Final Report of the Cosmetic Ingredient Review Expert Panel

Amended Safety Assessment of Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Acid, Hydrogenated Coconut Oil, Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Alcohol, Coconut Oil Decyl Esters, Decyl Cocoate, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate, Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl Cocoate

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Cosmetic Ingredient Review

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Final Report on the Safety Assessment of Amended Safety Assessment of Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Acid, Hydrogenated Coconut Oil, Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Alcohol, Coconut Oil Decyl Esters, Decyl Cocoate, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate, Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl Cocoate

Abstract: Cocos Nucifera (Coconut) Oil is the cosmetic ingredient name for the oil pressed from the dried fruit of coconuts. Coconut Oil is often composed of 90% saturated triglycerides and low in nonglyceride impurities. Coconut Oil may function as a fragrance ingredient, hair conditioning agent, or skin-conditioning agent and is reported in 626 cosmetics at concentrations from 0.0001 to 70%. Cosmetic ingredients can consist of fatty acids derived from Coconut Oil, hydrogenated forms of these fatty acids, corresponding fatty alcohols, simple esters and inorganic salts, and sulfated salts, all of these fatty acids. While most Coconut Oil derivatives are skin conditioning agents, a wide variety of other cosmetic functions are described. Oral toxicity studies indicate Coconut Oil and Hydrogenated Coconut Oil are relatively nontoxic by ingestion, and as a single 5 g/kg dose to rats, neither compound caused deaths. Rats fed 25% Coconut Oil for 90 d had only slight fatty change of the liver. Hydrogenated Coconut Oil (15%) had no effect on the life span of mice. Hydrogenated Coconut Oil was nontoxic as a single 3 g/kg dermal dose, was nonirritating to the skin in single-insult occlusive patch tests in guinea pigs, and was not a sensitizer. Coconut Oil did not cause skin irritation in rabbits in a 24-h single-insult occlusive patch test. Undiluted Coconut Acid caused minimal irritation in rabbits when assayed in a 24-h single-insult occlusive patch test. Some studies suggested low eye irritation potential in Coconut Oil and Hydrogenated Coconut Oil. Coconut Oil significantly reduced the increase in prostate weight and prostate weight to body weight ratio related to benign prostatic hyperplasia induced by testosterone injections in rats. Clinical tests of bar soap containing Coconut Oil up to 13% resulted in no irritation to mild irritation, with neither phototoxicity nor photosensitivity. A tanning butter containing 2.5% Coconut Oil did not cause reactions in a 6-wk repeat insult predictive patch test. Potassium Cocoate was an irritant in less than 1% of subjects with pre-existing dermatitis. Lipstick containing 10% Hydrogenated Coconut Oil caused no irritation after a single patch application and no indication of sensitization in retests performed 14 d later. Coconut Oil was not an allergen at 100% concentration in 12 subjects. The salts and esters of this large group of ingredients derived from Coconut Oil are expected to have similar toxicological profiles as the Oil, its hydrogenated forms, and its constituent fatty acids. In solution, the salts are expected to dissociate in any product formulation independent of whether the salt is sodium, ammonium, magnesium, or potassium. The esters likely will break down into their component parts, none of which present any safety issues, e.g. lauryl alcohol and coconut fatty acids for Lauryl Cocoate. The Expert Panel recognizes that use concentration data are not available for all ingredients in this group and that some ingredients in this group are not in current use. The Panel considers that the concentrations for the ingredients that are in use would apply to those with similar functions, but not those in current use. In the absence of inhalation toxicity data, the Expert Panel determined that Coconut Oil and its derivatives can be used safely in hair sprays, because the product particle size is not respirable. The Expert Panel stressed that the cosmetics industry should continue to limit pesticide residues and heavy metals that may be present in botanical ingredients before blending into cosmetic formulation. In addition, aflatoxin should not be present in Coconut Oil and ingredients derived from Cocos nucifera. With these limitiations, Coconut Oil and the other ingredients derived from Cocos nucifera are safe as cosmetic ingredients in the practices of use and concentration described in this safety assessment

INTRODUCTION

Cocos Nucifera (Coconut) Oil and its derivatives, Coconut Acid, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil, are used by industry as a convenient source of lower chain length fatty acids.

A safety assessment for these ingredients was published in 1986 with the conclusion from the Cosmetic Ingredient Review (CIR) Expert Panel that these ingredients are “safe for use as cosmetic ingredients” (Elder 1986).

The Panel determined that the available data in the original safety assessment on Coconut Oil, Coconut Acid, Hydrogenated

Coconut Oil, and Hydrogenated Coconut Acid are sufficient to support the safety of an additional 21 cosmetic ingredients in the coconut oil and related fatty alcohols, fatty acid esters, and salts group: Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate,

Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Alcohol, Coconut Oil Decyl Esters, Decyl Cocoate,

Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate, Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl Cocoate. These ingredients consist of fatty acids derived from Coconut Oil, hydrogenated forms of these fatty acids, corresponding fatty alcohols, simple esters of these fatty acids, inorganic salts of these fatty acids, and sulfated salts of these fatty acids.

While not considered as additional ingredients to this safety assessment, the CIR Expert Panel has also published safety assessments for Butylene Glycol (Elder 1985, Andersen 2006), Glyceryl Cocoate (Andersen 2004), Methyl Alcohol (Andersen 2001), Propylene Glycol Dicocoate (Andersen 1999), and Sorbitan Cocoate (Andersen 2002), finding them safe for use as cosmetic ingredients. Included in these safety assessments were dermal absorption, acute inhalation toxicity, acute oral toxicity, acute dermal toxicity, subchronic and chronic oral toxicity, comedogenicity, ocular irritation, dermal irritation, reproductive and developmental toxicity, genotoxicity, carcinogenicity, and photosensitization studies.

The CIR Expert Panel previously reviewed the safety of Lanolin Acid and Lanolin Alcohol (Elder 1980), finding that the fatty acids and the corresponding fatty alcohols in lanolin are equivalently safe. This safety assessment was re-reviewed in 2003 and the conclusion was reaffirmed (Andersen 2005).

Table 1 summarizes use information and gives the conclusion on these previously reviewed ingredients.

Table 1. Previously reviewed related ingredients.

Ingredient	Uses	Use Concentrations (%)	Conclusion	Reference
Butylene Glycol	165	<0.1 - >50	safe as presently used in cosmetics	Elder 1985
	813	0.00007 - 89	reaffirmed in 2006.	Andersen 2006
Glyceryl Cocoate	1	0.3 - 5	safe as a cosmetic ingredient in the present practices of use and concentration.	Andersen 2004
Methyl Alcohol	4	0.1 - 5	safe as used to denature alcohol used in cosmetic products.	Andersen 2001
Propylene Glycol Dicocoate	not in use[a]	not in use[a]	safe as a cosmetic ingredient in the present practices of use.[a]	Andersen 1999
Sorbitan Cocoate	not in use[a]	not in use[a]	safe for use as a cosmetic ingredient under the present practices of use.[a]	Andersen 2002
Lanolin Acid	51	>0.1 - 10	safe for topical application to humans in the present practice of use and concentration	Elder 1980;
	44	1-3	;reaffirmed in 2005.	Andersen 2005
Lanolin Alcohol	738	≤0.1 - >50	safe for topical application to humans in the present practice of use and concentration	Elder 1980
	337	0.6 - 4	;reaffirmed in 2005.	Andersen 2005

[a] Were ingredients not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to other related chemicals.

CHEMISTRY

Definition

The definitions and structures of the Coconut Oil ingredients presented in this report as given in the International Cosmetic Ingredient Dictionary and Handbook (Gottschalck and Bailey 2008) are found in Table 2a. Technical and trade names for these ingredients are presented in Table 2b.

The primary constituents of Coconut Oil are trimyristin, trilaurin, tripalmitin, tristearin, and various other triglycerides (O'Neil 2006). The average fatty acid content is presented in Table 3. About 90% of the oil is saturated (Solomons 1978).

Table 2a. Definitions, structures, and functions of Cocos Nucifera (Coconut) Oil and derivatives (Gottschalck and Bailey 2008).

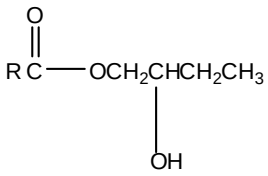
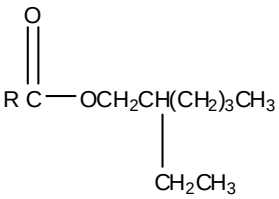
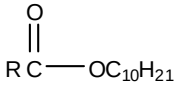
Ingredient	Definition	Structure	Function(s)
Cocos Nucifera (Coconut) Oil (CAS No. 8001-31-8)	A fixed oil obtained by expression from the kernels of the seeds of Cocos nucifera.	-	Fragrance Ingredient; Hair Conditioning Agent; Skin-Conditioning Agent-Miscellaneous; Skin-Conditioning Agent-Occlusive
Coconut Acid (CAS No. 61788-47-4)	A mixture of fatty acids derived from Cocos Nucifera (Coconut) Oil.	-	Surfactant-Cleansing Agent
Coconut Alcohol (CAS No. 68425-37-6)	A mixture of fatty alcohols derived from Coconut Acid.	-	Emulsion Stabilizer; Surfactant-Foam Booster; Viscosity Increasing Agent-Aqueous; Viscosity Increasing Agent-Nonaqueous
Butylene Glycol Cocoate	The ester of butylene glycol and Coconut Acid that conforms generally to the structure on the right where RCO- represents the Coconut Acid moiety.		Emulsion Stabilizer; Viscosity Increasing Agent-Nonaqueous
Caprylic/Capric/Coco Glycerides	A mixture of mono, di, and triglycerides of caprylic, capric, and coconut acids.	-	Skin-Conditioning Agent-Emollient
Cocoglycerides (CAS No. 68606-18-8)	A mixture of mono, di, and triglycerides derived from Coconut Oil.	-	Skin-Conditioning Agent-Emollient
Coconut Oil Decyl Esters	A product obtained by the transesterification of decyl alcohol and Cocos Nucifera (Coconut) Oil.	-	Skin-Conditioning Agent-Occlusive
Decyl Cocoate	The ester of decyl alcohol and the fatty acids derived from Cocos nucifera (Coconut) Oil.	-	Skin-Conditioning Agent-Occlusive
Ethylhexyl Cocoate (CAS Nos. 91052-62-9, 92044-87-6)	The ester of 2-ethylhexanol and Coconut Acid that conforms to the structure to the right where RCO- represents the fatty acid radical derived from Coconut Oil.		Skin-Conditioning Agent-Emollient
Isodecyl Cocoate	The ester of branched chain decyl alcohols and Coconut Acid that conforms to the structure to the right where RCO- represents the fatty acids derived from Coconut Oil.		Skin-Conditioning Agent-Emollient

Table 2a (continued) . Definitions, structures, and functions of Cocos Nucifera (Coconut) Oil and derivatives (Gottschalck and Bailey 2008).

