Safety Assessment of *Helianthus annuus* (Sunflower)-Derived Ingredients as Used in Cosmetics

Status: Draft Report for Panel Review
Release Date: November 20, 2015
Panel Meeting: Date: December 14-15, 2015

The 2015 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, 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 Lillian J. Gill, D.P.A. This report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

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Cosmetic Ingredient Review

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MEMORANDUM

To: CIR Expert Panel and Liaisons

From: Lillian C. Becker, M.S.
Scientific Analyst and Writer

Date: November 20, 2015

Subject: *Helianthus annuus* (Sunflower)-Derived Ingredients as Used in Cosmetics

Attached is the draft report of *Helianthus annuus* (sunflower)-derived ingredients as used in cosmetics. [*Helian122015Rep*] All 13 of these ingredients are derived from parts of the *H. annuus* (sunflower) plant. The sunflower seed oils (with the exception of ozonized sunflower seed oil) were reviewed in the vegetable-derived oils report and are not included here.

The SLR was posted on October 5, 2015 with a request for any additional data.

The Council has submitted concentration of use data, and summaries of HRIPTs and use studies of products containing *H. annuus* (sunflower)-derived ingredients. [*helian122015Data1-5*] Council comments have been addressed. [*helian122015PCPC*]

If the data included in this report adequately address the safety of the *H. annuus* (sunflower)-derived ingredients, the Panel should formulate a Conclusion, provide the rationale to be described in the Discussion, and issue a tentative report for public comment. If the data are not sufficient for making a determination of safety, then an Insufficient Data Announcement should be issued that provides a listing of the data that are needed.

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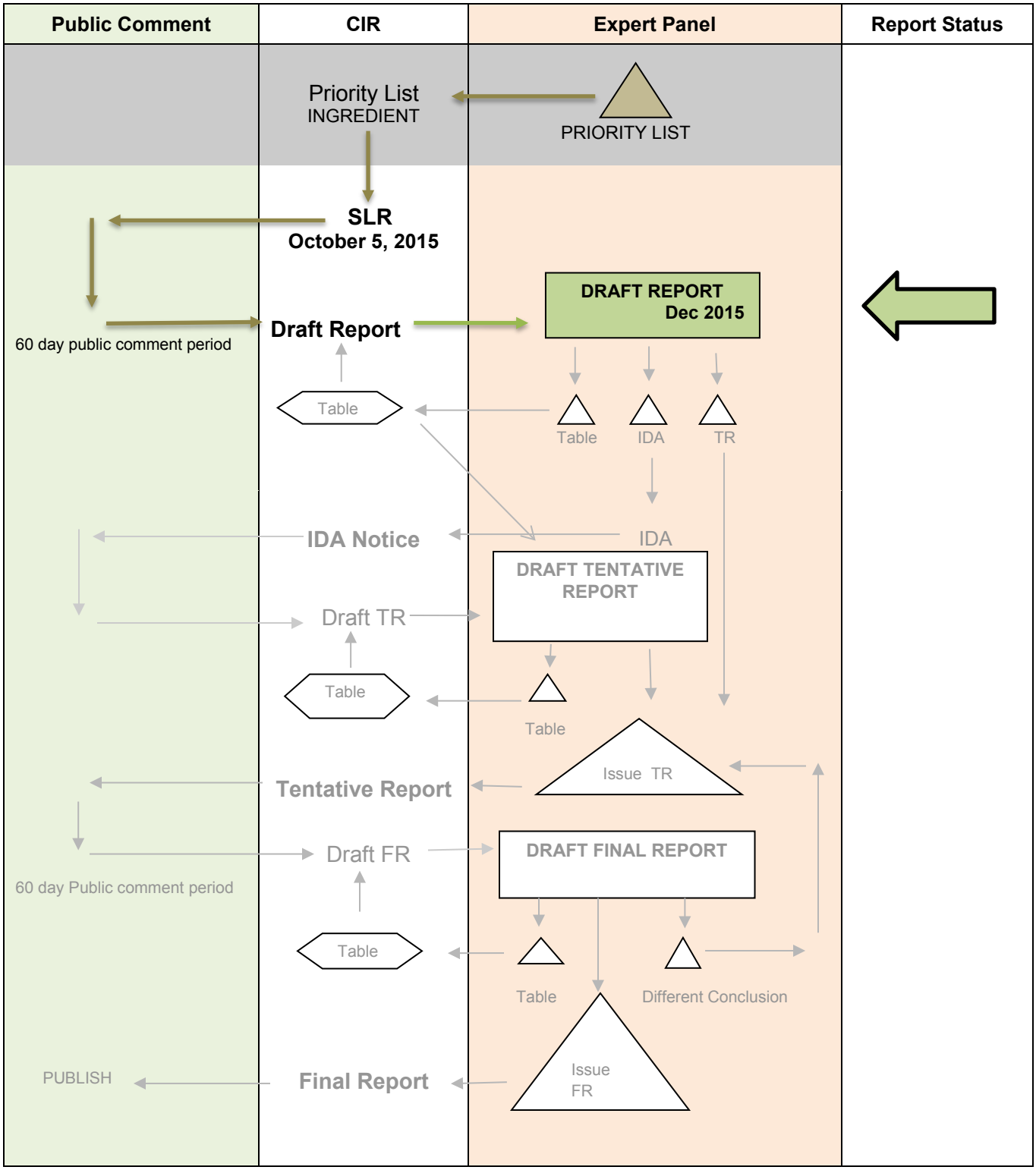
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Helianthus annuus (sunflower)-derived ingredients

MEETING Dec 2015



History – *Helianthus annuus* (Sunflower)-Derived Ingredients

2014 – Added to the priority list

September, 2015 – SLR was posted with the following data requests:

- Characterization of constituents of each of these ingredients
- Method of manufacture for cosmetics for each of these ingredients including methods for removing constituents of concern
- Dermal and inhalation toxicity data for each of these ingredients at or above the reported concentrations of use
- Reproductive and developmental toxicity, genotoxicity, and carcinogenicity data for each of these ingredients at or above the reported concentrations of use
- Dermal and ocular irritation data for each of these ingredients at or above the reported concentrations of use
- Irritation and sensitization data of each of these ingredients at or above the reported concentrations of use

December, 2015 – The Panel is to examine the draft report.

***H. annuus*-Derived Ingredients** Data Profile for **December, 2015**. Writer - Lillian Becker

	ADME			Acute toxicity			Repeated dose toxicity			Irritation			Sensitization					
	Dermal Penetration	Log K_{ow}	Use	Oral	Dermal	Inhale	Oral	Dermal	Inhale	Ocular Irritation	Dermal Irr. Animal	Dermal Irr Human	Sensitization Animal	Sensitization Human	Repro/Devel toxicity	Genotoxicity	Carcinogenicity	Phototoxicity
Helianthus annuus (sunflower) extract			X											X				
Helianthus annuus (sunflower) flower extract			X															
Helianthus annuus (sunflower) leaf/stem extract																		
Helianthus annuus (sunflower) sprout extract																		
Helianthus annuus (sunflower) seed			X															
Helianthus annuus (sunflower) seed butter																		
Helianthus annuus (sunflower) seedcake			X															
Helianthus annuus (sunflower) seed extract			X									X		X				
Helianthus annuus (sunflower) seed flour																		
Hydrolyzed sunflower seed wax			X															
Hydrogenated sunflower seed extract																		
Ozonized sunflower seed oil												X						
Helianthus annuus (sunflower) seed wax			X									X		X				

Search Strategy – Sunflower

SciFinder

“Sunflower toxicity” – 682 hits. Remove patents, 559 hits. English, 386 hits. 13 possibly useful.

NTP

“sunflower” and “Helianthus annuus” – 1 hit. Not useful.

Google – National Sunflower Association

PubMed

("HELIANTHUS ANNUUS (SUNFLOWER)"[TW] OR "HELIANTHUS ANNUUS (SUNFLOWER)"[TW] OR "HELIANTHUS ANNUUS"[TW] OR "HELIANTHUS ANNUUS (SUNFLOWER)"[TW] OR "HELIANTHUS ANNUUS"[TW] OR "SUNFLOWER"[TW]) – 5948 hits; culled with toxic* - 121 hits, none useful.

"HELIANTHUS ANNUUS" AND toxic* - 76 hits, none useful.

ECHA

Helianthus Annuus, Helianthus Annuus extract, and Helianthus Annuus, ext. are preregistered substances that have no data available yet.

GOOGLE

Data from Purdue, FDA, and Feedipedia.

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INTRODUCTION

This is a review of the available scientific literature and unpublished data relevant to assessing the safety of *Helianthus annuus* (sunflower)-derived ingredients as used in cosmetics. According to the *International Cosmetic Ingredient Dictionary and Handbook*, the functions of these ingredients include skin-conditioning agents – miscellaneous, abrasives, and absorbents (Table 1).[1] The 13 ingredients in this safety assessment are:

Helianthus Annuus (Sunflower) Extract
Helianthus Annuus (Sunflower) Flower Extract
Helianthus Annuus (Sunflower) Leaf/Stem Extract
Helianthus Annuus (Sunflower) Sprout Extract
Helianthus Annuus (Sunflower) Seed Extract
Helianthus Annuus (Sunflower) Seed
Helianthus Annuus (Sunflower) Seed Butter
Helianthus Annuus (Sunflower) Seedcake
Helianthus Annuus (Sunflower) Seed Flour
Helianthus Annuus (Sunflower) Seed Wax
Hydrogenated Sunflower Seed Extract
Hydrolyzed Sunflower Seed Wax
Ozonized Sunflower Seed Oil

The ingredients in this report are grouped together because they are extracts, waxes, or powders (flour) derived from plant parts of *Helianthus annuus*, the sunflower. Helianthus annuus (sunflower) seed oil, and other *Helianthus annuus*-derived seed oils (with the exception of ozonized sunflower seed oil), were included in the Cosmetic Ingredient Review (CIR) safety assessment of plant-derived oils and are therefore not covered in this review.[2]

In that safety assessment of plant-derived oils, the CIR Expert Panel (Panel) concluded that helianthus annuus (sunflower) seed oil, helianthus annuus (sunflower) seed oil unsaponifiables, hydrogenated sunflower seed oil, and sunflower seed acid were safe as used (Table 2).[2] The Panel has also reviewed the safety of phytosterols, plant-derived sterols that include phytosteryl sunflower sedate, as used in cosmetics and concluded that they were also safe as used.[3]

The seeds of *Helianthus annuus*, both raw and roasted, are consumed by humans on a regular basis. The rest of the plant, as well as the seeds, are fed to farm animals and pets. Exposure from food use would result in much larger systemic exposures than those from use in cosmetic products because exposure through the skin has much less potential for systemic effects than from absorption through oral exposures. This is because the rates of absorption and metabolism of these ingredients in the skin are expected to be negligible compared to the corresponding rates in the digestive tract. Additionally, there are only a few reported cases of food allergies to the seeds and of inhalation allergies to the pollen.[4-12] Therefore, the oral toxicity of these ingredients will not be the focus of this safety assessment although oral information may be included here. The primary focus of this safety assessment of *Helianthus annuus* (sunflower)-derived ingredients as used in cosmetics is on the potential for irritation and sensitization from dermal and inhalation exposure; systemic toxicity potential of *Helianthus* annuus-derived ingredients via oral exposure is not addressed further in this report. The primary focus of this safety assessment is the review of safety based on topical exposure. It is noted that *Helianthus annuus* is a member of the *Asteraceae* family; members of this family are known to comprise, in part, sensitizers.[6,10,13-15]

Botanicals such as *Helianthus annuus* (sunflower)-derived ingredients contain hundreds of constituents, some of which have the potential to cause toxic effects. For example, sesquiterpene lactones may cause allergic reactions and toxicity in sufficient amounts. In this assessment, CIR is reviewing information available to evaluate the potential toxicity of each of the *Helianthus annuus* (sunflower)-derived ingredients as a whole, complex substance. Except for specific constituents of concern, CIR is not reviewing information that may be available to assess the potential toxicity of the individual constituents of which *Helianthus annuus* are composed.

The ingredient names, according to the *International Cosmetic Ingredient Dictionary and Handbook*, are written as listed above, without italics and without abbreviations. When referring to the plant from which these ingredients are derived in this safety assessment, standard scientific practice will be followed, using *italics* (e.g., *Helianthus annuus*).

