


Final Report on the Safety Assessment of *Cocos nucifera* (Coconut) Oil and Related Ingredients

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Abstract

Cocos nucifera (coconut) oil, oil from the dried coconut fruit, is composed of 90% saturated triglycerides. It 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%. The related ingredients covered in this assessment are fatty acids, and their hydrogenated forms, corresponding fatty alcohols, simple esters, and inorganic and sulfated salts of coconut oil. The salts and esters are expected to have similar toxicological profiles as the oil, its hydrogenated forms, and its constituent fatty acids. Coconut oil and related ingredients are safe as cosmetic ingredients in the practices of use and concentration described in this safety assessment.

Keywords

Cocos nucifera (coconut) oil, cosmetics, safety

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.”¹

A summary of the Expert Panel assessment is provided below:

In cosmetic products, coconut oil is used as a cleanser, foaming agent, or stabilizer at concentrations up to 50%. Acute, chronic, and subchronic oral toxicity studies indicate that coconut oil and hydrogenated coconut oil are relatively nontoxic by ingestion. Neither compound produced significant skin or eye irritation in laboratory animals. No sensitization was reported. Clinical assessment of cosmetic products containing coconut oil produced very minimal skin irritation reactions. There was no indication that these ingredients were primary irritants, sensitizers, or phototoxic compounds following human testing. It is concluded that coconut oil, coconut acid, hydrogenated coconut oil, and hydrogenated coconut acid are safe for use as cosmetic ingredients.

This report summarizes only new information reviewed in considering if the safety of additional cosmetic ingredients could be supported.

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.

The CIR Expert Panel has also published safety assessments for components of some of the ingredients covered by this assessment, including butylene glycol, glyceryl cocoate, methyl alcohol, propylene glycol dicocoate, and sorbitan cocoate, finding

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Table 1. Previously Reviewed Ingredients

Ingredient	Uses	Use Concentrations (%)	Conclusion	Reference
Butylene glycol	165	<0.1->50	Safe as presently used in cosmetics	Elder ⁷
	813	0.00007-89	Reaffirmed in 2006	Andersen ⁶
Glyceryl cocoate	1	0.3-5	Safe as a cosmetic ingredient in the present practices of use and concentration	Andersen ⁵
Methyl alcohol	4	0.1-5	Safe as used to denature alcohol used in cosmetic products	Andersen ³
Propylene glycol dicocoate	Not in use ^a	Not in use ^a	Safe as a cosmetic ingredient in the present practices of use ^a	Andersen ²
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 ⁴
Lanolin acid	51	>0.1-10	Safe for topical application to humans in the present practice of use and concentration	Elder ⁸
	44	1-3	Reaffirmed in 2005	Andersen ⁶
Lanolin alcohol	738	≤0.1->50	Safe for topical application to humans in the present practice of use and concentration	Elder ⁸
	337	0.6-4	Reaffirmed in 2005	Andersen ⁶

^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.

them safe for use as cosmetic ingredients.²⁻⁷ 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, finding that the fatty acids and the corresponding fatty alcohols in lanolin are equivalently safe.⁸ This safety assessment was rereviewed in 2003 and the conclusion was reaffirmed.⁹

Table 1 provides a listing of previously reviewed ingredients.

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 are found in Table 2.¹⁰

The primary constituents of coconut oil are trimyristin, trilaurin, tripalmitin, tristearin, and various other triglycerides.¹¹ About 90% of the triglycerides are saturated.

Physical Properties

The Physical properties of coconut oil, including analytical methods used to determine its composition, have previously been published.¹ Table 3 describes the material specifications of butylene glycol cocoate, decyl cocoate, hydrogenated coco-glycerides, and potassium cocoate.

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% to

70%. The expressed material has a water content of 4% to 10%.¹² Crude coconut oil is obtained through mechanical expression of copra. The oil is then refined, bleached, and deodorized to remove free fatty acids, phospholipids, color, odor, flavor components, and other nonoil materials.¹³ 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.

Various processing parameters in expressing coconut oil from dried coconut gratings have been studied including 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.¹⁴

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.¹⁵

Hydrogenated coco-glycerides are produced by esterification of coconut fatty acids (C12-C18) with glycerol.¹⁶

Esterification of coconut fatty acids (C12-C18) with butylene glycol produces butylene glycol cocoate.¹⁷ Potassium cocoate is produced in a trade name mixture by combining the fatty acids of coconut oil with potassium hydroxide.

