CPTC. Hen's egg tst chorioallantoic membrane (HET-CAM) of a 50% dilution of an eye mask containing 0.2% Ribes Nigrum (Black Currant) Seed Oil. HET-CAM 07-7331-038. Unpublished data (summary). 2007. Unpublished data submitted by the Personal Care Products Council on May 27, 2010. 1 page.
- 322. Eurofins. Evaluation of the ocular irritation potential of the product by direct application on monolayers of rabbit cornea fibroblasts: Neutral red release method SUN ESSENCE Cloudberry Seed Oil (Rubus Chamaemorus Seed Oil). Unpublished data. 2007. Unpublished data submitted by the Personal Care Products Council on November 18, 2010. 9 pages.
- 323. Eurofins. Ocular irritation potential of Vaccinium Vitus-Idaea Seed Oil Neutral Red release assay. 12-16-2005. Unpublished data submitted by the Council on Nov. 24, 2010. (1 p).
- 324. Clinical Research Laboratories, Inc. An in-use safety evaluation to determine the ocular irriation potential of a cosmetic product. CRL study number: CRL 135208. Unpublished data. 1-12-2009. Unpublished data submitted by the Personal Care Products Council on May 17, 2010. 9 pages.
- 325. IRSI. 4-week use study of an eye mask containing 0.2% Ribes Nigrum (Black Currant) Seed Oil. Ophth 07-7331-050. Unpublished data (summary). 2007. Unpublished data submitted by the Personal Care Products Council on May 27, 2010. 1 page.
- 326. Brown, AC, Koett, J, Johnson, DW, Semaskvich, NM, Holck, P, Lally, D, Cruz, L, Young, R, Higa, B, and Lo, S. Effectiveness of kukui nut oil as a topical treatment for psoriasis. *Int J Toxicol*. 2005;44:684-687.
- 327. Hirao, A, Oiso, N, Matsuda, H, Kawara, S., and Kawada, A. Occupational allergic contact dermatitis due to cashew nut oil. *Contact Dermatitis*. 2008;59:131-132.
- 328. Kanny, G., Fremont, S., Nicolas, J. P., and Moneret-Vautrin, D. A. Food allergy to sunflower oil in a patient sensitized to mugwort pollen. *Allergy*. 1994;49:561-564.
- 329. Sugiura, K and Sugiura, M. Di-isostearyl malate and macademia nut oil in lipstick caused cheilitis. *J Eur Acad Dermatol Venereol.* 2009;23:(5):606-607.
- van Joost T., Smitt, J. H., and van Ketel, W. G. Sensitization to olive oil (olea europeae). Contact Dermatitis. 1981;7:(6):309-310.
- 331. de Boer, E. M. and van Ketel, W. G. Contact allergy to an olive oil containing ointment. *Contact Dermatitis*. 1984;11:(2):128-129.
- 332. Jung, H. D. and Holzegel, K. [Contact allergy to olive oil]. Derm Beruf. Umwelt. 1987;35:(4):131-133.
- 333. Malmkvist Padoan S., Pettersson, A., and Svensson, A. Olive oil as a cause of contact allergy in patients with venous eczema, and occupationally. *Contact Dermatitis*. 1990;23:(2):73-76.
- 334. Isaksson, M. and Bruze, M. Occupational allergic contact dermatitis from olive oil in a masseur. *J Am Acad Dermatol.* 1999;41:(2 Pt 2):312-315.
- Wong, G. A. and King, C. M. Occupational allergic contact dermatitis from olive oil in pizza making. *Contact Dermatitis*. 2004;50:(2):102-103.
- Williams, J. D. and Tate, B. J. Occupational allergic contact dermatitis from olive oil. *Contact Dermatitis*. 2006;55:(4):251-252.
- Beukers, S. M., Rustemeyer, T., and Bruynzeel, D. P. Cheilitis due to olive oil. *Contact Dermatitis*. 2008;59:(4):253-255.

- 338. Kranke, B., Komericki, P., and Aberer, W. Olive oil--contact sensitizer or irritant? *Contact Dermatitis*. 1997;36:(1):5-10.
- 339. de Groot, A. C., van der Meeren, H. L., and Weyland, J. W. Contact allergy to avocado oil in a sunscreen. *Contact Dermatitis*. 1987;16:(2):108-109.
- 340. Oiso, N., Yamadori, Y., Higashimori, N., Kawara, S., and Kawada, A. Allergic contact dermatitis caused by sesame oil in a topical Chinese medicine, shi-un-ko. *Contact Dermatitis*. 2008;58:(2):109.



TO: F. Alan Andersen, Ph.D. Director - COSMETIC INGREDIENT REVIEW (CIR)

- **FROM:** John Bailey, Ph.D. Industry Liaison to the CIR Expert Panel
- **DATE:** January 20, 2011
- SUBJECT: Comments on the Tentative Report on Plant-Derived Fatty Acid Oils as Used in Cosmetics
- General comment Somewhere in this report it would be helpful to state that the crude plant oils may contain many additional components depending on the species from which the ingredient is derived.
- p.1 It would be helpful if the Introduction would mention why it is appropriate to include the unsaponifiables in this report. Unsaponifiables are not mixtures of triglycerides containing fatty acids and fatty acid derivatives.
- p.1 The introduction indicates that Orbignya oleifera and Orbignya speciosa are two names for the same species. Composition information is included in the tentative report for O. oleifera, which should also cover the name O. speciosa. Therefore O. speciosa needs to be removed from the list of insufficient data ingredients. In addition, a memo providing composition information on O. speciosa (from a supplier selling the oil under the O. speciosa name) was provided to CIR on January 10, 2011.
- p.1-2 As there are many references available on oils and how composition affects physical/chemical properties, it would be helpful to note that more in depth discussions are available elsewhere and provide a few example references.
- p.5 As some of the oils in this report are not edible, please remove the word "edible" from the Non-Cosmetic Use section. It would be helpful if the regulatory status of Rapeseed Oil/Canola Oil found in the Code of Federal Regulations were added to this report. 21 CFR 184.1555 (http://www.accessdata.fda. govlscriptslcdrhlcfdocslcfcfrlCFRSearch.cfrn) limits the erucic acid content in low erucic acid rapeseed oil used in food to 2%. The Federal Register also states that low erucic acid rapeseed oil is not to be used in infant formula.
- p.5 In the Animal Toxicology section, it would also be helpful to note that for those oils that are edible, exposure to the oil from food use would result in a much larger systemic dose than the systemic dose resulting from use in cosmetic products.
- p.7 Please include the concentrations tested in the Mucosal Irritation section.
- p.7, 8 Please revised the following sentence. "Individuals who have food allergies to a plant protein rarely elicit allergic reactions when exposed to refined oils of the same plant." The subject of

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this sentence is "Individuals", they may exhibit an allergic reaction, but they do not cause (elicit) the allergic reaction.

- p.8 In the Summary, it would be helpful to give the range of concentrations of the oils tested for irritation and sensitization.
- p.8 In the Summary, please provide the concentration of Corylus Avellana (Hazel) Seed Oil that was tested for comedogenicity.
- p.8 In the Summary, please provide what type of findings were reported in the case studies.
- p.9 It would be helpful if it was stated earlier in the report the reason why the CIR Expert Panel is concerned about arachidonic acid (other than it has an CIR insufficient data conclusion). Arachidonic acid is used as a model for dermal inflammation. Direct application of arachidonic acid to the ears of mice results in inflammation. It should also be noted that the arachidonic acid in the plant oils is primarily part of triglycerides, not free arachidonic acid. It is free arachidonic acid that results in a dermal inflammatory response.
- p.9 Publically available fatty acid composition data has been identified for the following ingredients in the list of insufficient data ingredients. This information needs to be added to the report and the Discussion and Conclusion need to be changed to reflect the information about these ingredients. Orbignya Speciosa Kernel Oil should be considered safe for use as it an alternate name for Orbignya Oleifera Seed Oil.

Actium Lappa Seed Oil

Wang C, Zhang X, Li F. 2002. Analysis of fatty acid in Arctium lappa L. seed oil by GC-MS. Journal of Plant Resources and Environment 11(4): 58-59. [Chinese language]

See attached for the English abstract and a translation of the fatty acid composition table.

Citrus Paradisi (Grapefruit) Seed Oil

- Waheed A, Mahmud S, Saleem M, Ahmad T. 2009. Fatty acid composition of neutral lipid: Classes of Citrus seed oil. Journal of Saudi Chemical Society 13: 269-272.
- See attached paper

Coix Lacryma-Jobi (Job's Tears) Seed Oil

http://plants.jstor.org/upwta/2_430 gives the following information for the fatty acid composition of this oil "The seed-oil is recorded as a mixture of: oleic acid, 53%; linoleic acid, 30.5%; palmitic acid, 16.0% and traces of stearic and linolenic acids." cited to Busson 1965.