CHEMISTRY AND CHARACTERIZATION

Helianthus annuus

Helianthus annuus is an annual plant in the family *Asteraceae* (synonym *Compositae*), daisy or sunflower family, sub family *Asteroideae*.[16-19] The plant is a dicot with a height range of 0.7-3.5 m.[19] *Helianthus annuus* leaves are rough, broad, coarsely toothed, and mostly alternate. What is often called the "flower" of the *Helianthus annuus* is actually a "flower head" called a pseudanthium or captulum, which is made up of numerous small individual five-petaled flowers ("florets"). The outer flowers, which resemble petals, are called ray flowers. These ray flowers consist of a ligule composed of fused petals of an asymmetrical ray flower. They are sexually sterile and may be yellow, red, orange, or other colors. The flowers in the center of the head are called disk flowers, and these are arranged spirally. If pollenated, usually by insects, the flowers mature into fruit (seeds). The taproot is strong and penetrates to a depth of 3 m and has large lateral spread of surface roots. Wild *Helianthus annuus* is a widely branched annual plant with multiple flower heads that mature sequentially.

Helianthus annuus seeds are achenes (or fruits) that consist of a kernel (true seed) and a pericarp (hull), which are 4-sided and flat.[18,20] These seeds are approximately 0.6 cm long and 0.3 cm wide. Oil seeds (seeds having high oleic acid content; oil content >40% and 35%-38% protein) usually have a black seed coat; edible seeds (oil content approximately 30%) usually have a hull that is dark brown or white. The kernel consists of an embryo, endosperm, and seed coat. The

pericarp (maternal tissue) consists of several layers: cuticle (external layer), epidermis, hypodermis, phytomelanin layer, fibrose tissue, and parenchymal layers adjacent to the kernel.

The pseudanthium (flower head) may contain 1000–4000 florets, with the potential of as many seeds.[21] The average yield of seeds in a pseudanthium is 1200-1500.[20] The average yield of seeds range from 900–1,575 kg/ha; yields of over 3,375 kg/ha have been reported

Helianthus annuus is native to western North America.[19] The plant was introduced to Europe and Russia in the 16th century and has spread to tropical and temperate countries including Russia, Argentina, the combined European Union, China, India, Turkey, and South Africa.[22] Hybridization and selective breeding has increased oil production. The breeding resulted in the development of strains with high oleic acid content, referred to as oil-seed.[23]

Definition

The definitions and functions of the *Helianthus annuus* (sunflower)-derived ingredients included in this report are provided in Table 1. In some cases, the definition provides insight on the method(s) of manufacture.

The ingredients in this report are related by source, as each is a derivative of a part, or parts, of the *Helianthus annuus* plant. While the identity and concentrations of ingredient constituents may vary from plant part to plant part, and by extraction method, those constituents and their concentrations cannot be known until such information is provided. Constituent information is not necessarily needed to determine if these ingredients should be grouped together. However, should such ingredient-specific, constituent information be provided, any differences therein are likely to be informative in the determination of safety.

Physical and Chemical Properties

Helianthus annus (sunflower) extract is a brownish yellow powder with a characteristic odor (Table 3).

The color of helianthus annuus (sunflower) seed flour changes with pH.[24] From pH 2-7, the color is cream white. At a pH of 8, it is grey; at pH of 9 it is yellowish grey, at pH of 10 it is light brown, and at pH of 10.5 it is dark brown.

Constituents and Components

Helianthus annuus *Plants*

The *Helianthus annuus* plant has a high amount of moisture at maturity.[25] The composition of the *Helianthus annuus* plant (minus the pseudanthium) varies with maturity level (Table 4).

Helianthus annuus leaves are known to contain high levels of saponins, but they have not been quantified.[25]

The fatty acid profile of *Helianthus annuus* varies with selective breeding; a specific example is provided in Tables 5.[25] Overall, oleic acid (C18:1) may be present as low as 14%-39.4% in wild/conventional (edible) plant seeds and as high as 75%-90.7% in selectively bred plant (oil) seeds; palmitic acid (C16:0) may be present as low as 2.6%-5.0% in high oleic acid oil seeds or as high as 5.0%-7.6% in low oleic acid oil seeds. The phytosterols and tocopherols also vary with the oleic acid content in the seeds of wild and bred plants (Table 6).

The vitamin with the greatest content in *Helianthus annuus* non-oilseed kernels is folate at 239.86 µg/100 g dry material (Table 7). The "active ingredient" in helianthus annuus (sunflower) flower extract is reported to be vitamin F.[26]

The hulls are difficult to remove from the oilseed strains of *Helianthus annuus* seed and thus, the data on oilseed includes the hulls (Tables 5, 6, and 7). Hulls are easily separated from the non-oilseed strains of *Helianthus annuus*, and thus, the non-oilseed data does not include the hull.

The amino acid content profile of *Helianthus annuus* seed flour includes phenylalanine + tyrosine (8.2 g/100 g crude protein) and leucine (6.5 g/100 g crude protein; Table 8).[25] The fatty acid methyl esters detected in *Helianthus annuus* seed flour were palmitate (12.04% of detected fatty acids), stearate (8.26%), oleate (31.14%), and linoleate (48.56%).[24] The unheated flour is reported to be made up of 6.80% moisture, 45.50% protein, 4.40% crude fat, 2.00% crude fiber, and 8.10% ash and the heated flour is reported to be made up of 8.56% moisture, 42.37% protein, 9.20% crude fat, 1.90% crude fiber, and 7.70% ash.

The composition (e.g., crude protein, fiber, and fat) of *Helianthus annuus* seed meal (possible precursor to *Helianthus annuus* seed extract and seed cake) may vary with the source and depending on whether or not the seed hull is included or the seeds are partially dehulled (Table 9).[25] This also applies to amino acids and crude protein contained in the meal (Table 10).

Electrophoresis showed that protein bands were similar among 3 *Helianthus annuus* seed strain samples.[27] There were 3 polypeptides groups of helianthinin fraction detected. Of these, 2 were acidic (α, MW=36,800-42,900 and α', MW=31,000-35,300), and 1 was basic (β, MW=21,000-29,600). The molecular weight of the 2S albumin proteins ranged from 11,500-20,100. *Helianthus annuus* proteins are rich in globulins (55%-60 %), albumins (17%-23 %), and glutelins (11%-17 %).[28]

Helianthus annuus (sunflower) seed wax is a complex mixture consisting of long chain non-glyceride esters, and a small amount of free fatty alcohols and free fatty acids.[29]

Constituents of Concern

Helianthus annuus plants are reported to contain sesquiterpene lactones, which may cause allergic reactions.[13,30]

The carcinogen benz[a]pyrene (3,4-benzpyrene) has been detected in unrefined *Helianthus annuus* seed oil.[31] The source may be endogenous synthesis, atmospheric pollution, or contamination from the soil.

Helianthus annuus petals were reported to contain saponins, helianthosides A, B, and C derived from echinocystic acid.[32]

A 14-amino-acid, backbone-cyclized protein (SFTI-12) has been reported in the seeds of *Helianthus annuus*; it possesses potent trypsin inhibitory activity as well as weaker inhibitory activity against proteases such as thrombin.[33]

Helianthus annuus kernels and hulls contain phenolic compounds, which include chlorogenic and caffeic acids; these are easily oxidized during common processing causing green to brown discoloration in protein isolates and/or concentrates.[34,35] These compounds have been studied both for their additive/synergistic effect on carcinogenesis and their anti-carcinogenic properties with no definitive result.[36]

Helianthus annuus seeds have been found to contain an allergen, 2S albumin, which shows homology to the 2S albumins in other seeds.[37] The 2S albumin proteins in other seeds, such as rapeseed, castor beans, cottonseed, Brazil nuts, and walnuts, have been associated with allergenicity. Consequently, the 2S albumin proteins in *Helianthus annuus* seed may also be allergens.

Method of Manufacture

A scheme of the general manufacturing process of *Helianthus annuus* oil, flour/protein, and meal is depicted in Figure 1.

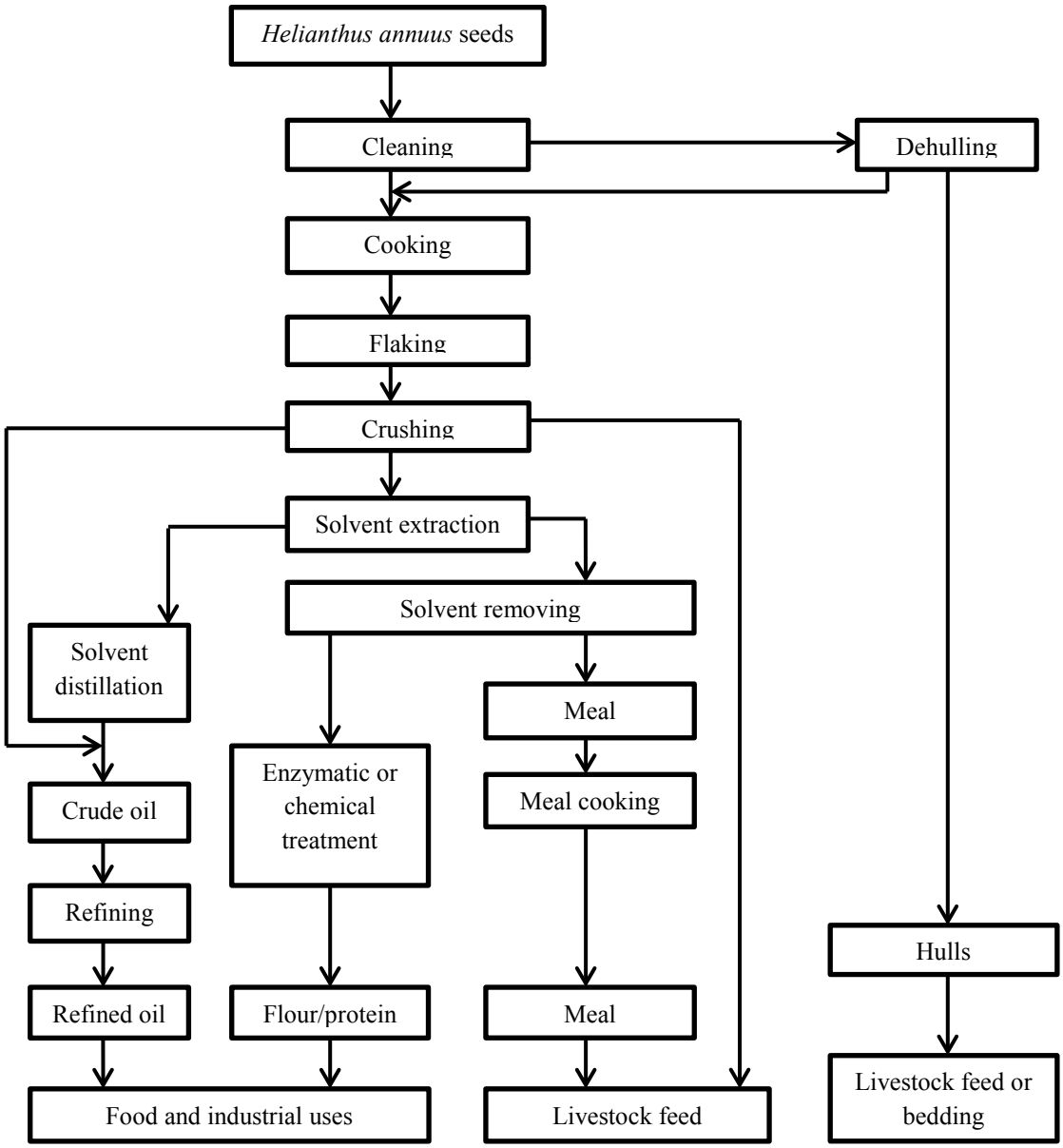

Figure 1. Method of manufacture of *Helianthus annuus* (sunflower)-derived products.[25]

One supplier reports that helianthus annuus (sunflower) extract is a water/grain alcohol extract of the macerated dried bark.[38]

One supplier reports that helianthus annuus (sunflower) flower extract is a water/grain alcohol extract of the macerated dried flowers (1:5 extract:dried flowers).[26]

Impurities

A supplier reported that helianthus annuus (sunflower) extract (the extract of the dried bark) contained ≤5% ash or moisture; ≤10 ppm heavy metals, and ≤1 ppm organic residues.[38] There were no pesticides detected and solvent (water/grain alcohol) residue was ≤0.01%. The total yeast and mold detected was ≤50 colony forming units (cfu)/g. The sample was negative for *Escherichia coli*, *Salmonella*, and *Staphyloccoccus*.

The same supplier reported that helianthus annuus (sunflower) extract (defined as the extract of the dried flowers) contained ≤5% ash and ≤1 ppm pesticide residues.[26] A sample had an ash content of 3.53%.

The carcinogen benz[a]pyrene (3,4-benzpyrene) has been detected in unrefined *Helianthus annuus* seed oil.[31] While the source may be endogenous synthesis, atmospheric pollution, or contamination from the soil, there is also evidence that levels of benz[a]pyrene increase in plant products as a result of processing.

