Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics

Status:	Draft Report for Panel Review
Release Date:	November 15, 2019
Panel Meeting Date:	December 9-10, 2019

The 2019 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D., Lisa A. Peterson, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Alice Akinsulie, former Scientific Analyst/Writer, and Christina Burnett, Senior Scientific Analyst/Writer.

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Memorandum

To: CIR Expert Panel Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst
Date: November 15, 2019
Subject: Draft Safety Assessment on *Cocos nucifera* (Coconut)-Derived Ingredients

Enclosed is the Draft Report of the Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics. (It is identified as *cocosn122019rep* in the pdf document.) The Scientific Literature Review (SLR) of these botanical ingredients was issued by CIR on August 29, 2019. These ingredients are reported to function in cosmetics as skin-conditioning agents, while some are reported to have other functions, such as humectants, abrasives, and hair conditioning agents.

The Panel should note that in botanical cosmetic ingredients, the term "water" refers to the aqueous solution of the steam distillate of plant parts; however, in the food industry, "coconut water" is the common term for the endosperm liquid of the coconut fruit.

The Council provided concentration of use survey data (*cocosn122019data1* through *cocosn122019data6; cocosn122019data8; cocosn122019data9*), human dermal irritation and sensitization data on Cocos Nucifera (Coconut) Liquid Endosperm (*cocosn122019data7*), and method of manufacturing and specifications for Cocos Nucifera (Coconut) Fruit Extract (*cocosn122019data10*). Comments on the SLR were received from the Council and addressed (*cocosn122019pcpc*).

According to 2019 VCRP data, Cocos Nucifera (Coconut) Fruit Extract is reported to be used in 429 formulations, 222 of which are leave-on formulations. All other in-use ingredients are reported to be used in 64 formulations or less. The results of the concentration of use survey conducted by the Council in 2019 indicate that Cocos Nucifera (Coconut) Liquid Endosperm has the highest maximum concentration of use; it is used at up to 6.5% in shampoos (non-coloring). Cocos Nucifera (Coconut) Liquid Endosperm also has the highest maximum concentration of use in dermal leave-on formulations; it is used at up to 1.5% in face and neck products. Cocos Nucifera (Coconut) Fruit Extract is reported to be used at up to 0.12% in leave-on hair products. No uses were reported in the VCRP or by the Council for Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract.

If no further data are needed to reach a conclusion of safety, the Panel should formulate a Discussion and issue a Tentative Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an Insufficient Data Announcement.

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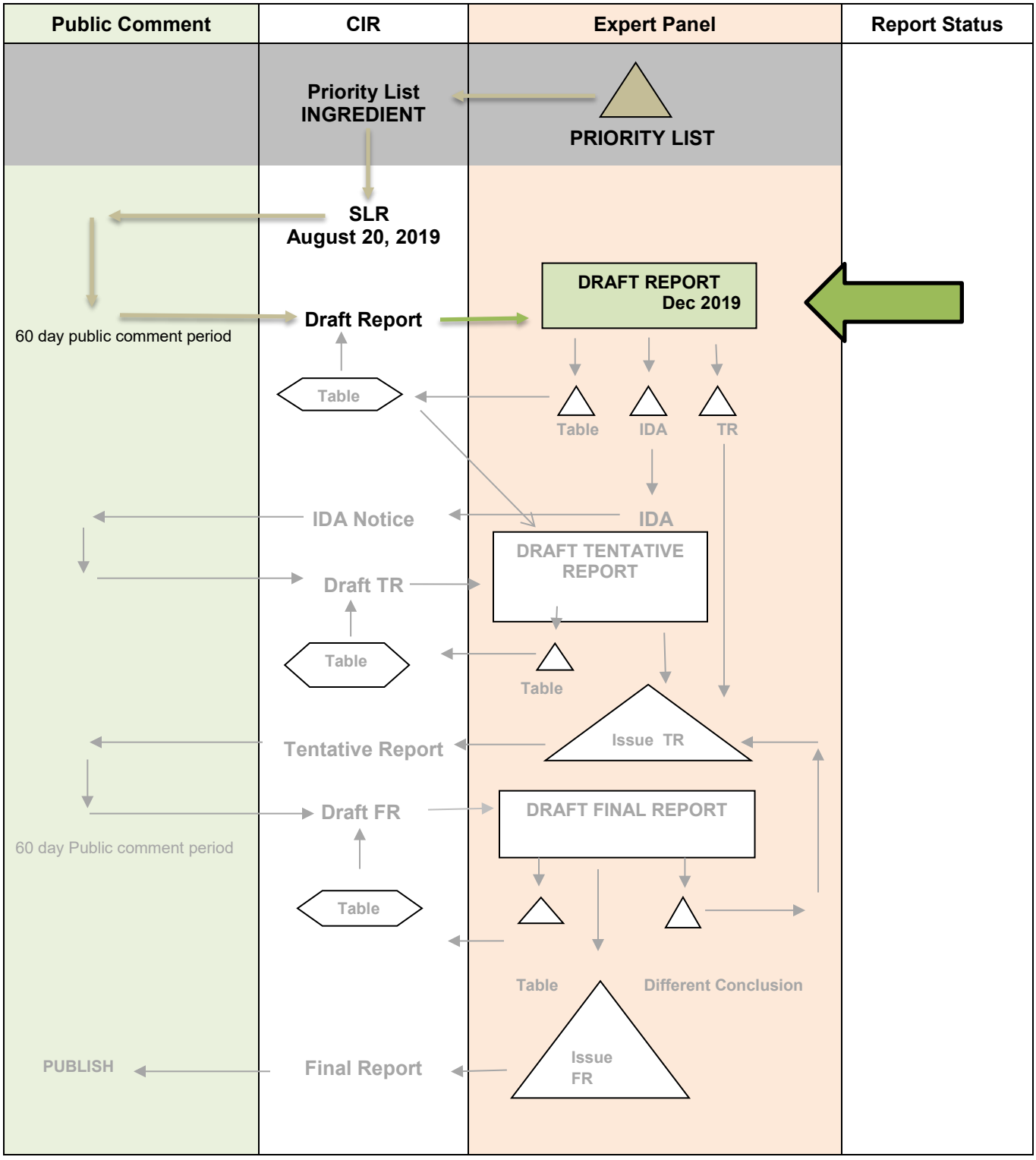
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY *Cocos nucifera* (coconut)-derived ingredients

MEETING December 2019



Coconut-Derived Ingredients History

August 29, 2019 – Scientific Literature Review announced.

Coconut Derived Ingredients, December 2019 – Christina Burnett

	Reported Use	GRAS	Method of Mfg	Constituents	Impurities	Toxico-kinetics		Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irr.			Dermal Sens.			Phototoxicity	Ocular Irr.		Clinical Studies	
						Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro/In Chemico	Animal	Human		In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Cocos Nucifera (Coconut) Flower Extract	X		X	X																									
Cocos Nucifera (Coconut) Fruit	X																												
Cocos Nucifera (Coconut) Fruit Extract	X		X		X				X						X	X				X		X	X		X	X	X			
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract																														
Cocos Nucifera (Coconut) Fruit Juice	X																													
Cocos Nucifera (Coconut) Fruit Powder	X																													
Cocos Nucifera (Coconut) Fruit Water	X		X																											
Cocos Nucifera (Coconut) Liquid Endosperm	X			X											X	X				X			X		X		X			
Cocos Nucifera (Coconut) Shell Powder	X			X																										

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

Cocos Nucifera (Coconut)-Derived Ingredients

Ingredient	CAS #	InfoB	SciFin	PubMed	TOXNET	FDA	EU	ECHA	IUCLID	SIDS	ECETOC	HPVIS	NICNAS	NTIS	NTP	WHO	FAO	NIOSH	FEMA	Web
Cocos Nucifera (Coconut) Fruit Extract	999000685	1/1	✓	0/22	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Flower Extract		1/1	✓	0/10	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit	999002544	1/1	✓	10/243	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract		1/1	✓	0/3	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit Juice	999001659	1/1	✓	0/16	NR	✓	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit Powder	999003837	1/1	✓	0/3	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit Water	-	1/1	✓	0/90	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Oil	8001-31-8	1/1	✓	15/304	✓	✓	Listed; No Restriction	NR	NR	NR	NR	NR	No assessment	NR	NR	NR	NR	NR	✓	✓
Cocos Nucifera (Coconut) Seed Butter	999004789	1/1	✓	0/7	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Shell Powder	999001305	1/1	✓	0/19	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Water/ Coconut Liquid Endosperm	977026257	1/1	✓	0/16	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓

***NR – No results were found; Check mark - Data available; 0/0 – relevant/hits**

Botanical and/or Fragrance Websites (if applicable)

Ingredient	CAS #	Dr. Duke's	Taxonomy	GRIN	Sigma-Aldrich	IFRA	RIFM
Cocos Nucifera (coconut) (generic search)	8001-31-8	✓	✓	✓	✓	NR	NR

Search Strategy

Web search: Cocos Nucifera Fruit Extract; Copra oil; Cocoanut oil; Coconut butter; Coconut extract; Coconut kernel extract; Coconut palm oil; oconut palm oil; Copra oil; coconut water; Allergic Contact Dermatitis cocos nucifera, references were then narrowed by “adverse effects, including toxicity” or “dermal” or “sensitization” or “irritation”.

Coconut oil allergy: [21 hits in pubmed]
Cocos Nucifera (Coconut) Fruit Extract: 21hits, 1 relevant
Cocos Nucifera (Coconut) Flower Extract :10 hits; 0 relevant
Cocos Nucifera (Coconut) Fruit; 243 hits; 0 relevant ; coconut nucifera (coconut) fruit toxicity; 8 hits; 0 relevant; coconut nucifera coconut fruit in vitro; 26 hits; 2 relevant
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract; 21 hits; 0 relevant
Cocos Nucifera (Coconut) Fruit Juice; 6 hits; 0 relevant
Cocos Nucifera (Coconut) Fruit Powder; 25 hits; 0 relevant
Cocos Nucifera (Coconut) Oil; 303 hits;
Cocos Nucifera (Coconut) Seed Butter; 7 hits;
Cocos Nucifera (Coconut) Shell Powder
Cocos Nucifera (Coconut) Water**

Typical Search Terms

- INCI names
- CAS numbers
- chemical/technical names
- additional terms will be used as appropriate

LINKS

Search Engines

- Pubmed (- http://www.ncbi.nlm.nih.gov/pubmed)
- Toxnet (https://toxnet.nlm.nih.gov/); (includes Toxline; HSDB; ChemIDPlus; DART; IRIS; CCRIS; CPDB; GENE-TOX)
- Scifinder (https://scifinder.cas.org/scifinder)

appropriate qualifiers are used as necessary
search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI - http://webdictionary.personalcarecouncil.org

- FDA databases http://www.ecfr.gov/cgi-bin/ECFR?page=browse
- FDA search databases: http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm;,
- EAFUS: http://www.accessdata.fda.gov/scripts/fcn/fcnnavigation.cfm?rpt=eafuslisting&displayall=true
- GRAS listing: http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm
- SCOGS database: http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm
- Indirect Food Additives: http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives
- Drug Approvals and Database: http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM135688.pdf
- FDA Orange Book: https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm
- OTC ingredient list: https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm135688.pdf
- (inactive ingredients approved for drugs: http://www.accessdata.fda.gov/scripts/cder/iig/

