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Final Report on the Safety Assessment of Coconut Oil, Coconut Acid, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil

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.

INTRODUCTION

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.

CHEMISTRY

Definition

Coconut Oil (CAS: 8001-31-8)

Coconut Oil is obtained by expression from the kernels of the seeds of *Cocos nucifera*.[1] The primary constituents are trimyristin, trilaurin, tripalmitin, tristearin, and various other triglycerides.[2] The average fatty acid content is presented in Table 1. About 90% of the oil is saturated.[3]

TABLE 1. Average Percent Fatty Acid Content of Coconut Oil (Weight Percent)[3,5-7]

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

Coconut Acid (CAS: 61788-47-4)

Coconut Acid is a mixture of fatty acids derived from coconut oil by hydrolysis. The fatty acid composition is the same as that for coconut oil.[4]

Hydrogenated Coconut Oil (CAS: 977056-87-3)

Hydrogenated Coconut Oil is a white, odorless, flaky material and is derived from the controlled hydrogenation of coconut oil.[4]

Hydrogenated Coconut Acid (CAS: 977058-93-7)

Hydrogenated Coconut Acid is the end product of controlled hydrogenation of Coconut Acid.[1]

PHYSICAL PROPERTIES

Coconut Oil is a pale yellow, semisolid, edible oil that is stable in air at room temperatures. 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.[4]

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.[7] The physical properties of the oils are presented in Table 2.

TABLE 2. Physical Properties of Coconut Oil and Hydrogenated Coconut Oil[2,4]

	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

Reactivity

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.[7]

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.[7]

Method of Manufacture

Coconut Oil is obtained from copra, where it is present in quantities of 60–70%. The expressed material has a water content of 4–10%.[5]

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.

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.[5] It is the presence of lactones at approximately 150 ppm that provides the characteristic coconut flavor. They are present as a series of δ-lactones with 6, 8, 10, 12, and 14 carbon atoms.[7]

Crude samples of Coconut Oil contain traces of polycyclic aromatic hydrocarbons (PAH), particularly when the copra is smoke-dried.[8,9] A combination of activated charcoal treatment and steam vacuum deodorization are the common refining methods most likely to remove PAH from edible oils.[9]

Aflatoxin contamination of raw and dried copra was reported.[10-13] 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.[10] Conventional refining processes remove aflatoxin that may be found in crude peanut or corn oils,[14] and it may be inferred that such procedures can be applicable to all vegetable oils treated by alkali refining, water washing, and bleaching.[15]

USE

Purpose, Scope, and Extent of Use in Cosmetics

Coconut Oil and its derivatives are used as cleansers, foaming agents, or stabilizers in a wide variety of cosmetic products.[16,17] The frequency of use of each ingredient in the various types of cosmetics is given in Table 3. The cumulative total for the five ingredients is 274, with a concentration range of ≤0.1 to 50%.[17]

The cosmetic product formulation listing made available by the Food and Drug Administration (FDA) is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations. Ingredients are listed in prescribed concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product; the actual concentration in such a case would be a fraction of that reported to the FDA. The fact that data are only submitted within the framework of preset concentration ranges also provides the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a 2- to 10-fold error in the assumed ingredient concentration. Table 3 lists the cosmetic products that contain these ingredients.

Surfaces, Frequency, and Duration of Contact

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 eye 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.

Noncosmetic Use

The traditional use of Coconut Oil is in the manufacture of soap, but it is also used in other industrial processes. Coconut Oil is now being incorporated into a

TABLE 3. Product Formulation Data[17]