Commercial *Helianthus annuus* seeds that have not been shelled were shown to be contaminated with pollen, a potential allergen.[10]

Aflatoxins or molds that produce aflatoxins have been detected in some dried *Helianthus annuus* seeds samples.[39-41] Not all samples are contaminated.[42]

USE

Cosmetic

The safety of the cosmetic ingredients included in this safety assessment is evaluated based on the data the Panel receives from the U.S. Food and Drug Administration (FDA) and the cosmetics industry on the expected cosmetic use of ingredients. The data from the FDA are those it collects from manufacturers on the use of individual ingredients in cosmetics by cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP). Those received from the cosmetic industry are submitted in response to a survey conducted by the Personal Care Products Council (Council) of the maximum reported use concentrations by category.

According to 2015 VCRP data, helianthus annuus (sunflower) seed extract had the highest reported number of reported uses in this safety assessment at 380 formulations (Table 11).[43] Helianthus annuus (sunflower) extract had the next highest number of reported uses in 91 formulations. All other in-use ingredients are reported to be used in 70 or fewer formulations.

The results of the concentration of use survey conducted by the Council in 2015 indicate that hydrolyzed sunflower seed wax had the highest reported maximum concentration of use; it is used at up to 10% in rinse-off skin cleansing formulations.[44,45] The highest maximum concentration of use reported for products resulting in leave-on exposure is 4% in helianthus annuus (sunflower) seed wax in mascara and 4% in hydrolyzed sunflower seed wax in lipstick.

The ingredients not in use according to the VCRP and industry survey are listed in Table 12.

In some cases, reports of uses were received in the VCRP, but no concentration of use data were available. For example, helianthus annuus (sunflower) flower extract is reported to be used in 5 formulations, but no use concentration data were available. In other cases, no reported uses were received in the VCRP, but use concentrations were provided in the industry survey. For example, helianthus annuus (sunflower) seed was not reported in the VCRP to be in use, but the industry survey indicated that it is used in 2 types of hair products and a suntan product. It should be presumed that helianthus annuus (sunflower) seed is used in at least one cosmetic formulation for which a concentration of use is reported.

Helianthus annuus (sunflower) extract (concentration not reported), helianthus annuus (sunflower) seed extract (up to 0.1%), helianthus annuus (sunflower) seedcake (up to 0.41%), helianthus annuus (sunflower) seed wax (up to 4%), and hydrolyzed sunflower seed wax (up to 3.5%) are reported to be used in products used near the eye. Helianthus annuus (sunflower) seed extract (up to 1%), helianthus annuus (sunflower) seedcake (up to 0.00012%), helianthus annuus (sunflower) seed wax (up to 3.4%), and hydrolyzed sunflower seed wax (up to 4%) are used in products that may be ingested. Helianthus annuus (sunflower) extract (0.075%), helianthus annuus (sunflower) flower extract (concentration not reported), helianthus annuus (sunflower) seed extract (up to 1%), helianthus annuus (sunflower) seedcake (up to 0.12%), helianthus annuus (sunflower) seed wax (up to 3.4%), and hydrolyzed sunflower seed wax (up to 3.4%) are used in products that may come in contact with mucus membranes. Products containing these ingredients may be applied as frequently as several times per day and may come in contact with the skin or hair for variable periods following application. Daily or occasional use may extend over many years.

Additionally, some of the *Helianthus annuus* (sunflower)-derived ingredients are used in cosmetic sprays and could possibly be inhaled; for example, helianthus annuus (sunflower) seed extract is reported to be used at up to 0.05% in hair sprays and helianthus annuus (sunflower) seedcake is reported to be used at up to 0.0012% in spray face and neck products. In practice, 95%-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.[46,47] 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.[48,49]

All of the *Helianthus annuus* (sunflower)-derived ingredients named in the report are not restricted from use in any way under the rules governing cosmetic products in the European Union (EU).[50]

Non-Cosmetic

Helianthus annuus is cultivated primarily for the seeds which yield the world's second most common source of edible oil.[19] Hulled seed press-cake is used as a high protein feed for livestock. The raw kernels are used as feed for poultry and cage birds. The stalks and leaves are used for fodder, silage and as a green-manure crop.[51,52] The seed hulls are used for filler in livestock feed and bedding. A yellow dye is extracted from the flowers.

Non-oilseed seeds are used for confectionary purposes.[25] De-hulled seeds (kernels) are eaten roasted and salted alone or in other foods (e.g., salads and cakes). Whole *Helianthus annuus* seeds (with hulls) are also eaten as a snack food. Such seeds contain less oil.

Helianthus annuus seeds are not listed as a major allergen by the Food Allergen Labeling and Consumer Protection Act.[53]

Helianthus annuus seeds are used to make an alternative to peanut butter.[54] In the EU, sunflowers and seeds are not required to be labelled as allergens.[55]

In the EU, the flowers and seed oil from the seeds of *Helianthus annuus* were on the market as food or food ingredients and were consumed to a significant degree before 15 May 1997.[56] Thus its access to the market is not subject to the Novel Food Regulation (EC) No. 258/97. However, other specific legislation may regulate the placing on the market of this product as a food or food ingredient in some Member States.

Traditional medicinal uses of *Helianthus annuus* seeds are reported to be as a diuretic, expectorant, and is used to treat colds, coughs, throat, and lung ailments.[21] The flowers and seeds are reported to be used in folk remedies for cancer in Venezuela. The flowers and seeds are also reported to have multiple uses, including: antiseptic, aphrodisiac, bactericidal, diuretic, expectorant, and malaria preventative uses. *Helianthus annuus* plants have multiple uses in folk remedies, including: bronchitis, carbuncles, cold, colic, cough, diarrhea, eye ailments, fever, flu, inflammations, rheumatism, urogenital ailments, and wounds.

Ozonized sunflower seed oil is used in topical medications to treat various foot fungi.[57]

Native Americans have been reported to use *Helianthus annuus* in multiple ways.[58] The seed and root were used to ward off illness in neonates by feeding them to newly pregnant women. The ground seed flour was used for food; roasted and ground seeds were made into cakes and used to feed livestock. The flower head was used as a vegetable. The sap was chewed to ward off thirst.

The stalks have been used to make acoustic ceiling tiles, door cores (with flame suppressors, burn-resistant doors), deburring and polishing abrasives for metal, and plant starter material.[59]

Helianthus annuus plants are used in phytoremediation to extract heavy metals and other toxic substances from the soil (e.g., lead, arsenic and uranium).[60,61] This plant is also used in rhizofiltation to neutralize radionuclides and other toxic substances and to remove harmful bacteria from water.[62]

TOXICOKINETICS

Since these ingredients are complex mixtures, data on the toxicokinetics of *Helianthus annuus* (sunflower)-derived ingredients would not be practical. However, since these ingredients are consumed as food and feed, exposure to the components of these ingredients in cosmetics is expected to be lower than dietary exposure.

TOXICOLOGICAL STUDIES

Dermal

Acute and repeated dose dermal toxicity data on *Helianthus annuus* (sunflower)-derived ingredients were not found in the published literature and no unpublished data were provided.

Oral

Acute and repeated dose oral toxicity data on *Helianthus annuus* (sunflower)-derived ingredients were not found in the published literature and no unpublished data were provided. However, as noted earlier, some of the ingredients reviewed in this safety assessment and various plant parts may be consumed as food and/or feed, and daily exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. Therefore, the systemic toxicity potential of *Helianthus annuus* (sunflower)-derived ingredients via oral exposure is not the focus of this safety assessment. The primary focus is the potential for irritation and sensitization reactions after dermal exposure to these ingredients.

Inhalation

Acute and repeated dose inhalation toxicity data on *Helianthus annuus* (sunflower)-derived ingredients were not found in the published literature and no unpublished data were provided.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

Reproductive and developmental toxicity data on *Helianthus annuus* (sunflower)-derived ingredients were not found in the published literature and no unpublished data were provided.

GENOTOXICITY

Genotoxicity data on *Helianthus annuus* (sunflower)-derived ingredients were not found in the published literature and no unpublished data were provided.

CARCINOGENICITY

Carcinogenicity data on *Helianthus annuus* (sunflower)-derived ingredients were not found in the published literature and no unpublished data were provided.

IRRITATION AND SENSITIZATION

Irritation

Dermal

In a 4-week use study of a moisturizer containing helianthus annuus (sunflower) seed extract (0.0335%) in humans with sensitive skin and a 2-week use study of a lipstick containing helianthus annuus (sunflower) seed wax (4%), there were no signs of the potential for dermal irritation (Table 13).[63,64]

OZONIZED SUNFLOWER SEED OIL

A topical medication containing ozonized sunflower seed oil (measured as 8%-12% hydroxiperoxides of unsaturated triglycerides as active oxygen; amount not specified, assumed as needed to treat the skin disease) was dermally administered to human subjects (n=100) who had tinea pedis 2 times per day, for 6 weeks.[57] There were no adverse events reported including irritation, edema, and erythema. The ability to observe adverse events on the skin increased as the tinea pedis reduced.

Ocular

Ocular irritation data on *Helianthus annuus* (sunflower)-derived ingredients were not found in the published literature and no unpublished data were provided.

Sensitization

Dermal – Human

In human repeated insult patch tests (HRIPT), a moisturizer containing helianthus annuus (sunflower) seed extract (0.0335%) and 2 different lipsticks containing helianthus annuus seed wax (3.34% and 4%) were not irritating or sensitizing (Table 13).[65-67] A lipstick containing helianthus annuus (sunflower) seed wax (3.34%) was non-sensitizing in a 2-week use study in subjects with sensitive skin.

HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT

A patch test of helianthus annuus (sunflower) extract (1%) was performed in subjects (n=9) that were known to have developed allergies to chrysanthemums (another member of the *Asteraceae* family).[17] To make the extract, freshly cut *Helianthus annuus* plants were dipped whole into peroxide-free diethyl ether for 60 sec; the ether was then dried over sodium sulfate for 8 h to a dry residue. The residue was incorporated into white petrolatum. The test substance was administered using plaster strip and the test site was observed at 24, 48, and 72 h. Five of the subjects had positive reactions ranging from + to +++.

HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT

Patch tests and IgE tests of helianthus annuus (sunflower) seed extract (concentration not specified) were performed in subjects (n=17) with established fruit, nut, and/or legume allergies, including 2 subjects with a confirmed *Helianthus annuus* seed allergy.[68] Negative and positive controls for skin testing were saline solution and histamine dihydrochloride, respectively. Seven (41%) of the subjects had a positive reaction by 1 or both of the allergy tests; it was not specified whether the 2 subjects with the *Helianthus annuus* seed allergy had positive results.

An *Helianthus annuus* seed extract (1:100 w/v) was used in skin prick tests in atopic subjects (n=84; each positive for a common allergen).[69] A commercial radioallergosorbent test (RAST) was also performed. The *Helianthus annuus* extract was prepared from hulled seed after pressing with a hydraulic press to remove the oil. The pressed seeds were extracted with physiologic saline overnight and centrifuged. The supernatant was ultracentrifuged and the middle fraction extracted and sterilized. There were 18 positive reactions for the skin prick test, of these 3 were also positive for the RAST. The positive reactions strongly correlated to owning a cage bird and a history of at least 1 food allergy.

A skin prick test and food-specific IgE assays were conducted in subjects (n=65 adults) with various fruit and or seed allergies, including 2 subjects with allergies to *Helianthus annuus* seeds.[68] The 17 of 65 subjects had a positive reaction to *Helianthus annuus* seeds in 1 or both of the assays; none of the subjects with positive reactions had a positive reaction to a double-blind placebo-controlled food challenge for *Helianthus annuus* seeds.

Oral

There are cases of food allergies to *Helianthus annuus* seeds reported in the literature (Table 14).[7,68,70-72] These allergies are confirmed with skin prick tests, RASTs, and/or double-blind, placebo-controlled food challenges. It has been shown that there is the possibility that during the harvesting process, the seeds are contaminated with pollen, which may be a cause of the allergic reaction.[10]

Inhalation

There are cases of people developing allergies to *Helianthus annuus* pollen.[4,10,14,15,70,73-76] These tend to be people who live in areas that grow *Helianthus annuus* or work in facilities that process these plants and handle the plant material. Some perceived allergies to the seeds have been found to be allergies to the pollen (Table 14).[10,73]

For example, subjects who worked in an animal feed processing plant (n=35) were administered skin prick tests of the components of the feed, which included helianthus annuus (sunflower) seeds.[76] The subjects had worked in the plant an average of 14 years (3-30 years) and were exposed to feed "aerosols" 8 h per shift. The skin prick tests were of aqueous preparations of the components of the feed (1:10 w/v dilution). Positive reactions to the helianthus annuus (sunflower) seeds were observed in 19 (54.3%) of the exposed subjects. There was only 1 positive reaction to *Helianthus annuus* seed in the control group of subjects who did not work in the plant (n=30).