- HPVIS (EPA High-Production Volume Info Systems) - https://ofmext.epa.gov/hpvis/HPVISlogon
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/
- Office of Dietary Supplements https://ods.od.nih.gov/
- FEMA (Flavor & Extract Manufacturers Association) - http://www.femaflavor.org/search/apachesolr_search/

- EU CosIng database: http://ec.europa.eu/growth/tools-databases/cosing/
- ECHA (European Chemicals Agency – REACH dossiers) – http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1

- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - http://www.ecetoc.org
- European Medicines Agency (EMA) - http://www.ema.europa.eu/ema/
- IUCLID (International Uniform Chemical Information Database) - https://iuclid6.echa.europa.eu/search
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- http://webnet.oecd.org/hpv/ui/Search.aspx
- SCCS (Scientific Committee for Consumer Safety) opinions: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- NICNAS (Australian National Industrial Chemical Notification and Assessment Scheme)- https://www.nicnas.gov.au/

- International Programme on Chemical Safety http://www.inchem.org/
- FAO (Food and Agriculture Organization of the United Nations) - http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/
- WHO (World Health Organization) technical reports - http://www.who.int/biologicals/technical_report_series/en/

- www.google.com - a general Google search should be performed for additional background information, to identify references that are available, and for other general information

Botanical Websites, if applicable

- Dr. Duke's - https://phytochem.nal.usda.gov/phytochem/search
- Taxonomy database - http://www.ncbi.nlm.nih.gov/taxonomy
- GRIN (U.S. National Plant Germplasm System) - https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx
- Sigma Aldrich plant profiler- http://www.sigmaaldrich.com/life-science/nutrition-research/learning-center/plant-profiler.html
- American Herbal Products Association Botanical Safety Handbook (database) - http://www.ahpa.org/Resources/BotanicalSafetyHandbook.aspx
- European Medicines Agency Herbal Medicines - http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp
- National Agricultural Library NAL Catalog (AGRICOLA) https://agricola.nal.usda.gov/
- The Seasoning and Spice Association List of Culinary Herbs and Spices
- http://www.seasoningandspice.org.uk/ssa/background_culinary-herbs-spices.aspx

Fragrance Websites, if applicable

- IFRA (International Fragrance Association) – http://www.ifraorg.org/
- Research Institute for Fragrance Materials (RIFM) - http://rifm.org/

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INTRODUCTION

Most of the *Cocos nucifera* (coconut)-derived ingredients detailed in this safety assessment are reported to function in cosmetics as skin-conditioning agents, while some are reported to have other functions, such as humectants, abrasives, and hair conditioning agents, according to the web-based based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*; Table 1).[1] Cocos Nucifera (Coconut) Liquid Endosperm is reported to function only as a fragrance ingredient. The CIR does not review ingredients that function only as fragrance ingredients because, as fragrances, the safety of these ingredients is evaluated by the Research Institute for Fragrance Materials (RIFM); therefore, a query to RIFM about the review status of this ingredient is currently being conducted.

This assessment of the safety of the following 9 coconut-derived ingredients is based on the data contained in this report:

Cocos Nucifera (Coconut) Flower Extract
Cocos Nucifera (Coconut) Fruit
Cocos Nucifera (Coconut) Fruit Extract
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract
Cocos Nucifera (Coconut) Fruit Juice
Cocos Nucifera (Coconut) Fruit Powder
Cocos Nucifera (Coconut) Fruit Water
Cocos Nucifera (Coconut) Liquid Endosperm
Cocos Nucifera (Coconut) Shell Powder

The Panel has reviewed the safety of some of the components of these ingredients. In 1986, CIR first issued a final report on the safety of Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil; the Panel concluded that the ingredients are safe for use as cosmetic ingredients.[2] In 2011, CIR published a report on the safety of Cocos Nucifera (Coconut) Oil and related ingredients with a conclusion that the ingredients are safe for use as cosmetic ingredients.[3] Finally, the CIR Expert Panel reviewed the safety of plant-derived fatty acid oils; the Panel concluded that the 244 plant-derived fatty acid oils, including Cocos Nucifera (Coconut) Oil and Cocos Nucifera (Coconut) Seed Butter, are safe in present practices of use and concentration.[4]

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. Due to the paucity of published safety and toxicity data on these ingredients, this report includes summary information included in technical dossiers, when appropriate.[5] A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that CIR typically evaluates, are provided on the CIR website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

These ingredients are all derived from the same species, *Cocos nucifera.* As such, there is likely some overlap of constituents and/or potential impurities. Botanicals, such as *Cocos nucifera*-derived ingredients, may contain hundreds of constituents, some of which may have the potential to cause toxic effects. In this assessment, CIR is reviewing the potential toxicity of each of the botanical ingredients as a whole, complex mixture. CIR is not reviewing the potential toxicity of the individual constituents. Additionally, some of the ingredients reviewed in this safety assessment are consumed as food, and daily exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. Therefore, the primary focus of the safety assessment of these ingredients as used in cosmetics is on the potential for effects from topical exposure.

Included in this safety assessment are data on a tradename mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus*. It is yet unclear if this supplier is providing a fermentation product of Cocos Nucifera (Coconut) Fruit Extract, or a true mixture of two different cosmetic ingredients.

Note: In many of the published studies, it is not known how the substance being tested compares to the cosmetic ingredient. Therefore, if it is not known whether the chemicals being discussed are cosmetic ingredients, the test substances will be identified simply as "coconut extract" or "*Cocos nucifera* extract," using lowercase and/or appropriate italicization to identify genus and species. If it is known that the substance is a cosmetic ingredient, the International Nomenclature Committee (INC) terminology "Cocos Nucifera (Coconut) …" (e.g. Cocos Nucifera (Coconut) Fruit Extract) will be used. Also, often in the published literature, the specific identities of the ingredients were not discerned (specifically, Cocos Nucifera (Coconut) Liquid Endosperm or coconut water). If it is not known how the substances being tested in these studies compare to the cosmetic ingredients being reviewed in this assessment, the terminology used in the study (e.g., "coconut water") will be used. However, if it can be discerned that the data are on coconut liquid endosperm, the INCI name (Cocos Nucifera (Coconut) Liquid Endosperm) will be used in place of coconut water. In botanical cosmetic ingredients, the term "water" refers to the aqueous solution of the steam distillate of plant parts; however, in the food industry, "coconut water" is the common term for the endosperm liquid of the coconut fruit.

CHEMISTRY

Definition Plant and Identification

The definitions of the *Cocos nucifera*-derived ingredients included in this review are provided in Table 1.[1] Table 2 lists the generic definitions of the parts of plants that are most pertinent to the ingredients in this report.[1] *Cocos nucifera* L. is native to Indonesia, Papua New Guinea, Indonesia, Philippines, Australia, and Vanuatu.[6] *Cocos nucifera* is an important member of the family Arecaceae (palm family), and is more commonly known as coconut.[7] The plant is an arborescent monocotyledonous tree of approximately 25 m in height (giant coconut) with a dense canopy.[7] The giant adult coconut produces 12 – 14 groups of flowers that emit from the main stem (inflorescence spikes) yearly, while the adult dwarf coconut can emit 18 spikes in the same period.

The coconut fruit is a fibrous drupe with a smooth outside skin (exocarp), which may vary from green to red brown, or even ivory in color.[8-10] The exocarp and mesocarp make up the "husk" of the coconut. The mesocarp is the hard, fibrous reddish-brown husk from which coir or fiber is obtained. Between the shell and the kernel is a thin brown seed coat or testa, which adheres to the hard endosperm or kernel (also called meat or jelly), about 12 mm thick in a mature nut. The edible part of the coconut fruit is the endosperm tissue. In young fruit, the endosperm is a liquid called “coconut water,” while in mature fruit, the endosperm is called coconut meat. The kernel (called copra when dried to 60% moisture) constitutes 40% – 70% of the weight of the husked nut and contains about 50% water and 30% - 40% oil. “Coconut water” is not the same as “coconut milk;” the latter is obtained by grating coconut meat, with or without the addition of water.[9]

Physical and Chemical Properties

Cocos Nucifera (Coconut) Fruit Extract

A supplier reported that Cocos Nucifera (Coconut) Fruit Extract prepared in water is a colorless to light yellow liquid with a characteristic odor.[11] At 25ºC, the pH is 6.7 and the specific gravity is 0.99 - 1.00. This ingredient is soluble in any proportion in water.

No other physical and chemical properties on these cosmetic ingredients were discovered in the published literature, and no other unpublished data were submitted.

Method of Manufacture

Cocos Nucifera (Coconut) Flower Extract

The method described herein is general to the processing of a coconut flower extract, and it is unknown if it applies to cosmetic ingredient manufacture**.** The shade-dried flowers of *Cocos nucifera* were extracted with various solvents.[12] Chloroform, methanol, ethanol, hydroalcohol (80% aqueous ethanol), and aqueous batches of extracts of flowers of *Cocos nucifera* were prepared at ~10% solute. The excess solvent in the extracts was removed by distillation and concentrated using a water batch. The extracts were then collected in a Petri dish and stored in desiccators at room temperature.

Cocos Nucifera (Coconut) Fruit Extract

A supplier reported that Cocos Nucifera (Coconut) Fruit Extract is produced by extracting the fruit with specified eluent(s) under appropriate temperature conditions to yield a concentrate.[11] Typical eluents include water, butylene glycol, glycerin, *Carthamus tinctorius* (safflower) seed oil, and propylene glycol. The concentrate containing phytochemical constituents is then blended with the desired diluent(s) and preservation system to produce the final ingredient.

Cocos Nucifera (Coconut) Fruit Water

In general, botanical waters are prepared from the leaves, stems, flowers, bark, roots, or other parts of a plant or the whole plant.[1] The condensate from steam distillation produces two distinct fractions that contain the volatile ingredients from the plant. The water insoluble fraction contains the "oil." The water-soluble fraction contains ingredients from the plant that are water soluble, and is identified by the term "Water" in the INCI name.

Composition

Cocos Nucifera (Coconut) Flower Extract

Cocos nucifera flower extracts that were prepared as described above, were used in phytochemical analysis.[12] The chloroform extract showed the presence of alkaloids, flavonoids, tannins and carbohydrates. The methanol extract showed the presence of alkaloids, flavonoids, phenols, carbohydrates, and amino acids. The ethanol extract contains phytosterols and tannins. The hydroalcoholic extract showed the presence of flavonoids, phenols, tannins, and carbohydrates. The aqueous extract contains alkaloids, flavonoids, phenols, tannins, and carbohydrates. The various extracts of *Cocos nucifera* flowers showed the absence of saponins and anthraquinones.