Several other websites including this one

http://database.prota.org/PROTAhtml/Coix%20lacryma-jobi_En.htm indicates that Busson 1965 is the following French language book

Busson, F. 1965. Plantes alimentaires de l'Ouest Africain: Etude botanique, biologique et chimique. Marseille: Ministere de la Cooperation.

According to the National Agricultural Library website, this book is available at their facility.

Lycium Barbarum Seed Oil

See memo provided to CIR on January 18, 2011 for fatty acid composition information

Morinda Citrifolia Seed Oil

West BJ, Jenson, CJ, Westerndorf, J. 2008. A new vegetable oil from noni (Morinda citrifolia) seeds. International Journal of Food Science and Technology 43(11): 1988-1992.

Abstract

The nutritional quality and safety of oil extracted from noni (Morinda citrifolia) seeds was evaluated to determine its potential as a useful vegetable oil. The average oil content of noni seeds was found to be 124.9 g/kg. The mean linoleic acid content of crude noni seed oil was 59.4%. The average β -sitosterol, campesterol, stigmasterol, and α -tocopherol contents of noni seed oil were 4310, 2195, 2020, and 382 mg/kg, respectively. No evidence of acute oral toxicity was observed for noni seed or the oil at 5 g/kg b.w. and 10 mL/kg b.w., respectively. Noni seed oil was not gentoxic in the *Salmonella typhimurium* reverse mutation assay or the in vitro mammalian chromosomal aberration assay. These results indicate that noni seeds may be a useful new source of vegetable oil.

Chunhieng T, Hay L, Montet. 2005. Detailed study of the juice composition of noni (*Morinda citrifolia*) fruits from Cambodia. Fruits 60(1): 13-24.

Abstract

Introduction. Noni (Morinda citrifolia) has a long history related to medical uses in Southeast Asian countries. Today, noni grows in the majority of the southern Pacific areas, in India, the Caribbean, South America and the West Indies. One of the challenges of recent years was to process Morinda citrifolia fruit juice, to make a more modern drug from a traditional product. In order to obtain better understanding of the medicinal characteristics of the noni fruit cultivated in Cambodia, the biochemical and mineral compositions of the raw juice extracted from M. citrifolia fruits were determined. Materials and methods. Whole fresh fruits of M. citrifolia which came to France from Cambodia were preserved at -20 °C during the duration of the experimentation. Commercial Tahitian noni juice was bought pasteurized to be used as a reference. The extraction was carried out on two batches of Cambodian fruits using a hydraulic press. Contents in oil, fatty acids, proteins, amino-acids, sugars and minerals of juices were analyzed. Results. Composition of noni juice of different origin was determined, compared, and discussed in relation to the biochemical and mineral composition of other vegetable oils. Conclusion. The biochemical composition of the noni juice, which showed a high content of antioxidant molecules, is not sufficient to explain the famous medicinal effects of noni juice. Certain molecules, in particular alkaloids, still have to be studied.

Schinziophyton Rautanenii Kernel Oil

This article (the abstract at http://www.actahort.org/books/756/756 43.htm) addresses the composition of this oil

ISHS Acta Horticulturae 756: International Symposium on Medicinal and Nutraceutical Plants

MUNGONGO COLD PRESSED OIL (SCHINZIOPHYTON RAUTANENII): A NEW NATURAL PRODUCT WITH POTENTIAL COSMETIC APPLICATIONS Authors: H.R. Juliani, A.R. Koroch, J.E. Simon, C. Wamulwange Keywords: manketi, fatty acid, seed oil, chemical composition, quality control Abstract

Mungongo tree (Schinziophyton rautanenii, Euphorbiaceae) occurs naturally in Southern and Western Zambia, where it is locally known as mungongo and is called manketi in Angola, Namibia, Botswana, western Zimbabwe and northern Mozambique. Mungongo is a deciduous short-boled tree reaching 15 m in height. The edible oil which is extracted from mungongo seeds is used locally in cooking, food preparation and personal care products. The seed oil has applications in modern cosmetics and personal care products due to its healing and nurturing properties, such as a body rub during dry winter months or as a skin cleanser and moisturizer. The objective of this paper was to study the chemistry and quality of mungongo seed oil from Zambia, and explore potential new uses and applications of this 'new oil' for the cosmetic industry. The edible oil is expressed by cold pressure from seeds. According to the extraction method and efficiency of unit employed, yields of 28% of oil (traditional hand press) to 38% of oil (hydraulic press) can be achieved. Mungongo seed oils from Zambian samples showed a light yellow oil, with the refractive index of 1.4830, acid values 1.6%, the peroxide value 10 (mg/kg), and the solidification point of -7°C, suggesting that this oil is rich in unsaturated fatty acids. Mungongo seed oil composition showed that these oils were rich in elaeostearic acid (18:3) (25%), linoleic acid (18:2) (37%), oleic acid (18:1) (15%), palmitic and stearic acid (18:0) (8-9%, respectively). In Zambia alone, the estimated production of about 3000 MT of seed would yield around 840 MT of oil. This would represent a modest product supply for a niche oil product and simultaneously have a high impact for the local and regional communities. As the land where the Mungongo trees are indigenous is not suitable for agricultural exploitation and all the nuts are collected from the wild, the development of additional uses and external markets for this under-recognized oilseed could benefit the rural communities and provide a new export product from Africa and a new ingredient for the global cosmetic industry.

p.9 - Citrus Grandis (Grapefruit) Seed Oil is missing from the list of safe ingredients in the conclusion. p.10 - Please change Elaeis (Palm) Oil to Elaeis (Palm) Fruit Oil.

p.10, 53 - Please correct the spelling of "Genuina" to "Gevuina".

p.10, 15, 56, 72, 74 - Please correct the spelling of "Europea" (in olive fruit oil) to "Europaea".

p.11 - In the list of insufficient data ingredients, it would also be helpful to indicate (*) those ingredients not reported to be used.

- p.21, Table 3 To be consistent with the rest of the entries in this table, Hazel Seed Oil should be listed under Corylus.
- p.25, Table 4 Where is the footnote that goes with a in the title?
- p.25-37, Table 4 The presentation in the "Others" row when additional identity information is not know is not consistent.
- p.34, Table 4 It would be helpful to have more detailed information on the fatty acid composition of Prunus Armeniaca (Apricot) Kernel Oil in this report. This information may be in the following references.

Abd El-Aal MH, Khalil MKM, Rahma EH. 1986. Apricot kernel oil: Characterization, chemical composition and utilization in some baked products. Food Chemistry 19(4): 287-298.

Abstract

Apricot kernel oil was extracted, characterized and evaluated for use in preparing biscuits and cake. The hexane-extracted oil fraction has a light yellow colour and is free from toxic material (hydrocyanic acid). The major fatty acids were oleic, linoleic and palmitic. Chloroform-methanol extracts consisted mainly of neutral lipids in which triglycerides were predominant components. The triglycerides consisted of six types of glycerides. Glycolipids and phospholipids were the minor fractions of the total lipids and their major constituents were acylsterylglycosides (62.3%) and phosphatidyl choline (72.2%), respectively.

Evaluation of the crude apricot kernel oil added to different types of biscuits and cake revealed that it has excellent properties and is comparable with corn oil at the same level. It did not affect the flavour, colour and texture of these products.

Jamieson GS, Mckinney RS. 1933. California apricot oil. Journal of the American Oil Chemists' Society. 10(8): 147-149.

Abstract

The characteristics and the percentages of the fatty acids present in apricot kernel oil as glycerides have been determined. The oil studied was found to contain about 90.6 per cent of unsaturated acids consisting of a mixture of oleic and linoleic acids. The saturated acids amounted to about 3.6 per cent and were composed almost entirely of palmitic and stearic acids.

Mention is made of the utilization of the press cake for the recovery of volatile oil, for fertilizer, and as a feed for livestock. An analysis of the press cake is given. A table of the smoking points for various fats and oils by the J. M. McCoy procedure is given for comparison with that of apricot kernel oil.

In addition to the established use of the oil by cosmetic manufacturers, other possible outlets include its use as a salad and cooking oil, for the roasting of shelled nuts, and for the manufacture of soap. p.38-48, Table 5a - Please add "of ingredients not previously reviewed by CIR" to the title of this table. p.40, Table 5a - Based on the Agricultural Research Database at

<u>http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl?</u> it is likely that *Citrullus lanatus* and *Citrullus vulgaris* are two names for the same plant. Rather than a separate column for *C. vulgaris*, please footnote *C. lanatus* and indicate that one use of *C. vulgaris* was reported in the VCRP.