Product category	Total no. of formulations in category	Total no. containing ingredient	No. of product formulations within each concentration range (%)							
			Unreported concentration	>50	>25–50	>10–25	>5–10	>1–5	>0.1–1	≤0.1
Coconut Acid										
Hair straighteners	64	2	–	–	–	–	2	–	–	–
Hair shampoos (noncoloring)	909	3	–	–	–	–	1	2	–	–
Other personal cleanliness products	227	1	–	–	–	–	1	–	–	–
Shaving cream (aerosol, brushless, and lather)	114	29	–	–	–	2	–	24	3	–
Other skin care preparations	349	1	–	–	–	1	–	–	–	–
1981 TOTALS		36	–	–	–	3	4	26	3	–
Coconut Oil										
Baby shampoos	35	1	–	–	–	1	–	–	–	–
Baby lotions, oils, powders, and creams	56	2	–	–	–	1	1	–	–	–
Other baby products	15	3	–	–	–	1	2	–	–	–
Bath oils, tablets, and salts	237	2	–	–	–	1	–	–	1	–
Eyebrow pencil	145	2	–	–	–	–	2	–	–	–
Hair conditioners	478	6	–	1	–	–	2	2	1	–
Hair shampoos (noncoloring)	909	9	–	–	1	3	3	–	1	1
Tonics, dressings, and other hair grooming aids	290	11	–	–	–	1	1	5	4	–
Other hair preparations (noncoloring)	177	1	–	–	–	–	–	1	–	–
Blushers (all types)	819	1	–	–	–	1	–	–	–	–
Bath soaps and detergents	148	15	–	–	–	10	4	–	–	1

TABLE 3. (Continued)

Product category	Total no. of formulations in category	Total no. containing ingredient	No. of product formulations within each concentration range (%)							
			Unreported concentration	>50	>25–50	>10–25	>5–10	>1–5	>0.1–1	≤0.1
Other personal cleanliness products	227	4	–	–	–	2	1	1	–	–
Shaving cream (aerosol, brushless, and lather)	114	20	–	–	–	–	6	3	11	–
Shaving soap (cakes, sticks, etc.)	7	1	–	–	–	1	–	–	–	–
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	680	5	–	–	1	1	–	1	2	–
Face, body, and hand skin care preparations (excluding shaving preparations)	832	6	–	–	–	–	1	3	2	–
Moisturizing skin care preparations	747	5	–	–	–	1	1	–	3	–
Night skin care preparations	219	2	–	–	–	1	–	–	1	–
Wrinkle smoothers (removers)	38	1	–	–	–	–	–	–	1	–
Skin care preparations	349	2	–	1	–	–	1	–	–	–
Suntan gels, creams, and liquids	164	18	–	–	–	3	1	12	2	–
Other suntan preparations	28	5	–	1	–	4	–	–	–	–
1981 TOTALS		122	–	3	2	31	27	28	29	2
Hydrogenated Coconut Fatty-Acid										
Bath soaps and detergents	148	1	–	–	–	–	–	1	–	–
1981 TOTALS		1	–	–	–	–	–	1	–	–

Hydrogenated Coconut Oil										
Eyebrow pencil	145	3	–	–	–	–	2	1	–	–
Eyeliner	396	2	–	–	–	–	2	–	–	–
Eye shadow	2582	1	–	–	–	–	–	–	1	–
Mascara	397	1	–	–	–	–	–	1	–	–
Other eye makeup preparations	230	1	–	–	–	–	1	–	–	–
Perfumes	657	1	–	–	1	–	–	–	–	–
Blushers (all types)	819	1	–	–	–	–	–	–	1	–
Makeup foundations	740	2	–	–	–	–	1	–	1	–
Lipstick	3319	20	–	–	–	1	16	1	2	–
Rouges	211	1	–	–	–	–	–	–	1	–
Makeup fixatives	22	1	–	–	–	–	–	–	–	1
Cuticle softners	32	1	–	1	–	–	–	–	–	–
Bath soaps and detergents	148	1	–	–	–	–	–	1	–	–
Shaving cream (aerosol, brushless, and lather)	114	2	–	–	–	–	–	–	2	–
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	680	6	–	–	–	–	2	2	–	2
Face, body, and hand skin care preparations (excluding shaving preparations)	832	3	–	–	–	–	–	3	–	–
Moisturizing skin care preparations	747	5	–	–	–	–	1	2	2	–
Night skin care preparations	219	3	–	–	–	–	1	1	1	–
Wrinkle smoothers (removers)	38	3	–	–	–	–	–	2	1	–
Other skin care preparations	349	2	–	–	–	–	1	1	–	–
Suntan gels, creams, and liquids	164	4	–	–	–	–	1	3	–	–
1981 TOTALS		64	–	1	1	1	28	18	12	3