CLINICAL USE

Case Reports

There are multiple case reports of children and adults who are allergic to *Helianthus annuus* seeds (Table 14).[4-6,8-12,77] Contacts were by dermal, oral, and/or inhalation exposure.

SUMMARY

This is a review of the available scientific literature relevant to assessing the safety of *Helianthus annuus* (sunflower)-derived ingredients as used in cosmetics. The reported functions of these ingredients in cosmetics include skin-conditioning agents – miscellaneous, abrasives, and absorbents.

The ingredients in this report are grouped together because they are extracts, waxes, or powders derived from plant parts of *Helianthus. annuus*, the sunflower.

The seeds of *Helianthus annuus* are consumed by humans, both raw and roasted, on a regular basis. The remaining parts of the plant, as well as the seeds, are fed to farm animals and pets. Exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. Therefore, the oral toxicity of these ingredients will not be the focus of this safety assessment though oral information may be included here. The primary focus of this safety assessment of *Helianthus annuus* (sunflower)-derived ingredients as used in cosmetics is on the potential for irritation and sensitization from dermal exposure. It is noted that *Helianthus annuus* is a member of the *Asteraceae* family; members of this family are known to comprise, in part, sensitizers.

According to the 2015 VCRP data, helianthus annuus (sunflower) seed extract had the highest reported number of uses in 380 formulations of the ingredients in this safety assessment. Helianthus annuus (sunflower) extract had the next highest number of reported uses in 91 formulations. All other in-use ingredients are reported to be used in 70 or fewer formulations.

In the 2015 Council survey, hydrolyzed sunflower seed wax had the highest reported maximum concentration of use; it is used at up to 10% in skin cleansing formulations. The highest maximum concentration of use reported for products resulting in leave-on exposure is 4% in helianthus annuus (sunflower) seed wax in mascara and 4% in hydrolyzed sunflower seed wax in lipstick.

In a 4-week use study of a moisturizer containing helianthus annuus (sunflower) seed extract at 0.0335% in humans with sensitive skin and a 2-week use study of a lipstick containing helianthus annuus (sunflower) seed wax at 4%, there were no signs of dermal irritation

Ozonized sunflower seed oil, at up to 12% hydroxiperoxides of unsaturated triglycerides as active oxygen, produced no adverse effects when administered to human subjects with tinea pedis twice daily for 6 weeks.

In HRIPTSs of cosmetic products, a moisturizer containing helianthus annuus (sunflower) seed extract at 0.0335% and 2 lipsticks containing helianthus annuus seed wax at 3.34% and 4% were not irritating or sensitizing. A lipstick containing helianthus annuus (sunflower) seed wax at 3.34% was non-sensitizing in a 2-week use study in subjects with sensitive skin.

In a patch test of helianthus annuus (sunflower) extract in human subjects with known allergies to another member of the *Asteraceae* family, 5 of 9 subjects had positive reactions ranging from + to +++.

In a patch test in human subjects with known food allergies, 7 of 17 subjects had positive reactions to helianthus annuus (sunflower) seed extract in a patch test and/or an IgE test. The concentration was not specified.

In a skin prick of helianthus annuus (sunflower) seed extract (1:100 w/v) in human subjects with a common allergy, 18 of 84 subjects had a positive result; 3 of these were also positive in a RAST.

There are multiple case reports of people with food allergies to *Helianthus annuus* seeds. These allergies are confirmed with skin prick tests, RASTs, and/or double-blind, placebo-controlled food challenges.

There are multiple cases of humans developing allergies to *Helianthus annuus* plants and/or seeds, possibly from inhalation of the pollen. For example, 19 of 35 subjects who work in a facility processing animal feed, including *Helianthus annuus*, had positive reactions in a skin prick test for and aqueous extract (1:10 w/v) of the plant.

DISCUSSION

[*To be determined*]

CONCLUSION

[*To be determined*]

TABLES AND FIGURES

Table 1. Definitions and functions of the *Helianthus annuus*-derived ingredients in this safety assessment.[1]

Ingredient	Definition	Functions
Helianthus Annuus (Sunflower) Extract	Helianthus Annuus (Sunflower) Seed Extract is the extract of the whole plant, *Helianthus annuus*.	Skin-conditioning agent – miscellaneous
Helianthus Annuus (Sunflower) Flower Extract	Helianthus Annuus (Sunflower) Flower Extract is the extract of the flowers of *Helianthus annuus*.	Skin-conditioning agent – miscellaneous
Helianthus Annuus (Sunflower) Leaf/Stem Extract	Helianthus Annuus (Sunflower) Leaf/Stem Extract is the extract of the leaves and stems of *Helianthus annuus*.	Skin-conditioning agent – miscellaneous
Helianthus Annuus (Sunflower) Sprout Extract	Helianthus Annuus (Sunflower) Sprout Extract is the extract of the sprouts of *Helianthus annuus*.	Skin-conditioning agent – miscellaneous
Helianthus Annuus (Sunflower) Seed	Helianthus Annuus (Sunflower) Seed is the seed of *Helianthus annuus*.	Abrasive; Skin-conditioning agent – miscellaneous
Helianthus Annuus (Sunflower) Seed Butter	Helianthus Annuus (Sunflower) Seed Butter is the fat obtained from the seeds of *Helianthus annuus*.	Skin-conditioning agent – emollient; skin-conditioning agent - occlusive
Helianthus Annuus (Sunflower) Seedcake	Helianthus Annuus (Sunflower) Seedcake is the residue from the expression of oil from the seeds of *Helianthus annuus*.	Abrasive; absorbent; bulking agent; Skin-conditioning agent – miscellaneous
Helianthus Annuus (Sunflower) Seed Extract	Helianthus Annuus (Sunflower) Seed Extract is the extract of the seeds of *Helianthus annuus*.	Skin-conditioning agent – miscellaneous; sunscreen agent
Helianthus Annuus (Sunflower) Seed Flour	Helianthus Annuus (Sunflower) Seed Flour is the flour obtained from the finely ground seeds of *Helianthus annuus*.	Abrasive; absorbent; bulking agent; viscosity increasing agent
Hydrolyzed Sunflower Seed Wax	Helianthus Annuus (Sunflower) Seed Wax is the wax obtained from the seed of the sunflower, *Helianthus annuus*.	Skin-conditioning agent – miscellaneous
Hydrogenated Sunflower Seed Extract	Hydrogenated Sunflower Seed Extract is the end-product obtained by the controlled hydrogenation of helianthus annuus (sunflower) seed extract	Skin-conditioning agent – miscellaneous
Ozonized Sunflower Seed Oil	Ozonized Sunflower Seed Oil is the end-product of the controlled ozone treatment of helianthus annuus (sunflower) seed oil.	Skin-conditioning agent – miscellaneous
Helianthus Annuus (Sunflower) Seed Wax	Helianthus Annuus (Sunflower) Seed Wax is the wax obtained from the seed of the sunflower, *Helianthus annuus*.	Skin-conditioning agent – miscellaneous

Table 2. The conclusion and maximum concentration of use reported in CIR safety assessment of ingredients related to the *Helianthus annuus* ingredients in this report.

Ingedient(s)	Conclusion	Maximum reported concentration of use reported for ingredients in the safety assessment	Reference
Helianthus Annuus (Sunflower) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Hydrogenated Sunflower Seed Oil, and Sunflower Seed Acid in "Plant-Derived Fatty Acid Oils"	Safe as used.	100%	[2]
Phytosteryl Sunflower Seedate, C10-40 Isoalkyl Acid Phytosterol Esters, Dihydrophytosteryl Octyldecanoate, Phytosteryl Buyrate, Phytosteryl Caprylate/Caprate, Phytosterol Hydroxystearate, Phytosteryl Isostearate, Phytostearyl Linoleate, Phytostearyl Linoleate/Linolenate, Phytosteryl Nopnanoate, Phytosteryl Oleate, Beta-Sitosterol, Beta-Sitosteryl Acetate, and Phytosterols in "Phytosterols"	Safe as used	8%	[3]

Table 3. Chemical and physical properties of *Helianthus annuus*-derived ingredients.

Property	Value	Reference
Helianthus annuus (sunflower) extract		
Physical Form	Fine powder	38
Color	Brownish yellow	38
Odor	Characteristic	38
Water Solubility	Soluble	38
Helianthus annuus (sunflower) flower extract		
Physical Form	Solid, powder	26
Color	Brownish yellow	26
Odor	Characteristic	26
Water Solubility	Soluble	26
Hydrolyzed sunflower seed wax		
Physical Form	Solid wax	29
Color	Yellow	29
Odor	Very low	29
Density/Specific Gravity @ 20 °C	0.87-0.95	29
Melting Point °C	74-77	29
Boiling Point °C	>200	29
Water Solubility	Insoluble	29

Table 4. Composition of *Helianthus annuus* whole plant at different growth stages.[25]

	Mature		Before bloom	Beginning of bloom	In bloom	After bloom
	Source 1	Source 2	Source 3			
	g/100g fresh weight					
Dry matter	-	30	12	20	14	15
	g/100 g dry matter					
Crude protein	11-12	12.5	19.3	13.9	14.7	14.0
Crude fat	10.12	10.7	2.7	4.4	2.4	2.8
Acid-detergent fiber	32.0	39	-	-	-	-
Lignin	10-16	12.3	-	-	-	-

- = No data

Table 5. Sample comparison of oil content (g/100 g dry material) in oilseed (high in oleic acid content) and non-oilseed *Helianthus annuus*.[25]

Acid	Oilseed (includes hulls)[1]	Non-oilseed (no hulls)
Myristic acid (C14:0)	0.02	0.05
Palmitic acid (C16:0)	2.84	2.95
Palmitoleic acid (C16:1)	0.03	0.05
Stearic acid (C18:0)	2.12	2.33
Oleic acid (C18:1)	8.48	9.89
Linoleic acid (C18.:2)	27.8	34.48
Linolenic acid (C18:3)	0.04	0.07
Arachidic acid (C20:1)	0.06	0.05

[1] The hulls are difficult to remove from the oilseed strains of *Helianthus annuus* seed, so the data on oilseed includes the hulls. Hulls are easily separated from the non-oilseed strains of *Helianthus annuus*, and thus, the non-oilseed data does not include the hull.

Table 6. Composition of phytosterols and tocopherols as a function of oleic acid content in *Helianthus annuus* seeds.[25]

Sterol	Conventional/wild	Mid oleic acid	High oleic acid[a]
Total sterols	240-500(mg/g)	ND	170-520(mg/g)
β-sitosterol[b]	50%-70%	56%-58%	42%-70%
Campesterol[b]	6.5%-13.0%	9.1%-9.6%	5%-13%
Stigmasterol[b]	6.0%-13.0%	9.0%-9.3%	4.5%-13%
Total tocopherols (mg/g)	44-152	50.9-74.1(mg/g)	45-112(mg/g)
α (vitamin E) (mg/g)	40.3-93.5(mg/g)	48.8-66.8(mg/g)	40-109(mg/g)
B (mg/g)	ND-4.5(mg/g)	1.9-5.2(mg/g)	1.0-3.5(mg/g)
γ (mg/g)	ND-3.4(mg/g)	0.2-1.9(mg/g)	0.3-3.0(mg/g)

NR=not determined

[a] The hulls are difficult to remove from the oilseed strains of *Helianthus annuus* seed, so the data on oilseed includes the hulls. Hulls are easily separated from the non-oilseed strains of *Helianthus annuus*, and thus, the non-oilseed data does not include the hull.

[b] Percent of total sterols

Table 7. The vitamin content of non-oilseed seeds of *Helianthus annuus*.[25]

Vitamin	Amount (/100 g dry materials)[1]
Vitamin C (mg)	1.48
Thiamine (mg)	2.42
Riboflavin (mg)	0.26
Niacin (mg)	4.75
Pantothenic acid (mg)	7.13
Vitamin B-6 (mg)	0.81
Folate (μg)	239.86
Vitamin A (IU)	52.84
Vitamin E (α tocopherol) (mg)	36.46
Vitamin K (μg)	2.85

[1] Hulls are easily separated from the non-oilseed strains of *Helianthus annuus*, so the non-oilseed data does not include the hull.