Cocos Nucifera (Coconut) Liquid Endosperm

The aqueous part of the coconut endosperm contains mainly water (~94 - 95 g/100 g).[9] Components found in liquid endosperm are dependent on coconut type (young, young green, mature green), and the average weight, age, and source of

the coconut. Components that may be present include sugars (sucrose, glucose, fructose), sugar alcohols (mannitol, sorbitol, myo-inositol, scyllo-inositol), lipids; fatty acids, amino acids (alanine, β-alanine, γ-aminobutyric acid, arginine, asparagine and glutamine, aspartic acid, asparagine, cystine, glutamic acid, glutamine, glycine, homoserine, histidine, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, pipecolic acid, proline, serine, tyrosine, tryptophan, threonine, valine, dihydroxyphenylaline, hydroxyproline and pipecolic acid), nitrogenous compounds (ethanolamine and ammonia), organic acids (malic acid and pyridinoline), and enzymes. Furthermore, naturally-occurring phytohormones were identified in the liquid endosperm from young green and mature coconuts, including indole-3-acetic acid, various cytokinins, gibberellins and abscisic acid, and salicylic acid. The liquid endosperm of tender coconut water contains vitamin B, especially nicotinic acid (vitamin B3), pantothenic acid (vitamin B5), biotin, riboflavin (vitamin B2), folic acid, trace amounts of thiamine B1, and pyridoxine B6.[13]

Cocos Nucifera (Coconut) Shell Powder

The mineral composition of the coconut shell was examined.[14] The outer pericarp of the *Cocos nucifera* shell was collected, air-dried, ground into a fine powder, and then sieved with 2 mm mesh pore size. The proximate analysis of the composition of coconut shell pericarp indicated that it is composed of carbohydrates (52.63%), crude fiber (32.39%), moisture (10.10%), ash (2.28%), crude fat/oil (2.14%), and protein (0.46%). The mineral composition of the coconut shell was reported to be 11.64 mg/100 g phosphorus, 16.02 mg/100 g calcium, 1.22 mg/100 g magnesium, 0.76 mg/100 g sodium, 3.30 mg/100 g potassium, 618.00 mg/100 g iron, 1.20 mg/100 g zinc and of 6.00 mg/100 g manganese.

Impurities

Cocos Nucifera (Coconut) Fruit Extract

A supplier reported that a trade name mixture containing 20% Cocos Nucifera Fruit Extract and 80% *Lactobacillus* is free of the following heavy metals (< 20 ppm, max.), lead (< 10 ppm, max.), antimony (< 5 ppm, max.), arsenic (< 2 ppm, max.), mercury (< 1 ppm, max.), and cadmium (< 1 ppm, max.), according to the product specifications.[5]

Another supplier reported that Cocos Nucifera (Coconut) Fruit Extract concentrate in a glycerin and water base had 0.115 mg/l arsenic and 0.083 mg/l nickel.[11] Antimony, cadmium, chromium, iron, lead, and mercury were below levels of detection. No residual pesticides were detected. The 26 allergens defined by the European Union Cosmetic Directive were below threshold levels in a concentrate of Cocos Nucifera (Coconut) Fruit Extract concentrate in an alcohol base.

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in the FDA Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by the cosmetic industry in response to a survey, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

According to 2019 VCRP data, Cocos Nucifera (Coconut) Fruit Extract is reported to be used in 429 formulations, 222 of which are leave-on formulations (Table 3).[15] All other in-use ingredients are reported to be used in 64 formulations or less. The results of the concentration of use survey conducted by the Council in 2019 indicate that Cocos Nucifera (Coconut) Liquid Endosperm has the highest maximum concentration of use; it is used at up to 6.5% in shampoos (non-coloring).[16-18] Cocos Nucifera (Coconut) Liquid Endosperm also has the highest maximum concentration of use in dermal leave-on formulations; it is used at up to 1.5% in face and neck products. Cocos Nucifera (Coconut) Fruit Extract is reported to be used at up to 0.12% in leave-on hair products. No uses were reported in the VCRP or by the Council for Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract.

Cocos nucifera (coconut)-derived ingredients may be used in products that can be incidentally ingested or come into contact with mucous membranes; for example**,** Cocos Nucifera (Coconut) Liquid Endosperm is reported to be used in a lipstick at up to 0.32%.[17] Additionally, *Cocos nucifera* (coconut)-derived ingredients are reported to be used in products that could possibly be inhaled; e.g. Cocos Nucifera (Coconut) Liquid Endosperm is used in spray face and neck products at 1.5% and Cocos Nucifera (Coconut) Fruit Juice is used in a face powder formulation (concentration of use not reported).[15,17,18] In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters > 10 µm, with propellant sprays yielding a greater fraction of droplets/particles < 10 µm compared with pump sprays.[19,20] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[21,22] Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.[23-25]

The coconut-derived ingredients described in this report are not restricted from use in any way under the rules governing cosmetic products in the European Union.[26]

Non-Cosmetic

Coconut fruit can be made into a variety of foods and beverages.[9] Coconut water is served directly as a beverage, while coconut milk is usually used as a food ingredient in various traditional cooking recipes.

The juice and shell of *Cocos nucifera* have been researched for use as antifungal and antibacterial treatments.[13,27-29] Various parts of the coconut including (coconut liquid endosperm, husk fiber, and coconut juice) have also been researched for use as alternative or therapeutic treatments (as herbal medicines or dietary supplements) for dermal wounds, health promotion, and cardiovascular protection.[30-34] The electrolyte composition of coconut water (e.g., potassium) can cause vasodilation in blood vessels; therefore, coconut water has been used as intravenous fluid for hydration and as a resuscitation fluid.[35] Coconut flower clusters (also called inflorescence) and coconut juice are reportedly used in traditional folk medicine in Southeast Asia to treat menstrual cycle disorders.[36,37]

TOXICOKINETIC STUDIES

No relevant toxicokinetics studies on coconut-derived ingredients were found in the public literature, and unpublished data were not submitted. In general, toxicokinetics data are not expected to be found on botanical ingredients because each botanical ingredient is a complex mixture of constituents.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

Cocos Nucifera (Coconut) Fruit Extract

An alcoholic extract of *Cocos nucifera* fruit was administered orally to male albino mice (6/group).[38] Mice received a single dose of *Cocos nucifera* fruit extract at doses of 0.25, 0.5, 1, 1.5, 2, 2.5, or 3 g/kg body weight via gavage. The control group received 1 ml of saline. Mice were observed for toxicity, morbidity, or mortality for 24 h. No deaths, significant decreases in body weight, or gross pathological abnormalities were observed in either species.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Cocos Nucifera (Coconut) Fruit Extract

The potential reproductive toxicity of an alcoholic extract of *Cocos nucifera* fruit was tested in two groups of male albino mice (8/group).[38] A negative control group was administered saline; and test groups 1 and 2 were given 125 mg/kg and 200 mg/kg of the alcoholic extract, respectively, of coconut fruit for 15 days. The left and right testis with epididymides were removed and weighed after removing the fat and surrounding tissues. Sperm counts were made from a homogenized solution of saline and caudal epididymides. There was a significant ($p < 0.01$) increase in relative testicular weight/ body weight in test group 1 compared to the control group. However, test group 2 showed a significant decrease in testis weight/body weight compared to the control group and test group 1. Also, an increase in sperm concentration was noted in male mice administered 125 mg/kg of coconut fruit extract.

Cocos Nucifera (Coconut) Liquid Endosperm

Groups of 5 gravid female albino rats received coconut water starting the day after the rats were mated.[39] The animals were dosed for 21 days (entire gestation period) as follows: group 1 (the control group) was given 1.0 ml/100 g of distilled water; group 2 was given 0.5 ml/100 g of coconut water; group 3 received 1.0 ml/100 g coconut water; and group 4 was administered 2.0 ml/100 g coconut water. The rats were weighed on days 1, 7, 14, and 21. Rats underwent laparotomy on day 10 of pregnancy, and upon delivery, the number of litter from each female was counted. An increase in body weight was noted in pregnant female rat of all dose groups compared to the control. No significant differences in the implantation site and number of litter between treated groups and the control group were observed.

The reproductive effects of coconut water were studied in male Wistar rats (5/group).[40] The first group was given 20 ml/kg of distilled water and served as the control. Group 2 was orally administered 20 ml/kg of corn oil, group 3 was given 20 ml/kg of coconut water, group 4 was administered 200 mg/kg of danazol (a synthetic androgen), and group 5 was given 200 mg/kg of danazol and 20 ml/kg coconut water. The rats received the test materials daily for 6 weeks. The rats showed a significant ($p < 0.05$) increase in sperm count, sperm motility, and sperm viability in groups 3 and 5 while a significant reduction in these variables was observed in group 4. A significant increase in luteinizing hormone (LH), follicle-stimulating hormone (FSH) and testosterone levels were observed in groups 3 and 5 when compared with group 4. All test groups showed a significant increase in reduced glutathione, total protein, and a significant reduction in malondialdehyde in testicular homogenates, when compared with the control and corn oil groups.

GENOTOXICITY

In Vitro

Cocos Nucifera (Coconut) Fruit Extract

The genotoxicity potential of a trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* was evaluated in a bacterial reverse mutation assay using *Salmonella typhimurium* strains: TA98, TA100, TA1537, TA1535 and *Escherichia coli* strain WP2uvrA.[5] The test article dissolved in sterile distilled water was administered at concentrations of 1.5, 5.0, 15, 50, 150, 500, 1500, and 5000 µg/plate, with and without metabolic activation. Appropriate positive and negative controls were used. The trade name mixture was not genotoxic.

Cocos Nucifera (Coconut) Liquid Endosperm

The genotoxicity potential of a trade name mixture containing 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate was evaluated in a bacterial reverse mutation assay using *S. typhimurium* strains: TA98, TA100, TA1537, TA1535 and *E. coli* strain WP2uvrA.[41] The test article dissolved in sterile distilled water was administered at concentrations of 1.5, 5.0, 15, 50, 150, 500, 1500, and 5000 µg/plate, with and without metabolic activation. Appropriate positive and negative controls were used. The trade name mixture containing Cocos Nucifera (Coconut) Liquid Endosperm was non-genotoxic.

In Vivo

No in vivo genotoxicity studies were discovered in the published literature, and no unpublished data were submitted.

CARCINOGENICITY

No carcinogenicity studies were discovered in the published literature, and no unpublished data were submitted.

OTHER RELEVANT STUDIES

Estrogenic Effects

Cocos Nucifera (Coconut) Fruit Juice

A study was performed to analyze the estrogenic effects of young coconut fruit juice using 4 groups of female Wistar rats (10/group).[37] The test material was prepared from reconstituted young coconut juice powder daily for oral administration. The first group consisted of ovariectomized rats, the second group consisted of sham-operated rats (placebo surgery), the third group consisted of ovariectomized rats injected intraperitoneally with exogenous estrogen (2.5 g/kg of estradiol benzoate) twice a week for four weeks, and the fourth group consisted of ovariectomized rats that were orally administered young coconut fruit juice (100 ml/kg/day) for four weeks. The rats were killed on the first day of the sixth week of the study, and their serum estradiol (E2) level was measured by chemiluminescent immunoassay. The ovariectomized rat group administered young coconut juice had significantly higher serum E2 levels ($P < 0.05$) than the control ovariectomized group. A significant increase ($P < 0.05$) was also observed when compared with the sham-operated group. A significant reduction ($P < 0.05$) in neuronal cell death was observed in ovariectomized rats administered young coconut fruit juice compared to the control ovariectomized group. The authors concluded that young coconut juice has estrogen-like characteristics.