- p.54, Table 6 As this is not a comprehensive listing of non-cosmetic uses of the plant oils, please change the title to "Examples of non-cosmetic uses of oils. Why is only Anacardium Occidentale (Cashew) Seed Oil listed as a folk remedy? Borago Officinalis Seed Oil is listed in the first edition of the PDR for herbal medicine, so it could also be considered a "folk medicine" (or dietary supplement). What is meant by "pharmaceutical"? If this means use as an inactive in drugs, the FDA database of inactive drug ingredients (at http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm) lists the following plant oil ingredients (found by searching the database for oil): almond oil, canola oil, corn oil, cottonseed oil, hydrogenated cottonseed oil, hydrogenated palm oil, soybean oil, hydrogenated soybean oil, olive oil, palm kernel oil, peanut oil, safflower oil, sesame oil, vegetable oil and hydrogenated vegetable oil.
- p.55, Table 7. p.71, Table 9 To be consistent with the other entries, please use the INCI name for baobab oil. Why is some information from old CIR report in italics, but other information from old CIR reports not in italics?
- p.58-70, Table 8, p.71-73, Table 9 The titles of these tables need to be changed to indicate that they also includes *in vitro* studies.
- p.63, Table 8 Under Hydrogenated Cottonseed Oil, what is meant by "mildly low"?
- p.66, Table 8 Please modify this table to indicate that *Orbignya oleifera* and *Orbignya speciosa* are two names for the same species.
- p.68, Table 8 There are two bolded headings for Ribes Nigrum (Black Currant) Seed Oil.
- p.73, Table 9 Under Linum Usitatissimum (Linseed) Seed Oil, please correct "w-wk stud;".



TO: F. Alan Andersen, Ph.D. Director - COSMETIC INGREDIENT REVIEW (CIR)

- FROM: John Bailey, Ph.D. J. Surgert Panel
- **DATE:** January 10, 2011

SUBJECT: Composition of Orbignya Speciosa Kernel Oil

A supplier reports the following fatty acid composition for Orbignya Speciosa Kernel Oil

C 8:0 Caprylic: 2 - 10% C10:0 Capric: 2 - 12% C12:0 Lauric: 35 - 50% C14:0 Myristic: 12 - 25% C16:0 Palmitic: 4 - 15% C18:0 Stearic: 1 - 7% C18:1 Oleic: 5-20% C18:2 Linoleic: < 3%



TO: F. Alan Andersen, Ph.D. Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: John Bailey, Ph.D. Industry Liaison to the CIR Expert Panel

DATE: January 18, 2011

SUBJECT: Composition of Lycium Barbarum Seed Oil

A website concerning the benefits of *Lycium barbarum* (<u>http://www.goji.co.za/n_seedoil.html</u>) provides the following fatty acid composition for this oil.

| Fatty Acid | Content (%) |
|------------------|-------------|
| Palm Acid | 7.2 |
| Stearic Acid | 3 |
| Oleic Acid | 19.1 |
| Linoleic | 68.3 |
| Linolenic | 2.8 |
| Arachidonic Acid | 0.68 |

Composition of this oil may also be found in a recent <u>Food Science and Technology Article</u>, which can be purchased from Science Direct (found by searching Google for fatty acid composition of Lycium Barbarum seed oil).

Supercritical CO2 cell breaking extraction of Lycium barbarum seed oil and determination of its chemical composition by HPLC/APCI/MS and antioxidant activity

Li Guolianga, b, Shi Junyoua, b, 1, Suo Youruia, Sun Zhiweia, b, Xia Liana, b, Zheng Jiea, b, You Jinmaoa and Liu Yongjuna, ,

a Northwest Plateau Institute of Biology, Chinese Academy of Sciences, Xining 810001, PR China b Graduate School of the Chinese Academy of Sciences, Beijing 100039, PR China Received 27 September 2009; revised 8 October 2010; accepted 13 October 2010. Available online 26 October 2010.

Abstract

The extraction parameters for oil extraction from Lycium barbarum seed including extraction pressure, temperature and time were optimized using an orthogonal test design. The optimum conditions for supercritical CO2 extraction were as follows: extraction pressure, 30 MPa; extraction temperature, 45 °C; dynamic extraction time, 60 min; CO2 flow, 25 kg/h. The oil yield under the conditions proposed was 19.28 g/100 g. The effect of cell wall breakage pretreatment was investigated by supercritical CO2 rapid depressurization, and results indicated this pretreatment could result in a rapid and efficient extraction. A sensitive fluorescent reagent 2-(11H-benzo[a]carbazol-11-yl) ethyl 4-methylbenzenesulfonate (BCETS) was utilized as pre-column labeling regent to determine fatty acids (FA) from Lycium barbarum seed oils obtained by different extraction methods. The main FA were: C18:2, C18:1, C16, C20:6, C18:3, and C20. The oil from L. barbarum seed exhibited excellent antioxidant activity in 2,2-diphenyl-1-picrylhydrazyl(DPPH)radical scavenging assay and β-carotene bleaching test, and its antioxidant activity compared well with the references ascorbic acid and a-tocopherol.



TO: F. Alan Andersen, Ph.D. Director - COSMETIC INGREDIENT REVIEW (CIR)

- **FROM:** John Bailey, Ph.D. Industry Liaison to the CIR Expert Panel
- **DATE:** January 20, 2011

SUBJECT: Updated Concentration of Use Information Plant Oils

The uses of Citrus Grandis (Grapefruit) Seed Oil have been removed as the companies reporting use of this ingredient are actually using an essential oil made from the peel.

Concentration of Use Minor Plant Seed Oils Mach 2010 Survey

Actinidia Chinensis (Kiwi) Seed Oil, Adansonia Digitata Oil, Adansonia Digitata Seed Oil, Hydrogenated Adansonia Digitata Seed Oil, Amaranthus Hypochondriacus Seed Oil, Arctium Lappa Seed Oil, Argania Spinosa Kernel Oil, Hydrogenated Argania Spinosa Kernel Oil, Astrocarym Murumuru Seed Butter, Sodium Astrocaryum Murumuruate, Avena Sativa (Oat) Kernel Oil, Borago Officinalis Seed Oil, Brassica Oleracea Italica (Broccoli) Seed Oil, Camelina Sativa Seed Oil, Hydrogenated Camelina Sativa Seed Oil, Camellia Oleifera Seed Oil, Hydrogenated Camellia Oleifera Seed Oil, Camellia Sinensis Seed Oil, Carica Papaya Seed Oil, Caryocar Brasiliense Fruit Oil, Chenopodium Quinoa Seed Oil, Citrullus Lanatus (Watermelon) Seed Oil, Citrus Aurantifolia (Lime) Seed Oil, Hydrogenated Lime Seed Oil, Hydrogenated Lime Seed Oil Unsaponifiables, Citrus Aurantium Dulcis (Orange) Seed Oil, Citrus Aurantium Dulcis (Orange) Seed Oil Unsaponifiables, Hydrogenated Orange Seed Oil, Hydrogenated Orange Seed Oil Unsaponifiables, Citrus Grandis (Grapefruit) Seed Oil, Citrus Grandis (Grapefruit) Seed Oil Unsaponifiables, Citrus Paradisi (Grapefruit) Seed Oil, Hydrogenated Grapefruit Seed Oil, Hydrogenated Grapefruit Seed Oil Unsaponifiables, Citrus Limon (Lemon) Seed Oil, Coix Lacryma-Jobi (Job's Tears) Seed Oil, Cucumis Sativus (Cucumber) Seed Oil, Cucurbita Pepo (Pumpkin) Seed Oil, Hydrogenated Pumpkin Seed Oil, Cynara Cardunculus Seed Oil, Euterpe Oleracea Fruit Oil, Fragaria Ananassa (Strawberry) Seed Oil, Fragaria Chiloensis (Strawberry) Seed Oil, Fragaria Vesca (Strawberry) Seed Oil, Fragaria Virginiana (Strawberry) Seed Oil, Guizotia Abyssinica Seed Oil, Irvingia Gabonensis Kernel Butter, Limnanthes Alba (Meadowfoam) Seed Oil, Hydrogenated Meadowfoam Seed Oil, Linum Usitatissimum (Linseed) Oil, Linseed Acid, Mangifera Indica (Mango) Seed Oil, Mangifera Indica (Mango) Seed Butter, Sodium Mangoseedate, Moringa Oleifera Seed Oil, Moringa Pterygosperma Seed Oil, Oenothera Biennis (Evening Primrose) Oil, Hydrogenated Evening Primrose Oil, Orbignya Oleifera Seed Oil, Babassu Acid, Potassium Babassuate, Sodium Babassuate, Perilla Ocymoides Seed Oil, Prunus Armeniaca (Apricot) Kernel Oil, Hydrogenated Apricot Kernel Oil, Hydrogenated Apricot Kernel Oil Unsaponifiables, Prunus Armeniaca (Apricot) Kernel Oil Unsaponifiables, Prunus Avium (Sweet Cherry) Seed Oil, Prunus Domestica Seed Oil, Prunus Persica (Peach) Kernel Oil, Hydrogenated Peach Kernel Oil, Pyrus Malus (Apple) Seed Oil, Ribes Nigrum (Black Currant) Seed Oil, Hydrogenated Black Currant Seed Oil, Ribes Rubrum (Currant) Seed Oil, Rubus Idaeus (Raspberry) Seed Oil, Hydrogenated Raspberry Seed Oil, Sclerocarya Birrea Seed Oil, Silybum Marianum Seed Oil, Solanum Lycopersicum (Tomato) Seed Oil, Solanum Lycopersicum (Tomato) Fruit Oil, Theobroma Cacao (Cocoa) Seed Butter, Sodium Cocoa Butterate, Theobroma Grandiflorum Seed Butter, Sodium Theobromoa Grandiflorum Seedate, Torreya Nucifera Seed Oil, Vaccinum Macrocarpon (Cranberry) Seed Oil, Hydrogenated Cranberry Seed Oil, Vitis Vinifera (Grape) Seed Oil, Sodium Grapeseedate, Hydrogenated Grapeseed Oil*