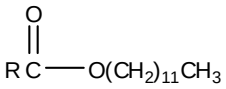
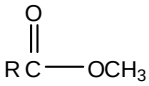
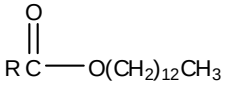
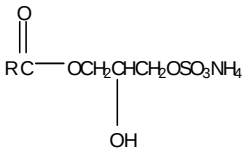
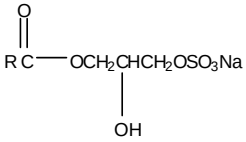
Ingredient	Definition	Structure	Function(s)
Lauryl Cocoate	The ester of lauryl alcohol and the fatty acids derived from Coconut Oil that conforms to the structure to the right where RCO- represents the fatty acids derived from Coconut Oil.		Skin-Conditioning Agent-Emollient; Skin-Conditioning Agent-Occlusive
Methyl Cocoate (CAS No. 61788-59-8)	The ester of methyl alcohol and coconut fatty acids. It conforms generally to the structure on the right where RCO- represents the fatty acids derived from Coconut Oil.		Skin-Conditioning Agent-Emollient
Octyldodecyl Cocoate	The ester of octyldodecanol and Coconut Acid.	-	Skin-Conditioning Agent-Emollient
Pentaerythrityl Cocoate	The ester of Coconut Acid and pentaerythritol.	-	Skin-Conditioning Agent-Miscellaneous
Tridecyl Cocoate	The ester of tridecyl alcohol and Coconut Acid. It conforms to the structure to the right where RCO- represents the fatty acids derived from Coconut Oil.		Skin-Conditioning Agent-Occlusive
Magnesium Cocoate	The magnesium salt of Coconut Acid.	-	Anticaking Agent; Slip Modifier; Viscosity Increasing Agent-Nonaqueous
Potassium Cocoate (CAS No. 61789-30-8)	The potassium salt of Coconut Acid.	-	Surfactant-Cleansing Agent; Surfactant-Emulsifying Agent
Sodium Cocoate (CAS No. 61789-31-9)	The sodium salt of Coconut Acid.	-	Surfactant-Cleansing Agent; Surfactant-Emulsifying Agent
Ammonium Cocomonoglyceride Sulfate (CAS No. 61789-03-5)	Ammonium salt of sulfated fatty acids derived from Coconut Oil where RCO- represents the fatty acids derived from Coconut Oil.		Surfactant-Cleansing Agent
Sodium Cocomonoglyceride Sulfate (CAS No. 61789-04-6)	Sodium salt of sulfated fatty acids derived from Coconut Oil.		Surfactant - Cleansing Agent
Hydrogenated Coconut Oil (CAS No. 84836-98-6)	The end product of controlled hydrogenation of Cocos Nucifera (Coconut) Oil.	-	Skin-Conditioning Agent-Occlusive
Hydrogenated Coconut Acid (CAS No. 68938-15-8)	The end product of controlled hydrogenation of Coconut Acid.	-	Opacifying Agent; Surfactant-Cleansing Agent

Table 2a (continued) . Definitions, structures, and functions of Cocos Nucifera (Coconut) Oil and derivatives (Gottschalck and Bailey 2008).

Ingredient	Definition	Structure	Function(s)
Hydrogenated Coco-Glycerides (CAS No. 91744-42-2)	A mixture of mono, di, and triglycerides of hydrogenated Coconut Oil.	-	Skin-Conditioning Agent-Emollient
Potassium Hydrogenated Cocoate	The potassium salt of hydrogenated Coconut Acid.	-	Surfactant-Cleansing Agent
Sodium Hydrogenated Cocoate	The sodium salt of hydrogenated Coconut Acid.	-	Surfactant-Cleansing Agent

Physical Properties

Coconut Oil is a pale yellow, semi-solid, edible oil that is stable in air at room temperature. It is miscible in carbon disulfide, chloroform, ether, and petroleum benzin and insoluble in water. Hydrogenated Coconut Oil and Hydrogenated Coconut Acids are white, waxy, flaky, odorless materials. They are obtained by hydrogenation of Coconut Oil and/or Coconut Acid. Following hydrogenation, Coconut Oil and Coconut Acid are soluble in mineral oil and isopropyl myristate but are not soluble in alcohol or water. An infrared spectrum for Coconut Oil has been published (Estrin et al. 1982).

According to Swern (1979), unlike other oils, Coconut Oil undergoes little change in melting point and consistency following hydrogenation because of its high degree of saturation. Even complete hydrogenation serves only to convert approximately 10% of the entire oil; associated with this process is a melting point change of only 10-12°C. The narrow range of plasticity of Coconut Oil and the inability of the processor to modify greatly the properties of the oil restrict the use of Coconut Oil in edible products. The physical properties of the oils are presented in Table 4.

Table 2b. Technical and trade names Cocos Nucifera (Coconut) Oil and derivatives (Gottschalck and Bailey 2008).

Ingredient	Technical Name(s)	Trade Name(s)
Cocos Nucifera (Coconut) Oil	Coconut absolute; Coconut Fatty Acid Triglyceride; Coconut Oil; Copra Oil	AEC Coconut Oil RD; Akogreen C; Certified Organic Coconut Oil; Certified Organic Extra Virgin Coconut Oil; Coconut (Cocos Nucifera) Oil PC; Coconut Oil; Cocos Nucifera Oil ies; Cropure Coconut; EmCon COCO; Huile de Coco Vierge; Hydrobase 24/26; Jeen Coconut Oil; Kristal; Lipovol C-76; Nikkol Trifat C-24; Phytol Coco; Pureco 76; Rita Coconut Oil 76
Coconut Acid	Acids, Coconut; Coco Fatty Acid; Coconut Fatty Acid; Coconut Fatty Acids; Coconut Oil Acids; Cocos Nucifera (Coconut) Acid	AEC Coconut Acid; C-108; C-110; Emery 622; Emery 626; Kortacid C 60; Kortacid C 70; Kortacid CG; Prifac 7901
Hydrogenated Coconut Oil	Coconut Oil, Hydrogenated	AEC Hydrogenated Coconut Oil; Hydrobase 32/34; Lipex 401; Rita Hydrogenated Coconut Oil; Sabowax HCO; Witocan 42/44
Hydrogenated Coconut Acid	Acids, Coconut, Hydrogenated; Coconut Acid, Hydrogenated; Fatty Acids, Coco, Hydrogenated; Hydrogenated Coconut Fatty Acid	Prifac 5900; Prifac 5901
Ammonium Cocomonoglyceride Sulfate	-	-

Table 2b (continued). Technical and trade names Cocos Nucifera (Coconut) Oil and derivatives (Gottschalck and Bailey 2008).

Ingredient	Technical Name(s)	Trade Name(s)
Butylene Glycol Cocoate	-	Cocoate BG
Caprylic/Capric/Coco Glycerides	-	-
Cocoglycerides	Glycerides, Coconut, Mono-, Di- and Tri-	AEC Cocoglycerides; Dub Cog; Myritol 331; Novata AB PH; Novata A PH; Novata BCF PH; Novata BC PH; Novata BD PH; Novata B PH; Novata 299 PH
Coconut Alcohol	Alcohols, Coco; Coconut Fatty Alcohol; Cocos Nucifera (Coconut) Alcohol	CO-618
Coconut Oil Decyl Esters	-	Coco Ceresters
Decyl Cocoate	-	Tegosoft DC
Ethylhexyl Cocoate	Coconut Fatty Acids, 2-Ethylhexyl Ester; Octyl Cocoate	AEC Ethylhexyl Cocoate; Crodamol OC; Dub CO; Estol 1540; Radia 7722; Radia 7778; Trioxene E
Hydrogenated Coco-Glycerides	-	Akosoft 36; Lipocire NA 10 Pastilles; Softisan 100; Softisan 138; Softisan 142; Witepsol E 75; Witepsol E 76; Witepsol E 85; Witepsol H 5; Witepsol H 12; Witepsol H 15; Witepsol H 19; Witepsol H 32; Witepsol H 35; Witepsol H 37; Witepsol H 39; Witepsol H 175; Witepsol W 25; Witepsol W 31; Witepsol W 32; Witepsol W 35; Witepsol W 45; Witocan P
Isodecyl Cocoate	Coconut Fatty Acids, Isodecyl Ester	Trioxene
Lauryl Cocoate	-	Cetinol 1212
Magnesium Cocoate	Coconut Fatty Acids, Magnesium Salts; Fatty Acids, Coconut Oil, Magnesium Salt	-
Methyl Cocoate	Fatty Acids, Coco, Methyl Esters	AEC Methyl Cocoate; CE-618
Octyldodecyl Cocoate	-	Guerbester Coco 20
Pentaerythrityl Cocoate	-	-
Potassium Cocoate	Fatty Acids, Coconut Oil, Potassium Salts; Potassium Cocoate Solution	AEC Potassium Cocoate; Custoblend 40K; Mackadet 40K; Nansa PC38; Norfox 1101; Potassium Cocoate
Potassium Hydrogenated Cocoate	-	-
Sodium Cocoate	Fatty Acids, Coconut Oil, Sodium Salts	AEC Sodium Cocoate; Norfox Coco Powder
Sodium Cocomonoglyceride Sulfate	Glycerides, Coconut Oil Mono-, Sulfated, Sodium Salts; Sodium Coconut Monoglyceride Sulfate	Nikkol SGC-80N; Plantapon CMGS; Poem-LS-90
Sodium Hydrogenated Cocoate	-	-
Tridecyl Cocoate	Coconut Fatty Acid, Tridecyl Ester	Saboderm ITL; Trioxene D

Table 3. Average Percent Fatty Acid Content of Cocos Nucifera (Coconut) Oil (Weight %) (Solomons 1978, Allen et al. 1969, Altman and Dittmer 1964, Swern 1979).