Table 8. Amino acid content in *Helianthus annuus* seed flour.[25]

Amino acid	Amount (g/100 g of crude protein)
Isoleucine	3.7
Leucine	6.5
Lysine	3.4
Methionine + cysteine	4.1
Tryptophan	1.5
Phenylalanine + tyrosine	8.2
Valine	4.9
Threonine	3.3

Table 9. Composition of *Helianthus annuus* meal derived from whole and part-dehulled seeds from different sources.[25]

	Whole seed meal		Part-dehulled seed meal		Hulls
	Source 1 (mean±sd)	**Source 2 (mean)**	**Source 1 (mean±sd)**	**Source 2 (mean)**	**Source 3 (mean (range))**
			g/100 g fresh weight		
Dry matter	88.7±1.4	-	89.7±1.2	92.0	87.8 (85.0-92.0)
			g/100 g dry matter		
Crude protein	27.7±2.2	28.4	33.4±2.2	38.0	5.0 (3.5-9.0
Crude fiber	25.5±2.6	-	21.2±2.0	20.0	45.0 (40.0-50.0)
Crude fat	2.0±0.8	1.4	6.7±0.5	8.0	3.0 (0.5-3.0)
Minerals (ash)	6.2±0.6	7.7	6.7±0.5	8.0	
Neutral-detergent fiber	41.1±3.7	40.0	35.9±3.6	36.0	70.0 (65.0-75.0)
Acid-detergent fiber	29.3±3.0	30.0	24.7±2.4	24.0	56.0 (50.0-63.0)
Lignin	10.1±1.4	-	8.2±1.2	-	
Ash	-	-	-	-	2.7 (2.0-3.0)
Calcium	-	-	-	-	0.30 (0.25-0.35)
Phosphorus	-	-	-	-	0.15 (0.10-0.20)
Magnesium	-	-	-	-	0.20 (0.15-0.25)

- = No data
sd = standard deviation

Table 10. Amino acid and protein content (g/100g dry matter) of *Helianthus annuus* meal derived from whole and part-dehulled seeds from 3 sources.[25]

	Non-dehulled *Helianthus annuus* meal			Dehulled *Helianthus annuus* meal	
Amino acid	**Source 1**	**Source 2**	**Source 3**	**Source 2**	**Source 3**
Arginine	2.32	2.64	2.56	3.15	3.17
Histidine	0.74	0.73	0.61	0.99	0.97
Isoleucine	1.16	1.43	1.11	1.55	1.59
Leucine	1.82	2.07	1.78	2.48	2.47
Lysine	1.01	1.12	1.11	1.29	1.38
Methionine	0.65	0.66	0.56	0.88	0.89
Cystine	0.50	0.53	0.56	0.71	0.71
Phenylalanine	1.31	1.37	1.28	1.78	1.85
Threonine	1.06	1.16	1.17	1.43	1.44
Tryptophan	0.34	0.42	0.50	0.47	0.46
Valine	1.41	1.66	1.78	1.87	1.94
Glycine	-	-	-	-	2.26
Tyrosine	-	0.84	-	1.11	1.01
Serine	-	-	1.11	-	1.66
Crude protein	28.4	29.8	25.9	45.4	41.0

- = No data

Table 11. Frequency of use according to duration and exposure of *Helianthus annuus* (sunflower)-derived ingredients.[43-45]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Helianthus Annuus (Sunflower) Extract		**Helianthus Annuus (Sunflower) Flower Extract**		**Helianthus Annuus (Sunflower) Seed Extract**		**Helianthus Annuus (Sunflower) Seed**	
Total/range	**91**	**0.0000015-0.075**	**5**	NR	**380**	**0.000015-1**	**NR**	**0.00002-0.00091**
Duration of use[a]								
Leave-on	48	0.0003-0.05	2	NR	202	0.000015-1	NR	0.00091
Rinse-off	42	0.0000015-0.001	3	NR	177	0.000015-0.13	NR	0.00002
Diluted for (bath) use	1	0.075	NR	NR	1	0.0003-0.0016	NR	NR
Exposure type								
Eye area	4	NR	NR	NR	10	0.0003-0.1	NR	NR
Incidental ingestion	NR	NR	NR	NR	7	0.0002-1	NR	NR
Incidental Inhalation-sprays	7; 22[b]; 8[c]	0.0005[b]	1[b]	NR	26; 52[b]; 50[c]	0.000015-0.05; 0.00003-0.025[b]	NR	0.00091[b]
Incidental inhalation-powders	1;8[c]	0.0003[d]	NR	NR	50[c]	0.0025-0.032[d]	NR	NR
Dermal contact	34	0.0003-0.075	4	NR	128	0.0001-0.24	NR	NR
Deodorant (underarm)	1[b]	NR	1[b]	NR	2[b]	NR	NR	NR
Hair-noncoloring	55	0.0000015-0.0025	1	NR	216	0.000015-0.13	NR	0.00002-0.00091
Hair-coloring	2	NR	NR	NR	29	0.00009	NR	NR
Nail	NR	NR	NR	NR	NR	0.0001	NR	NR
Mucous Membrane	5	0.075	2	NR	24	0.0002-1	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	Helianthus Annuus (Sunflower) Seedcake		**Helianthus Annuus (Sunflower) Seed Wax**		**Hydrolyzed Sunflower Seed Wax**		
Total/range	**70**	**0.000015-0.41**	**NR**	**0.0038-4**	**21**	**3.3-10**	
Duration of use							
Leave-on	59	0.000015-0.41	NR	0.19-4	21	3.3-4	
Rinse-off	11	0.000015-0.12	NR	0.0038	NR	10	
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	
Exposure type							
Eye area	9	0.000015-0.41	NR	3.6-4	2	3.5	
Incidental ingestion	NR	0.00012	NR	3.4	9	3.3-4	
Incidental Inhalation-sprays	30[b]; 10[c]	0.0012; 0.000015[b]	NR	0.19[b]	5[b]; 2[c]	NR	
Incidental inhalation-powders	10[c]	0.41[d]	NR	0.52-0.75[d]	2[c]	NR	
Dermal contact	69	0.000015-0.41	NR	0.19-3.6	11	10	
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	
Hair-noncoloring	NR	NR	NR	0.0038	NR	NR	
Hair-coloring	1	NR	NR	NR	NR	NR	
Nail	NR	NR	NR	NR	NR	NR	
Mucous Membrane	NR	0.00012-0.12	NR	3.4	9	3.3-4	
Baby	NR	NR	NR	NR	NR	NR	

NR = Not Reported; Totals = Rinse-off + Leave-on Product Uses.
Note: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses.
[a] 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.
[b] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.
[c] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.
[d] It is possible these products may be powders, but it is not specified whether the reported uses are powders.

Table 12. *Helianthus annuus* (sunflower)-derived ingredients with no reported uses.[43-45]

Helianthus Annuus (Sunflower) Leaf/Stem Extract	Helianthus Annuus (Sunflower) Sprout Extract
Helianthus Annuus (Sunflower) Seed Butter	Helianthus Annuus (Sunflower) Seed Flour
Hydrogenated Sunflower Seed Extract	Ozonized Sunflower Seed Oil

Table 13. Human irritation and sensitization studies on products containing *Helianthus annuus* (sunflower)-derived ingredients.

Ingredient	Product; concentration	Study; n	Results	Reference
Helianthus Annuus (Sunflower) Seed Extract	Moisturizer; 0.0335%	HRIPT; 102	Not irritating or sensitizing	65
Helianthus Annuus (Sunflower) Seed Extract	Moisturizer; 0.0335%	4-week use study; 34	No signs of the potential for dermal irritation	64
Helianthus Annuus (Sunflower) Seed Wax	Lipstick; 4%	HRIPT; 114	There were no adverse events. It was concluded that this product was not a potential dermal irritant.	67
Helianthus Annuus (Sunflower) Seed Wax	Lipstick; 3.34%	HRIPT; 107	Not irritating or sensitizing	66
Helianthus Annuus (Sunflower) Seed Wax	Lipstick; 3.34%	2-week use study in humans with sensitive skin; 26	Not irritating or sensitizing	63

Table 14. Case reports of children and adults with oral, dermal, and inhalation allergic reactions to *Helianthus annuus* seeds and plants.

Case History	Testing	Reference
	Oral Exposure	
3-year-old boy presented with oral discomfort that developed after eating *Helianthus annuus* seeds for the first time. Treatment with diphenhydramine and rest resolved the reaction. A few weeks later, he had a similar reaction to a snack bar made with *Helianthus annuus* seed "butter". He was not treated but observed by his parents. In a subsequent episode, the boy had a similar reaction to a bread roll with poppy seeds; this required epinephrine and an emergency room visit. This child had a history of mild infantile atopic dermatitis. There was an older sibling with a confirmed peanut allergy and the home had been peanut-free for some time and alternatives, such as *Helianthus annuus* seed "butter" had been fed to the children.	A SPT of a slurry of fresh *Helianthus annuus* seed resulted in a 1-mm wheal within 3-4 min and severe pruritus. A similar reaction was elicited from poppy seeds (>10 mm wheal) and a reaction to pumpkin seeds (8 mm wheal).	8
5-year-old girl with a diagnosed peanut allergy (at 18 months of age) presented with generalized urticaria and angioedema of the lips. She had just eaten a few bites of *Helianthus annuus* seed butter (reportedly from a facility that does not process peanuts).	SPT at 18 months were positive for peanuts (6 mm wheal) and negative for *Helianthus annuus* seed; at 5 years, the tests were positive for peanuts (21 mm wheal) and *Helianthus annuus* seed (16 mm wheal).	77
11-year-old boy who presented with generalized urticaria/ angioedema and bronchospasm within 30 min of eating *Helianthus annuus* seeds. Epinephrine relieved the symptoms. He had eaten *Helianthus annuus* seeds at least once before without any reactions. He had a history of seasonal allergic rhinitis for the previous 2-3 years.	Scratch tests and RAST to *Helianthus annuus* seed extract were positive as well as tree molds and grasses.	9
A 22-year-old female, with a history of atopic dermatitis and Japanese cedar pollinosis, ate 5 pieces of *Helianthus annuus* seed chocolates. She experienced sudden nausea and dyspnea 5 min later, followed by development of wheals all over her body. In the emergency room, wheezing was heard in the region of her larynx. Her bulbar conjunctiva was hyperemic. She was treated with injections of epinephrine and corticosteroids. Later, although she again ate chocolate confections, no immediate allergic reactions occurred. She recalled having often eaten *Helianthus annuus* seeds as a snack during high school.	SPT, CAP assay, ELISA, the ImmunoCAP® inhibition assay, immunoblot and immunoblot inhibition assays, and N-terminal sequence analysis. SPT were performed with the native protein extract from *Helianthus annuus* seeds and 7 other extracts from the *Asteraceae* family. There were positive reactions to the extracts of *Helianthus annuus* seeds in SPTs but not in other extracts. The level of serum IgE antibody for *Helianthus annuus* seed was high (35.1 UA/ml, class 4). There was a high titer of IgE antibody specific for Japanese cedar pollen (27.2 IU/ml, class 4). Her serum was negative for specific IgE antibodies against mugwort, birch, ragweed, dandelion, latex, chocolate, cacao, peanuts, almonds, Brazil nuts, and gelatin. ELISA of the extract from *Helianthus annuus* seeds showed higher	12

Table 14. Case reports of children and adults with oral, dermal, and inhalation allergic reactions to *Helianthus annuus* seeds and plants.