| Ingredient | Product Category | Concentration of Use |
|-------------------------------------|---|----------------------|
| Actinidia Chinensis (Kiwi) Seed Oil | Hair conditioners | 0.1% |
| Actinidia Chinensis (Kiwi) Seed Oil | Shampoos (noncoloring) | 0.1% |
| Adansonia Digitata Oil | Lipstick | 0.01% |
| Argania Spinosa Kernel Oil | Bath oils, tablets, and salts | 0.05% |
| Argania Spinosa Kernel Oil | Eyebrow pencil | 0.1% |
| Argania Spinosa Kernel Oil | Eyeliner | 0.1% |
| Argania Spinosa Kernel Oil | Eye shadow | 0.2% |
| Argania Spinosa Kernel Oil | Eye lotion | 1% |
| Argania Spinosa Kernel Oil | Mascara | 0.1% |
| Argania Spinosa Kernel Oil | Hair conditioners | 1% |
| Argania Spinosa Kernel Oil | Hair sprays (aerosol fixatives) | 0.01% |
| Argania Spinosa Kernel Oil | Shampoos (noncoloring) | 0.1% |
| Argania Spinosa Kernel Oil | Hair dyes and colors (all types requiring caution statement and patch test) | 0.1% |

| Argania Spinosa Kernel Oil | Other hair coloring preparations | 0.07% |
|----------------------------------|---|------------|
| Argania Spinosa Kernel Oil | Blushers (all types) | 0.1% |
| Argania Spinosa Kernel Oil | Lipstick | 0.1-1% |
| Argania Spinosa Kernel Oil | Nail polish and enamel | 0.001-0.1% |
| Argania Spinosa Kernel Oil | Bath soaps and detergents | 0.001-2% |
| Argania Spinosa Kernel Oil | Deodorants (underarm) | 0.001% |
| Argania Spinosa Kernel Oil | Other personal cleanliness products | 0.5% |
| Argania Spinosa Kernel Oil | Aftershave lotions | 0.005% |
| Argania Spinosa Kernel Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.002% |
| Argania Spinosa Kernel Oil | Face and neck creams, lotions, and powders | 0.5-3% |
| Argania Spinosa Kernel Oil | Body and hand creams, lotions, and powders | 4-10% |
| Argania Spinosa Kernel Oil | Moisturizing creams, lotions and powders | 0.04% |
| Argania Spinosa Kernel Oil | Night creams, lotions and powders | 0.04-0.1% |
| Argania Spinosa Kernel Oil | Other skin care preparations | 2-3% |
| Astrocaryum Murumuru Seed Butter | Eyeliner | 0.06% |
| Astrocaryum Murumuru Seed Butter | Eye shadow | 0.2% |
| Astrocaryum Murumuru Seed Butter | Eye lotion | 0.5% |
| Astrocaryum Murumuru Seed Butter | Hair conditioners | 0.001-0.2% |
| Astrocaryum Murumuru Seed Butter | Shampoos (noncoloring) | 0.09% |
| Astrocaryum Murumuru Seed Butter | Tonics, dressings, and other hair grooming aids | 0.2% |
| Astrocaryum Murumuru Seed Butter | Foundations | 1% |
| Astrocaryum Murumuru Seed Butter | Lipstick | 1-7% |
| Astrocaryum Murumuru Seed Butter | Other makeup preparations | 0.001% |
| Astrocaryum Murumuru Seed Butter | Face and neck creams, lotions, and powders | 1% |
| Astrocaryum Murumuru Seed Butter | Body and hand creams, lotions, and powders | 0.1-0.2% |
| Astrocaryum Murumuru Seed Butter | Other skin care preparations | 0.2% |
| Astrocaryum Murumuru Seed Butter | Indoor tanning preparations | 0.1% |
| Astrocaryum Murumuru Seed Butter | Other suntan preparations | 0.2% |
| Sodium Astrocaryum Murumuruate | Bath soaps and detergents | 0.002% |
| Sodium Astrocaryum Murumuruate | Other shaving preparations products | 0.005% |
| Sodium Astrocarvum Murumuruate | | 0.0007 |

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| Avena Sative (Oat) Kernel Oil | Baby lotions, oils, powders and creams | 0.1% | |
|--|---|------------|------|
| Avena Sative (Oat) Kernel Oil | Other baby products | 0.1% | |
| Avena Sative (Oat) Kernel Oil | Eye lotion | 0.2% | |
| Avena Sative (Oat) Kernel Oil | Shampoos (noncoloring) | 0.1% | |
| Avena Sative (Oat) Kernel Oil | Lipstick | 2% | ļ |
| Avena Sative (Oat) Kernel Oil | Bath soaps and detergents | 0.01-0.1% | |
| Avena Sative (Oat) Kernel Oil | Face and neck creams, lotions, and powders | 0.5% | |
| Avena Sative (Oat) Kernel Oil | Body and hand crams, lotions, and powders | 0.1-3% | |
| Avena Sative (Oat) Kernel Oil | Moisturizing creams, lotions and powders | 0.1% | |
| Avena Sative (Oat) Kernel Oil | Night creams, lotions and powders | 0.1-0.5% | |
| Borago Officinalis Seed Oil | Eye lotion | 0.001-0.5% | |
| Borago Officinalis Seed Oil | Tonics, dressings and other hair grooming aids | 0.1% | |
| Borago Officinalis Seed Oil | Lipstick | 0.01% | |
| Borago Officinalis Seed Oil | Bath soaps and detergents | 0.001% | |
| Borago Officinalis Seed Oil | Other personal cleanliness products | 0.01% | 23. |
| Borago Officinalis Seed Oil | Preshave lotions (all types) | 0.04% | 1.14 |
| Borago Officinalis Seed Oil | Shaving cream (aerosol, brushless, and lather) | 0.5% | · |
| Borago Officinalis Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.1% | |
| Borago Officinalis Seed Oil | Face and neck creams, lotions and powders | 1% | |
| Borago Officinalis Seed Oil | Body and hand crams, lotions, and powders | 0.05-1% | |
| Borago Officinalis Seed Oil | Body and hand sprays | 0.1% |] |
| Borago Officinalis Seed Oil | Moisturizing creams, lotions and powders | 1% |] |
| Borago Officinalis Seed Oil | Night creams, lotions and powders | 0.5% |] |
| Borago Officinalis Seed Oil | Other skin care preparations | 0.5% |] |
| Borago Officinalis Seed Oil | Indoor tanning preparations | 0.5% |] |
| Brassica Oleracea Italica (Broccoli) Seed Oil | Hair conditioners | 0.5% | |
| Brassica Oleracea Italica (Broccoli) Seed Oil | Shampoos (noncoloring) | 0.001% | |
| Brassica Oleracea Italica (Broccoli) Seed Oil | Tonics, dressings, and other hair grooming aids | 3% | |
| Camelina Sativa Seed Oil | Eye lotion | 0.05% | |
| Camelina Sativa Seed Oil | Hair conditioners | 1% | 1 |