Cytotoxicity and Cellular Effects

Cocos Nucifera (Coconut) Fruit Extract

A cellular viability assay was used to assess the ability of a trade name mixture of 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* to increase cellular metabolic activity in normal human dermal fibroblasts (NDHF).[5] Concentrations of 0.01% and 0.1% were diluted into serum-free media and incubated for 24 hours. The test article increased cellular viability by 16.5% and 10.3%, respectively. This mixture exhibited positive effects on cell metabolism.

Cocos Nucifera (Coconut) Shell Powder

The cytotoxic properties of coconut shell crude extract (concentrations of crude ranging from 0.1 mg/ml to 5 mg/ml) was evaluated in a DNA fragmentation analysis involving immortalized human epithelioid (HeLa) cells.[42] After a 48-hour incubation period, cell viability was measured using a 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay. At concentrations ranging from 0.1 mg/ml to 5 mg/ml, the percentage of inhibition gradually increased from 60% to 85%. The median inhibitory concentration (IC_{50}) was 1.77 mg/ml. The authors concluded that the cytotoxic activity was found due to the apoptosis induced in HeLa cells, which was demonstrated by DNA fragmentation analysis.

DERMAL IRRITATION AND SENSITIZATION

Dermal irritation and sensitization studies are summarized in Table 4. The results of in vitro dermal irritation studies of a trade name mixtures containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* and a trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate found these substances non-irritating. A trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* (as a 5% dilution in distilled water) was not a dermal irritant under occlusion in human volunteers. Two different trade name mixtures containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* and 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate were predicted to be non-sensitizing in in chemico models. A trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* (diluted to 5% in distilled water) and a leave-on product containing 1.47% Cocos Nucifera (Coconut) Liquid Endosperm were not irritating and not sensitizing in human repeat insult patch tests (HRIPTs).

Phototoxicity/Photosensitization

In Vitro

Cocos Nucifera (Coconut) Fruit Extract

A trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* was tested for phototoxicity using an in vitro EpiDerm™ model assay.[5] Fifty µL of the test article, at concentrations of 0.4%, 1.23%, and 3.7%, were applied to 2 tissue inserts and allowed to incubate overnight. Deionized water was used as the negative control and chlorpromazine was used as positive control. The day after application, the appropriate tissue inserts were irradiated with 1.7 mW/cm^2 (= 6 J/cm^2) long-wave UV (UVA) for 60 minutes. No phototoxic effects were observed.

OCULAR IRRITATION STUDIES

In Vitro

Cocos Nucifera (Coconut) Fruit Extract

The ocular irritation potential of a trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* was evaluated using the EpiOcular™ model (human corneal epithelial model) assay.[5] Each tissue was dosed with 20 µL DPBS prior to administering the test article. Fifty µL of the undiluted test article were then applied to 2 tissue inserts which were incubated for 30 minutes for liquid substances and 90 minutes for solid substances. Sterile DPBS and sterile deionized water were used as negative controls and 5% SDS solution and methyl acetate were used as positive controls. The test substance was considered to be non-irritating.

Cocos Nucifera (Coconut) Liquid Endosperm

The EpiOcular™ model assay was used to evaluate the irritation potential of a trade name material containing 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate, using the same protocol described above.[41] The test substance was considered to be non-irritating.

SUMMARY

According to the *Dictionary*, most of the 9 *Cocos nucifera* (coconut)-derived ingredients detailed in this safety assessment are reported to function in cosmetics as skin-conditioning agents, while some are reported to have other functions, such as humectants, abrasives, and hair conditioning agents. Botanicals, such as *Cocos nucifera*-derived ingredients, may contain hundreds of constituents, some of which may have the potential to cause toxic effects. In this assessment, CIR is reviewing the potential toxicity of each of the botanical ingredients as a whole, complex mixture. CIR is not reviewing the potential toxicity of the individual constituents. Additionally, some of the ingredients reviewed in this safety assessment may be consumed in food, and daily exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. Therefore, the primary focus of the safety assessment of these ingredients as used in cosmetics is on the potential for effects from topical exposure.

According to 2019 VCRP data, Cocos Nucifera (Coconut) Fruit Extract is reported to be used in 429 formulations, 222 of which are leave-on formulations. All other in-use ingredients are reported to be used in 64 formulations or less. The results of the concentration of use survey conducted by the Council in 2019 indicate that Cocos Nucifera (Coconut) Liquid Endosperm has the highest maximum concentration of use; it is used at up to 6.5% in shampoos (non-coloring). Cocos Nucifera (Coconut) Liquid Endosperm also has the highest maximum concentration of use in dermal leave-on formulations; it is used at up to 1.5% in face and neck products. Cocos Nucifera (Coconut) Fruit Extract is reported to be used at up to 0.12% in leave-on hair products. No uses were reported in the VCRP or by the Council for Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract.

Coconut fruit and coconut water (i.e. coconut liquid endosperm) can be made into a variety of foods and beverages. The juice and shell have been researched for use in alternative or therapeutic treatments.

An alcoholic extract of *Cocos nucifera* fruit increased relative testicular weight/body weight at 125 mg/kg, but significant decreased testis weight/body weight at 200 mg/kg in male mice. An increase in sperm concentration was noted in male mice that received 125 mg/kg of the test material. In a study of female rats, coconut water at up to 2.0 ml/100 g caused an increase in body weight pregnant rats when compared to the control. No significant differences in the implantation site and number of litter between treated groups and the control group were observed. In a study of coconut water in male rats, significant increases in sperm count, sperm motility, and sperm viability in groups that received coconut water were observed. A significant increase in LH, FSH, and testosterone levels were also observed in these groups.

Trade name mixtures containing Cocos Nucifera (Coconut) Liquid Endosperm (98%) and Cocos Nucifera (Coconut) Fruit Extract (20%) were not genotoxic in separate Ames assays, with or without metabolic activation.

A study performed to analyze the estrogenic effects of coconut fruit juice in rats found that ovariectomized rats that received young coconut juice had significantly higher serum E2 levels than the control ovariectomized rats and sham-operated rats. A significant reduction in neuronal cell death was observed ovariectomized rats administered young coconut fruit juice when compared to the control ovariectomized group.

A cellular viability assay of a trade name mixture of 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* found the test article increased cellular viability. Coconut shell crude extract (0.1 mg/ml to 5 mg/ml) inhibited HeLa cells, which gradually increased from 60% to 85% in a dose-dependent manner.

The results of in vitro dermal irritation studies of a trade name mixtures containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* and a trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate found these substances non-irritating. A trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* (as a 5% dilution in distilled water) was not a dermal irritant under occlusion in human volunteers. Two different trade name mixtures containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* and 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate were predicted to be non-sensitizing by in chemico models. A trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* (diluted to 5% in distilled water) and a leave-on product containing 1.47% Cocos Nucifera (Coconut) Liquid Endosperm were not irritating and not sensitizing in HRIPTs.

No phototoxic effects were observed in a trade name mixture containing 20% Cocos Nucifera (Coconut Fruit Extract) and 80% *Lactobacillus* tested at concentrations of 0.4%, 1.23%, and 1.23%. The results of in vitro ocular irritation studies of a trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* and a trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate found these substances non-irritating.

No relevant in vivo genotoxicity studies or carcinogenicity studies were discovered in the published literature, and no unpublished data were submitted. No relevant toxicokinetics studies were found in the published literature; however, in general, toxicokinetics data are not expected to be found on botanical ingredients because each botanical ingredient is a complex mixture of constituents.

DISCUSSION

To be determined…

CONCLUSION

To be determined…

TABLES

Table 1. Definitions and functions of the ingredients in this safety assessment.[1]

Ingredient	Definition	Function(s)
Cocos Nucifera (Coconut) Flower Extract	Cocos Nucifera (Coconut) Flower Extract is the extract from the flowers of *Cocos nucifera.*	Humectants; Skin-Conditioning Agents - Humectant; Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit	Cocos Nucifera (Coconut) Fruit is the fruit (or hardened endosperm) of *Cocos nucifera*.	Abrasives; Skin-Conditioning Agents- Miscellaneous
Cocos Nucifera (Coconut) Fruit Extract	Cocos Nucifera (Coconut) Fruit Extract is the extract of Cocos Nucifera (Coconut) Fruit	Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract	Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract is the extract of Cocos Nucifera (Coconut) Fruit and Cocos Nucifera (Coconut) Fruit Juice.	Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit Juice	Cocos Nucifera (Coconut) Fruit Juice is the liquid expressed from Cocos Nucifera (Coconut) Fruit.	Hair Conditioning Agents; Skin-Conditioning Agents-Humectant
Cocos Nucifera (Coconut) Fruit Powder	Cocos Nucifera (Coconut) Fruit Powder is the powder obtained from the dried, ground Cocos Nucifera (Coconut) Fruit.	Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit Water	Cocos Nucifera (Coconut) Fruit Water is an aqueous solution of the steam distillate obtained from the fruit of *Cocos nucifera*.	Hair Conditioning Agents; Skin-Conditioning Agents – Miscellaneous
Cocos Nucifera (Coconut) Liquid Endosperm	Cocos Nucifera (Coconut) Liquid Endosperm is the watery liquid obtained from the young fruit, *Cocos nucifera*.	Fragrance Ingredients
Cocos Nucifera (Coconut) Shell Powder	Cocos Nucifera (Coconut) Shell Powder is the powder obtained from the dried, ground shells of *Cocos nucifera.*	Abrasives; Bulking Agents

Table 2. Generic plant part definitions as they apply to coconut-derived ingredients.[1]

Plant Part	Definition
Drupe	A fleshy (usually one-seeded) fruit with a hard “stone” surrounding the seed
Endosperm	Energy storage tissue inside seeds
Flower	The reproductive shoot in flowering plants, usually with sepals, petals, stamens and pistil(s)
Fruit	Mature, ripened ovary of flowering plant, containing seeds
Husk	A dry outer covering of a fruit or seed
Juice	The liquid contained in the vegetative parts or fruits
Liquid endosperm	Energy storage tissue inside a seed that is in liquid form
Shell	The hard, usually fibrous layer of some fruits, especially nuts or the stones of drupes

Table 3. Frequency (2019) and concentration of use (2019) for coconut-derived ingredients.[15-18]