Fatty Acid	Saturated	Unsaturated
(C_6) Caproic	0 - 1	-
(C_8) Caprylic	5 - 9	-
(C_{10}) Capric	6 - 10	-
(C_{12}) Lauric	44 - 52	-
(C_{14}) Myristic	13 - 19	-
(C_{16}) Palmitic	8 - 11	-
(C_{18}) Stearic	1 - 3	-
(C_{16}) Palmitoleic	-	0 - 1
(C_{18}) Oleic	-	5 - 8
(C_{18}) Linoleic	-	Trace - 2.5

Table 5 describes the material specifications of Butylene Glycol Cocoate, Decyl Cocoate, Hydrogenated Coco-Glycerides, and Potassium Cocoate.

Reactivity

Swern (1979) stated that, since it is highly saturated, Coconut Oil is resistant to atmospheric oxidation at room temperature. By the active oxygen method (AOM), the stability of refined Coconut Oil was 250 h. The addition of common antioxidants and stabilizers increases the AOM stability to nearly 350 h.

Analytical Methods

The composition of Coconut Oil may be determined by several different techniques, including thin-layer chromatography and gas-liquid chromatography. A review of these and other techniques has been published (Swern 1979).

Laureles et al. (2002) used gas chromatography and high-performance liquid chromatography to measure the fatty acid and triacylglycerol content of the oil of 17 coconut (Cocos nucifera L.) hybrids and parentals. Composition varied among varieties.

Method of Manufacture

Coconut Oil is obtained from copra (the dried meat, or kernel, of the coconut), where it is present in quantities of 60-70%. The expressed material has a water content of 4-10% (Allen et al. 1969). Crude Coconut Oil is obtained through mechanical expression of copra. The oil is then refined, bleached, and deodorized to removed free fatty acids, phospholipids, color, odor, flavor components, and other non-oil materials (National Academy of Sciences 1996). Hydrogenated Coconut Oil is prepared by the hydrogenation of Coconut Oil. Coconut Acid is derived from Coconut Oil by hydrolysis and isolation of the fatty material, which is then distilled. Hydrogenated Coconut Acid is prepared by the hydrogenation of Coconut Acid.

Mpagalile and Clarke (2005) studied various processing parameters in expressing Coconut Oil from dried coconut gratings. The parameters included pressing time, particle size, pressing pressure, moisture content, and temperature. This study found that Coconut Oil expression efficiency was significantly dependent on the moisture content of the coconut gratings.

The different fatty acid fractions of Coconut Oil can be esterified with a mono-alcohol or a polyol to produce various esters. Alcohols of coconut fatty acids are manufactured by high pressure hydrogenation of coconut fatty acids or coconut fatty acid methyl esters. The coconut fatty alcohols can be further processed by sulfation, ethoxylation, amination, phosphatization, sulfitation, etc. (Hui 1996).

Gattefossé (2001) reported that Hydrogenated Coco-Glycerides are produced by esterification of coconut fatty acids (C12-C18) with glycerol. Esterification of coconut fatty acids (C12-C18) with butylene glycol produces Butylene Glycol Cocoate (Gattefossé 2007).

Potassium Cocoate is produced in a trade name mixture by combining the fatty acids of coconut oil with potassium hydroxide (Taiko Oil Chemical Co., Ltd. 2008).

Impurities

Coconut Oil is usually quite low in color bodies, pigments, phosphatides, gums, and other nonglyceride substances commonly found in much larger quantities in other vegetable oils. It may contain free fatty acids, low concentrations of sterols, tocopherol, and squalene (Allen et al. 1969). It is the presence of lactones at approximately 150 ppm that provides the characteristic coconut flavor. They are present as a series of d-lactones with 6, 8, 10, 12, or 14 carbon atoms (Swern 1979).

Table 4. Physical Properties of Coconut Oil and Hydrogenated Coconut Oil. (O'Neil 2006, Estrin et al. 1982).

Property	Coconut Oil	Hydrogenated Coconut Oil
Density	0.903	-
Refractive Index n_D^{40}	1.4485 - 1.4495	-
Acid Value	<6	0.2
Saponification Value	255 - 258	238 - 248
Iodine Value	8 - 9.5	3.0
Melting Range	21 - 25°C	36 - 37°C

Table 5. Material specifications for Butylene Glycol Cocoate, Decyl Cocoate, Hydrogenated Coco-Glycerides, and Potassium Cocoate.

Specification	Butylene Glycol Cocoate	Decyl Cocoate	Hydrogenated Coco-Glycerides	Hydrogenated Coco-Glycerides	Potassium Cocoate
Source	Gattefossé 2007	Evonik Industries 1999; Evonik Industries 2008	Gattefossé 2001	Sasol 2007	Nikko Chemical Co., Ltd. 2008
Trade Name	Cocoate BG	Tegosoft DC	Lipocire NA-10	Witepsol; Massa Estarinum	Nikkol MNK-40 (mixed product)
Appearance	Oil limpid liquid at 20˚C	Liquid	Waxy solid	Hard fats in pastill shape	White to yellow liquid
Odor	Characteristic	Almost odorless	Faint	Odorless	Faint characteristic
Color	< 2.0 (Gardner Scale)	< 125.0 (Hazen); light yellow	< 3.0 (Gardner Scale)	White	200 max. (APHA)
Flash Pont	NA	> 100 ˚C	NA	NA	NA
Melting Point	NA	NA	33.0 - 36.0 ˚C (capillary tube) 34.0 - 37.0 ˚C (drop point)	30.0 - 44.0 ˚C	NA
Specific Gravity	0.900 - 0.920 at 20 ˚C	0.85 g/cm^3 at 25 ˚C	NA	NA	1.010 - 1.060 at 20 ˚C
Refractive Index	1.440 - 1.460 at 20 ˚C	NA	NA	NA	NA
Acid Value	< 3.0 mg KOH/g	< 1.00 mg KOH/g	< 0.5 mg KOH/g	0.2-1.3 mg KOH/g	NA
Free Butylene Glycol	< 4.0%	NA	NA	NA	NA
Monoesters Content	45.0 - 70.0%	NA	NA	NA	NA
Diesters Content	30.0 - 55.0%	NA	NA	NA	NA
Water Content	< 0.20%	< 0.100 %	<0.50%	NA	NA
Saponification Value	NA	155.0 - 170.0 mg KOH/g	230 - 250 mg KOH/g	215-255 mg KOH/g	NA
Iodine Value	NA	< 10.00 g I_2/100 g	< 2.0 g I_2/100 g	2-8 g I_2/100 g	NA
Hydroxyl Value	NA	< 5.0 mg KOH/g	< 15 mg KOH/g	2-70 mg KOH/g	NA
Peroxide Value	NA	< 2.0 meq O_2/kg	< 1.2 meq O_2/kg	1-4 meq O_2/kg	NA
Alkaline Impurities	NA	NA	< 30 ppm NaOH	max. 0.15 ml HCL/2g	NA
Unsaponifiable Matter Content	NA	NA	< 0.6%	0.3-3.0%	NA
Evaporation Residue (105 ˚C, 90 min)	NA	NA	NA	NA	38.0 - 42.0%
Total Ashes Content	NA	NA	< 0.05%	max. 0.05%	NA

Table 5 (continued) . Material specifications for Butylene Glycol Cocoate, Decyl Cocoate, Hydrogenated Coco-Glycerides, and Potassium Cocoate.

Specification	Butylene Glycol Cocoate	Decyl Cocoate	Hydrogenated Coco-Glycerides	Hydrogenated Coco-Glycerides	Potassium Cocoate
Heavy Metals Content	NA	max. 20 ppm	< 10 ppm	max. 10 ppm	20 ppm max (arsenic 2 ppm max)
Hg; As; Cd; Ni respective	NA	< 1 ppm	NA	NA	NA
pH (10%)	NA	NA	NA	NA	10.0 - 11.0

Crude samples of Coconut Oil contain traces of polycyclic aromatic hydrocarbons (PAH), particularly when the copra is smoke-dried (Grimmer and Hildebrandt 1968, Biernoth and Rost 1968). A combination of activated charcoal treatment and steam vacuum deodorization are the common refining methods most likely to remove PAH from edible oils (Biernoth and Rost 1968).

Aflatoxin contamination of raw and dried copra is reported (Arseculeratne et al. 1976, Dietrich and Hoffmann 1978, Goldblatt and Dollear 1977, Tuason and Madamba 1981). Improper drying, handling, and storage greatly increase the possibility of contamination by aflatoxins, secondary metabolites of the mold Aspergillus flavus, growing on copra. Smoke drying of copra inhibited aflatoxin formation (Arseculeratne et al. 1976). Conventional refining processes remove aflatoxin that may be found in crude peanut or corn oils (Parker and Melnick 1966), and it may be inferred that such procedures can be applicable to all vegetable oils treated by alkali refining, water washing, and bleaching (Dollear 1969).The FDA has defined the action levels for aflatoxin content in foods 20 ppb (FDA 2000).

USE

Cosmetic

Table 6 presents the product formulation data for Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Oil, Hydrogenated Coconut Acid, Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Alcohol, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Magnesium Cocoate, Methyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, and Sodium Cocoate. The total uses of each ingredient were supplied to the Food and Drug Administration (FDA) by industry as part of the Voluntary Cosmetic Ingredient Reporting Program (VCRP). Total uses for Coconut Oil and Coconut Acid have increased significantly since the original safety assessment in 1986 in which Coconut Oil had 122 total uses and Coconut Acid had 36 uses (Elder 1986). The FDA reported that these ingredients had a total of 626 and 142 total uses, respectively, in 2007 (FDA 2007).