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| Camelina Sativa Seed Oil | Lipstick | 0.05-0.5% |
|---|---|-----------|
| Camelina Sativa Seed Oil | Skin Cleansing (cold creams, cleansing lotions, liquids and pads) | 0.002% |
| Camelina Sativa Seed Oil | Face and neck creams, lotions, and powders | 0.05-1% |
| Camelina Sativa Seed Oil | Body and hand crams, lotions, and powders | 0.1-0.9% |
| Camelina Sativa Seed Oil | Moisturizing creams, lotions and powders | 0.04% |
| Camelina Sativa Seed Oil | Night creams, lotions and powders | 0.04% |
| Camellia Oleifera Seed Oil | Bath oils, tablets, and salts | 0.05% |
| Camellia Oleifera Seed Oil | Eye lotions | 2% |
| Camellia Oleifera Seed Oil | Tonics, dressings, and other hair grooming aids | 2% |
| Camellia Oleifera Seed Oil | Blushers (all types) | 1% |
| Camellia Oleifera Seed Oil | Lipstick | 3% |
| Camellia Oleifera Seed Oil | Bath soaps and detergents | 0.01-0.1% |
| Camellia Oleifera Seed Oil | Skin Cleansing (cold creams, cleansing lotions, liquids and pads) | 0.003% |
| Camellia Oleifera Seed Oil | Body and hand crams, lotions, and powders | 0.01-1% |
| Camellia Oleifera Seed Oil | Moisturizing creams, lotions and powders | 0.08% |
| Camellia Oleifera Seed Oil | Night creams, lotions and powders | 0.08% |
| Camellia Oleifera Seed Oil | Other suntan preparations | 0.01% |
| Camellia Sinensis Seed Oil | Shampoos (noncoloring) | 0.1% |
| Camellia Sinensis Seed Oil | Lipstick | 0.1% |
| Camellia Sinensis Seed Oil | Bath soaps and detergents | 0.1% |
| Camellia Sinensis Seed Oil | Deodorants (underarm) | 0.1% |
| Camellia Sinensis Seed Oil | Body and hand crams, lotions, and powders | 0.1% |
| Camellia Sinensis Seed Oil | Moisturizing creams, lotions and powders | 0.1% |
| Camellia Sinensis Seed Oil | Night creams, lotions and powders | 0.1% |
| Carica Papaya Seed Oil | Moisturizing creams, lotions and powders | 0.1% |
| Carica Papaya Seed Oil | Night creams, lotions and powders | 0.1% |
| Caryocar Brasilinese Fruit Oil | Lipstick | 0.2% |
| Caryocar Brasilinese Fruit Oil | Skin Cleansing (cold creams, cleansing lotions, liquids and pads) | 0.0005% |
| Chenopodium Quinoa Seed Oil | Hair rinses (coloring) | 0.3% |
| Citrullus Lanatus (Watermelon) Seed Oil | Face and neck creams, lotions, and powders | 2% |

| Cucurbita Pepo (Pumpkin) Seed Oil | Eye lotion | 0.003% |
|---------------------------------------|---|------------|
| Cucurbita Pepo (Pumpkin) Seed Oil | Moisturizing creams, lotions and powders | 0.1% |
| Cucurbita Pepo (Pumpkin) Seed Oil | Night creams, lotions and powders | 0.1% |
| Euterpe Oleracea Fruit Oil | Bath oils, tablets, and salts | 0.05% |
| Euterpe Oleracea Fruit Oil | Eye lotion | 0.5% |
| Euterpe Oleracea Fruit Oil | Lipstick | 0.002% |
| Euterpe Oleracea Fruit Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.00001% |
| Euterpe Oleracea Fruit Oil | Other suntan preparations | 0.001% |
| Irvingia Gabonensis Kernel Butter | Lipstick | 0.003-0.3% |
| Irvingia Gabonensis Kernel Butter | Face and neck creams, lotions, and powders | 0.2-0.4% |
| Irvingia Gabonensis Kernel Butter | Body and hand creams, lotions, and powders | 0.03% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Bath oils, tablets, and salts | 0.9% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Bubble baths | 0.5% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Eyeliner | 6-20% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Eye lotion | 0.1-0.4% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Other fragrance preparations | 3% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Hair conditioners | 0.1-1% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Tonics, dressings, and other hair grooming aids | 0.5% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Hair dyes and colors (all types requiring caution statement and patch test) | 0.2-2% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Foundations | 0.01-5% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Lipstick | 0.6-26% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Cuticle softeners | 0.5% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Bath soaps and detergents | 0.01% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Other personal cleanliness products | 0.6% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Shaving cream (aerosol, brushless, and lather) | 0.05% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.002% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Depilatories | 2% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Face and neck creams, lotions, and powders | 0.08-72% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Body and hand creams, lotions, and powders | 0.005-27% |
| Limnanthes Alba (Meadowfoam) Seed Oil | Body and hand sprays | 0.1% |

| Limnanthes Alba (Meadowfoam) Seed Oil | Moisturizing creams, lotions and powders | 0.04- 74% | |
|--|---|-------------|------------|
| Limnanthes Alba (Meadowfoam) Seed Oil | Night creams, lotions and powders | 0.04-3% | |
| Limnanthes Alba (Meadowfoam) Seed Oil | Other skin care preparations | 0.1-1% | |
| Linum Usitatissimum (Linseed) Seed Oil | Bath oils, tablets, and salts | 0.02% | |
| Linum Usitatissimum (Linseed) Seed Oil | Bubble baths | 0.2% | |
| Linum Usitatissimum (Linseed) Seed Oil | Eye lotion | 0.01% | |
| Linum Usitatissimum (Linseed) Seed Oil | Mascara | 10% | |
| Linum Usitatissimum (Linseed) Seed Oil | Hair conditioners | 0.001-0.01% | |
| Linum Usitatissimum (Linseed) Seed Oil | Shampoos (noncoloring) | 0.001-0.1% | |
| Linum Usitatissimum (Linseed) Seed Oil | Tonics, dressings, and other hair | 0.01% | |
| Linum Usitatissimum (Linseed) Seed Oil | Lipstick | 0.01% | |
| Linum Usitatissimum (Linseed) Seed Oil | Cuticle softeners | 0.05% | |
| Linum Usitatissimum (Linseed) Seed Oil | Nail polish and enamel | 0.002% | |
| Linum Usitatissimum (Linseed) Seed Oil | Bath soaps and detergents | 0.003-0.4% | 8 C. A |
| Linum Usitatissimum (Linseed) Seed Oil | Deodorants (underarm) | 0.05-0.1% | in de mare |
| Linum Usitatissimum (Linseed) Seed Oil | Aftershave lotions | 4% | |
| Linum Usitatissimum (Linseed) Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.01-1% | |
| Linum Usitatissimum (Linseed) Seed Oil | Face and neck creams, lotions, and powders | 0.01-0.5% | |
| Linum Usitatissimum (Linseed) Seed Oil | Body and hand creams, lotions, and powders | 0.1-0.2% | |
| Linum Usitatissimum (Linseed) Seed Oil | Moisturizing creams, lotions and powders | 0.01-0.1% | |
| Linum Usitatissimum (Linseed) Seed Oil | Night creams, lotions and powders | 0.1% | |
| Mangifera Indica (Mango) Seed Oil | Eyeliner | 5% | 000 |
| Mangifera Indica (Mango) Seed Oil | Hair conditioners | 0.2% | |
| Mangifera Indica (Mango) Seed Oil | Hair straighteners | 0.05% | |
| Mangifera Indica (Mango) Seed Oil | Shampoos (noncoloring) | 0.1% | |
| Mangifera Indica (Mango) Seed Oil | Tonics, dressings, and other hair grooming aids | 0.01% | |
| Mangifera Indica (Mango) Seed Oil | Hair dyes and colors (all types requiring caution statement and patch test) | 0.05% | |
| Mangifera Indica (Mango) Seed Oil | Lipstick | 0.03-6% | |
| Mangifera Indica (Mango) Seed Oil | Bath soaps and detergents | 0.1% | |
| Mangifera Indica (Mango) Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.003-0.5% | |

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| Mangifera Indica (Mango) Seed Oil | Face and neck creams, lotions, and powders | 0.2-3% |
| Mangifera Indica (Mango) Seed Oil | Body and hand creams, lotions, and powders | 0.1-0.9% |
| Mangifera Indica (Mango) Seed Oil | Moisturizing creams, lotions and powders | 0.08% |
| Mangifera Indica (Mango) Seed Oil | Night creams, lotions and powders | 0.08% |
| Mangifera Indica (Mango) Seed Oil | Other skin care preparations | 1% |
| Mangifera Indica (Mango) Seed Oil | Indoor tanning preparations | 0.1% |
| Mangifera Indica (Mango) Seed Butter | Eye shadow | 0.02% |
| Mangifera Indica (Mango) Seed Butter | Hair sprays (aerosol fixatives) | 0.02% |
| Mangifera Indica (Mango) Seed Butter | Shampoos (noncoloring) | 0.1-0.5% |
| Mangifera Indica (Mango) Seed Butter | Tonics, dressings, and other hair grooming aids | 0.5% |
| Mangifera Indica (Mango) Seed Butter | Blushers (all types) | 0.02% |
| Mangifera Indica (Mango) Seed Butter | Face powders | 0.02% |
| Mangifera Indica (Mango) Seed Butter | Foundations | 0.02-5% |
| Mangifera Indica (Mango) Seed Butter | Lipstick | 1-5% |
| Mangifera Indica (Mango) Seed Butter | Makeup bases | 0.01% |
| Mangifera Indica (Mango) Seed Butter | Cuticle softeners | 0.5% |
| Mangifera Indica (Mango) Seed Butter | Bath soaps and detergents | 0.0005-0.1% |
| Mangifera Indica (Mango) Seed Butter | Other personal cleanliness products | 0.5% |
| Mangifera Indica (Mango) Seed Butter | Shaving cream (aerosol, brushless and lather) | 0.1% |
| Mangifera Indica (Mango) Seed Butter | Depilatories | 0.05% |
| Mangifera Indica (Mango) Seed Butter | Face and neck creams, lotions, and powders | 1-3% |
| Mangifera Indica (Mango) Seed Butter | Body and hand creams, lotions, and powders | 0.1-3% |
| Mangifera Indica (Mango) Seed Butter | Moisturizing creams, lotions and powders | 0.1% |
| Mangifera Indica (Mango) Seed Butter | Night creams, lotions and powders | 0.1% |
| Mangifera Indica (Mango) Seed Butter | Other skin care preparations | 0.04-2% |
| Moringa Oleifera Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.01% |
| Moringa Pterygosperma Seed Oil | Eye lotion | 3% |
| Moringa Pterygosperma Seed Oil | Tonics, dressings, and other hair grooming aids | 0.02% |
| Moringa Pterygosperma Seed Oil | Other personal cleanliness products | 0.003% |
| Moringa Pterygosperma Seed Oil | Body and hand creams, lotions, and powders | 0.004% |
| Oenothera Biennis (Evening Primrose) Oil | Bubble baths | 0.2% |