wide variety of food products and medicines.[7] The FDA regulates Coconut Oil and Coconut Fatty Acid as indirect food additives[18] and classifies both materials as an inactive pharmaceutical ingredient for over-the-counter (OTC) rectal suppository preparations.[19] A review of the safety of Coconut Oil for use as a food packaging material is available.[20]

BIOLOGICAL PROPERTIES

Absorption and Metabolism

Basu and Nath[21] 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 days, digestibility was 98%.[22]

Thomasson[23] compared the growth-promoting potential of a number of fats and oils, including coconut fat, for young rats, using groups of 8–12, 21-day-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 weeks. 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.

ANIMAL TOXICOLOGY

Oral Toxicity

Acute Oral Toxicity

Undiluted Coconut Oil was administered to 10 rats via intubation at a dose of 5 g/kg. No deaths resulted during the 7-day observation period, and the material was judged nontoxic by ingestion.[24–26]

Undiluted Hydrogenated Coconut Oil was administered orally by intubation to a total of 20 rats at a dose of 5 g/kg. No animal died during the 7-day observation period.[27–29]

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-day observation period. At the end of the study, necropsy was performed on half of the animals, and no abnormalities were observed.[30,31]

Subchronic Oral Toxicity

Wistar rats (120 day old) of each sex 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 littermates fed stock diets were controls. Three males and three females were killed at 15, 30, 60, and 90 days 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.[32]

Chronic Oral Toxicity

Morin[33] reported no difference in the lifespans of LAF_1J 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 Toxicity

Acute Dermal Toxicity

Undiluted Hydrogenated Coconut Oil was applied at a dose of 3 g/kg to the skin of 12 guinea pigs. No deaths occurred during the 7-day observation period.[34-36]

Skin irritation

Undiluted Coconut Oil was applied to the skin of 9 rabbits by means of a 24-hour single-insult occlusive patch test. No irritation was observed.[37]

Undiluted Hydrogenated Coconut Oil was tested using the same procedure on four separate groups of 9 rabbits each. No irritation was observed in three groups.[38-40] A Primary Irritation Index (PII) of 0.11/8.0 indicating minimal skin irritation was reported for the fourth group.[41]

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.[42,43]

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 days. No irritation was observed.[30,31]

Bar soaps containing 13% Coconut Oil were evaluated for skin irritation using single-insult occlusive patch test procedures in 14 separate studies. Two sites on New Zealand White rabbits of both sexes were clipped of hair, and abraded by four 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). Primary irritation scores ranged from 1.6 to 4.0. Results of skin irritation studies are summarized in Table 4.

Skin 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.[44] The procedure is divided into four phases: (1) induction phase, (2) dose range phase, (3) booster phase, and (4) challenge phase. Ten test animals and ten controls are used in the induction, booster, and challenge phases,

TABLE 4. Skin Irritation, Single-insult Occlusive Patch Test

Ingredient	Vehicle	No. of rabbits	Concentration tested (%)	Dose	Group PII	Observation period (h)	Reference
Coconut Oil	None	9	100	Unspecified	0/8	24	38
					0.11/8		24
					0/8		37
					0/8		39
					0/8		40
Coconut Acid	None	9	100	Unspecified	0.17/4	24	42
	Corn oil		10		0.13/4		43
Coconut Oil (as sodium salt)	Bar soap and water	6	5	0.5	2.0/8	24 and 72	46
		6			1.6/8		47
		6			1.6/8		48
		8			2.5/8		49
		4			2.4/8		50
		2			2.9/8		51
		4			2.5/8		52
		4			2.4/8		53
		6			2.8/8		54
		6			2.5/8		55
		6			2.7/8		56
		6			3.3/8		57
		6			3.8/8		58
		6			4.0/8		59

and a separate group of ten animals is used for the dose range phase. In the induction phase, test animals received two 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.[45]