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives.

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
Cocos Nucifera (Coconut) Oil		
Baby products		
Shampoos	1 (55)	0.05
Lotions, oils, powders, and creams	5 (132)	0.3
Other	6 (138)	0.01[1]
Bath products		
Oils, tablets, and salts	- (257)	0.05 - 23
Soaps and detergents	130 (1329)	0.3 - 41
Bubble baths	1 (262)	0.04 - 1
Other	10 (239)	0.05 - 1

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives **(*continued*).**

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
Cocos Nucifera (Coconut) Oil (continued)		
Eye makeup		
Eyebrow pencils	- (147)	0.4
Eyeliners	2 (684)	0.4 - 25
Eye shadow	1 (1196)	0.1 - 0.5
Eye lotion	2 (177)	0.3 - 80
Eye makeup remover	1 (131)	0.4
Mascara	1 (463)	0.01 - 0.4
Other	- (288)	0.4 - 43
Fragrance products		
Colognes and toilet waters	1 (1288)	0.1
Powders	1 (278)	0.1
Other	5 (399)	26
Noncoloring hair care products		
Conditioners	26 (1249)	0.0001 - 0.01
Sprays/aerosol fixatives	- (371)	0.3
Hair straighteners	17 (144)	2
Shampoos	22 (1403)	0.01 - 0.3
Tonics, dressings, etc.	22 (1097)	1 - 13
Other	10 (716)	-
Hair coloring products		
Dyes and colors	142 (2481)	-
Tints	1 (58)	-
Bleaches	2 (152)	-
Makeup		
Blushers	1 (539)	0.1 - 0.5
Face powders	- (613)	0.1
Foundations	1 (635)	0.1
Leg and body paint	1 (29)	-
Lipsticks	19 (1912)	0.2 - 51
Makeup bases	- (164)	0.1
Rouges	- (99)	0.4
Other	12 (406)	0.1 - 10
Nail care products		
Basecoats and undercoats	- (62)	2
Cuticle softeners	- (18)	0.1
Nail polishes and enamels	- (419)	0.005 - 0.1
Other	2 (124)	0.1 - 0.2[2]
Personal hygiene products		
Deodorants (underarm)	- (540)	0.1 - 16
Douches	- (12)	16
Feminine deodorants	- (21)	16
Other	12 (514)	0.0005 - 16[3]
Shaving products		
Shaving cream	10 (162)	2 - 9
Shaving soap	- (6)	16
Other	1 (107)	-

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives ***(continued)*.**

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
Cocos Nucifera (Coconut) Oil (continued)		
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	16 (1368)	-
Face and neck creams, lotions, powders, and sprays	7 (1195)	0.3 - 10
Body and hand creams, lotions, powders, and sprays	59 (1513)	1 - 8[4]
Foot powders and sprays	- (48)	6
Moisturizers	43 (2039)	0.01 - 25
Night creams, lotions, powders, and sprays	3 (343)	2
Paste masks/mud packs	3 (418)	2
Skin fresheners	2 (285)	-
Other	10 (1244)	0.3 - 2[5]
Suntan products		
Suntan gels, creams, liquids, and sprays	12 (156)	0.1 - 50
Indoor tanning preparations	1 (200)	0.5
Other	2 (62)	0.5 - 2[6]
Total uses/ranges for Cocos Nucifera (Coconut) Oil	**626**	**0.0001 - 80**
Coconut Acid		
Baby products		
Other	1 (138)	-
Bath products		
Oils, tablets, and salts	- (257)	6
Soaps and detergents	93 (1329)	0.04 - 14
Other	- (239)	0.5
Eye makeup		
Eyeliner	1 (684)	-
Noncoloring hair care products		
Shampoos	2 (1403)	0.03 - 0.3
Makeup		
Face powders	2 (613)	-
Foundations	7 (635)	-
Personal hygiene products		
Other	1 (514)	0.04 - 2[7]
Shaving products		
Aftershave lotion	1 (395)	-
Shaving cream	23 (162)	6 - 9
Shaving soap	1 (6)	-
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	4 (1368)	2 - 9
Face and neck creams, lotions, powders, and sprays	1 (1195)	-
Body and hand creams, lotions, powders, and sprays	1 (1513)	-
Moisturizers	1 (2039)	-
Paste masks (mud packs)	1 (418)	-
Other	2 (1244)	-
Total uses/ranges for Coconut Acid	**142**	**0.03 - 14**

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives ***(continued)*.**

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
	Hydrogenated Coconut Acid	
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	- (1368)	10
Moisturizers	- (2039)	6
Total uses/ranges for Hydrogenated Coconut Acid	**-**	**6 - 10**
	Hydrogenated Coconut Oil	
Baby products		
Other baby products	1 (138)	2 - 50
Bath products		
Soaps and detergents	1 (1329)	39
Bubble baths	- (262)	20
Other	- (239)	0.5
Eye makeup		
Eyebrow pencils	3 (147)	0.3 - 9
Eyeliners	5 (684)	0.8 - 22
Eye shadow	- (1196)	0.2 - 10
Eye lotion	- (177)	0.8 - 9
Eye makeup remover	- (131)	9
Mascara	- (463)	1 - 9
Other	1 (288)	1 - 11
Fragrance products		
Sachets	- (28)	0.3
Other	- (399)	0.3
Noncoloring hair care products		
Conditioners	2 (1249)	0.001 - 2
Rinses	- (47)	0.5
Shampoos	- (1403)	1
Tonics, dressings, etc.	- (1097)	0.001 - 0.9
Other	1 (716)	0.5
Hair coloring products		
Dyes and colors	- (2481)	0.6
Rinses	- (43)	0.5
Makeup		
Face powders	3 (613)	0.4
Foundations	4 (635)	0.6 - 7
Lipsticks	6 (1912)	0.7 - 29
Makeup bases	1 (164)	-
Other	1 (406)	0.5 - 2
Nail care products		
Cuticle softeners	- (18)	1
Nail creams and lotions	- (17)	0.8
Other	- (124)	2 - 25
Oral hygiene products		
Mouthwashes and breath fresheners	- (85)	17

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives ***(continued)*.**

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
Hydrogenated Coconut Oil (continued)		
Personal hygiene products		
Feminine hygiene deodorants	- (21)	1
Shaving products		
Aftershave lotions	- (395)	0.9
Shaving cream	- (162)	0.3
Shaving soap	1 (6)	-
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	3 (1368)	0.06 - 2
Face and neck creams, lotions, powders, and sprays	4 (1195)	1 - 2
Body and hand creams, lotions, powders, and sprays	5 (1513)	0.7 - 3
Foot powders and sprays	- (48)	0.7
Moisturizers	9 (2039)	0.6
Night creams, lotions, powders, and sprays	2 (343)	0.5 - 2
Paste masks/mud packs	- (418)	0.5
Other	7 (1244)	1 - 50
Suntan products		
Suntan gels, creams, liquids, and sprays	1 (156)	-
Indoor tanning preparations	1 (200)	-
Total uses/ranges for Hydrogenated Coconut Oil	**62**	**0.001 - 50**
Butylene Glycol Cocoate		
Makeup		
Foundations	- (635)	2
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	1 (1368)	-
Moisturizers	- (2039)	1
Other	- (1244)	1[8]
Total uses/ranges for Butylene Glycol Cocoate	**1**	**1 - 2**
Caprylic/Capric/Coco Glycerides		
Skin care products		
Face and neck creams, lotions, powders, and sprays	- (1195)	4
Total uses/ranges for Caprylic/Capric/Coco Glycerides	**-**	**4**
Cocoglycerides		
Baby products		
Lotions, oils, powders, and creams	2 (132)	2
Bath products		
Other	1 (239)	-
Eye makeup		
Eyeliner	1 (684)	10
Eye lotion	1 (177)	5
Fragrance products		
Other	1 (399)	-
Makeup		
Foundations	1 (635)	-
Lipsticks	2 (1912)	6 - 14

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives ***(continued)*.**

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
	Cocoglycerides (continued)	
Personal hygiene products		
Other	- (514)	3[9]
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	8 (1368)	-
Face and neck creams, lotions, powders, and sprays	5 (1195)	1
Body and hand creams, lotions, powders, and sprays	5 (1513)	4 - 13
Moisturizers	2 (2039)	2
Night creams, lotions, powders, and sprays	3 (343)	0.2
Other	3 (1244)	-
Suntan products		
Suntan gels, creams, liquids, and sprays	1 (156)	5
Other	3 (62)	-
Total uses/ranges for Cocoglycerides	**39**	**0.2 - 14**
	Coconut Alcohol	
Bath products		
Soaps and detergents	1 (1329)	-
Noncoloring hair care products		
Shampoos	2 (1403)	-
Personal hygiene products		
Other	- (514)	0.8[10]
Shaving products		
Shaving cream	1 (162)	-
Skin care products		
Face and neck creams, lotions, powders, and sprays	1 (1195)	0.9
Moisturizers	1 (2039)	-
Night creams, lotions, and powders	- (343)	0.8
Other	- (1244)	0.2[11]
Total uses/ranges for Coconut Alcohol	**6**	**0.2 - 0.9**
	Ethylhexyl Cocoate	
Baby products		
Baby lotions, oils, powders and creams	- (132)	5
Bath products		
Bath oils, tablets and salts	- (257)	6
Eye makeup		
Eye shadow	1 (1196)	0.2
Eye lotion	- (177)	0.02
Other eye makeup preparations	4 (288)	-
Noncoloring hair care products		
Conditioners	1 (1249)	-
Tonics, dressings, etc.	1 (1097)	-
Makeup		
Foundations	1 (635)	0.1 - 6
Lipsticks	- (1912)	0.01 - 19
Makeup bases	1 (164)	-