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.

Table 2. Definitions, Structures, and Functions of *Cocos nucifera* (Coconut) Oil and Derivatives

Ingredient	Definition	Structure	Function(s)
<i>Cocos nucifera</i> (coconut) oil (CAS No. 8001-31-8)	A fixed oil obtained by expression from the kernels of the seeds of <i>Cocos nucifera</i> .	–	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 <i>Cocos nucifera</i> (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.	$\begin{array}{c} \text{O} \\ \parallel \\ \text{R C} \text{---} \text{OCH}_2\text{CH}(\text{CH}_2)_2\text{CH}_2 \\ \\ \text{OH} \end{array}$	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 <i>Cocos nucifera</i> (coconut) oil.	–	Skin-conditioning agent-occlusive
Decyl cocoate	The ester of decyl alcohol and the fatty acids derived from <i>Cocos nucifera</i> (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.	$\begin{array}{c} \text{O} \\ \parallel \\ \text{R C} \text{---} \text{OCH}_2\text{CH}(\text{CH}_2)_2\text{CH}_3 \\ \\ \text{CH}_2\text{CH}_3 \end{array}$	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.	$\begin{array}{c} \text{O} \\ \parallel \\ \text{R C} \text{---} \text{OC}_{10}\text{H}_{21} \end{array}$	Skin-conditioning agent-emollient
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.	$\begin{array}{c} \text{O} \\ \parallel \\ \text{R C} \text{---} \text{O}(\text{CH}_2)_{11}\text{CH}_3 \end{array}$	Skin-conditioning agent-emollient; skin-conditioning agent-occlusive

(continued)

Table 2 (continued)

Ingredient	Definition	Structure	Function(s)
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.	$\begin{array}{c} \text{O} \\ \parallel \\ \text{R C} - \text{OCH}_3 \end{array}$	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.	$\begin{array}{c} \text{O} \\ \parallel \\ \text{R C} - \text{O}(\text{CH}_2)_{12}\text{CH}_3 \end{array}$	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.	$\begin{array}{c} \text{O} \\ \parallel \\ \text{RC} - \text{OCH}_2\text{CH}(\text{CH}_2\text{OSO}_3\text{NH}_4) \\ \\ \text{OH} \end{array}$	Surfactant-cleansing agent

Table 3. Material Specifications for Butylenes 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 point	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/2 g	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
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

It may contain free fatty acids, low concentrations of sterols, tocopherol, and squalene.¹² 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.¹⁸

Other potential impurities, including polycyclic aromatic hydrocarbons (PAH) and aflatoxin contamination of raw and dried copra, have been reported and have previously been described.¹

Use

Cosmetic

Table 4 presents the product use and concentration 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.¹ The FDA reported that these ingredients had a total of 626 and 142 total uses, respectively, in 2007.¹⁹

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

Table 4. Cosmetic Product Uses and Concentrations for *Cocos nucifera* (Coconut) Oil and Its Derivatives

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
<i>Cocos nucifera</i> (coconut) oil		
Baby products		
Shampoos	1 (55)	0.05
Lotions, oils, powders, and creams	5 (132)	0.3
Other	6 (138)	0.01 ^a
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
Eye makeup		
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 ^b
Personal hygiene products		
Deodorants (underarm)	—(540)	0.1-16
Douches	—(12)	16
Feminine deodorants	—(21)	16
Other	12 (514)	0.0005-16 ^c
Shaving products		
Shaving cream	10 (162)	2-9
Shaving soap	—(6)	16
Other	1 (107)	—
Skin care products		

(continued)

Table 4 (continued)

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
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 ^d
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 ^e
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 ^f
Total uses/ranges for <i>Cocos nucifera</i> (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		
Eyeliners	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 ^g
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
Hydrogenated coconut acid		
Skin care products		

(continued)

Table 4 (continued)

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
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
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

(continued)

Table 4 (continued)

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
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 ^h
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		
Eyebrow pencils	1 (684)	10
Eye lotion	1 (177)	5
Fragrance products		
Other	1 (399)	-
Makeup		
Foundations	1 (635)	-
Lipsticks	2 (1912)	6-14
Personal hygiene products		
Other	-(514)	3 ⁱ
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