	# of Uses[15]	Max Conc of Use (%)[43]	# of Uses[15]	Max Conc of Use (%)[43]	# of Uses[15]	Max Conc of Use (%)[43]
	Coconut Flower Extract**		**Cocos Nucifera (Coconut) Fruit**		**Cocos Nucifera (Coconut) Fruit Extract**	
Totals*	**5**	**NR**	**24**	**0.001- 1**	**429**	**0.0000016 – 0.02**
Duration of Use						
Leave-On	1	NR	15	0.001	222	0.00001 – 0.02
Rinse-Off	3	NR	8	0.001 - 1	202	0.0000016 – 0.04
Diluted for (Bath) Use	1	NR	1	NR	5	NR
Exposure Type						
Eye Area	NR	NR	NR	NR	2	NR
Incidental Ingestion	NR	NR	1	NR	2	NR
Incidental Inhalation-Spray	NR	NR	4[a]; 2[b]	0.001[b]	23; 31[a];142[b]	0.0000016-0.011; 0.02[b]
Incidental Inhalation-Powder	NR	NR	4[a]	NR	31[a]	0.0007 – 0.02[c]
Dermal Contact	3	NR	19	0.001 - 1	364	0.00005 – 0.04
Deodorant (underarm)	NR	NR	NR	NR	2[b]	NR
Hair - Non-Coloring	2	NR	3	0.001	62	0.0000016 – 0.04
Hair-Coloring	NR	NR	NR	NR	NR	0.003
Nail	NR	NR	1	NR	NR	NR
Mucous Membrane	3	NR	9	0.001	138	0.0025 – 0.04
Baby Products	NR	NR	NR	NR	1	NR

	Cocos Nucifera (Coconut) Fruit Juice		**Cocos Nucifera (Coconut) Fruit Powder**		**Cocos Nucifera (Coconut) Fruit Water**	
Totals*	**28**	**0.006 – 1**	**18**	**NR**	**NR**	**0.0012-0.0098**
Duration of Use						
Leave-On	21	0.006 - 1	6	NR	NR	NR
Rinse Off	7	0.41	9	NR	NR	0.0012-0.0098
Diluted for (Bath) Use	NR	NR	3	NR	NR	NR
Exposure Type						
Eye Area	2	NR	NR	NR	NR	NR
Incidental Ingestion	NR	0.006	1	NR	NR	NR
Incidental Inhalation-Spray	2[a]	NR	4[a]; 1[b]	NR	NR	NR
Incidental Inhalation-Powder	1; 2[a]	0.015 - 1[c]	4[a]	NR	NR	NR
Dermal Contact	25	0.015 -1	16	NR	NR	0.0012-0.0098
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	3	NR	1	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	6	0.006	9	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR

	Cocos Nucifera (Coconut) Liquid Endosperm***		**Cocos Nucifera (Coconut) Shell Powder**		
Totals*	**64**	**0.0021 – 6.5**	**33**	**NR**	
Duration of Use					
Leave-On	46	0.0065 - 1.5	12	NR	
Rinse-Off	18	0.0021 - 6.5	21	NR	
Diluted for (Bath) Use	NR	NR	NR	NR	
Exposure Type					
Eye Area	NR	NR	NR	NR	
Incidental Ingestion	NR	0.32	1	NR	
Incidental Inhalation-Spray	5; 6[a]; 28[b]	0.0065-1.5; 0.1[b]	4[a]	NR	
Incidental Inhalation-Powder	6[a]	0.008[c]	4[a]	NR	
Dermal Contact	48	0.0021-1.5	32	NR	
Deodorant (underarm)	NR	NR	NR	NR	
Hair - Non-Coloring	12	0.0021-6.5	NR	NR	
Hair-Coloring	4	NR	NR	NR	
Nail	NR	NR	NR	NR	
Mucous Membrane	3	0.32	19	NR	
Baby Products	NR	NR	NR	NR	

NR = Not reported.

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

**Coconut Flower Extract is reported in the VCRP; it was assumed it refers to Cocos Nucifera (Coconut) Flower Extract

***Referred to as Cocos Nucifera (Coconut) Water in the VCRP

[a.] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

[b.] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

[c.] It is possible these products may be powders, but it is not specified whether the reported uses are powders.

Table 4. Dermal irritation and sensitization

Ingredient/Concentration/ Dose/Vehicle	Test System	Method	Results	Reference
		Irritation – In Vitro		
Trade name mixture of 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus*; 30 µL	Reconstructed human epidermal tissue	EpiDerm™ model	Non-irritating	[5]
Trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate; 30 µL	Reconstructed human epidermal tissue	EpiDerm™ model	Non-irritating	[41]
		Irritation - Human		
Trade name mixture of 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus*; 5% dilution in distilled water; 0.2 ml tested	5 male and 45 female subjects	Dermal irritation study; occlusive patches applied for 48 h and scored 48 h after patch removal	No irritation	[44]
		Sensitization – In Chemico		
Trade name mixture of 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus*; 0.98 to 2000 µM in dimethyl sulfoxide (DMSO)	KeratinoSens™ cell line	ARE-Nrf2 luciferase test method in accordance with Organization for Economic Co-operation and Development Test Guideline (OECD TG) 422D; 12 test concentrations tested in triplicate and incubated for 48 h; positive control was cinnamic aldehyde in DMSO and negative control was a 1% DMSO	Not sensitizing; IC_{50} was > 1000 µM	[5]
Trade name mixture of 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus*	Cysteine and lysine peptides	Direct peptide reactivity assay (DPRA) in accordance with OECD 442C	Not sensitizing; mean depletion rate was 2.37%	[5]
Trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate; 0.98 to 2000 µM in DMSO	KeratinoSens™ cell line	ARE-Nrf2 luciferase test method in accordance with Organization for Economic Co-operation and Development Test Guideline (OECD TG) 422D; 12 test concentrations tested in triplicate and incubated for 48 h; positive control was cinnamic aldehyde in DMSO and negative control was a 1% DMSO	Not sensitizing; IC_{50} was > 1000 µM	[41]
Trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate	Cysteine and lysine peptides	Direct peptide reactivity assay (DPRA) in accordance with OECD 442C	Not sensitizing; mean depletion rate was 2.37%	[41]
		Sensitization- Human		
Trade name mixture of 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus*; diluted to 5% in distilled water; 0.2 ml tested	50 subjects	HRIPT; test sites occluded; 10 - 14 day rest period prior to 24 h challenge patch; reactions scored 24 and 48 h post application	Not irritating and not sensitizing	[45]
1.47% Cocos Nucifera (Coconut) Liquid Endosperm in a leave-on facial spray; 0.2 g tested	104 subjects	HRIPT; test sites semi-occluded; approximate 2-week rest period prior to challenge patch; reactions score 24 and 72 h post application	Not irritating and not sensitizing	[46]

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2019 FDA VCRP Raw Data

02A - Bath Oils, Tablets, and Salts	COCOS NUCIFERA (COCONUT) FRUIT	1
05I - Other Hair Preparations	COCOS NUCIFERA (COCONUT) FRUIT	3
07E - Lipstick	COCOS NUCIFERA (COCONUT) FRUIT	1
08C - Nail Creams and Lotions	COCOS NUCIFERA (COCONUT) FRUIT	1
10A - Bath Soaps and Detergents	COCOS NUCIFERA (COCONUT) FRUIT	4
10E - Other Personal Cleanliness Products	COCOS NUCIFERA (COCONUT) FRUIT	3
11B - Beard Softeners	COCOS NUCIFERA (COCONUT) FRUIT	3
12A - Cleansing	COCOS NUCIFERA (COCONUT) FRUIT	1
12C - Face and Neck (exc shave)	COCOS NUCIFERA (COCONUT) FRUIT	2
12D - Body and Hand (exc shave)	COCOS NUCIFERA (COCONUT) FRUIT	2
12F - Moisturizing	COCOS NUCIFERA (COCONUT) FRUIT	2
12J - Other Skin Care Preps	COCOS NUCIFERA (COCONUT) FRUIT	1
01C - Other Baby Products	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
02A - Bath Oils, Tablets, and Salts	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	2
02B - Bubble Baths	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	2
02D - Other Bath Preparations	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
03D - Eye Lotion	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
03F - Mascara	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
04A - Cologne and Toilet waters	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	6
04E - Other Fragrance Preparation	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	16
05A - Hair Conditioner	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	20
05B - Hair Spray (aerosol fixatives)	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
05C - Hair Straighteners	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
05E - Rinses (non-coloring)	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	3
05F - Shampoos (non-coloring)	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	20
05G - Tonics, Dressings, and Other Hair Grooming Aids	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	15
05H - Wave Sets	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
05I - Other Hair Preparations	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
09A - Dentifrices	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	2
10A - Bath Soaps and Detergents	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	101
10B - Deodorants (underarm)	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	2
10E - Other Personal Cleanliness Products	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	30
12A - Cleansing	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	23
12C - Face and Neck (exc shave)	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	6
12D - Body and Hand (exc shave)	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	25
12F - Moisturizing	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	125
12G - Night	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
12H - Paste Masks (mud packs)	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1
12I - Skin Fresheners	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	1

12J - Other Skin Care Preps	COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	20
03D - Eye Lotion	COCOS NUCIFERA (COCONUT) FRUIT JUICE	2
05I - Other Hair Preparations	COCOS NUCIFERA (COCONUT) FRUIT JUICE	3
07B - Face Powders	COCOS NUCIFERA (COCONUT) FRUIT JUICE	1
07C - Foundations	COCOS NUCIFERA (COCONUT) FRUIT JUICE	8
07F - Makeup Bases	COCOS NUCIFERA (COCONUT) FRUIT JUICE	5
10A - Bath Soaps and Detergents	COCOS NUCIFERA (COCONUT) FRUIT JUICE	6
12A - Cleansing	COCOS NUCIFERA (COCONUT) FRUIT JUICE	1
12C - Face and Neck (exc shave)	COCOS NUCIFERA (COCONUT) FRUIT JUICE	2
02A - Bath Oils, Tablets, and Salts	COCOS NUCIFERA (COCONUT) FRUIT POWDER	1
02D - Other Bath Preparations	COCOS NUCIFERA (COCONUT) FRUIT POWDER	2
05I - Other Hair Preparations	COCOS NUCIFERA (COCONUT) FRUIT POWDER	1
09A - Dentifrices	COCOS NUCIFERA (COCONUT) FRUIT POWDER	1
10A - Bath Soaps and Detergents	COCOS NUCIFERA (COCONUT) FRUIT POWDER	5
11E - Shaving Cream	COCOS NUCIFERA (COCONUT) FRUIT POWDER	1
12A - Cleansing	COCOS NUCIFERA (COCONUT) FRUIT POWDER	2
12C - Face and Neck (exc shave)	COCOS NUCIFERA (COCONUT) FRUIT POWDER	2
12D - Body and Hand (exc shave)	COCOS NUCIFERA (COCONUT) FRUIT POWDER	2
12F - Moisturizing	COCOS NUCIFERA (COCONUT) FRUIT POWDER	1
12C - Face and Neck (exc shave)	COCOS NUCIFERA (COCONUT) MILK POWDER	1
09C - Other Oral Hygiene Products	COCOS NUCIFERA (COCONUT) SHELL POWDER	1
10A - Bath Soaps and Detergents	COCOS NUCIFERA (COCONUT) SHELL POWDER	8
10E - Other Personal Cleanliness Products	COCOS NUCIFERA (COCONUT) SHELL POWDER	10
12A - Cleansing	COCOS NUCIFERA (COCONUT) SHELL POWDER	1
12C - Face and Neck (exc shave)	COCOS NUCIFERA (COCONUT) SHELL POWDER	3
12D - Body and Hand (exc shave)	COCOS NUCIFERA (COCONUT) SHELL POWDER	1
12H - Paste Masks (mud packs)	COCOS NUCIFERA (COCONUT) SHELL POWDER	1
12J - Other Skin Care Preps	COCOS NUCIFERA (COCONUT) SHELL POWDER	8
04E - Other Fragrance Preparation	COCOS NUCIFERA (COCONUT) WATER	5
05A - Hair Conditioner	COCOS NUCIFERA (COCONUT) WATER	2
05F - Shampoos (non-coloring)	COCOS NUCIFERA (COCONUT) WATER	5
05G - Tonics, Dressings, and Other Hair Grooming Aids	COCOS NUCIFERA (COCONUT) WATER	2
05I - Other Hair Preparations	COCOS NUCIFERA (COCONUT) WATER	3
06D - Hair Shampoos (coloring)	COCOS NUCIFERA (COCONUT) WATER	4
07C - Foundations	COCOS NUCIFERA (COCONUT) WATER	1
07F - Makeup Bases	COCOS NUCIFERA (COCONUT) WATER	1