Case History	Testing	Reference
	absorbance than the controls (P < 0.01). There were no reactions to the 4 kinds of nuts. The ImmunoCAP® inhibition assay of the extract from *Helianthus annuus* r seeds showed suppression that depended on the concentration of the inhibitor (*Helianthus annuus* seed). The same test for Japanese cedar pollen with *Helianthus annuus* seeds showed no suppression. Several IgE-binding protein bands on the immunoblot assay using the extract from *Helianthus annuus* seeds were identified. These IgE-binding protein bands were almost undetectable when using control sera. On the inhibition immunoblot assay using the *Helianthus annuus* seed extract, the IgE-binding signal of one band (13 kDa) disappeared completely. The N-terminal amino acid sequence of the IgE-binding protein band (13 kDa) of *Helianthus annuus* seed closely matched LTP from *Helianthus annuus* seeds. The author concluded that LTP is able to induce severe and systemic symptoms and sensitization by the oral route in fruit allergic patients who do not have associated pollen allergy	
A 22-year-old woman developed systemic allergic reactions comprising rhinitis, nasal congestion, tearing, and facial and generalized urticaria after eating shelled *Helianthus annuus* seeds. The symptoms resolved in a few hours. She had no history of allergy to seed that she shelled herself.	Skin prick test-positive for *Helianthus annuus* pollen and dust mites; negative for other pollens and foods. Open food challenge-positive for shelled *Helianthus annuus* seeds. Analysis showed that the shelled seeds were contaminated with pollen.	10
A 37-year-old woman experienced anaphylaxis (diffuse pruritus, urticaria, angioedema, nausea and vomiting, chest tightness, and wheezing, followed by vascular collapse and loss of consciousness) within 20 min of ingesting *Helianthus annuus* seeds. She was treated with epinephrine, intravenous fluids, diphenhydramine and steroids. Over the next week, she had several episodes of lip and facial swelling in the morning on awakening. She had a history of eating *Helianthus annuus* seeds without incident and she had no prior allergic reactions to foods. She had a history of anaphylactic reactions to fire ant venom. Her general health was good, and she was taking no medications.	P-K test- Heated and unheated serum from the subject was used. After injections of the serums, skin sites were challenged with intradermal injections of commercial *Helianthus annuus* seed extracts (1:1000 w/v; 0.02 mL). The passive transfer recipient was strongly positive at the unheated serum site on challenge with *Helianthus annuus* seed extract. The heated serum site challenged with *Helianthus annuus* seed extract was negative. Skin Prick Test-commercial *Helianthus annuus* seed extract resulted in a 12x16 mm wheal; causative seed extract resulted in a 16x16 mm wheal; cold-pressed *Helianthus annuus* oil was negative. RAST-Commercial *Helianthus annuus* seed extract (1:20 w/v in 50% glycerin) and an extract prepared from the causative seeds (extracted in diluent saline, 1 gm/100 mL, filtered) resulted in a class 4 reaction (a moderate reaction). Open challenge to the inner upper lip and oral mucosa-refined and cold-pressed oil had no reaction.	7
A 58-year-old man present with "tingling of his lips", a generalized itching sensation, and laryngeal edema that began within 5 min of ingesting 3 *Helianthus annuus* seeds. He developed abdominal pain, generalized angioedema, and bronchospasm within 30 min of arriving at the hospital. Most of the symptoms were resolved with epinephrine, but he was hypotensive, so he was admitted for treatment with theophylline and steroids. He had a history of perennial rhinitis and reported sensitivity to walnuts. He had no known allergies to foods in the *Asteraceae* family.	Scratch tests and RASTs to a *Helianthus annuus* seed extract were positive along with June grass and ragweed. The *Helianthus annuus* seed extract was an aqueous paste made by emulsifying washed *Helianthus annuus* seeds in buffered saline.	9
Dermal Exposure		
A 23-year-old man, with a history of rhinoconjunctivitis, asthma, and hypersensitivity to grass pollens presented with contact urticaria from dermal contact with peeled *Helianthus annuus* seeds. The symptoms (itching, erythema, and wheal-and-flare reactions) appeared 15 min after contact. He reported tolerating the consumption of *Helianthus annuus* seeds with occasional pruritus or the oral mucosa and mild obstruction of the pharynx after eating larger amounts of the seeds. He tolerated *Helianthus annuus* oil both dermally and orally.	Total serum IgE was 456 IU/mL (strongly positive). Local urticaria was observed after 30 min in a closed patch test of peeled *Helianthus annuus* seed; and open patch test showed only local erythema. An itchy wheal of 5 mm was observed in a prick test of *Helianthus annuus* seed.	5
A 50-year-old woman who presented with generalized urticaria, facial angioedema, laryngeal edema, wheezing, and dyspnea about 2 h after ingesting several *Helianthus annuus* seeds. The symptoms were relieved by antihistamine. She had eaten these seeds in the past. She reported that when she handled *Helianthus annuus* seeds that she used to feed birds, she developed pruritus of her hands. She had no other history of food sensitivity; she had a history of allergic rhinitis and occasional mild bronchospasm since childhood, for which she was not taking medication.	Scratch tests and RAST titers to the *Helianthus annuus* seed extract were positive with mixed results to grass, ragweed, tree pollens walnut, and peanut	9
A 62-year-old man presented with forehead dermatitis that had lasted for 2 months. It was resolved with topical corticosteroids but returned when treatment stopped. The man handled cattle fodder that was composed of *Helianthus annuus* plants.	Patch tested with European standard series and *Asteraceae* plant series. Positive results were observed for *Helianthus annuus* leaves and the cattle fodder.	6

Table 14. Case reports of children and adults with oral, dermal, and inhalation allergic reactions to *Helianthus annuus* seeds and plants.

Case History	Testing	Reference
Inhalation Exposure		
A 24-year-old man had developed rhinitis and conjunctivitis over 5 years of exposure to *Helianthus annuus* pollens and then developed asthma during the fifth year. All respiratory and ocular symptoms resolved when he discontinued exposure to *Helianthus annuus* plants and pollen. He later had a food allergic reaction while eating honey containing 30% *Helianthus annuus* pollen.	Skin prick tests and RAST to an *Helianthus annuus* pollen extract (1/20 w/v) showed that he had developed an occupational allergy; skin test results with *Helianthus annuus* seed were negative. Bronchial provocation tests were performed after a rest period away from exposure to *Helianthus annuus* pollens, but there was no nonspecific hyperactivity. It was found by RAST that *Helianthus annuus* pollen does not cross-react with other pollens from the *Asteraceae* family or with *Helianthus annuus* seed. The honey that elicited food intolerance was demonstrated to inhibit significantly *Helianthus annuus* pollen RAST.	4
A 31-year-old man developed rhinochonjuctivitis and asthma when exposed to dried *Helianthus annuus* seeds. After working as a baker for approximately 9 years, he started working in a bakery that used *Helianthus annuus* seeds. After 3 months, he developed rhinochonjuctivitis and asthma, even when his coworkers were handling the *Helianthus annuus* seeds. He reported having experienced an anaphylactic reaction after eating approximately half a *Helianthus annuus* seed. The symptoms were increasing as he continued to work in the bakery. After changing jobs to another bakery, he still exhibited rhinitis and asthma at work and developed nocturnal asthma attacks. The subject stopped working at bakeries but still experienced symptoms, even with treatment of inhaled fluticasone propionate and salbutamol.	After 8 months without exposure to *Helianthus annuus* seeds, a baseline lung function test was conducted showing FEV_1=3.17 (72% of predicted value) and FEV_1/forced vital capacity ratio of 62%. The subject had a 20% decrease in these scores after tipping lactose powder back and forth between 2 trays, indicating a marked nonspecific bronchial hyper-responsiveness. The next day, the tray experiment was repeated with *Helianthus annuus* seeds for 5 min. There was a 39% decrease in FEV_1. The next day, the same types of exposure to flour (assumed wheat) for 75 min resulted in a 42% decrease in FEV_1. Skin prick test-positive reactions to dust mites but not extracts of wheat, barley, rye, and oats. An extract of *Helianthus annuus* seed dust was prepared by stirring the dust in phosphate-buffered saline (20% w/v) for 10 min; a 1/10 dilution of the seed extract was used, there was a 10-mm wheal reaction. Skin prick tests of *Helianthus annuus* and other *Asteraceae* pollen were negative. *Helianthus annuus* seed dust elicited positive reactions in inhalation challenges and immunologic tests (details not provided). The author suggested that the continued respiratory symptoms, even after months of avoidance, showed a probable sensitization to α-amylase and that sensitization can develop from the inhalation of *Helianthus annuus* seed dust.	11

CAP - cell-based antioxidant protection; ELISA - enzyme-linked immunosorbent assay; FEV - forced expiratory volume; K-P test - Prausnitz-Küstner; LTP – lipid transfer protein; RAST – radioallergosorbent test; SPT – skin prick test

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2015 VCRP Data
Helianthus annuus (Sunflower)-Derived Ingredients

HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	02D - Other Bath Preparations	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	03D - Eye Lotion	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	03E - Eye Makeup Remover	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	03G - Other Eye Makeup Preparations	2
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	04A - Cologne and Toilet waters	3
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	04C - Powders (dusting and talcum, excluding aftershave talc)	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	04E - Other Fragrance Preparation	2
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	05A - Hair Conditioner	15
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	05B - Hair Spray (aerosol fixatives)	2
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	05C - Hair Straighteners	3
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	05F - Shampoos (non-coloring)	15
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	05G - Tonics, Dressings, and Other Hair Grooming Aids	15
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	05I - Other Hair Preparations	5
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	06D - Hair Shampoos (coloring)	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	10B - Deodorants (underarm)	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	10E - Other Personal Cleanliness Products	4
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	12A - Cleansing	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	12C - Face and Neck (exc shave)	5
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	12D - Body and Hand (exc shave)	3
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	12F - Moisturizing	5
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	12G - Night	2
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	12H - Paste Masks (mud packs)	1
HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT	12J - Other Skin Care Preps	1
		91

HELIANTHUS ANNUUS (SUNFLOWER) FLOWER EXTRACT	05F - Shampoos (non-coloring)	1
HELIANTHUS ANNUUS (SUNFLOWER) FLOWER EXTRACT	10A - Bath Soaps and Detergents	1
HELIANTHUS ANNUUS (SUNFLOWER) FLOWER EXTRACT	10B - Deodorants (underarm)	1
HELIANTHUS ANNUUS (SUNFLOWER) FLOWER EXTRACT	10E - Other Personal Cleanliness Products	1
HELIANTHUS ANNUUS (SUNFLOWER) FLOWER EXTRACT	12F - Moisturizing	1
		5

HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	03D - Eye Lotion	5
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	03G - Other Eye Makeup Preparations	4
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	05G - Tonics, Dressings, and Other Hair Grooming Aids	1
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	12A - Cleansing	9
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	12C - Face and Neck (exc shave)	7
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	12D - Body and Hand (exc shave)	3
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	12F - Moisturizing	26
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	12G - Night	3
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	12H - Paste Masks (mud packs)	2
HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE	12J - Other Skin Care Preps	10
		70

HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	02D - Other Bath Preparations	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	03C - Eye Shadow	2
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	03D - Eye Lotion	3
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	03G - Other Eye Makeup Preparations	5
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	04A - Cologne and Toilet waters	9
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	05A - Hair Conditioner	66
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	05B - Hair Spray (aerosol fixatives)	17

HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	05F - Shampoos (non-coloring)	55
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	05G - Tonics, Dressings, and Other Hair Grooming Aids	32
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	05I - Other Hair Preparations	46
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	21
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	06C - Hair Rinses (coloring)	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	06D - Hair Shampoos (coloring)	3
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	06G - Hair Bleaches	2
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	06H - Other Hair Coloring Preparation	2
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	07A - Blushers (all types)	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	07C - Foundations	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	07E - Lipstick	7
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	07F - Makeup Bases	2
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	07I - Other Makeup Preparations	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	10A - Bath Soaps and Detergents	13
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	10B - Deodorants (underarm)	2
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	10E - Other Personal Cleanliness Products	3
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	11E - Shaving Cream	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	11G - Other Shaving Preparation Products	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	12A - Cleansing	6
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	12C - Face and Neck (exc shave)	24
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	12D - Body and Hand (exc shave)	26
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	12F - Moisturizing	14
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	12G - Night	3
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	12H - Paste Masks (mud packs)	3
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	12J - Other Skin Care Preps	4
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	13A - Suntan Gels, Creams, and Liquids	2
HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT	13B - Indoor Tanning Preparations	1
		380

HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	03D - Eye Lotion	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	03F - Mascara	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	07A - Blushers (all types)	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	07E - Lipstick	9
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	07I - Other Makeup Preparations	2
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	12C - Face and Neck (exc shave)	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	12D - Body and Hand (exc shave)	1
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	12F - Moisturizing	4
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	12G - Night	1
		21

No uses were reported for:

Helianthus Annuus (Sunflower) Leaf/Stem Extract
Helianthus Annuus (Sunflower) Sprout Extract
Helianthus Annuus (Sunflower) Seed
Helianthus Annuus (Sunflower) Seed Butter
Hydrolyzed Sunflower Seed Wax
Hydrogenated Sunflower Seed Extract
Ozonized Sunflower Seed Oil

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Memorandum

TO: Lillian Gill, D.P.A.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: October 26, 2015

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

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

Helianthus Annuus (Sunflower) Leaf/Stem Extract
Helianthus Annuus (Sunflower) Seed Extract
Helianthus Annuus (Sunflower) Extract
Helianthus Annuus (Sunflower) Flower Extract
Helianthus Annuus (Sunflower) Seed
Helianthus Annuus (Sunflower) Seed Butter
Helianthus Annuus (Sunflower) Seedcake
Helianthus Annuus (Sunflower) Seed Flour
Helianthus Annuus (Sunflower) Seed Wax
Helianthus Annuus (Sunflower) Sprout Extract
Hydrogenated Sunflower Seed Extract
Hydrolyzed Sunflower Seed Wax
Ozonized Sunflower Seed Oil