(continued)

Table 4 (continued)

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
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 ^l
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 ^k
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)	–
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 ^l

(continued)

Table 4 (continued)

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
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 ^m
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 ⁿ
Nail care products		
Nail polish and enamel	–(419)	0.08
Personal hygiene products		
Other	1 (514)	2 ^o
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)	–
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

(continued)

Table 4 (continued)

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
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
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

(continued)

Table 4 (continued)

Product Category	2007 Uses (Total Number of Products in a Category) ¹⁹	2006/2007/2008 Concentrations ^{32,33,34} (%)
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

^a 0.01% in baby wipes.^b 0.1% in a nail brightener.^c 0.0005% in a body wash.^d 1% in body and hand sprays.^e 0.3% in a body mousse.^f 2% in a tanning oil spray.^g 0.08% in a liquid hand soap; 2% in a body wash.^h 1% in a lip moisture cream.ⁱ 3% in a body scrub.^j 0.8% in a body wash.^k 0.2% in an exfoliating cream.^l 16% in a body and hand spray.^m 2% in a concealer; 8% in a brow powder wax.ⁿ 0.5% in a lip cream; 8% and 12% in lip pencils.^o 2% in a body scrub.

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.

Because coconut oil and its related ingredients are used in sprays, the effects of aerosol on safety has to be considered. The potential adverse effects of inhaled aerosols depend on the specific chemical species, the concentration, the duration of the exposure, and the site of deposition within the respiratory system.²⁰ In general, the smaller the particle, the further into the respiratory tree the particle will deposit and the greater the impact on the respiratory system.

Anhydrous hair spray particle diameters of 60 to 80 μm have been reported, and pump hair sprays have particle diameters of $\geq 80 \mu\text{m}$.^{21,22} The mean particle diameter is around 38 μm in a typical aerosol spray. In practice, aerosols should have at least 99% of particle diameters in the 10 to 110 μm range. This means that most aerosol particles are deposited in the nasopharyngeal region and are not respirable. 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.^{23,24} 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.²⁵

Noncosmetic Use

Coconut oil is used in the manufacturing of soaps, edible fats, chocolate, candies, candles, and night lights.¹¹ 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.²⁶ Coconut oil is also listed as a substance generally recognized as safe (GRAS) by the FDA in food packing material.²⁷ Hydrogenated cocoglycerides are hard fats used in a pharmaceutical products as an excipient in suppositories.²⁸

Absorption, Distribution, Metabolism, Excretion

No new bioavailability data relevant to cosmetic use of coconut oil was available.

Animal Toxicology

The previous safety assessment concluded that coconut oil and hydrogenated coconut oil are relatively nontoxic by ingestion and that hydrogenated coconut oil was nontoxic, nonirritating, and not a sensitizer.¹

Genotoxicity

The genotoxic potential of saponified coconut oil (SCO) in several prokaryote systems has been studied.²⁹ 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. Saponified coconut oil 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.

Clinical Assessment of Safety

Skin Irritation

The skin irritation potential of potassium cocoate in participants with preexisting dermatitis was assessed.³⁰ The skin of 40 healthy volunteers and 480 participants with active skin diseases were patch tested with 15 μ L of 5% aqueous potassium cocoate. Positive responses were observed in 5 participants (0.9%). Intensities of the positive responses were not reported; however, 2 participants had active psoriasis and 3 had active eczema.

Skin Sensitization

Coconut oil was not an allergen at 100% concentration in 12 participants in a double-blind randomized controlled pilot study.³¹ The participants had known allergic reactions to cocamidopropyl betaine (CAPB) and were patch tested with several coconut oil derivatives to determine whether reactions were due to cross-reactivity and allergenicity to surfactants containing these ingredients.

Summary

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% to 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.

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

The skin irritation potential of potassium cocoate in participants with preexisting dermatitis was assessed. Positive responses were observed in 0.9% of the participants. Coconut oil was not an allergen at 100% concentration in 12 participants in a double-blind randomized controlled pilot study. Coconut oil was evaluated for its therapeutic potential in several studies.

Discussion

The Expert Panel recognized 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, for example, 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.

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 cocoate are safe for use as cosmetic ingredients. 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.

Authors Note

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