10A - Bath Soaps and Detergents	COCOS NUCIFERA (COCONUT) WATER	3
12A - Cleansing	COCOS NUCIFERA (COCONUT) WATER	4
12C - Face and Neck (exc shave)	COCOS NUCIFERA (COCONUT) WATER	4
12D - Body and Hand (exc shave)	COCOS NUCIFERA (COCONUT) WATER	2
12F - Moisturizing	COCOS NUCIFERA (COCONUT) WATER	21
12I - Skin Fresheners	COCOS NUCIFERA (COCONUT) WATER	1
12J - Other Skin Care Preps	COCOS NUCIFERA (COCONUT) WATER	2
13B - Indoor Tanning Preparations	COCOS NUCIFERA (COCONUT) WATER	4
02D - Other Bath Preparations	COCONUT FLOWER EXTRACT	1
05F - Shampoos (non-coloring)	COCONUT FLOWER EXTRACT	1
05I - Other Hair Preparations	COCONUT FLOWER EXTRACT	1
10A - Bath Soaps and Detergents	COCONUT FLOWER EXTRACT	2

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Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: June 1, 2018

SUBJECT: Concentration of Use by FDA Product Category: Coconut-Derived Ingredients

Concentration of Use by FDA Product Category – Coconut-Derived Ingredients*

Cocos Nucifera (Coconut) Fruit Extract
Cocos Nucifera (Coconut) Flower Extract
Cocos Nucifera (Coconut) Fruit
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract
Cocos Nucifera (Coconut) Fruit Juice
Cocos Nucifera (Coconut) Fruit Powder
Cocos Nucifera (Coconut) Oil
Cocos Nucifera (Coconut) Seed Butter
Cocos Nucifera (Coconut) Shell Powder
Cocos Nucifera (Coconut) Water**

Ingredient	Product Category	Maximum Concentration of Use
Cocos Nucifera (Coconut) Fruit Extract	Hair conditioners	0.00005-0.04%
Cocos Nucifera (Coconut) Fruit Extract	Hair sprays Aerosol Pump spray	 0.011% 0.0001%
Cocos Nucifera (Coconut) Fruit Extract	Shampoos (noncoloring) Aerosol	0.00005-0.011% 0.0000016%
Cocos Nucifera (Coconut) Fruit Extract	Tonics, dressings and other hair grooming aids Not spray	0.02-0.12% 0.00001%
Cocos Nucifera (Coconut) Fruit Extract	Hair dyes and colors	0.003%
Cocos Nucifera (Coconut) Fruit Extract	Bath soaps and detergents	0.0025-0.04%
Cocos Nucifera (Coconut) Fruit Extract	Shaving soap	0.01%
Cocos Nucifera (Coconut) Fruit Extract	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0005%
Cocos Nucifera (Coconut) Fruit Extract	Face and neck products Not spray Spray	 0.0007-0.02% 0.0005%
Cocos Nucifera (Coconut) Fruit Extract	Body and hand products Not spray Spray	 0.0032-0.02% 0.00005%
Cocos Nucifera (Coconut) Fruit Extract	Moisturizing products Not spray	 0.0005%
Cocos Nucifera (Coconut) Fruit	Hair conditioners	0.001%
Cocos Nucifera (Coconut) Fruit	Shampoos (noncoloring)	0.001%
Cocos Nucifera (Coconut) Fruit	Tonics, dressings and other hair grooming aids	0.001%
Cocos Nucifera (Coconut) Fruit	Bath soaps and detergents	0.001%
Cocos Nucifera (Coconut) Fruit Juice	Foundations	0.36%
Cocos Nucifera (Coconut) Fruit Juice	Makeup bases	0.36%
Cocos Nucifera (Coconut) Fruit Juice	Face and neck products Not spray	 1%
Cocos Nucifera (Coconut) Fruit Juice	Body and hand products Not spray	 0.015%
Cocos Nucifera (Coconut) Oil	Baby lotions, oils and creams Not powder	 3-4.4%
Cocos Nucifera (Coconut) Oil	Bath oils, tablets and salts	0.99%

Cocos Nucifera (Coconut) Oil	Eyeliners	0.26-24.7%
Cocos Nucifera (Coconut) Oil	Eye shadows	0.25-0.3%
Cocos Nucifera (Coconut) Oil	Eye lotions	4.4%
Cocos Nucifera (Coconut) Oil	Mascaras	0.05-0.13%
Cocos Nucifera (Coconut) Oil	Hair conditioners	0.005-4.5%
Cocos Nucifera (Coconut) Oil	Hair sprays Aerosol Pump spray	 3.9-5% 0.5%
Cocos Nucifera (Coconut) Oil	Hair straighteners	0.1%
Cocos Nucifera (Coconut) Oil	Rinses (noncoloring)	2%
Cocos Nucifera (Coconut) Oil	Shampoos (noncoloring)	0.01-0.1%
Cocos Nucifera (Coconut) Oil	Tonics, dressings and other hair grooming aids	0.01-72.7%
Cocos Nucifera (Coconut) Oil	Other hair preparations (noncoloring)	0.0001%
Cocos Nucifera (Coconut) Oil	Hair dyes and colors	0.01-0.5%
Cocos Nucifera (Coconut) Oil	Hair rinses (coloring)	0.5%
Cocos Nucifera (Coconut) Oil	Hair shampoos (coloring)	0.005%
Cocos Nucifera (Coconut) Oil	Hair bleaches	0.005-0.29%
Cocos Nucifera (Coconut) Oil	Other hair coloring preparations	7.1%
Cocos Nucifera (Coconut) Oil	Foundations	0.092-10.7%
Cocos Nucifera (Coconut) Oil	Lipstick	0.63-20.5%
Cocos Nucifera (Coconut) Oil	Makeup bases	10.4%
Cocos Nucifera (Coconut) Oil	Makeup fixatives	0.17%
Cocos Nucifera (Coconut) Oil	Other makeup preparations	0.9%
Cocos Nucifera (Coconut) Oil	Cuticle softeners	0.049-10.8%
Cocos Nucifera (Coconut) Oil	Nail polish and enamel removers	0.02%
Cocos Nucifera (Coconut) Oil	Other manicuring preparations	3%
Cocos Nucifera (Coconut) Oil	Dentifrices (aerosol, liquid, pastes and powders)	0.0004%
Cocos Nucifera (Coconut) Oil	Bath soaps and detergents	0.0051-4.7%
Cocos Nucifera (Coconut) Oil	Deodorants Not spray Aerosol	 0.01% 0.5%
Cocos Nucifera (Coconut) Oil	Aftershave lotions	0.43%
Cocos Nucifera (Coconut) Oil	Shaving cream	0.016-10%
Cocos Nucifera (Coconut) Oil	Shaving soap	3%
Cocos Nucifera (Coconut) Oil	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0001-19%
Cocos Nucifera (Coconut) Oil	Depilatories	0.1%
Cocos Nucifera (Coconut) Oil	Face and neck products Not spray	 0.26-2.5%
Cocos Nucifera (Coconut) Oil	Body and hand products Not spray Spray	 0.01-98.5% 0.01%
Cocos Nucifera (Coconut) Oil	Moisturizing products	

	Not spray Spray	0.5-20% 5%
Cocos Nucifera (Coconut) Oil	Night products Not spray	 1%
Cocos Nucifera (Coconut) Oil	Paste masks and mud packs	2%
Cocos Nucifera (Coconut) Oil	Other skin care preparations	2-24%
Cocos Nucifera (Coconut) Oil	Suntan products Not spray Aerosol Pump spray	 0.5% 0.51% 0.51%
Cocos Nucifera (Coconut) Oil	Indoor tanning preparations	5.8%
Cocos Nucifera (Coconut) Oil	Other suntan preparations Not spray	 0.045%
Cocos Nucifera (Coconut) Water**	Hair conditioners	0.0021-0.1%
Cocos Nucifera (Coconut) Water**	Hair sprays Aerosol	 0.0065%
Cocos Nucifera (Coconut) Water**	Shampoos (noncoloring)	0.0021-6.5%
Cocos Nucifera (Coconut) Water**	Tonics, dressings and other hair grooming aids	0.1%
Cocos Nucifera (Coconut) Water**	Foundations	0.65%
Cocos Nucifera (Coconut) Water**	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0021-0.03%
Cocos Nucifera (Coconut) Water**	Face and neck products Spray	 1.5%
Cocos Nucifera (Coconut) Water**	Body and hand products Not spray	 0.008%

*Ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

**After the survey was completed, the name of Cocos Nucifera (Coconut) Water was changed to Cocos Nucifera (Coconut) Liquid Endosperm.