Ingredient	Product Category	Maximum Concentration of Use
Helianthus Annuus (Sunflower) Seed Extract	Bubble baths	0.0003%
Helianthus Annuus (Sunflower) Seed Extract	Other bath preparations	0.0016%
Helianthus Annuus (Sunflower) Seed Extract	Eyeliner	0.016%
Helianthus Annuus (Sunflower) Seed Extract	Eye shadow	0.018%
Helianthus Annuus (Sunflower) Seed Extract	Eye lotion	0.016-0.024%
Helianthus Annuus (Sunflower) Seed Extract	Eye makeup remover	0.0032%
Helianthus Annuus (Sunflower) Seed Extract	Mascara	0.0003-0.1%
Helianthus Annuus (Sunflower) Seed Extract	Other eye makeup preparations	0.016%
Helianthus Annuus (Sunflower) Seed Extract	Colognes and toilet waters	0.0002%
Helianthus Annuus (Sunflower) Seed Extract	Other fragrance preparations	0.0002%
Helianthus Annuus (Sunflower) Seed Extract	Hair conditioners	0.000015-0.006%
Helianthus Annuus (Sunflower) Seed Extract	Hair sprays Aerosol Pump spray	 0.000018-0.025% 0.000015-0.05%
Helianthus Annuus (Sunflower) Seed Extract	Shampoos (noncoloring)	0.000015-13%
Helianthus Annuus (Sunflower) Seed Extract	Tonics, dressings and other hair grooming aids	0.00003-0.025%
Helianthus Annuus (Sunflower) Seed Extract	Wave sets	0.0075%
Helianthus Annuus (Sunflower) Seed Extract	Other hair preparations (noncoloring)	0.000025-0.025%
Helianthus Annuus	Hair dyes and colors	0.00009%

(Sunflower) Seed Extract		
Helianthus Annuus (Sunflower) Seed Extract	Blushers	0.0001%
Helianthus Annuus (Sunflower) Seed Extract	Foundations	0.0016-0.24%
Helianthus Annuus (Sunflower) Seed Extract	Lipstick	0.0002-1%
Helianthus Annuus (Sunflower) Seed Extract	Rouges	0.002%
Helianthus Annuus (Sunflower) Seed Extract	Makeup fixatives	0.003%
Helianthus Annuus (Sunflower) Seed Extract	Nail polish and enamel	0.0001%
Helianthus Annuus (Sunflower) Seed Extract	Baths soaps and detergents	0.0003%
Helianthus Annuus (Sunflower) Seed Extract	Other personal cleanliness products	0.0003%
Helianthus Annuus (Sunflower) Seed Extract	Preshave lotions	0.003%
Helianthus Annuus (Sunflower) Seed Extract	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.00032-0.032%
Helianthus Annuus (Sunflower) Seed Extract	Face and neck products Not spray	0.0032-0.032%
Helianthus Annuus (Sunflower) Seed Extract	Body and hand products Not spray	0.0025-0.0064%
Helianthus Annuus (Sunflower) Seed Extract	Moisturizing products Not spray	0.0032-0.034%
Helianthus Annuus (Sunflower) Seed Extract	Night products Not spray	0.032%
Helianthus Annuus (Sunflower) Seed Extract	Paste masks and mud packs	0.0003-0.016%
Helianthus Annuus (Sunflower) Seed Extract	Skin fresheners	0.0016%
Helianthus Annuus (Sunflower) Seed Extract	Other skin care preparations	0.013-0.032%
Helianthus Annuus (Sunflower) Seed Extract	Indoor tanning preparations	0.0003%
Helianthus Annuus (Sunflower) Extract	Bath oils, tablets and salts	0.075%
Helianthus Annuus (Sunflower) Extract	Hair conditioners	0.0000015-0.001%
Helianthus Annuus (Sunflower) Extract	Hair straighteners	0.0000015%
Helianthus Annuus (Sunflower) Extract	Shampoos (noncoloring)	0.0005%

Helianthus Annuus (Sunflower) Extract	Tonics, dressings and other hair grooming aids Not spray	0.0005% 0.0025%
Helianthus Annuus (Sunflower) Extract	Wave sets	0.0006%
Helianthus Annuus (Sunflower) Extract	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0003%
Helianthus Annuus (Sunflower) Extract	Face and neck products Not spray	 0.0003%
Helianthus Annuus (Sunflower) Extract	Other skin care preparations	0.05%
Helianthus Annuus (Sunflower) Seed	Hair conditioners	0.00002%
Helianthus Annuus (Sunflower) Seed	Tonics, dressings and other hair grooming aids	0.00091%
Helianthus Annuus (Sunflower) Seedcake	Eye lotion	0.41%
Helianthus Annuus (Sunflower) Seedcake	Eye makeup remover	0.000015%
Helianthus Annuus (Sunflower) Seedcake	Foundations	0.21%
Helianthus Annuus (Sunflower) Seedcake	Lipstick	0.00012%
Helianthus Annuus (Sunflower) Seedcake	Bath soaps and detergents	0.12%
Helianthus Annuus (Sunflower) Seedcake	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.081%
Helianthus Annuus (Sunflower) Seedcake	Face and neck products Not spray Spray	 0.41% 0.0012%
Helianthus Annuus (Sunflower) Seedcake	Body and hand products Not spray	 0.41%
Helianthus Annuus (Sunflower) Seedcake	Other skin care preparations	0.081-0.41%
Helianthus Annuus (Sunflower) Seedcake	Suntan products Not spray	 0.000015%
Helianthus Annuus (Sunflower) Seedcake	Indoor tanning preparations	0.000015%
Helianthus Annuus (Sunflower) Seed Wax	Eye shadow	3.6%
Helianthus Annuus (Sunflower) Seed Wax	Mascara	4%
Helianthus Annuus	Shampoos (noncoloring)	0.0038%

(Sunflower) Seed Wax		
Helianthus Annuus (Sunflower) Seed Wax	Lipstick	3.4%
Helianthus Annuus (Sunflower) Seed Wax	Face and neck products Not spray	0.52-0.75%
Helianthus Annuus (Sunflower) Seed Wax	Suntan products Not spray	1.7%
Helianthus Annuus (Sunflower) Seed Wax	Indoor tanning preparation	0.19%
Hydrolyzed Sunflower Seed Wax	Mascara	3.5%
Hydrolyzed Sunflower Seed Wax	Lipstick	3.3-4%
Hydrolyzed Sunflower Seed Wax	Skin cleansing (cold creams, cleansing lotions liquids and pads)	10%

*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.

Information collected in 2015

Table prepared July 2, 2015

Updated October 26, 2015: Helianthus Annuus (Sunflower) Seed Extract: eye lotion: high concentration corrected from 0.24% to 0.024%; hair conditioners: high concentration corrected from 5% to 0.006%; shampoos high concentration corrected from 5% to 0.13%;hair dyes and colors and bath soaps and detergents: high concentration 5% deleted; moisturizing products high concentration 0.032% changed to 0.034%; Helianthus Annuus Seed: suntan products (not spray): deleted product category; Helianthus Annuus (Sunflower) Seed Wax: lipstick: high concentration changed from 3.9% to 3.4%

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Memorandum

TO: Lillian Gill, D.P.A.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: October 23, 2015

SUBJECT: Information on Products Containing Helianthus Annuus (Sunflower) Seed Wax or Seed Extract

Anonymous. 2009. Summary of an HRIPT of a lipstick containing 3.34% Helianthus Annuus (Sunflower) Seed Wax.

Anonymous. 2009. Summary of a 2-week use study of a lipstick containing 3.34% Helianthus Annuus (Sunflower) Seed Wax.

Anonymous. 2011. Summary of an HRIPT of a moisturizer containing 0.0335% Helianthus Annuus (Sunflower) Seed Extract.

Anonymous. 2011. Summary of a 4-week use study of a moisturizer containing 0.0335% Helianthus Annuus (Sunflower) Seed Extract.

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

Summaries of Studies of Products Containing Helianthus Annuus (Sunflower) Seed Wax or Helianthus Annuus (Sunflower) Seed Extract

Year Completed:	2009
Study Type:	HRIPT
Product Type:	Lipstick
Concentration of Ingredient:	3.34% Helianthus Annuus (Sunflower) Seed Wax
Number of Subjects:	107
Conclusion:	Did not demonstrate a potential for eliciting irritation or sensitization in human subjects.

Year Completed:	2009
Study Type:	2-week use test in persons with sensitive skin
Product Type:	Lipstick
Concentration of Ingredient:	3.34% Helianthus Annuus (Sunflower) Seed Wax
Number of Subjects:	26
Conclusion:	Did not induce clinically relevant irritation; suitable for sensitive skin.

Year Completed:	2011
Study Type:	HRIPT
Product Type:	Moisturizer
Concentration of Ingredient:	0.0335% Helianthus Annuus (Sunflower) Seed Extract
Number of Subjects:	102
Conclusion:	Did not induce irritation or any evidence of induced allergic contact dermatitis in human subjects.

Year Completed:	2011
Study Type:	4-week use test in persons with sensitive skin
Product Type:	Moisturizer
Concentration of Ingredient:	0.0335% Helianthus Annuus (Sunflower) Seed Extract
Number of Subjects:	34
Conclusion:	Did not demonstrate a potential for eliciting dermal irritation in a population with clinically-demonstrated sensitive skin.

Memorandum

TO: Lillian Gill, D.P.A.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: October 26, 2015

SUBJECT: HRIPT of Lipstick Containing Hydrolyzed Sunflower Seed Wax

Consumer Product Testing Co. 2012. Repeated insult patch test of a lipstick containing 4% Hydrolyzed Sunflower Seed Wax.

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Consumer Product Testing Co

FINAL REPORT

TEST: Repeated Insult Patch Test
Protocol No.: CP-01.01S

TEST MATERIAL: 2011.751.001
Lipstick containing 4% Hydrolyzed Sunflower Seed Wax

EXPERIMENT REFERENCE NUMBER: C11-6299.06

Reviewed by: Richard R. Eisenberg, M.D.
Medical Director
Board Certified Dermatologist

Approved by: Michael Caswell, Ph.D., CCRC, CCRA
Director, Clinical Evaluations

Approved by: Joy Frank, R.N.
Executive Vice President, Clinical Evaluations

70 New Dutch Lane • Fairfield, New Jersey 07004-2514 • (973) 808-7111 • Fax (973) 808-7234

Consumer Product Testing Co.

QUALITY ASSURANCE UNIT STATEMENT

Trial Number: C11-6299.06

The Consumer Product Testing Company, Incorporated (CPTC) Quality Assurance Unit (QAU) is responsible for auditing the conduct, content and reporting of all clinical trials that are conducted at CPTC.

This trial has been conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, CPTC Standard Operating Procedures, and the approved protocol.

The CPTC QAU has reviewed all data, records, and documents relating to this trial and also this Final Report. The following QAU representative signature certifies that all data, records, and documents relating to this trial and also this Final Report have been reviewed and are deemed to be acceptable, and that the trial conforms to all of the requirements as indicated above.

All records and documents pertaining to the conduct of this trial shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QAU to obtain custody of trial records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, trial-related records shall be destroyed at the end of the CPTC archive period in a manner that renders them useless.

Quality Assurance Representative

2/10/12
Date

70 New Dutch Lane • Fairfield, New Jersey 07004-2514 • (973) 808-7111 • Fax (973) 808-7234
Clinical • Toxicology • Analytical Chemistry • Microbiology

Objective: To determine by repetitive epidermal contact the potential of a test material to induce primary or cumulative irritation and/or allergic contact sensitization.

Participants: One hundred twenty-four (124) qualified subjects, male and female, ranging in age from 16 to 78 years, were selected for this evaluation. One hundred fourteen (114) subjects completed this study. The remaining subjects discontinued their participation for various reasons, none of which were related to the application of the test material.

Inclusion Criteria:

a. Male and female subjects, age 16[a] and over.
b. Absence of any visible skin disease which might be confused with a skin reaction from the test material.
c. Prohibition of use of topical or systemic steroids and/or antihistamines for at least seven days prior to study initiation.
d. Completion of a Medical History form and the understanding and signing of an Informed Consent form.
e. Considered reliable and capable of following directions.

Exclusion Criteria:

a. Ill health.
b. Under a doctor's care or taking medication(s) which could influence the outcome of the study.
c. Females who are pregnant or nursing.
d. A history of adverse reactions to cosmetics or other personal care products.

Test Material: 2011.751.001

Study Schedule:

Panel #	Initiation Date	Completion Date
20110425	December 28, 2011	February 4, 2012

[a]With parental or guardian consent

Methodology:

The upper back between the scapulae served as the treatment area. Approximately 0.2 g of the test material, or an amount sufficient to cover the contact surface, was applied to the 3/4" x 3/4" absorbent pad portion of an adhesive dressing. This was then applied to the appropriate treatment site to form an occlusive patch.

Induction Phase:

Patches were applied three (3) times per week (e.g., Monday, Wednesday, and Friday) for a total of nine (9) applications. The site was marked to ensure the continuity of patch application. Following supervised removal and scoring of the first Induction patch, participants were instructed to remove all subsequent Induction patches at home, twenty-four hours after application. The evaluation of this site was made again just prior to re-application. If a participant was unable to report for an assigned test day, one (1) makeup day was permitted. This day was added to the Induction period.