| Oenothera Biennis (Evening Primrose) Oil | Eye lotion | 0.00002-0.5% |
|--|---|--------------|
| Oenothera Biennis (Evening Primrose) Oil | Eye makeup remover | 0.002% |
| Oenothera Biennis (Evening Primrose) Oil | Shampoos (noncoloring) | 0.05-0.1% |
| Oenothera Biennis (Evening Primrose) Oil | Tonics, dressings, and other hair grooming aids | 0.1% |
| Oenothera Biennis (Evening Primrose) Oil | Blushers (all types) | 0.08% |
| Oenothera Biennis (Evening Primrose) Oil | Foundations | 58% |
| Oenothera Biennis (Evening Primrose) Oil | Lipstick | 0.1-15% |
| Oenothera Biennis (Evening Primrose) Oil | Cuticle softeners | 3% |
| Oenothera Biennis (Evening Primrose) Oil | Nail creams and lotions | 0.001-0.3% |
| Oenothera Biennis (Evening Primrose) Oil | Nail polish and enamel | 0.001% |
| Oenothera Biennis (Evening Primrose) Oil | Bath soaps and detergents | 0.1-0.2% |
| Oenothera Biennis (Evening Primrose) Oil | Deodorants (underarm) | 0.2% |
| Oenothera Biennis (Evening Primrose) Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.001-0.5% |
| Oenothera Biennis (Evening Primrose) Oil | Face and neck creams, lotions, and powders | 0.08-2% |
| Oenothera Biennis (Evening Primrose) Oil | Body and hand creams, lotions, and powders | 0.1-2% |
| Oenothera Biennis (Evening Primrose) Oil | Moisturizing creams, lotions and powders | 0.04-0.1% |
| Oenothera Biennis (Evening Primrose) Oil | Night creams, lotions and powders | 0.008-3% |
| Oenothera Biennis (Evening Primrose) Oil | Paste masks (mud packs) | 0.1% |
| Oenothera Biennis (Evening Primrose) Oil | Other skin care preparations | 0.002-0.1% |
| Oenothera Biennis (Evening Primrose) Oil | Indoor tanning preparations | 0.003% |
| Oenothera Biennis (Evening Primrose) Oil | Other suntan preparations | 0.5% |
| Orbignya Oleifera Seed Oil | Bath capsules | 0.1% |
| Orbignya Oleifera Seed Oil | Other bath preparations | 0.01% |
| Orbignya Oleifera Seed Oil | Eye shadow | 0.5-0.6% |
| Orbignya Oleifera Seed Oil | Hair conditioners | 0.3-2% |
| Orbignya Oleifera Seed Oil | Hair sprays (aerosol fixatives) | 0.02% |
| Orbignya Oleifera Seed Oil | Tonics, dressings, and other hair grooming aids | 0.1-1% |
| Orbignya Oleifera Seed Oil | Foundations | 0.5% |
| Orbignya Oleifera Seed Oil | Lipstick | 0.001-2% |
| Orbignya Oleifera Seed Oil | Bath soaps and detergents | 27% |
| Orbignya Oleifera Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.05% |

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| Orbignya Oleifera Seed Oil | Body and hand creams, lotions, and powders | 0.005-1% |] |
|---------------------------------------|---|-------------|-----------------------------|
| Orbignya Oleifera Seed Oil | Foot powders and sprays | 2% |] |
| Orbignya Oleifera Seed Oil | Moisturizing creams, lotions and powders | 0.1% | |
| Orbignya Oleifera Seed Oil | Night creams, lotions and powders | 0.1% |] |
| Orbignya Oleifera Seed Oil | Other skin care preparations | 4% |] |
| Orbignya Oleifera Seed Oil | Suntan gels, creams, and liquids | 0.0009% | |
| Sodium Babassuate | Bath soaps and detergents | 8% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Baby lotions, oils, powders and creams | 4% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Other bath preparations | 7% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Eye shadow | 0.002-2% |] |
| Prunus Armeniaca (Apricot) Kernel Oil | Eye lotion | 0.2-9% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Eye makeup remover | 18% |] |
| Prunus Armeniaca (Apricot) Kernel Oil | Mascara | 0.002-0.05% |] |
| Prunus Armeniaca (Apricot) Kernel Oil | Powders (dusting and talcum) (excluding aftershave) | 0.1% |] |
| Prunus Armeniaca (Apricot) Kernel Oil | Other fragrance preparations | 0.02-1% | 1.1 |
| Prunus Armeniaca (Apricot) Kernel Oil | Hair conditioners | 0.003-89% | - 10 - 10 - 10 - 10 - 10 |
| Prunus Armeniaca (Apricot) Kernel Oil | Hair sprays (aerosol fixatives) | 0.0009% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Hair straighteners | 0.0001% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Rinses (noncoloring) | 0.05% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Shampoos (noncoloring) | 0.1-0.5% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Tonics, dressings, and other hair grooming aids | 0.001-0.1% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Hair dyes and colors (all types requiring caution statement and patch test) | 0.1% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Blushers (all types) | 0.2% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Face powders | 0.1-0.6% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Foundations | 0.1-1% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Leg and body paints | 0.001% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Lipstick | 0.001-5% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Other makeup preparations | 0.2% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Basecoats and undercoats (manicuring preparations) | 0.05% | |
| Prunus Armeniaca (Apricot) Kernel Oil | Cuticle softeners | 0.05-5% |] |
| Prunus Armeniaca (Apricot) Kernel Oil | Nail creams and lotions | 2-40% | |
| | | | _ |

| Prunus Armeniaca (Apricot) Kernel Oil | Nail polish and enamel | 0.05% |
|---------------------------------------|---|-------------|
| Prunus Armeniaca (Apricot) Kernel Oil | Nail polish and enamel removers | 0.002-0.01% |
| Prunus Armeniaca (Apricot) Kernel Oil | Bath soaps and detergents | 0.1-9% |
| Prunus Armeniaca (Apricot) Kernel Oil | Deodorants (underarm) | 0.003-0.1% |
| Prunus Armeniaca (Apricot) Kernel Oil | Other personal cleanliness products | 0.01-0.5% |
| Prunus Armeniaca (Apricot) Kernel Oil | Aftershave lotions | 0.5% |
| Prunus Armeniaca (Apricot) Kernel Oil | Shaving cream (aerosol, brushless, and lather) | 0.1% |
| Prunus Armeniaca (Apricot) Kernel Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.001-3% |
| Prunus Armeniaca (Apricot) Kernel Oil | Depilatories | 0.00001-2% |
| Prunus Armeniaca (Apricot) Kernel Oil | Face and neck creams, lotions, and powders | 0.05-17% |
| Prunus Armeniaca (Apricot) Kernel Oil | Body and hand creams, lotions, and powders | 0.03-12% |
| Prunus Armeniaca (Apricot) Kernel Oil | Moisturizing creams, lotions and powders | 0.1-3% |
| Prunus Armeniaca (Apricot) Kernel Oil | Night creams, lotions and powders | 0.1-8% |
| Prunus Armeniaca (Apricot) Kernel Oil | Paste masks (mud packs) | 2% |
| Prunus Armeniaca (Apricot) Kernel Oil | Skin fresheners | 0.01% |
| Prunus Armeniaca (Apricot) Kernel Oil | Other skin care preparations | 0.0001-0.5% |
| Prunus Armeniaca (Apricot) Kernel Oil | Suntan gels, creams, and liquids | 0.01-0.05% |
| Prunus Armeniaca (Apricot) Kernel Oil | Indoor tanning preparations | 0.01-1% |
| Prunus Armeniaca (Apricot) Kernel Oil | Other suntan preparations | 0.0005% |
| Prunus Avium (Sweet) Cherry Seed Oil | Bath soaps and detergents | 0.01-0.02% |
| Prunus Domestica Seed Oil | Preshave lotions (all types) | 0.04% |
| Prunus Persica (Peach) Kernel Oil | Bath oils, tablets, and salts | 0.1% |
| Prunus Persica (Peach) Kernel Oil | Other bath preparations | 1% |
| Prunus Persica (Peach) Kernel Oil | Other fragrance preparations | 2% |
| Prunus Persica (Peach) Kernel Oil | Hair dyes and colors (all types requiring caution statement and patch test) | 0.1% |
| Prunus Persica (Peach) Kernel Oil | Lipstick | 0.04-22% |
| Prunus Persica (Peach) Kernel Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.003-6% |
| Prunus Persica (Peach) Kernel Oil | Face and neck creams, lotions, and powders | 0.2-0.4% |
| Prunus Persica (Peach) Kernel Oil | Body and hand creams, lotions, and powders | 0.8-3% |
| Prunus Persica (Peach) Kernel Oil | Moisturizing creams, lotions and powders | 0.08% |