Hydrogenated Coconut Oil was evaluated for skin sensitization potential using a modified Buehler technique.[59] 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 three times weekly for a total of nine 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.[60]

Ocular Toxicity

Coconut Oil was assayed for eye irritation in rabbits. Undiluted Coconut Oil was instilled into the conjunctival sac of the eyes of each of two groups of rabbits (6 rabbits/group). Without subsequent water rinsing of the eyes, maximum irritation scores of 2 and 1 were reported for the two treatment groups (max = 110). These results were indicative of minimal eye irritation.[61,62]

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.[63] In another study, minimal irritation (2/110) was observed, and the eyes appeared normal by the third day.[64] In eight tests, negligible or minimal irritation was observed. The eyes were clinically normal by the second day.[65-72]

Undiluted Coconut Acid was assayed for ocular toxicity in three 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.[73,74] In 1 test, minimal irritation (1/110) was observed, with the eyes returning to normal by the third day.[75]

Tests of two 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 had disappeared by 48 and 24 h, respectively[30,31] (Table 5).

Tumorigenicity

High concentrations of dietary fat promoted the development of mammary tumors induced in rats by 7,12-dimethylbenz(a)anthracene. Coconut Oil, a saturated fat, was less effective than polyunsaturated fats.[76-79] Chan et al.[80] reported that mammary carcinogenesis in rats induced by N-methylnitrosourea was enhanced by high concentrations of dietary fat. The magnitude of the increase was dependent upon the type of fat. There was a positive correlation between the total oleate and linoleate intake and the incidence of tumors induced by N-methylnitrosourea.

The National Toxicology Program is currently testing Coconut Oil Acid diethanolamine condensate (2:1). Males and females of two species, Fischer 344 rats and B6C3F1 mice, are being used. The route of administration is skin painting.[81]

TABLE 5. Ocular Toxicity

Ingredient[a]	*Vehicle*	*Ingredient conc. tested (%)*	*No. of rabbits*	*Group maximization irritancy score*[b]	*Day of ocular clearing*	*Reference*
Coconut Oil	None	100	6	2	3	61
		100	6	1	2	62
Hydrogenated Coconut Oil	None	100	3	2	2	65
		100	3	1	2	66
		100	3	1	2	67
		100	6	6	4	63
		100	6	1	2	69
		100	6	2	3	64
		100	6	1	2	69
		100	6	1	2	70
		100	6	1	2	71
		100	6	1	2	72
Coconut Acid	None	100	6	9	4	73
		100	6	8	4	74
		100	6	1	3	75

[a]Eyes were not rinsed with water after application of test material.
[b]Maximum Irritation Score (Draize eye) = 110.

CLINICAL ASSESSMENT OF SAFETY

Skin Irritation

A bar soap containing 13% Coconut Oil was evaluated for skin irritation using standard Draize procedures.[82] One percent aqueous solutions of the product were applied with occlusive patches to the forearms of 106 panelists over a 3-week period. Very minimal skin reactions were recorded, and the researchers concluded the material was not hazardous under conditions of normal use.[83]

Bar soaps containing 13% Coconut Oil were evaluated in a 2-week normal use test. The investigators reported no unusual irritation response under normal use conditions in 72 panelists.[84]

Soap chamber tests employing Duhring chambers applied to the forearm[85] 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-day period. In one test with 10 panelists the soap was moderately irritating, and the researchers concluded it was safe under conditions of normal use.[86] In a second soap chamber test, minimal irritation was observed in a panel of 10 individuals.[87]

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-week period. No erythematous reactions were observed in 103 panelists after a single challenge in the sixth week of the study.[88]

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 days later.[89-92]

Phototoxicity

Bar soaps made with 13% Coconut Oil 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-week period. After each application, the treated sites were exposed to an inspectrolamp for 45 minutes. 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.[93]