With the exception of the first supervised Induction Patch reading, if any test site exhibited a moderate (2-level) reaction during the Induction Phase, application was moved to an adjacent area. Applications were discontinued for the remainder of this test phase, if a moderate (2-level) reaction was observed on this new test site. Applications would also be discontinued if marked (3-level) or severe (4-level) reactivity was noted.

Rest periods consisted of twenty-four hours following each Tuesday and Thursday removal, and forty-eight hours following each Saturday removal.

Challenge Phase:

Approximately two (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, following the same procedure described for Induction. The patch was removed and the site scored at the clinic twenty-four, forty-eight and seventy two hours post-application.

Methodology (continued):

Evaluation Criteria (Erythema and additional Dermal Sequelae):

0	=	No visible skin reaction	E	=	Edema
0.5	=	Barely perceptible	D	=	Dryness
1	=	Mild	S	=	Staining
2	=	Moderate	P	=	Papules
3	=	Marked	V	=	Vesicles
4	=	Severe	B	=	Bullae
			U	=	Ulceration
			Sp	=	Spreading

Erythema was scored numerically according to this key. If present, additional Dermal Sequelae were indicated by the appropriate letter code and a numerical value for severity.

Adverse Events: There were no adverse events.

Amendments: There were no amendments.

Deviations: Per Sponsor's request, an additional observation was conducted 48 hours post challenge application. It is the Principal Investigator's opinion that this will provide more information on the final results.

Results: The results of each participant are appended (Table 1).

Observations remained negative throughout the test interval.

Subject demographics are presented in Table 2.

Summary: Under the conditions of this study, test material, 2011.751.001, did not indicate a potential for dermal irritation or allergic contact sensitization.

Table 1
Panel #20110425

Individual Results

2011.751.001

Subject Number	24*hr	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site 24*hr	48 hr	72 hrs
1	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch

Table I
(continued)
Panel #20110425

Individual Results

2011.751.001

Subject Number	24*hr	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site 24*hr	48 hr	72 hrs
31	0	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0	0
56	DID NOT COMPLETE												
57	DID NOT COMPLETE												
58	DID NOT COMPLETE												
59	0	0	0	0	0	0	0	0	0	0	0	0	0
60	DID NOT COMPLETE												
61	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch

Table 1
(continued)
Panel #20110425

Individual Results

2011.751.001

Subject Number	24*hr	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site 24*hr	48 hr	72 hrs
62	0	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0	0
76	0	0	0	0	0	0	0	0	0	0	0	0	0
77	0	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	0	0	0	0	0	0	0	0	0
79	0	0	DID NOT COMPLETE										
80	0	0	0	0	0	0	0	0	0	0	0	0	0
81	0	0	0	0	0	0	0	0	0	0	0	0	0
82	0	0	0	0	0	0	0	0	0	0	0	0	0
83	0	0	0	0	0	0	0	0	0	0	0	0	0
84	0	0	0	0	0	0	0	0	DID NOT COMPLETE				
85	0	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch

Table 1
(continued)
Panel #20110425

Individual Results

2011.751.001

Subject Number	24*hr	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site 24*hr	48 hr	72 hrs
93	0	0	0	0	0	0	0	0	0	0	0	0	0
94	0	0	0	0	0	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0	0	0	0	0	0
96	0	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0	0
99	0	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0	0	0	0
101	0	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	0	0	0	0	0	0	0	0	0
103	0	0	DID NOT COMPLETE										
104	0	0	0	0	0	0	0	0	0	0	0	0	0
105	0	0	0	0	0	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0	0
109	0	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	0	0	0	0	0	0
111	0	0	0	0	0	0	0	0	0	0	0	0	0
112	0	0	0	0	0	0	0	0	0	0	0	0	0
113	0	0	0	0	0	0	0	0	0	0	0	0	0
114	0	0	0	0	0	0	0	0	0	0	0	0	0
115	0	0	0	0	0	0	0	0	0	0	0	0	0
116	0	0	0	0	0	0	0	0	0	0	0	0	0
117	0	0	DID NOT COMPLETE										
118	0	0	DID NOT COMPLETE										
119	0	0	0	0	0	0	0	0	0	0	0	0	0
120	0	0	0	0	0	0	0	0	0	0	0	0	0
121	0	0	DID NOT COMPLETE										
122	0	0	0	0	0	0	0	0	0	0	0	0	0
123	0	0	0	0	0	0	0	0	0	0	0	0	0
124	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch

Table 2
Panel #20110425

Subject Demographics

Subject Number	Initials	Age	Sex
1	M-B	41	F
2	LAN	43	F
3	KLT	37	F
4	M-O	68	F
5	MGV	61	F
6	DMC	45	F
7	JHA	61	F
8	FMR	67	F
9	PJM	58	F
10	CRB	76	M
11	RMH	60	F
12	A-S	34	F
13	GAC	69	F
14	BSP	70	F
15	CJL	61	F
16	EBO	75	F
17	TDV	67	F
18	ALC	77	F
19	SCF	42	F
20	TAK	49	F
21	CJD	71	F
22	JJM	16	F
23	EGV	77	F
24	DEF	56	F
25	AJR	22	M
26	KMD	27	F
27	BYG	38	F
28	JMR	68	F
29	NLL	51	F
30	RCB	66	M

Table 2
(continued)
Panel #20110425

Subject Demographics

Subject Number	Initials	Age	Sex
31	JLO	59	F
32	SDP	44	F
33	A-D	75	M
34	WLK	57	M
35	PFO	66	F
36	PAW	67	F
37	AJR	71	M
38	OUR	49	M
39	AMC	45	F
40	J-B	48	F
41	R-V	57	F
42	RAR	71	F
43	MER	67	F
44	ATL	22	F
45	LJR	61	F
46	C-T	49	M
47	P-R	49	M
48	KRS	21	F
49	PAS	60	F
50	EPR	45	F
51	C-S	27	F
52	SLK	32	F
53	TOK	27	M
54	KEM	17	F
55	BMM	47	F
56	J-F	30	F
57	C-C	69	F
58	L-P	65	F
59	DLT	49	F
60	RAG	66	F
61	F-O	55	M

Table 2
(continued)
Panel #20110425

Subject Demographics

Subject Number	Initials	Age	Sex
62	R-M	38	F
63	MMI	66	F
64	EMM	30	F
65	L-A	76	F
66	WRA	64	M
67	LCW	55	M
68	RSM	68	F
69	FKB	50	M
70	TAB	21	F
71	TAN	42	F
72	RDR	38	F
73	KJH	48	F
74	DJH	49	M
75	AJA	27	M
76	MAM	45	F
77	CCM	74	F
78	BNP	21	M
79	KTF	29	M
80	DMD	52	F
81	M-K	50	F
82	J-K	45	M
83	E-W	45	F
84	T-H	34	F
85	P-L	57	F
86	K-G	28	F
87	MPW	77	F
88	RPG	47	F
89	JCC	75	F
90	V-C	30	F
91	I-C	36	M
92	F-Y	32	F

Table 2
(continued)
Panel #20110425

Subject Demographics

Subject Number	Initials	Age	Sex
93	RCV	24	M
94	A-N	54	F
95	RMW	30	M
96	J-F	31	F
97	ALE	63	F
98	JAQ	17	F
99	TMM	28	F
100	CBB	35	M
101	C-F	26	F
102	R-F	54	F
103	S-S	21	F
104	JLF	37	F
105	D-S	78	M
106	M-S	49	F
107	SCR	20	F
108	BJL	50	F
109	L-S	53	F
110	DBL	51	F
111	RAF	61	M
112	CJF	62	F
113	RJF	31	M
114	C-R	36	F
115	NPM	49	M
116	N-S	69	M
117	LJA	51	F
118	RMA	19	M
119	BIM	61	F
120	D-A	34	F
121	CCO	52	F
122	KMB	25	F
123	EMB	56	F
124	BHQ	77	F

Memorandum

TO: Lillian Gill, D.P.A.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: November 2, 2015

SUBJECT: HRIPT of a Body Oil Containing Helianthus Annuus (Sunflower) Extract

Anonymous. 2015. Summary of a repeated insult patch test of a body oil containing 0.05% Helianthus Annuus (Sunflower) Extract.

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

2015

[redacted]

CLINICAL, SINGLE-BLIND, CONTROLLED STUDY OF THE SKIN IRRITATION AND SENSITIZATION POTENTIAL OF A PRODUCT TO BE APPLIED TO THE SKIN

SUMMARY

Product Name:	Body oil [redacted]
Product Code:	051598-04 that contains Helianthus Annuus (Sunflower) Extract at 0.05%.
Study Code:	[redacted] The dose was 0.025 mg/cm².
Report Code:	[redacted]
STUDY OBJECTIVE	To prove the absence of primary and accumulated skin irritation and sensitization potential of a product to be applied to the skin under maximized conditions, with controlled product amount and application site, supervised by a dermatologist.
METHODOLOGY	Both the test product and control were applied to patch test filter paper discs and then applied to the right or left back (scapular area) of the study subjects. The applications were performed on Mondays, Wednesdays and Fridays, during 3 consecutive weeks. Forty-eight hours (48h) after the application, the patch test was removed by expert technicians and, approximately 30 minutes after removal, the site was assessed in order to check the presence of clinical signs. After this period (induction) there was a, minimum, 10 day-period when no patch was applied to the study subjects' back (rest period). Then, the challenge period started. A single application of the patch test was performed, followed by readings after 48h and 72h. The study subjects were assessed by a dermatologist at the start and at the end of the study and supervised all along the study.
PRINCIPAL INVESTIGATOR	[redacted]
STUDY LENGTH	6 weeks
FREQUENCY OF APPLICATION	9 applications on the 3 first weeks (induction period). 1 application on the last week (challenge period).
APPLICATION SITE	Back (Scapular area).
NUMBER OF SUBJECTS	70 study subjects.
POPULATION DESCRIPTION	Female and male subjects, aged from 18 to 69 years old, phototype II to IV (Fitzpatrick).
ETHICS	This study was conducted in conformance with the Declaration of Helsinki principles, the applicable regulatory requirements, [redacted], and in spirit of the Good Clinical Practices [redacted] ICH E6: Good Clinical Practice).
RESULTS	During the study, no subjects presented skin clinical signs related to the product.
CONCLUSION	The product did not induce primary and accumulated skin irritation and sensitization process in the study group. The product was considered to be safe under the study conditions.

[redacted]

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Lillian Gill, D.P.A.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: October 26, 2015

SUBJECT: Comments on the Scientific Literature Review: Safety Assessment of *Helianthus annuus*-Derived Ingredients as Used in Cosmetics (report posted on CIR's website October 5, 2015)

The Council has no suppliers listed for the following ingredients:
Helianthus Annuus (Sunflower) Leaf/Stem Extract
Helianthus Annuus (Sunflower) Seedcake
Helianthus Annuus (Sunflower) Seed Flour
Hydrolyzed Sunflower Seed Wax

Key Issue

The fatty acid profile in the text in the Constituents and Components section states that oleic acid may be as low as 14-39% in conventional plant seeds and as high as 75-90.7% in selectively bred plant seeds. Although it appears to come from the same reference (25), the text does not agree with the information in Table 5 that gives levels of oleic as 8.48% in oilseed and 9.89% in non-oilseed. Please explain this discrepancy. As Table 5 shows a number of values for oilseeds to be lower than non-oilseed, it is not clear why the seeds in the first column are considered "oilseed".

Additional Considerations

Introduction - Please state which ingredients were reviewed in the plant oil report (Helianthus Annuus (Sunflower) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Hydrogenated Sunflower Seed Oil, Sunflower Seed Acid)

Please correct "sedate" to "seedate" (this error is also in Table 2 - Phytosteryl Sunflower Sedate)

Constituents of Concern - The information about benz[a]pyrene should be moved to the Impurities section.

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

Method of Manufacture - Please check reference 36. The sunflower extract was an extract of flowers not "bark" as stated in the Method of Manufacture section.

Cosmetic Use - Helianthus Annuus (Sunflower) Leaf/Stem Extract has been added to the COSING database. Unless an ingredient is in Annex II, ingredients assigned new INCI names are added to the COSING data base periodically as the Council provides the data so the European database can be updated.

Non-Cosmetic - It is not clear why this section focuses on food use in Europe. It should also state that sunflower ingredients are not required to be labeled as allergens in the United States.

It is not clear how *H. annuus* plants are used for "photoremediation" - it would make sense if it said "phytoremediation".

Table 2 - Please provide more details in the column titled "Maximum concentration of use in safety assessment". This column should identify the ingredient for which the maximum concentration was reported and the product category.

Table 13 - Please define LTP (lipid transfer protein) (reference 12)