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| Prunus Persica (Peach) Kernel Oil | Night creams, lotions and powders | 0.08% |
|---|--|---|
| Prunus Persica (Peach) Kernel Oil | Other suntan preparations | 0.05% |
| Ribes Nigrum (Black Currant) Seed Oil | Eye lotion | 0.08% |
| Ribes Nigrum (Black Currant) Seed Oil | Lipstick | 0.03-0.1% |
| Ribes Nigrum (Black Currant) Seed Oil | Nail creams and lotions | 0.2% |
| Ribes Nigrum (Black Currant) Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.05% |
| Ribes Nigrum (Black Currant) Seed Oil | Body and hand creams, lotions, and powders | 0.01% |
| Ribes Nigrum (Black Currant) Seed Oil | Moisturizing creams, lotions and powders | 0.1-0.3% |
| Ribes Nigrum (Black Currant) Seed Oil | Night creams, lotions and powders | 0.1% |
| Ribes Nigrum (Black Currant) Seed Oil | Other skin care preparations | 0.000001% |
| Rubus Idaeus (Raspberry) Seed Oil | Face and neck creams, lotions, and powders | 5% |
| Rubus Idaeus (Raspberry) Seed Oil | Night creams, lotions and powders | 0.1% |
| Sclerocarya Birrea Seed Oil | Hair conditioners | 1% |
| Sclerocarya Birrea Seed Oil | Shampoos (noncoloring) | 1% |
| Sclerocarya Birrea Seed Oil | Body and hand creams, lotions and powders | 1% |
| | | |
| Sclerocarya Birrea Seed Oil | Other skin care preparations | 1% |
| Sclerocarya Birrea Seed Oil Silybum Marianum Seed Oil | Other skin care preparations Foundations | 1% 0.5% |
| Sclerocarya Birrea Seed Oil Silybum Marianum Seed Oil Solanum Lycopersicum (Tomato) Fruit Oil | Other skin care preparations Foundations Eye shadow | 1% 0.5% 0.01% |
| Sclerocarya Birrea Seed Oil Silybum Marianum Seed Oil Solanum Lycopersicum (Tomato) Fruit Oil Solanum Lycopersicum (Tomato) Fruit Oil | Other skin care preparations Foundations Eye shadow Blushers (all types) | 1% 0.5% 0.01% 0.01% |
| Sclerocarya Birrea Seed Oil Silybum Marianum Seed Oil Solanum Lycopersicum (Tomato) Fruit Oil Solanum Lycopersicum (Tomato) Fruit Oil Solanum Lycopersicum (Tomato) Fruit Oil | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders | 1% 0.5% 0.01% 0.01% 0.05% |
| Sclerocarya Birrea Seed Oil Silybum Marianum Seed Oil Solanum Lycopersicum (Tomato) Fruit Oil | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders Lipstick | 1% 0.5% 0.01% 0.01% 0.05% 0.001% |
| Sclerocarya Birrea Seed Oil Silybum Marianum Seed Oil Solanum Lycopersicum (Tomato) Fruit Oil | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders Lipstick Other skin care preparations | 1% 0.5% 0.01% 0.01% 0.05% 0.001% 1% |
| Sclerocarya Birrea Seed Oil Silybum Marianum Seed Oil Solanum Lycopersicum (Tomato) Fruit Oil Theobroma Cacao (Cocoa) Seed Butter | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders Lipstick Other skin care preparations Baby lotions, oils, powders and creams | 1% 0.5% 0.01% 0.01% 0.05% 0.001% 1% 0.01% |
| Sclerocarya Birrea Seed OilSilybum Marianum Seed OilSolanum Lycopersicum (Tomato) Fruit OilSolanum Lycopersicum (Tomato) Fruit OilTheobroma Cacao (Cocoa) Seed Butter Theobroma Cacao (Cocoa) Seed Butter | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders Lipstick Other skin care preparations Baby lotions, oils, powders and creams Other baby products | 1% 0.5% 0.01% 0.01% 0.05% 0.001% 1% 0.01% 0.01% |
| Sclerocarya Birrea Seed OilSilybum Marianum Seed OilSolanum Lycopersicum (Tomato) Fruit OilSolanum Lycopersicum (Tomato) Fruit OilTheobroma Cacao (Cocoa) Seed ButterTheobroma Cacao (Cocoa) Seed ButterTheobroma Cacao (Cocoa) Seed Butter | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders Lipstick Other skin care preparations Baby lotions, oils, powders and creams Other baby products Bath oils, tablets and salts | 1% 0.5% 0.01% 0.05% 0.001% 1% 0.01% 0.01% 0.01% 0.1% |
| Sclerocarya Birrea Seed OilSilybum Marianum Seed OilSolanum Lycopersicum (Tomato) Fruit OilSolanum Lycopersicum (Tomato) Fruit OilTheobroma Cacao (Cocoa) Seed ButterTheobroma Cacao (Cocoa) Seed ButterTheobroma Cacao (Cocoa) Seed Butter | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders Lipstick Other skin care preparations Baby lotions, oils, powders and creams Other baby products Bath oils, tablets and salts Other bath preparations | 1% 0.5% 0.01% 0.05% 0.05% 0.001% 1% 0.01% 0.1% 0.1% 1.1% |
| Sclerocarya Birrea Seed OilSilybum Marianum Seed OilSolanum Lycopersicum (Tomato) Fruit OilSolanum Lycopersicum (Tomato) Fruit OilSolanum Lycopersicum (Tomato) Fruit OilSolanum Lycopersicum (Tomato) Fruit | Other skin care preparations Foundations Eye shadow Blushers (all types) Face powders Lipstick Other skin care preparations Baby lotions, oils, powders and creams Other baby products Bath oils, tablets and salts Other bath preparations Eyebrow pencil | 1% 0.5% 0.01% 0.05% 0.05% 0.001% 1% 0.01% 0.01% 0.01% 0.01% 0.01% 0.01% 0.01% 0.01% 0.01% 0.01% 0.01% 0.02% |

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| Theobroma Cacao (Cocoa) Seed Butter | Eye lotion | 0.9-4% |
|-------------------------------------|---|-------------|
| Theobroma Cacao (Cocoa) Seed Butter | Mascara | 0.0002% |
| Theobroma Cacao (Cocoa) Seed Butter | Hair conditioners | 1% |
| Theobroma Cacao (Cocoa) Seed Butter | Hair straighteners | 0.01% |
| Theobroma Cacao (Cocoa) Seed Butter | Shampoos (noncoloring) | 0.01-0.1% |
| Theobroma Cacao (Cocoa) Seed Butter | Tonics, dressings and other hair grooming aids | 0.1-2% |
| Theobroma Cacao (Cocoa) Seed Butter | Hair dyes and colors (all types requiring caution statement and patch test) | 0.1% |
| Theobroma Cacao (Cocoa) Seed Butter | Blushers (all types) | 0.4% |
| Theobroma Cacao (Cocoa) Seed Butter | Foundations | 0.2-2% |
| Theobroma Cacao (Cocoa) Seed Butter | Lipstick | 0.3-37% |
| Theobroma Cacao (Cocoa) Seed Butter | Makeup bases | 0.02% |
| Theobroma Cacao (Cocoa) Seed Butter | Makeup fixatives | 0.00004% |
| Theobroma Cacao (Cocoa) Seed Butter | Other makeup preparations | 9% |
| Theobroma Cacao (Cocoa) Seed Butter | Cuticle softeners | 0.1% |
| Theobroma Cacao (Cocoa) Seed Butter | Nail creams and lotions | 1% |
| Theobroma Cacao (Cocoa) Seed Butter | Bath soaps and detergents | 0.02-2% |
| Theobroma Cacao (Cocoa) Seed Butter | Deodorants (underarm) | 0.001-1% |
| Theobroma Cacao (Cocoa) Seed Butter | Other personal cleanliness products | 0.1% |
| Theobroma Cacao (Cocoa) Seed Butter | Aftershave lotions | 1% |
| Theobroma Cacao (Cocoa) Seed Butter | Shaving (aerosol, brushless and lather) | 0.01-0.1% |
| Theobroma Cacao (Cocoa) Seed Butter | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.0001-1% |
| Theobroma Cacao (Cocoa) Seed Butter | Depilatories | 0.05-1% |
| Theobroma Cacao (Cocoa) Seed Butter | Face and neck creams, lotions and powders | 0.08-3% |
| Theobroma Cacao (Cocoa) Seed Butter | Body and hand creams, lotions and powders | 0.000002-6% |
| Theobroma Cacao (Cocoa) Seed Butter | Foot powders and sprays | 0.4% |
| Theobroma Cacao (Cocoa) Seed Butter | Moisturizing creams, lotions and powders | 2% |
| Theobroma Cacao (Cocoa) Seed Butter | Night creams, lotions and powders | 2% |
| Theobroma Cacao (Cocoa) Seed Butter | Other skin care preparations | 0.1-25% |
| Theobroma Cacao (Cocoa) Seed Butter | Suntan gels, creams and liquids | 5% |
| Theobroma Cacao (Cocoa) Seed Butter | Indoor tanning preparations | 0.1-0.5% |
| Theobroma Cacao (Cocoa) Seed Butter | Other suntan preparations | 0.5% |