Photosensitization

Bar soaps made with 13% Coconut Oil were tested as a 3% aqueous solution. Patches containing 0.2 ml were applied three times a week for 24 h for a 3-week period to stripped skin. Sites were exposed to a Wood's lamp for 40 minutes and a sun lamp for 15 minutes following each application. Following a 2-week nontreatment period, duplicate challenge patches were applied. No evidence of phototoxicity was observed in any of the 10 panelists.[94]

A similar soap prepared as 1 and 3% aqueous solutions was tested on 52 panelists. Occlusive patches containing 0.4 ml of the test solution were applied to the arms three times a week for a 3-week period. Sites were exposed to sunlight for 30 minutes, 24 h after application. Following a 2-week nontreatment period, duplicate challenge patches were applied. Sun exposures were made 24 h following the challenge application. No evidence of photosensitization was noted[95] (Table 6).

SUMMARY

Coconut Oil is obtained by pressing the dried fruit of the coconut. Typically, it is 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.

In cosmetic products, Coconut Oil is used as a cleanser, foaming agent, or stabilizer. The highest reported concentrations in cosmetic products were 25–50%.

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 Hydroge-

TABLE 6. Clinical Assessment of Safety–Skin Tests

Ingredient	*Product (ingredient concentration–%)*	*Test*	*Vehicle*	*Results*	*No. of panelists*	*Reference*
Coconut Oil	Bar soap (13)	Draize irritation 2 72-h, 7 48-h patches	1% product aqueous solution	Very minimal erythema	106	86
	Bar soap (13)	2-week normal use	Undiluted	No unusual irritation	72	84
	Bar soap (13)	5-day soap chamber 1 24-h, 4 6-h patches	8% product aqueous solution	Moderate irritation	10	51
	Bar soap (13)	5-day soap chamber 1 24-h, 4 6-h patches	8% product aqueous solution	Minimal irritation	10	84
	Tanning butter (2.5)	3-week RIPT sensitization 9 24-h, 1 challenge patches	Undiluted	No erythema	103	87
	Bar soap (13)	3-day phototoxicity stripped skin	3% product aqueous solution	No phototoxicity	10	93
	Bar soap (13)	6-week photosensitization stripped skin	1 and 3% product aqueous solution	No photosensitization	52	95
	Bar soap (13)	6-week photosensitization stripped skin	3% product aqueous solution	No photosensitization	10	93
Hydrogenated Coconut Oil	Lipstick (10) (4 different formulations)	Schwartz-Peck Prophetic Patch test 1 48-h induction 1 48-h challenge	Undiluted	No irritation; no sensitization	204	87–90

nated Coconut Oil are relatively nontoxic by ingestion. Administered as a single 5 g/kg dose to rats, neither compound caused deaths over a 7-day observation period. In a 90-day 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 lifespans 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-day observation period. It was nonirritating to the skin in three 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. Primary irritation indices 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 ($\leq$2/110) was minimal, and in 1 test it was mild (6/110).

No mutagenicity data are available on any of the Coconut Oil ingredients. Coconut Oil was reported less effective than polyunsaturated fat as a tumor promoter for mammary tumors in rats induced by 7,12-dimethylbenz(a)anthracene.

Clinical assessment of cosmetic products containing Coconut Oil has used a variety of assays. Bar soaps containing 13% Coconut Oil, when tested using standard Draize procedures, produced very minimal skin reactions. In a 2-week 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. A tanning butter containing 2.5% Coconut Oil did not cause erythematous reactions in a 6-week repeat insult predictive patch test.

Lipstick containing 10% Hydrogenated Coconut Oil was tested using Schwartz-Peck prophetic patch procedures. There was no evidence of primary irritation after a single patch application and no indication of sensitization in retests performed 14 days later.

CONCLUSION

On the basis of the available information presented in this report, the CIR Expert Panel concludes that Coconut Oil, Coconut Acid, Hydrogenated Coconut Oil, and Hydrogenated Coconut Acid are safe for use as cosmetic ingredients.

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