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives ***(continued)*.**

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
Ethylhexyl Cocoate (continued)		
Personal hygiene products		
Underarm deodorants	- (540)	5
Shaving products		
Aftershave lotion	1 (395)	-
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	- (1368)	3 - 5
Face and neck creams, lotions, powders, and sprays	2 (1195)	5 - 41
Body and hand creams, lotions, powders, and sprays	2 (1513)	7 - 39[12]
Moisturizers	3 (2039)	3 - 4
Night creams, lotions, powders, and sprays	- (343)	3 - 8
Suntan products		
Suntan gels, creams, liquids, and sprays	1 (156)	4 - 10
Total uses/ranges for Ethylhexyl Cocoate	**18**	**0.01 - 41**
Hydrogenated Coco-Glycerides		
Bath products		
Soaps and detergents	1 (1329)	-
Bath oils, tablets, and salts	1 (257)	-
Eye makeup		
Eyebrow pencil	11 (147)	-
Eyeliners	58 (684)	12 - 23
Eye shadow	14 (1196)	5 - 23
Eye lotion	- (177)	0.8
Eye makeup remover	- (131)	4
Other	10 (288)	0.01 - 31[13]
Makeup		
Blushers	3 (539)	0.3 - 2
Face powders	8 (613)	0.04 - 10
Foundations	9 (635)	0.4
Lipsticks	18 (1912)	0.5 - 24
Makeup bases	1 (164)	-
Other	10 (406)	0.3 - 12[14]
Nail care products		
Nail polish and enamel	- (419)	0.08
Personal hygiene products		
Other	1 (514)	2[15]
Shaving products		
Shaving cream	1 (162)	-
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	1 (1368)	-
Face and neck creams, lotions, powders, and sprays	5 (1195)	6
Body and hand creams, lotions, powders, and sprays	8 (1513)	0.02 - 4
Moisturizers	15 (2039)	1 - 5
Night creams, lotions, powders, and sprays	5 (343)	3
Paste masks (mud packs)	- (418)	3
Other	9 (1244)	-

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives ***(continued)*.**

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
Hydrogenated Coco-Glycerides (continued)		
Suntan products		
Indoor tanning preparations	3 (200)	-
Total uses/ranges for Hydrogenated Coco-Glycerides	**192**	**0.01 - 31**
Magnesium Cocoate		
Bath products		
Soaps and detergents	11 (1329)	-
Total uses/ranges for Magnesium Cocoate	**11**	**-**
Methyl Cocoate		
Bath products		
Soaps and detergents	- (1329)	0.04
Noncoloring hair care products		
Shampoos	42 (1403)	0.05
Other hair preparations	5 (716)	-
Personal hygiene products		
Other personal cleanliness products	1 (514)	-
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	- (1368)	0.06
Other skin care preparations	1 (1244)	-
Total uses/ranges for Methyl Cocoate	**49**	**0.04 - 0.06**
Pentaerythrityl Cocoate		
Skin care products		
Face and neck creams, lotions, powders, and sprays	1 (1195)	-
Total uses/ranges for Pentaerythrityl Cocoate	**1**	**-**
Potassium Cocoate		
Bath products		
Soaps and detergents	11 (1329)	0.3 - 40
Bubble baths	- (262)	0.2
Noncoloring hair care products		
Shampoos	2 (1403)	15
Hair coloring products		
Tints	- (58)	0.003
Other	- (166)	0.003
Personal hygiene products		
Deodorants (underarm)	- (540)	0.3
Douches	- (12)	0.3
Feminine hygiene deodorants	- (21)	0.3
Other	3 (514)	0.3
Shaving products		
Shaving cream	3 (162)	7
Shaving soap	1 (6)	-
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	4 (1368)	28
Total uses/ranges for Potassium Cocoate	**24**	**0.003 - 40**

Table 6. Cosmetic product uses and concentrations for Cocos Nucifera (Coconut) Oil and its derivatives ***(continued)***.

Product Category	2007 uses (total number of products in a category; FDA 2007)	2006/2007/2008 concentrations (CTFA 2006, CTFA 2007, Council 2008) (%)
Sodium Cocoate		
Baby products		
Other	2 (138)	-
Bath products		
Soaps and detergents	146 (1329)	1 - 52
Bubble baths	3 (262)	-
Fragrance products		
Other	1 (399)	-
Noncoloring hair care products		
Conditioners	1 (1249)	-
Shampoos	48 (1403)	2
Tonics, dressings, etc.	1 (1097)	-
Other	5 (716)	-
Personal hygiene products		
Other	1 (514)	1 - 2
Shaving products		
Aftershave lotion	1 (395)	-
Shaving cream	2 (162)	6
Shaving soap	1 (6)	24
Skin care products		
Skin cleansing creams, lotions, liquids, and pads	16 (1368)	-
Paste masks (mud packs)	1 (418)	-
Other skin care preparations	1 (1244)	-
Total uses/ranges for Sodium Cocoate	**230**	**1 - 52**

[1] 0.01% in baby wipes.
[2] 0.1% in a nail brightener.
[3] 0.0005% in a body wash.
[4] 1% in body and hand sprays.
[5] 0.3% in a body mousse.
[6] 2% in a tanning oil spray.
[7] 0.08% in a liquid hand soap; 2% in a body wash.
[8] 1% in a lip moisture cream.
[9] 3% in a body scrub.
[10] 0.8% in a body wash.
[11] 0.2% in an exfoliating cream.
[12] 16% in a body and hand spray.
[13] 2% in a concealor; 8% in a brow powder wax.
[14] 0.5% in a lip cream; 8% and 12% in lip pencils.
[15] 2% in a body scrub.

A survey of current use concentrations was conducted by the Personal Care Products Council (Council), formerly known as the Cosmetic, Toiletry, and Fragrance Association (CTFA). No uses or concentrations were reported for the following Coconut Oil-derived ingredients: Ammonium Cocomonoglyceride Sulfate, Coconut Oil Decyl Esters, Decyl Cocoate, Lauryl Cocoate, Octyldodecyl Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl Cocoate. Coconut Oil is used in hair sprays, and effects on the lungs that may be induced by aerosolized products containing this ingredient are of concern.

GENERAL BIOLOGY

Jensen and O'Brien (1993) reviewed the potential adverse effects of inhaled aerosols, which depend on the specific chemical species, the concentration, the duration of the exposure, and the site of deposition within the respiratory system.

The aerosol properties associated with the location of deposition in the respiratory system are particle size and density. The parameter most closely associated with this regional deposition is the aerodynamic diameter, da, defined as the diameter of a sphere of unit density possessing the same terminal setting velocity as the particle in question. These

authors reported a mean aerodynamic diameter of 4.25 ± 1.5 μm for respirable particles that could result in lung exposure (Jensen and O'Brien, 1993).

Bower (1999), reported diameters of anhydrous hair spray particles of 60 - 80 μm and pump hair sprays with particle diameters of ≥80 μm. Johnsen (2004) reported that the mean particle diameter is around 38 μm in a typical aerosol spray. In practice, he stated that aerosols should have at least 99% of particle diameters in the 10 - 110 μm range.

Cosmetics that contain Coconut Oil and related substances are applied to all areas of the skin, including mucous membranes. These cosmetics are frequently applied to the face and have the potential for coming into contact with the eyes or being ingested from the lips. Products containing these ingredients may be applied up to several times a day and can remain in contact with the skin for long periods of time.

Coconut Oil and the derivatives discussed in this report are not included among the substances listed as prohibited, restricted, or provisionally allowed in the use of cosmetic products marketed in Japan [Ministry of Health, Labor, and Welfare (MHLW) 2005a, 2005b]. In addition, Coconut Oil and its derivatives are not restricted from use in any way under the rules governing cosmetic products in the European Union (2005).

Noncosmetic Use

Coconut Oil is used in the manufacturing of soaps, edible fats, chocolate, candies, candles, and night lights (O'Neil 2006). It is also used in place of lard in baking, in cotton dyeing, and as a base for ointments. The FDA has determined that Coconut Oil is a food additive permitted for direct addition to food for human consumption as a substitute for cocoa butter (21 CFR 172.861). Coconut Oil is also listed as a substance generally recognized as safe (GRAS) by the FDA in food packing material (21 CFR 182.70).

According to Sasol (2007), Hydrogenated Coco-Glycerides are hardfats used in a pharmaceutical product as an excipient in suppositories. This product complies with US and European Pharmacopoeia monographs.

Absorption, Distribution, Metabolism, Excretion

Basu and Nath (1945) found that 60% of 6 g/kg intubated doses of Coconut Oil was absorbed by rats within 6 h. In clinical studies in which volunteers received 50-140 g of Coconut Oil over 3 d, digestibility was 98% (Langworthy 1923).

Antiparasitic Effects

Calzada et al. (2007) studied the antitrichomonal activity of the methanolic extracts of 22 Mexican medicinal plants, including Cocos nucifera (in form of husk fiber), against Trichomonas vaginalis. The IC50 value was 5.8 μg/ml and the authors determined that extracts of Cocos nucifera may be useful in chemotherapy for parasitic infections.

ANIMAL TOXICOLOGY

Acute Oral Toxicity

Undiluted Coconut Oil was administered to 10 rats via intubation as a single dose of 5 g/kg. No deaths resulted during the 7-d observation period, and the material was judged nontoxic by ingestion (CTFA 1974a, CTFA 1976a, CTFA 1976b).

Undiluted Hydrogenated Coconut Oil was administered orally by intubation to a total of 20 rats as a single dose of 5 g/kg. No animal died during the 7-d observation period (CTFA 1973a, CTFA 1974b, CTFA 1976c).

Two lipstick formulations containing 10% Hydrogenated Coconut Oil were prepared as a 25% product suspension in corn oil. A single 5 g/kg oral dose was administered to 10 fasted Harlan rats of each sex. No deaths or toxicity occurred during the 7-d observation period. At the end of the study, necropsy was performed on half of the animals, and no abnormalities were observed (CTFA 1975a, CTFA 1975b).

Dermal

Undiluted Hydrogenated Coconut Oil was applied as a single dose of 3 g/kg to the skin of 12 guinea pigs. No deaths occurred during the 7-d observation period (CTFA 1973b, CTFA 1974c, CTFA 1974d).