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| Theobroma Grandiflorum Seed Butter | Eyeliner | 2% |
|---|---|------------|
| Theobroma Grandiflorum Seed Butter | Eye shadow | 0.1% |
| Theobroma Grandiflorum Seed Butter | Eye lotion | 2% |
| Theobroma Grandiflorum Seed Butter | Hair conditioners | 0.001-1% |
| Theobroma Grandiflorum Seed Butter | Shampoos (noncoloring) | 0.001-0.1% |
| Theobroma Grandiflorum Seed Butter | Tonics, dressings and other hair grooming aids | 0.01% |
| Theobroma Grandiflorum Seed Butter | Other hair preparations (noncoloring) | 1% |
| Theobroma Grandiflorum Seed Butter | Foundations | 5% |
| Theobroma Grandiflorum Seed Butter | Lipstick | 7% |
| Theobroma Grandiflorum Seed Butter | Bath soaps and detergents | 0.1% |
| Theobroma Grandiflorum Seed Butter | Deodorants (underarm) | 0.1% |
| Theobroma Grandiflorum Seed Butter | Other personal cleanliness products | 0.05% |
| Theobroma Grandiflorum Seed Butter | Aftershave lotions | 0.1% |
| Theobroma Grandiflorum Seed Butter | Shaving cream (aerosol, brushless and lather) | 0.1% |
| Theobroma Grandiflorum Seed Butter | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.003% |
| Theobroma Grandiflorum Seed Butter | Face and neck creams, lotions and powders | 2-5% |
| Theobroma Grandiflorum Seed Butter | Body and hand creams, lotions and powders | 0.1-5% |
| Theobroma Grandiflorum Seed Butter | Moisturizing creams, lotions and powders | 0.1% |
| Theobroma Grandiflorum Seed Butter | Night creams, lotions and powders | 0.1-3% |
| Theobroma Grandiflorum Seed Butter | Other skin care preparations | 0.00005% |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | Hair conditioners | 0.1% |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | Shampoos (noncoloring) | 0.01% |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | Tonics, dressings and other hair grooming aids | 0.1% |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | Foundations | 0.1% |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | Lipstick | 0.3% |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | Other makeup preparations | 0.002% |
| Vaccinium Macrocarpon (Cranberry) Seed Oil | Bath soaps and detergents | 0.003-0.1% |

| | Vaccinium Macrocarpon (Cranberry) Seed Oil | Face and neck creams, lotions and powders | 2% |
|--|---|---|------------|
| | Vaccinium Macrocarpon (Cranberry) Seed Oil | Body and hand creams, lotions and powders | 0.1% |
| | Vaccinium Macrocarpon (Cranberry) Seed Oil | Moisturizing creams, lotions and powders | 0.1% |
| | Vaccinium Macrocarpon (Cranberry) Seed Oil | Night creams, lotions and powders | 0.1% |
| | Vitis Vinifera (Grape) Seed Oil | Bath oils, tablets and salts | 0.1-0.5% |
| | Vitis Vinifera (Grape) Seed Oil | Bubble baths | 2% |
| | Vitis Vinifera (Grape) Seed Oil | Other bath preparations | 0.01% |
| | Vitis Vinifera (Grape) Seed Oil | Eye lotion | 5% |
| | Vitis Vinifera (Grape) Seed Oil | Eye makeup remover | 0.01% |
| | Vitis Vinifera (Grape) Seed Oil | Perfumes | 1% |
| | Vitis Vinifera (Grape) Seed Oil | Other fragrance preparations | 0.001-7% |
| ten Se e | Vitis Vinifera (Grape) Seed Oil | Hair conditioners | 0.01-0.3% |
| | Vitis Vinifera (Grape) Seed Oil | Shampoos (noncoloring) | 0.05-0.1% |
| $\Phi_{i}^{(1)}(\mathbf{x}) = - \left(\mathbf{x} \right)$ | Vitis Vinifera (Grape) Seed Oil | Tonics, dressings and other hair grooming aids | 0.01-0.1% |
| | Vitis Vinifera (Grape) Seed Oil | Hair dyes and colors (all types requiring caution statement and patch test) | 43% |
| | Vitis Vinifera (Grape) Seed Oil | Foundations | 0.2% |
| | Vitis Vinifera (Grape) Seed Oil | Lipstick | 0.03-7% |
| | Vitis Vinifera (Grape) Seed Oil | Cuticle softeners | 35% |
| | Vitis Vinifera (Grape) Seed Oil | Nail creams and lotions | 1% |
| | Vitis Vinifera (Grape) Seed Oil | Nail polish and enamel | 0.001% |
| | Vitis Vinifera (Grape) Seed Oil | Bath soaps and detergents | 0.01-7% |
| | Vitis Vinifera (Grape) Seed Oil | Deodorants (underarm) | 0.001-0.2% |
| | Vitis Vinifera (Grape) Seed Oil | Other personal cleanliness products | 0.001-1% |
| | Vitis Vinifera (Grape) Seed Oil | Aftershave lotions | 0.1-1% |
| | Vitis Vinifera (Grape) Seed Oil | Preshave lotions (all types) | 16-39% |
| | Vitis Vinifera (Grape) Seed Oil | Shaving cream (aerosol, brushless and lather) | 2% |
| | Vitis Vinifera (Grape) Seed Oil | Other shaving preparations | 0.1% |
| | Vitis Vinifera (Grape) Seed Oil | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.004-20% |
| | | | |

| Vitis Vinifera (Grape) Seed Oil | Depilatories | 0.5% |
|---------------------------------|---|----------|
| Vitis Vinifera (Grape) Seed Oil | Face and neck creams, lotions and powders | 0.1-8% |
| Vitis Vinifera (Grape) Seed Oil | Body and hand creams, lotions and powders | 0.01-41% |
| Vitis Vinifera (Grape) Seed Oil | Body and hand sprays | 1% |
| Vitis Vinifera (Grape) Seed Oil | Moisturizing creams, lotions and powders | 0.01-5% |
| Vitis Vinifera (Grape) Seed Oil | Night creams, lotions and powders | 0.01-5% |
| Vitis Vinifera (Grape) Seed Oil | Paste masks (mud packs) | 0.01% |
| Vitis Vinifera (Grape) Seed Oil | Other skin care preparations | 0.01-13% |
| Vitis Vinifera (Grape) Seed Oil | Indoor tanning preparations | 0.001% |
| Vitis Vinifera (Grape) Seed Oil | Other suntan preparations | 15% |
| Hydrogenated Grapeseed Oil | Other bath preparations | 0.5% |
| Hydrogenated Grapeseed Oil | Lipstick | 0.5% |
| Hydrogenated Grapeseed Oil | Cuticle softeners | 0.3% |

*Ingredients included in the title of the table, but not found in the table were included in the survey, but no uses were reported Information collected in 2010

Table prepared May 13, 2010

Table updated January 20, 2011 (removed Citrus Grandis uses - company using an essential oil from the peel) The following ingredients will be included in a later concentration of use survey: Camellia Japonica Seed Oil, Citrus Aurantifolia (Lime) Seed Oil Unsaponifiables, Persea Gratissima (Avocado) Oil, Hydrogenated Avocado Oil, Persea Gratissima (Avocado) Butter, Persea Gratissima (Avocado) Oil Unsaponifiables, Sodium Avocadoate, Triticum Vulgare (Wheat) Germ Oil, Hydrogenated Wheat Germ Oil, Hydrogenated Wheat Germ Oil Unsaponifiables, Triticum Aestivum (Wheat) Germ Oil, Triticum Vulgare (Wheat) Germ Oil Unsaponifiables and Wheat Germ Acid.