Information collected in 2018
Table prepared June 1, 2018

Distributed for Comment Only -- Do Not Cite or Quote

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: May 28, 2019

SUBJECT: Updated Use Information: Coconut-Derived Ingredients

Concentration of Use by FDA Product Category – Coconut-Derived Ingredients*

Cocos Nucifera (Coconut) Fruit Extract
Cocos Nucifera (Coconut) Flower Extract
Cocos Nucifera (Coconut) Fruit
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract
Cocos Nucifera (Coconut) Fruit Juice
Cocos Nucifera (Coconut) Fruit Powder
Cocos Nucifera (Coconut) Oil
Cocos Nucifera (Coconut) Seed Butter
Cocos Nucifera (Coconut) Shell Powder
Cocos Nucifera (Coconut) Water**

Ingredient	Product Category	Maximum Concentration of Use
Cocos Nucifera (Coconut) Fruit Extract	Hair conditioners	0.00005-0.04%
Cocos Nucifera (Coconut) Fruit Extract	Hair sprays Aerosol Pump spray	 0.011% 0.0001%
Cocos Nucifera (Coconut) Fruit Extract	Shampoos (noncoloring) Aerosol	0.00005-0.011% 0.0000016%
Cocos Nucifera (Coconut) Fruit Extract	Tonics, dressings and other hair grooming aids Not spray	0.02-0.12% 0.00001%
Cocos Nucifera (Coconut) Fruit Extract	Hair dyes and colors	0.003%
Cocos Nucifera (Coconut) Fruit Extract	Bath soaps and detergents	0.0025-0.04%
Cocos Nucifera (Coconut) Fruit Extract	Shaving soap	0.01%
Cocos Nucifera (Coconut) Fruit Extract	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0005%
Cocos Nucifera (Coconut) Fruit Extract	Face and neck products Not spray Spray	 0.0007-0.02% 0.0005%
Cocos Nucifera (Coconut) Fruit Extract	Body and hand products Not spray Spray	 0.0032-0.02% 0.00005%
Cocos Nucifera (Coconut) Fruit Extract	Moisturizing products Not spray	 0.0005%
Cocos Nucifera (Coconut) Fruit	Hair conditioners	0.001%
Cocos Nucifera (Coconut) Fruit	Shampoos (noncoloring)	0.001%
Cocos Nucifera (Coconut) Fruit	Tonics, dressings and other hair grooming aids	0.001%
Cocos Nucifera (Coconut) Fruit	Bath soaps and detergents	0.001%
Cocos Nucifera (Coconut) Fruit	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1%
Cocos Nucifera (Coconut) Fruit Juice	Foundations	0.36%
Cocos Nucifera (Coconut) Fruit Juice	Lipsitck	0.006%
Cocos Nucifera (Coconut) Fruit Juice	Makeup bases	0.36%
Cocos Nucifera (Coconut) Fruit Juice	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.41%
Cocos Nucifera (Coconut) Fruit Juice	Face and neck products Not spray	 1%

Cocos Nucifera (Coconut) Fruit Juice	Body and hand products Not spray	 0.015%
Cocos Nucifera (Coconut) Fruit Juice	Moisturizing products Not spray	 0.093%
Cocos Nucifera (Coconut) Oil	Baby lotions, oils and creams Not powder	 3-4.4%
Cocos Nucifera (Coconut) Oil	Bath oils, tablets and salts	0.99%
Cocos Nucifera (Coconut) Oil	Eyeliners	0.26-24.7%
Cocos Nucifera (Coconut) Oil	Eye shadows	0.25-0.3%
Cocos Nucifera (Coconut) Oil	Eye lotions	4.4%
Cocos Nucifera (Coconut) Oil	Mascaras	0.05-0.13%
Cocos Nucifera (Coconut) Oil	Hair conditioners	0.005-4.5%
Cocos Nucifera (Coconut) Oil	Hair sprays Aerosol Pump spray	 3.9-5% 0.5%
Cocos Nucifera (Coconut) Oil	Hair straighteners	0.1%
Cocos Nucifera (Coconut) Oil	Rinses (noncoloring)	2%
Cocos Nucifera (Coconut) Oil	Shampoos (noncoloring)	0.01-0.1%
Cocos Nucifera (Coconut) Oil	Tonics, dressings and other hair grooming aids	0.01-72.7%
Cocos Nucifera (Coconut) Oil	Other hair preparations (noncoloring)	0.0001%
Cocos Nucifera (Coconut) Oil	Hair dyes and colors	0.01-0.5%
Cocos Nucifera (Coconut) Oil	Hair rinses (coloring)	0.5%
Cocos Nucifera (Coconut) Oil	Hair shampoos (coloring)	0.005%
Cocos Nucifera (Coconut) Oil	Hair bleaches	0.005-0.29%
Cocos Nucifera (Coconut) Oil	Other hair coloring preparations	7.1%
Cocos Nucifera (Coconut) Oil	Foundations	0.092-10.7%
Cocos Nucifera (Coconut) Oil	Lipstick	0.63-20.5%
Cocos Nucifera (Coconut) Oil	Makeup bases	10.4%
Cocos Nucifera (Coconut) Oil	Makeup fixatives	0.17%
Cocos Nucifera (Coconut) Oil	Other makeup preparations	0.9%
Cocos Nucifera (Coconut) Oil	Cuticle softeners	0.049-10.8%
Cocos Nucifera (Coconut) Oil	Nail polish and enamel removers	0.02%
Cocos Nucifera (Coconut) Oil	Other manicuring preparations	3%
Cocos Nucifera (Coconut) Oil	Dentifrices (aerosol, liquid, pastes and powders)	0.0004%
Cocos Nucifera (Coconut) Oil	Bath soaps and detergents	0.0051-4.7%
Cocos Nucifera (Coconut) Oil	Deodorants Not spray Aerosol	 0.01% 0.5%
Cocos Nucifera (Coconut) Oil	Aftershave lotions	0.43%
Cocos Nucifera (Coconut) Oil	Shaving cream	0.016-10%
Cocos Nucifera (Coconut) Oil	Shaving soap	3%
Cocos Nucifera (Coconut) Oil	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0001-19%

Cocos Nucifera (Coconut) Oil	Depilatories	0.1%
Cocos Nucifera (Coconut) Oil	Face and neck products Not spray	 0.26-2.5%
Cocos Nucifera (Coconut) Oil	Body and hand products Not spray Spray	 0.01-98.5% 0.01%
Cocos Nucifera (Coconut) Oil	Moisturizing products Not spray Spray	 0.5-20% 5%
Cocos Nucifera (Coconut) Oil	Night products Not spray	 1%
Cocos Nucifera (Coconut) Oil	Paste masks and mud packs	2%
Cocos Nucifera (Coconut) Oil	Other skin care preparations	2-24%
Cocos Nucifera (Coconut) Oil	Suntan products Not spray Aerosol Pump spray	 0.5% 0.51% 0.51%
Cocos Nucifera (Coconut) Oil	Indoor tanning preparations	5.8%
Cocos Nucifera (Coconut) Oil	Other suntan preparations Not spray	 0.045%
Cocos Nucifera (Coconut) Water**	Hair conditioners	0.0021-0.1%
Cocos Nucifera (Coconut) Water**	Hair sprays Aerosol	 0.0065%
Cocos Nucifera (Coconut) Water**	Shampoos (noncoloring)	0.0021-6.5%
Cocos Nucifera (Coconut) Water**	Tonics, dressings and other hair grooming aids	0.1%
Cocos Nucifera (Coconut) Water**	Foundations	0.65%
Cocos Nucifera (Coconut) Liquid Endosperm	Lipstick	0.32%
Cocos Nucifera (Coconut) Water**	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0021-0.03%
Cocos Nucifera (Coconut) Water**	Face and neck products Spray	 1.5%
Cocos Nucifera (Coconut) Water**	Body and hand products Not spray	 0.008%

*Ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

**After the survey was completed, the name of Cocos Nucifera (Coconut) Water was changed to Cocos Nucifera (Coconut) Liquid Endosperm.

Information collected in 2018

Table prepared June 1, 2018

Updated May 28, 2019: late response received changes indicated in green

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Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: July 24, 2019

SUBJECT: Concentration of Use Information: Cocos Nucifera (Coconut) Fruit Water

Concentration of Use by FDA Product Category – Cocos Nucifera (Coconut) Fruit Water

Product Category	Maximum Concentration of Use
Shaving cream	0.0012%
Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0098%

Information collected in 2019

Table prepared July 23, 2019

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Personal Care Products Council
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Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: September 23, 2019

SUBJECT: Cocos Nucifera (Coconut) Liquid Endosperm

Anonymous. 2019. Summary: HRIPT on a product containing 1.47% Cocos Nucifera (Coconut) Liquid Endosperm.

1620 L Street, N.W., Suite 1200 | Washington, D.C. 20036 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org

September 2019

Summary: HRIPT on a product containing 1.47% Cocos Nucifera (Coconut) Liquid Endosperm (confirmed to be liquid endosperm)

Product Type	Concentration	Study Type	Subjects No.	Study Conditions	Conclusions
Leave-on Facial Spray	1.47%	HRIPT	104	Neat/Semi-occlusive	The test material did not induce irritation nor any evidence of induc allergic contact dermatitis in humar subjects.

The HRIPT is summarized as follows:

1) Test material (approximately 0.2g) was applied neat to the back between the scapulae and beltline with a semi-occlusive dressing.
2) During the induction phase, patches were applied 3 times per week (Monday, Wednesday, and Friday) for a total of nine applications. Patch was removed after 24 hours application, the evaluation was made just prior to re-application, rest periods consisted of 24 hours following each Tuesday and Thursday removal, and 48 hours following each Saturday removal.
3) Approximately 2 weeks after the final induction patch application, a challenge patch was applied to a virgin test site adjacent to the original induction patch site. The patch was removed and the site was evaluated at 24 and 72 hours post-application.

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Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: September 25, 2019

SUBJECT: Updated Use Information: Coconut-Derived Ingredients

Concentration of Use by FDA Product Category – Coconut-Derived Ingredients*

Cocos Nucifera (Coconut) Fruit Extract
Cocos Nucifera (Coconut) Flower Extract
Cocos Nucifera (Coconut) Fruit
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract
Cocos Nucifera (Coconut) Fruit Juice
Cocos Nucifera (Coconut) Fruit Powder
Cocos Nucifera (Coconut) Oil
Cocos Nucifera (Coconut) Seed Butter
Cocos Nucifera (Coconut) Shell Powder
Cocos Nucifera (Coconut) Water**

Ingredient	Product Category	Maximum Concentration of Use
Cocos Nucifera (Coconut) Fruit Extract	Hair conditioners	0.00005-0.04%
Cocos Nucifera (Coconut) Fruit Extract	Hair sprays Aerosol Pump spray	 0.011% 0.0001%
Cocos Nucifera (Coconut) Fruit Extract	Shampoos (noncoloring) Aerosol	0.00005-0.011% 0.0000016%
Cocos Nucifera (Coconut) Fruit Extract	Tonics, dressings and other hair grooming aids Not spray	0.02% 0.00001%
Cocos Nucifera (Coconut) Fruit Extract	Hair dyes and colors	0.003%
Cocos Nucifera (Coconut) Fruit Extract	Bath soaps and detergents	0.0025-0.04%
Cocos Nucifera (Coconut) Fruit Extract	Shaving soap	0.01%
Cocos Nucifera (Coconut) Fruit Extract	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0005%
Cocos Nucifera (Coconut) Fruit Extract	Face and neck products Not spray Spray	 0.0007-0.02% 0.0005%
Cocos Nucifera (Coconut) Fruit Extract	Body and hand products Not spray Spray	 0.0032-0.02% 0.00005%
Cocos Nucifera (Coconut) Fruit Extract	Moisturizing products Not spray	 0.0005%
Cocos Nucifera (Coconut) Fruit	Hair conditioners	0.001%
Cocos Nucifera (Coconut) Fruit	Shampoos (noncoloring)	0.001%
Cocos Nucifera (Coconut) Fruit	Tonics, dressings and other hair grooming aids	0.001%
Cocos Nucifera (Coconut) Fruit	Bath soaps and detergents	0.001%
Cocos Nucifera (Coconut) Fruit	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1%
Cocos Nucifera (Coconut) Fruit Juice	Foundations	0.36%