Short-Term Toxicity

Thomasson (1955) compared the growth-promoting potential of a number of fats and oils, including coconut fat, for young rats, using groups of 8-12, 21-d-old, male Wistar rats. Diets were formulated containing 10, 20, 30, 40, 50, 60, and 73 cal% of the test fat. Control groups were fed diets containing 20 cal% summer butterfat. The diets were fed for 6 wk. Only the 60 and 73 cal% groups of the coconut fat series differed significantly from control with respect to less weight gain by the treated animals. No mortality or morbidity were reported for the coconut fat groups.

Subchronic Toxicity

Wistar rats (120 d old) were used to compare the effects of diets containing 25% Coconut Oil or 25% butterfat fed ad libitum. Each experimental group contained 12 male and 13 female rats. Eight litter mates fed stock diets were controls. Three males and three females were killed at 15, 30, 60, and 90 d for microscopic examination and determination of hepatic lipid content. Both experimental groups developed a progressive increase in fat content of the liver, which was 20-30% higher than controls by the end of the study. Fatty change of the liver was very slight. No other pathological change was found in any animal of any group (Harris and Mosher 1940).

Chronic Toxicity

Morin (1967) reported no difference in the life spans of LAFd and C3H/HeJ mice fed for a lifetime diets of Purina Chow

supplemented with 15% Hydrogenated Coconut Oil, safflower oil, or sucrose. Each treatment group consisted of 60 mice of each strain.

Dermal Irritation

Undiluted Coconut Oil was applied to the skin of 9 rabbits by means of a 24-h single-insult occlusive patch test. No irritation was observed (CTFA 1976d).

Undiluted Hydrogenated Coconut Oil was tested using the same procedure on 4 separate groups of 9 rabbits each. No irritation was observed in 3 groups (CTFA 1975c, CTFA 1976e, CTFA 1976f). A Primary Irritation Index (PII) of 0.11/8.0 indicating minimal skin irritation was reported for the fourth group (CTFA 1975d).

Two lipstick formulations containing 10% Hydrogenated Coconut Oil were assayed for skin irritation using albino rabbits. For each formulation, 3 rabbits were shaved and received a 0.5 ml application of the lipstick daily for 4 d. No irritation was observed (CTFA 1975a, CTFA 1975b).

Undiluted Coconut Acid and a 10% solution in corn oil each were assayed with the 24-h single-insult patch test with 9 rabbits. PII scores of 0.13/4.0 and 0.12/4.0 were reported for the undiluted and diluted solutions, respectively, indicating minimal irritation (CTFA 1977a, CTFA 1977b).

Bar soaps containing 13% Sodium Cocoate were evaluated for skin irritation using single-insult occlusive patch test procedures in 14 separate studies (CTFA 1977c, CTFA 1977d, CTFA 1977e, CTFA 1978a, CTFA 1978b, CTFA 1978c, CTFA 1978d, CTFA 1978e, CTFA 1978f, CTFA 1978g, CTFA 1979a, CTFA 1979b, CTFA 1979c, CTFA no date). Two sites on New Zealand White rabbits of both sexes were clipped of hair, and abraded by 4 perpendicular epidermal incisions. A 0.5 ml dose of a 5% aqueous solution of the soap was then applied under occlusive gauze to the abraded sites for 24 h. Evaluations were conducted at 24 and 72 h. Skin irritation was evaluated on a scale of 0 (no irritation) to 8.0 (severe erythema and edema). PII scores ranged from 1.6 to 4.0.

Results of skin irritation studies are summarized in Tables 7a and 7b.

Dermal Sensitization

The skin sensitization potential of Coconut Oil was assayed in female Dunkin Hartley DLA guinea pigs by means of the Magnusson-Kligman maximization procedures. The procedure was divided into 4 phases: (1) induction phase, (2) dose range phase, (3) booster phase, and (4) challenge phase. Ten test animals and 10 controls were used in the induction, booster, and challenge phases, and a separate group of 10 animals was used for the dose range phase.

Table 7a. Skin irritation studies.

	Vehicle	N	% Tested	Period (h)	Group PII	Reference
Coconut Oil	None	9	100	24	0/8	CTFA 1976d
	None	9	100	24	0.11/8	CTFA 1975d
	None	9	100	24	0/8	CTFA 1976 c,e,f
	Lipstick	3	10	96	0/8	CTFA 1975 a,b
Coconut Acid	None	9	100	24	0.13/4	CTFA 1977a
	Corn Oil	9	10	24	0.12/4	CTFA 1977b
Coconut Oil (as sodium salt)						
	Bar soap & water	8	13	24 and 72	2.5/8	CTFA 1978a
	Bar soap & water	4	13	24 and 72	2.4/8	CTFA 1978b
	Bar soap & water	2	13	24 and 72	2.9/8	CTFA 1978c
	Bar soap & water	4	13	24 and 72	2.5/8	CTFA 1978d
	Bar soap & water	4	13	24 and 72	2.4/8	CTFA 1978e

Table 7b. 13% Coconut Oil (as sodium salt) delivered as bar soap and water in 6-rabbit studies over 24 and 72h.

Group PII	Reference
2.0/8	CTFA 1977c
1.6/8	CTFA 1977d,e
2.8/8	CTFA 1978f
2.5/8	CTFA 1978g
2.7/8	CTFA 1979a
3.3/8	CTFA 1979b
3.8/8	CTFA 1979c
4.0/8	CTFA (no date)

In the induction phase, test animals received 2 injections of each of the following in separate locations on the back: 50% aqueous Freund's complete adjuvant, 5% Coconut Oil in propylene glycol, and 5% Coconut Oil in 50% Freund's complete adjuvant. Control animals received the same treatment regimen of vehicles only. One week after induction, 5% sodium lauryl sulfate in petrolatum was applied to each induction site. Twenty-four hours later, a topical booster of 100% Coconut Oil was applied to the same sites. Control animals received 5% sodium lauryl sulfate in petrolatum and, 24 h later, full strength petrolatum as a booster. All control and test animals were wrapped occlusively for 48 h. Sodium lauryl sulfate was used in the booster phase when the dose range studies indicated that Coconut Oil was nonirritating.

Two weeks after the topical booster, the animals were challenged with topical applications of 50% and 100% Coconut Oil. The animals were wrapped with an occlusive patch, which was removed after 24 h. The challenge sites were graded 48 and 72 h after the beginning of the challenge. The Coconut Oil was nonirritating and failed to produce an allergic response (CTFA 1980a).

CTFA (no date) reported that Hydrogenated Coconut Oil was evaluated for skin sensitization potential using a modified Buehler technique. Prior to testing, the primary irritation threshold for Hydrogenated Coconut Oil was a 5% concentration in ethyl alcohol, which produced slight irritation upon repeated application. An occlusive Webril pad containing 0.5 ml of the 5% Hydrogenated Coconut Oil in ethyl alcohol was applied for 6 h to the shaved backs of 15 guinea pigs. The sites were covered with plastic wrap and Electroplast coverlets. This procedure was repeated 3 times weekly for a total of 9 induction applications. A control group of 5 animals was subjected to the same treatment using only the vehicle, 95% ethyl alcohol.

Two weeks after the last prechallenge application, all animals were challenged topically on untreated sites with the same procedure for application and dosage employed previously. Skin reactions were graded 24 h after the challenge patches were removed. No animals developed skin responses significantly greater than the controls. Using the Buehler procedure, Hydrogenated Coconut Oil was a nonsensitizer (CTFA no date).

Ocular Irritation

The results of the ocular irritation studies are summarized in Table 8.

Coconut Oil was assayed for eye irritation in rabbits. Undiluted Coconut Oil was instilled into the conjunctival sac of the eyes of each of 2 groups of rabbits (6 rabbits/group). Without subsequent water rinsing of the eyes, maximum irritation scores of 2 and 1 were reported for the 2 treatment groups (max = 110). These results were indicative of minimal eye irritation (CTFA 1976g, CTFA 1976h).

Table 8. Ocular Toxicity Studies**.**

Ingredient	Conc. Tested (%)	N[a]	Score [b]	Day of ocular clearing	Reference
Coconut Oil	100	6	2	3	CTFA 1976g
	100	6	1	2	CTFA 1976h
Hydrogenated Coconut Oil	100	6	6	4	CTFA 1973c
	100	6	2	2	CTFA 1973d
	100	6	1	2	CTFA 1973e
	100	6	1	2	CTFA 1973f
	100	6	2	3	CTFA 1976i
	100	6	1	2	CTFA 1976j
	100	6	1	2	CTFA 1976k
	100	6	1	2	CTFA 1976l
	100	6	1	2	CTFA 1976m
	100	6	1	2	CTFA 1976n
	10	6	NA	2	CTFA 1975a
	10	6	NA	1	CTFA 1975b
Coconut Acid	100	6	8	4	CTFA 1977f
	100	6	9	4	CTFA 1977g
	100	6	1	3	CTFA 1977h

[a] Eyes were not rinsed with water after application of test material.

[b]Maximum Irritation Score (Draize eye) = 110.

Undiluted Hydrogenated Coconut Oil was instilled into the eyes of 10 groups of 6 rabbits each in a single dose. The treated eyes received no subsequent water rinse. In 1 test, mild irritation (6/110) was observed. The eyes appeared normal by the fourth day (CTFA 1973c). In another study, minimal irritation (2/ 110) was observed, and the eyes appeared normal by the third day (CTFA 1976i). In eight tests, negligible or minimal irritation was observed. The eyes were clinically normal by the second day (CTFA 1973d, CTFA 1973e, CTFA 1973f, CTFA 1976j, CTFA 1976k, CTFA 1976l, CTFA 1976m, CTFA 1976n).

Tests of 2 lipstick formulations containing 10% Hydrogenated Coconut Oil were conducted with 6 albino rabbits each. Slight conjunctivitis was observed from both formulations (no score provided), but the reaction disappeared by 48 and 24 h, respectively (CTFA 1975a, CTFA 1975b).

Undiluted Coconut Acid was assayed for ocular toxicity in 3 groups of 6 rabbits each. In 2 tests, mild irritation (8/110 and 9/110) was observed. The eyes were considered normal by the fourth day (CTFA 1977f, CTFA 1977g, respectively). In 1 test, minimal irritation (1/110) was observed, with the eyes returning to normal by the third day (CTFA 1977h).

GENOTOXICITY

Petta et al. (2004) studied the genotoxic potential of saponified coconut oil (SCO) in several prokaryote systems. A plasmid treated with SCO did not have DNA strand breaks. Treatment of wild-type and repair deficient CC104 with SCO resulted in moderate cytotoxicity in the wild-type strain. SCO was not able to induce SOS function in Escherichia coli strains PQ35 and PQ37. In an Ames test conducted without metabolic activation, SCO was not mutagenic for Salmonella typhimurium strain TA98, but it displayed mutagenic potential for strains TA100 and TA104. The authors concluded that the cytotoxic, antioxidant, and mutagenic effects of SCO can be influenced by the aggregational state.

CARCINOGENICITY

Hyperplasia

de Lourdes Arruzazabala et al. (2007) studied the effects of Coconut Oil on benign prostatic hyperplasia in Sprague-Dawley rats. Six groups of 10 rats were injected with testosterone (3 mg/kg) to induce prostatic hyperplasia while a seventh group (negative control) was injected with soya oil. Of the groups injected with testosterone, 1 served as a positive control and the remaining groups received either saw palmetto lipid extract (400 mg/kg), sunflower oil (400 or 800 mg/kg), or Coconut Oil (400 or 800 mg/kg) orally for 14 d. The rats were weighed before treatment and weekly during treatment. At the end of the treatment period, the rats were killed and the prostates were removed and weighed. Coconut Oil at both dose levels significantly reduced the increase in prostate weight and prostate weight to body weight ratio that was induced by the testosterone injections. The percent inhibition was 61.5% and 82.0% for the 400 and 800 mg/kg dose levels, respectively.

CLINICAL ASSESSMENT OF SAFETY

Skin Irritation

A bar soap containing 13% Coconut Oil was evaluated for skin irritation using standard Draize procedures. One percent aqueous solutions of the product were applied with occlusive patches to the forearms of 106 panelists over a 3-wk period. Very minimal skin reactions were recorded, and the researchers concluded the material was not hazardous under conditions of normal use (CTFA 1978h).

Bar soaps containing 13% Coconut Oil were evaluated in a 2-wk normal use test. The investigators reported no unusual irritation response under normal use conditions in 72 panelists (CTFA 1981).

Soap chamber tests employing Duhring chambers applied to the forearm were conducted with 8% aqueous suspension of bar soaps containing 13% Coconut Oil. One 24-h patch and four 6-h patches were applied over a 5-d period. In one test with 10 panelists the soap was moderately irritating, and the researchers concluded it was safe under conditions of normal use (CTFA 1978i). In a second soap chamber test, minimal irritation was observed in a panel of 10 individuals (CTFA 1979d).

The skin irritation potential of Potassium Cocoate in subjects with pre-existing dermatitis was assessed by Santucci et al. (2003). The skin of 40 healthy volunteers and 480 subjects with active skin diseases were patch tested with 15 μL of 5% aqueous Potassium Cocoate. Positive responses were observed in 5 subjects (0.9%). Intensities of the positive responses were not reported; however, 2 subjects had active psoriasis and 3 had active eczema.

Skin Sensitization

A tanning butter containing 2.5% Coconut Oil was evaluated using a repeat insult predictive patch test. Nine 24-h induction patches were applied over a 3-wk period. No erythematous reactions were observed in 103 panelists after a single challenge in the sixth wk of the study (CTFA 1979e).

Four lipstick formulations containing 10% Hydrogenated Coconut Oil were tested with a single 48-h application on 204 white females. There was no evidence of primary irritation and no indication of sensitization on retests performed 14 d later (CTFA 1974e, CTFA 1974f, CTFA 1974g, CTFA 1974h).

Coconut Oil was not an allergen at 100% concentration in 12 subjects in a double-blind randomized controlled pilot study (Shaffer et al. 2006). The subjects had known allergic reactions to cocamidopropyl betaine (CAPB) and were patch tested with several coconut oil derivatives to determine if reactions were due to cross-reactivity and allergenicity to surfactants containing these ingredients.

Phototoxicity

Bar soaps made with 13% Sodium Cocoate were prepared as a 3% aqueous solution. Occlusive patches containing 0.2 ml of the test solution were applied to the tape-stripped backs of 10 volunteers over a 6-wk period. After each application, the treated sites were exposed to an inspectrolamp for 45 min. After UVA exposure, the area was exposed to about 2/3 of the minimal erythemal dose (MED) from an air-cooled Kromayer lamp. No evidence of phototoxicity was observed (CTFA 1980b).

Photosensitization

Bar soaps made with 13% Coconut Oil were tested as a 3% aqueous solution. Patches containing 0.2 ml were applied 3 times a week for 24 h for a 3-wk period to stripped skin. Sites were exposed to a Wood's lamp for 40 min and a sun lamp for 15 min following each application. Following a 2-wk nontreatment period, duplicate challenge patches were applied. No evidence of photosensitization was observed in any of the 10 panelists (CTFA 1979f).

A similar soap prepared as 1 or 3% aqueous solutions was tested on 52 panelists. Occlusive patches containing 0.4 ml of the test solution were applied to the arms 3 times a week for a 3-wk period. Sites were exposed to sunlight for 30 min, 24 h after application. Following a 2-wk nontreatment period, duplicate challenge patches were applied. Sun exposures were made 24 h following the challenge application. No evidence of photosensitization was noted (CTFA 1976o).

Therapeutic Studies

Dave et al. (1987) found that Coconut Oil in sun screens may increase the incidence of pityriasis versicolor. The lauric acid in Coconut Oil acts as a bactericidal agent that alters cutaneous bacterial flora necessary in resisting the growth of the yeast species.

The use of Coconut Oil as part of UVB treatment to accelerate psoriasis clearance was studied by George et al. (1993). In this single-blind controlled study, 29 patients with chronic plaque psoriasis each had 2 plaque sites treated with aerosolized Coconut Oil while 2 plaques on the other half of the body served as emollient-free controls. Following the application of the Coconut Oil, 14 of the patients underwent photochemotherapy twice weekly, while 15 patients underwent narrow-band UVB phototherapy 3 times a week. The UV dose in both groups started at 70% minimally phototoxic dose (MPD) or MED, with the dose increasing 40% at each visit. The psoriasis sites were scored every third treatment. The treatment was halted upon the clearance of the psoriasis. No difference was observed between the Coconut Oil-treated sites and the control sites in the patients that had phototherapy. The psoriasis in the patients that had photochemotherapy cleared more slowly in the plaques treated with Coconut Oil than those that were emollient-free. It was concluded that Coconut Oil did not accelerate psoriasis clearance.

A study by Mumcuoglu et al. (2002) describes the use of Coconut Oil in a natural remedy for controlling head louse infestations in a clinical trial in Israeli school children. The natural remedy also contained anise oil and ylang ylang oil. One hundred nineteen children were randomly treated with either the natural remedy or with a control product that contained permethrin, malathion, piperonyl butoxide, isododecane, and propellant gas. The natural remedy that contained Coconut Oil was successful in 92.3% of the children in this treatment group, which was compared to the 92.2% success rate of the children in the control group. One child in each group exhibited pruritus in the neck region after treatment.

In a randomized, double-blind study by Agero and Verallo-Rowell (2004), Coconut Oil was compared with mineral oil as a moisturizer for treatment of mild to moderate xerosis. Thirty-four patients, all with negative patch-test reactions to mineral oil and Coconut Oil, were given either mineral oil (18 subjects) or Coconut Oil (16 subjects) that was to be applied to their legs twice daily for 2 wk. During the baseline and weekly evaluations, the skin of the subjects was measured for hydration, lipid content, and symptoms of dryness, scaling, roughness, and pruritus. Both study groups showed signs of improvement with 72% of the subjects in the mineral oil group and 81% of the subjects in the Coconut Oil group improving 1 level in xerosis grading. No adverse effects were noted in either test group during the test period. The authors concluded that Coconut Oil was as effective and safe as mineral oil when used as a moisturizer.

Sankaranarayanan et al. (2005) studied the effects of Coconut Oil in neonates using massage therapy. One hundred twelve preterm and 112 term babies received Coconut Oil, mineral oil, or placebo (powder) massage 4 times daily until their 31st day of life (each group was randomized). The babies were assessed for weight gain velocity, length gain velocity, head growth, neuro-behavioral effects, and incidence of adverse reaction. When compared to preterm babies that received mineral oil and placebo massage, preterm babies that received a Coconut Oil massage had a significantly greater weight gain velocity. Preterm babies also had a greater length gain velocity when compared to placebo group. Term babies of the Coconut Oil group had a significantly greater weight gain velocity compared to the placebo group. There was no significant difference among the 3 test groups for head growth or neuro-behavioral effects. Adverse events in the form of a mild rash were observed in 2 babies in the preterm and 3 babies in the term Coconut Oil groups, in 2 babies in the preterm and 3 babies in the term mineral oil groups, and 2 babies in the preterm and 2 babies in the term placebo groups. Treatment was not discontinued in any of the subjects.

The use of Coconut Oil to treat a case of acute aluminum phosphide poisoning was reported by Shadnia et al. (2005). A 28-year-old man was admitted to a medical center 6 h after

a suicidal ingestion of seven 3-gram pellets of 56% aluminum phosphide (total dose = 11.76 grams). The patient exhibited signs and symptoms of severe phosphine gas toxicity. The treatment protocol consisted of gastric lavage with potassium permanganate solution; oral administration of charcoal and sorbitol suspension; intravenous administration of sodium bicarbonate, magnesium sulfate and calcium gluconate; and oral administration of sodium bicarbonate and Coconut Oil (200 ml every 2 h for several days). With the exception of the use of Coconut Oil, the treatment protocol was typical for phosphine gas toxicity. The patient survived and was released from the hospital 8 d after the poisoning.