Cocos Nucifera (Coconut) Fruit Juice	Lipsitck	0.006%
Cocos Nucifera (Coconut) Fruit Juice	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.41%
Cocos Nucifera (Coconut) Fruit Juice	Face and neck products Not spray	 1%
Cocos Nucifera (Coconut) Fruit Juice	Body and hand products Not spray	 0.015%
Cocos Nucifera (Coconut) Fruit Juice	Moisturizing products Not spray	 0.093%
Cocos Nucifera (Coconut) Oil	Baby lotions, oils and creams Not powder	 3-4.4%
Cocos Nucifera (Coconut) Oil	Bath oils, tablets and salts	0.99%
Cocos Nucifera (Coconut) Oil	Eyeliners	0.26-24.7%
Cocos Nucifera (Coconut) Oil	Eye shadows	0.25-0.3%
Cocos Nucifera (Coconut) Oil	Eye lotions	4.4%
Cocos Nucifera (Coconut) Oil	Mascaras	0.05-0.13%
Cocos Nucifera (Coconut) Oil	Hair conditioners	0.005-4.5%
Cocos Nucifera (Coconut) Oil	Hair sprays Aerosol Pump spray	 3.9-5% 0.5%
Cocos Nucifera (Coconut) Oil	Hair straighteners	0.1%
Cocos Nucifera (Coconut) Oil	Rinses (noncoloring)	2%
Cocos Nucifera (Coconut) Oil	Shampoos (noncoloring)	0.01-0.1%
Cocos Nucifera (Coconut) Oil	Tonics, dressings and other hair grooming aids	0.01-72.7%
Cocos Nucifera (Coconut) Oil	Other hair preparations (noncoloring)	0.0001%
Cocos Nucifera (Coconut) Oil	Hair dyes and colors	0.01-0.5%
Cocos Nucifera (Coconut) Oil	Hair rinses (coloring)	0.5%
Cocos Nucifera (Coconut) Oil	Hair shampoos (coloring)	0.005%
Cocos Nucifera (Coconut) Oil	Hair bleaches	0.005-0.29%
Cocos Nucifera (Coconut) Oil	Other hair coloring preparations	7.1%
Cocos Nucifera (Coconut) Oil	Foundations	0.092-10.7%
Cocos Nucifera (Coconut) Oil	Lipstick	0.63-20.5%
Cocos Nucifera (Coconut) Oil	Makeup bases	10.4%
Cocos Nucifera (Coconut) Oil	Makeup fixatives	0.17%
Cocos Nucifera (Coconut) Oil	Other makeup preparations	0.9%
Cocos Nucifera (Coconut) Oil	Cuticle softeners	0.049-10.8%
Cocos Nucifera (Coconut) Oil	Nail polish and enamel removers	0.02%
Cocos Nucifera (Coconut) Oil	Other manicuring preparations	3%
Cocos Nucifera (Coconut) Oil	Dentifrices (aerosol, liquid, pastes and powders)	0.0004%
Cocos Nucifera (Coconut) Oil	Bath soaps and detergents	0.0051-4.7%
Cocos Nucifera (Coconut) Oil	Deodorants Not spray	 0.01%

	Aerosol	0.5%
Cocos Nucifera (Coconut) Oil	Aftershave lotions	0.43%
Cocos Nucifera (Coconut) Oil	Shaving cream	0.016-10%
Cocos Nucifera (Coconut) Oil	Shaving soap	3%
Cocos Nucifera (Coconut) Oil	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0001-19%
Cocos Nucifera (Coconut) Oil	Depilatories	0.1%
Cocos Nucifera (Coconut) Oil	Face and neck products Not spray	 0.26-2.5%
Cocos Nucifera (Coconut) Oil	Body and hand products Not spray Spray	 0.01-98.5% 0.01%
Cocos Nucifera (Coconut) Oil	Moisturizing products Not spray Spray	 0.5-20% 5%
Cocos Nucifera (Coconut) Oil	Night products Not spray	 1%
Cocos Nucifera (Coconut) Oil	Paste masks and mud packs	2%
Cocos Nucifera (Coconut) Oil	Other skin care preparations	2-24%
Cocos Nucifera (Coconut) Oil	Suntan products Not spray Aerosol Pump spray	 0.5% 0.51% 0.51%
Cocos Nucifera (Coconut) Oil	Indoor tanning preparations	5.8%
Cocos Nucifera (Coconut) Oil	Other suntan preparations Not spray	 0.045%
Cocos Nucifera (Coconut) Water**	Hair conditioners	0.0021-0.1%
Cocos Nucifera (Coconut) Water**	Hair sprays Aerosol	 0.0065%
Cocos Nucifera (Coconut) Water**	Shampoos (noncoloring)	0.0021-6.5%
Cocos Nucifera (Coconut) Water**	Tonics, dressings and other hair grooming aids	0.1%
Cocos Nucifera (Coconut) Liquid Endosperm	Lipstick	0.32%
Cocos Nucifera (Coconut) Water**	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0021-0.03%
Cocos Nucifera (Coconut) Water**	Face and neck products Spray	 1.5%
Cocos Nucifera (Coconut) Water**	Body and hand products Not spray	 0.008%

*Ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

**After the survey was completed, the name of Cocos Nucifera (Coconut) Water was changed to Cocos Nucifera (Coconut) Liquid Endosperm.

Information collected in 2018
Table prepared June 1, 2018
Updated May 28, 2019: late response received changes indicated in green
Updated September 25, 2019: Cocos Nucifera (Coconut) Fruit Extract, Tonics, dressings and other hair grooming aids 0.12% concentration deleted; Cocos Nucifera (Coconut) Fruit Juice in makeup bases deleted; Cocos Nucifera (Coconut) Water** in foundations deleted

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Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: October 15, 2019

SUBJECT: Cocos Nucifera (Coconut) Fruit Extract

Anonymous. 2019. Cocos Nucifera (Coconut) Fruit Extract.

1620 L Street, N.W., Suite 1200 | Washington, D.C. 20036 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org

2019

- **Cocos Nucifera (Coconut) Fruit Extract**

Manufacturing Process:

The fruit is extracted with specified eluent(s) under appropriate temperature conditions, to yield a concentrate. The concentrate containing the phytochemical constituents is then blended with the desired diluent(s) and preservation system to produce the final ingredient. The ingredient is evaluated for physiochemical properties according to the specification requirements for the batch to be released. In addition, the concentrate is also evaluated for contaminants and physiochemical properties as needed.

Typical eluents include Water, Butylene Glycol, Glycerin, Carthamus Tinctorius (Safflower) Seed Oil, and Propylene Glycol

Heavy Metal & Pesticides/ Allergens/ Impurities:

The following heavy metal testing was conducted on the concentrate in a glycerin and water base:

	Heavy Metal	Detection	Reporting Limit	Heavy Metal	Detection	Reporting Limit
Heavy metals:	Antimony	Not Detected	0.005 mg/l	Iron	Not Detected	0.1 mg/l
	Arsenic	0.115 mg/l	0.008 mg/l	Lead	Not Detected	0.0025 mg/l
	Cadmium	Not Detected	0.001 mg/l	Mercury	Not Detected	0.0002 mg/l
	Chromium	Not Detected	0.002 mg/l	Nickel	0.083 mg/l	0.002 mg/l

Pesticides: There were no residual pesticides detected. (Parameters: 8081 GCS Pesticides and 8141 GCS, O/P Pesticides)

The following Allergen testing was conducted on the concentrate in an alcohol base:

	Fragrance Ingredient	Threshold	Fragrance Ingredient	Threshold
Presence of the 26 allergens defined by the 7th amendment to the EU Cosmetic Directive:	Amyl Cinnamal	<1ppm-0.0001%	Anise Alcohol	<1ppm-0.0001%
	Benzyl Alcohol	<1ppm-0.0001%	Benzyl Cinnamate	<1ppm-0.0001%
	Cinnamyl Alcohol	<1ppm-0.0001%	Farnesol	<1ppm-0.0001%
	Citral	<1ppm-0.0001%	Butylphenyl Methylpropional	<1ppm-0.0001%
	Eugenol	<1ppm-0.0001%	Linalool	<1ppm-0.0001%
	Hydroxycitronellal	<1ppm-0.0001%	Benzyl Benzoate	<1ppm-0.0001%
	Isoeugenol	<1ppm-0.0001%	Citronellol	<1ppm-0.0001%
	Amylcinnamyl Alcohol	<1ppm-0.0001%	Hexyl Cinnamal	<1ppm-0.0001%
	Benzyl Salicylate	<1ppm-0.0001%	Limonene	<1ppm-0.0001%
	Cinnamal	<1ppm-0.0001%	Methyl l2-octynoate	<1ppm-0.0001%
	Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	<1ppm-0.0001%	Alpha-Isomethyl Inone (Other Name: Methyl Lonone Gamma)	<1ppm-0.0001%
	Coumarin	<1ppm-0.0001%	Evernia Prunastri (Oak Moss) Extract	Not Detected
	Geraniol	<1ppm-0.0001%	Evernia Furfuracea (Tree Moss) Extract	Not Detected

*The given values correspond to the limit of determination OR *Results have been calculated form highest reported values published.

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Additional information:

- A typical product with the **Cocos Nucifera (Coconut) Fruit Extract** prepared in water has the following specifications:

Analysis:

Specification	Range	Actual
APPEARANCE	Colorless to light yellow liquid	PASS
MICROBIAL PLATE COUNT	Less than 100 organisms per gram	PASS
ODOR	Characteristic	PASS
PH	4.0 - 7.0 at 25° C	6.7
REFRACTIVE INDEX	1.3250 - 1.3400 at 25° C	1.3327
SOLUBILITY	Soluble in any proportion in water	PASS
SPECIFIC GRAVITY	0.99 - 1.01 at 25° C	1.00

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Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: September 25, 2019

SUBJECT: Scientific Literature Review: Safety Assessment of Coconut-Derived Ingredients as Used in Cosmetics (release date August 29, 2019)

The Personal Care Products Council has no suppliers listed for Cocos Nucifera (Coconut) Flower Extract and Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract.

The Personal Care Products Council respectfully submits the following comments on the scientific literature review, Safety Assessment of Coconut-Derived Ingredients as Used in Cosmetics.

Introduction - Please revise "plant-derived fatty acids" to "plant-derived fatty acid oils"

In the Introduction, it would be helpful to clearly describe the difference between the water (a distillation product - "aqueous solution of the steam distillate") and endosperm liquid. It would also be helpful to state that the food industry calls the endosperm liquid "coconut water".

Method of Manufacture - Please include how the cosmetic ingredient "water" is manufactured (the definition states: "aqueous solution of the steam distillate").

DART, Cocos Nucifera (Coconut) Fruit Extract - Please state the endpoints that were examined in the study in male mice (reference 34), as it is not clear what "no other effects" refers to. Please correct: "No other effects regarding treated were observed."

DART, Cocos Nucifera (Coconut) Liquid Endosperm - A study in which rats were treated only during gestation should be called a "developmental" rather than "reproductive" (this also needs to be corrected in the Summary). Please indicate what endpoints were examined in the study described in reference 36.

Neuroprotective Effect - Please explain why the study (reference 38) was done in ovariectomized rats.

Sensitization, Human, Cocos Nucifera (Coconut) Fruit Extract - Rather than "10-14 days after initial patch", the challenge was completed 10-14 days after the last induction patch.

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