Hair Penetration

Ruetsch et al. (2001) employed secondary ion mass spectrometry with time-of-flight mass spectrometry to determine the ability of Coconut Oil and mineral oil to penetrate the hair shaft in human hair samples. Because of Coconut Oil's polarity and affinity for hair protein, it was able to penetrate into the hair cortex, while mineral oil, a nonpolar oil, was not able to penetrate the hair fiber. This study also found that Coconut Oil reduced swelling of the hair fiber when the hair is exposed to water. Reduction in swelling aids in the protection of the hair fiber from hygral fatigue.

Rele and Mohile (2003) studied the effects of Coconut Oil on the prevention of hair damage. The effects of sunflower oil and mineral oil were also observed. Coconut Oil reduced protein loss in damaged and undamaged human hair samples in both pre- and post-wash grooming products while no reduction was observed in applications with sunflower and mineral oils. The authors believe that Coconut Oil's high affinity for proteins, low molecular weight, and molecular shape allow it to penetrate the inside of a hair shaft.

SUMMARY

Coconut Oil is obtained by pressing the dried fruit of the coconut. Typically, it is composed of 90% saturated triglycerides and low in nonglyceride impurities. Polycyclic aromatic hydrocarbons and aflatoxins have been found as contaminants of copra and crude Coconut Oil. These impurities are removed by conventional refining processes.

Uses and/or use concentrations were reported for the following: Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Acid, Coconut Alcohol, Cocos Nucifera (Coconut) Oil, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Hydrogenated Coconut Acid, Hydrogenated Coconut Oil, Magnesium Cocoate, Methyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, and Sodium Cocoate. Coconut Oil had the greatest number of uses reported by the FDA with 626. The use concentration range for Coconut Oil was 0.0001-70%. Coconut Oil and its derivatives are not restricted for use in the European Union or Japan.

Coconut Oil is used in the manufacturing of soaps, edible fats, chocolate, candies, candles, and night lights. It is also used in place of lard in baking, in cotton dyeing, and as a base for ointments.

Results of dietary studies suggest 95-98% of ingested Coconut Oil is absorbed. No specific data were available indicating the extent of percutaneous absorption of Coconut Oil. Coconut Oil was used as a saturated fat control for metabolism studies and caused slight rises in serum cholesterol concentrations. The longevity of experimental animals in metabolism studies was not affected by diets containing Coconut Oil.

The results of oral toxicity studies indicate that Coconut Oil and Hydrogenated Coconut Oil are relatively nontoxic by ingestion. Administered as a single 5 g/kg dose to rats, neither compound caused deaths over a 7-d observation period. In a 90-d subchronic feeding study of diets containing 25% Coconut Oil, rats had slight fatty change of the liver but no other pathological changes. The results of a chronic study in which mice were fed for a lifetime diets supplemented with 15% Hydrogenated Coconut Oil indicated no effect on life spans of the test animals.

Hydrogenated Coconut Oil was nontoxic when applied dermally. A single 3 g/kg dose applied to guinea pigs caused no deaths during a 7-d observation period. It was nonirritating to the skin in 3 single-insult occlusive patch tests. A primary irritation index of 0.11/8.0 indicating minimal irritation was reported in a fourth study. Hydrogenated Coconut Oil was not a sensitizer in guinea pigs when applied to the skin in a modified Buehler test.

Coconut Oil did not cause skin irritation when applied to rabbit skin in a 24-h single-insult occlusive patch test. It was nonsensitizing to the skin in a Magnusson-Kligman Maximization test.

Coconut Acid caused minimal irritation in rabbits when assayed in a 24-h single-insult occlusive patch test. PIIs of 0.13/4.0 and 0.17/4.0 were reported for 10% Coconut Acid in corn oil and undiluted Coconut Acid, respectively. These scores were indicative of minimal skin irritation.

Results of several studies suggest that the eye irritation potential of Coconut Oil and Hydrogenated Coconut Oil is low. Coconut Oil in Draize eye tests scored a maximum of 2/110, indicating minimal irritation. Hydrogenated Coconut Oil was assayed in 10 Draize eye tests. In 9 tests, eye irritation (2/110) was minimal, and in 1 test it was mild (6/110).

The genotoxic potential of saponified coconut oil (SCO) was evaluated in several prokaryote systems. This study found that the cytotoxic, antioxidant, and mutagenic effects of SCO can by influenced by the aggregational state.

Coconut Oil significantly reduced the increase in prostate weight and prostate weight to body weight ratio related to benign prostatic hyperplasia that was induced by the testosterone injections in rats.

Clinical assessments of cosmetic products containing Coconut Oil have used a variety of assays. Bar soaps containing 13% Sodium Cocoate, when tested using standard Draize procedures, produced very minimal skin reactions. In a 2-wk normal use test, bar soaps caused no unusual irritation response. The results of soap chamber tests of bar soaps were minimal irritation in one study and mild irritation in another. No phototoxicity or photosensitivity was produced by these same bar soap formulations.

The skin irritation potential of Potassium Cocoate in subjects with pre-existing dermatitis was assessed. Positive responses were observed in 0.9% of the subjects.

A tanning butter containing 2.5% Coconut Oil did not cause erythematous reactions in a 6-wk repeat insult predictive patch test. Lipstick containing 10% Hydrogenated Coconut Oil caused no evidence of primary irritation after a single patch application and no indication of sensitization in retests performed 14 d later. Coconut Oil was not an allergen at 100% concentration in 12 subjects in a double-blind randomized controlled pilot study.

In a case study, Coconut Oil was used in addition to the standard treatment protocol in a case of acute aluminum phosphide poisoning. The patient survived and was released from the hospital 8 d after the poisoning.

Coconut Oil was evaluated for its therapeutic potential is several studies. No difference was observed between the Coconut Oil-treated sites and the control sites in patients that had psoriasis. Coconut Oil was found to be a natural remedy for controlling head louse infestations in a clinical trial in Israeli school children.

Coconut Oil was determined to be as effective and safe as mineral oil when used as a moisturizer. Preterm and term babies that received Coconut Oil massages had a significantly greater weight gain velocity and a greater length gain velocity when compared to a placebo group.

A hair penetration study found that because of Coconut Oil's polarity and affinity for hair protein, it was able to penetrate into the hair cortex. This study also found that Coconut Oil reduced swelling of the hair fiber when the hair is exposed to water. Another study found that Coconut Oil reduced protein loss in damaged and undamaged human hair samples.

DISCUSSION

The Expert Panel noted that there are numerous animal and clinical studies on the health effects of dietary fats such as Coconut Oil and Hydrogenated Coconut Oil. These dietary fat studies were not included in this safety assessment, however, because they have little relevance in regard to the use of Coconut Oil and Hydrogenated Coconut Oil in cosmetic ingredients because of the lack of absorption via dermal application. The Expert Panel considered that the available acute, subchronic, chronic, ocular, dermal, and clinical toxicity data are adequate to support the safety of Coconut Acid, Coconut Oil, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil. The original safety assessment of the Coconut Oil group of ingredients did include oral toxicity studies that formed part of the basis for the determination of safety, along with animal and human dermal irritation and sensitization data. The conclusion that the original group of ingredients is safe for use as cosmetic ingredients is reaffirmed.

While very few toxicity studies were identified specifically in the published literature for the additional salts and esters that were added to this safety assessment, there is no reason to expect the salts and esters to differ in toxicity from Coconut Oil, Coconut Acid, Hydrogenated Coconut Oil, and Hydrogenated Coconut Acid. The salts and esters of the expanded group of Coconut ingredients are expected to have similar toxicological profiles as the regular and hydrogenated forms of the oil and the acid. In solution, the salts are expected to dissociate in any product formulation independent of whether the salt is sodium, ammonium, magnesium, or potassium. The esters likely will break down into their component parts, none of which present any safety issues, e.g. lauryl alcohol and coconut fatty acids for Lauryl Cocoate. The Coconut-derived ingredients that have been added to this safety assessment do not have any functional groups that pose any significant toxicity. Fatty alcohols of corresponding fatty acids present no safety issues in the experience of the CIR Expert Panel. Accordingly, the available data for Coconut Acid, Coconut Oil, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil are considered supportive of the safety of the expanded group of derivatives as used in cosmetics. Therefore, the Expert Panel determined that the toxicity data on Coconut Acid, Coconut Oil, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil could be extrapolated to include: Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Alcohol, Coconut Oil Decyl Esters, Decyl Cocoate, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate, Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl Cocoate.

The Expert Panel recognizes that use concentration data are not available for all ingredients in this group and that some ingredients in this group are not in current use. The Panel considers that the use concentrations for the ingredients that are in use are not likely to be different from the use concentration for Coconut Oil, Coconut Acid, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil. Were those ingredients not in current use to be used in the future, the Panel expects that they would be used in products and at concentrations similar to those reported for the Coconut Oil and Coconut Acid ingredients.

While aflatoxin contamination of raw and dried copra has been reported, the Panel believes that aflatoxin should not be present in Coconut Oil and ingredients derived from Cocos Nucifera; the Panel adopted the USDA designation of < 15 ppb as corresponding to "negative" aflatoxin content.

In the absence of inhalation toxicity data, the Panel determined that Coconut Oil and its derivatives can be used safely in hair sprays, because the product particle size is not respirable. The Panel reasoned that the particle size of aerosol hair sprays (~38 μm) and pump hair sprays (>80 μm) is large compared to respirable particulate sizes (≤10 μm).

The Expert Panel expressed concern regarding pesticide residues and heavy metals that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities in the ingredient before blending into cosmetic formulation.

CONCLUSION

Amended Conclusion

The CIR Expert Panel concludes that Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate, Caprylic/Capric/Coco Glycerides, Cocoglycerides, Coconut Acid, Coconut Alcohol, Coconut Oil Decyl Esters, Cocos Nucifera (Coconut) Oil, Decyl Cocoate, Ethylhexyl Cocoate, Hydrogenated Coco-Glycerides, Hydrogenated Coconut Acid, Hydrogenated Coconut Oil, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate, Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, Potassium Hydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium Hydrogenated Cocoate, and Tridecyl.[1]

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[1]Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

[2] Available from the Director, Cosmetic Ingredient Review, 1101 17th St., NW, Suite 412, Washington DC 20036-4702.

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