JOURNAL OF THE AMERICAN COLLEGE OF TOXICOLOGY
Volume 9, Number 2, 1990
Mary Ann Liebert, Inc., Publishers

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Final Report on the Safety Assessment of Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides

Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides are used in eye and face makeup preparations and in skin care preparations. Concentrations of use range from ≤0.1% to >50%. The fatty acid constituents of Tallow, and some of the corresponding fatty acid alcohols have been evaluated for safety by the Federation of American Societies of Experimental Biology, the Food and Drug Administration, and by an Expert Panel of the Cosmetic Ingredient Review. In all cases, the ingredients were found safe in present practices of use.

None of these constituents of Tallow were toxic through oral and dermal exposure, they were not ocular or dermal irritants, and they were neither dermal sensitizers nor photosensitizers. The same was true for other oils which contain varying concentrations of the constituents of Tallow.

Based on the CIR safety evaluations of the individual constituents of Tallow and of cosmetic ingredients containing the constituents of Tallow, and on the approval of Tallow for use in foods and other consumer products, it is concluded that Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides are safe as cosmetic ingredients in the present practices of use.

INTRODUCTION

The Tallow group includes Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides. Many of the constituents of Tallow have been reviewed by CIR. For example, the oleic acid group (including oleic, lauric, palmitic, myristic, and stearic acids) and cholesterol were found safe as used in cosmetics by the CIR Expert Panel.[1,2] In addition, a number of

fatty acid alcohols have been reviewed by CIR (stearyl and oleyl alcohols, and octyl dodecanol,[3] cetearyl, cetyl, isostearyl, myristyl, and behenyl alcohols;[4] in each case, the conclusion was safe as used. This report references each constituent of Tallow to the appropriate prior safety evaluation.

The Federation of American Societies for Experimental Biology (FASEB) and the FDA have issued final reports on the following Generally Recognized as Safe (GRAS) ingredients: Tallow, Hydrogenated Tallow, beef fat, glycerides (mono- and diglycerides of fat-forming fatty acids, or of edible fats and oils), stearic acid, oleic acid, and linoleic acid.[5–8] All have been found to be safe as currently used as either direct or indirect food additives.

CHEMISTRY

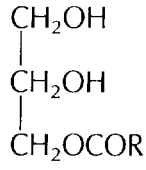
Definition and Properties

Tallow is defined as the fat from beef or mutton. The major constituents of Tallow are the glycerides of oleic (37–43%), palmitic (24–32%), stearic (20–25%), myristic (3–6%), and linoleic (2–3%) acids. Minor components include cholesterol and arachidonic, elaidic, and vaccenic acids.[9]

The hydrogenation of Tallow results in a greater degree of saturation of the fatty acid chains of the glycerides. Hydrogenation of the carboxyl group is used to obtain the corresponding fatty alcohols; this may also be acheived by the hydrogenation of the glycerides.[10] The saturated fatty acids are chemically more stable than the unsaturated fatty acids, and they are less likely to be oxidized. It is the oxidation reaction that causes fats to become rancid.[11]

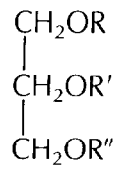
Tallow is a white solid.[12] The reported melting point ranges were 31–37°C[13] and 42.5–44°C.[12] The solidification range of Tallow is 40–46°C,[14] and it has an iodine value of 193–202,[15] and a flash point of 265°C.[13,15] It has a density of 0.895.[13] Tallow from mutton has a refractive index at 25°C of 1.46.[16] Tallow is insoluble in water and soluble in alcohol and ether.[12]

Tallow Glyceride (Tallow Monoglyceride) (CAS no. 61789-13-7) has the structural formula:



where COR is one of the fatty acid moieties of Tallow (oleic, palmitic, stearic, myristic, or linoleic acid).[17] It is a soft, waxy cream-colored solid. It has a melting point range of 59–61°C and a specific gravity of 0.92 at 80°C. Tallow Glyceride contains a minimum of 90.0% monoglycerides, 5.0% maximum diglycerides, 1.2% maximum free glycerol, and an acid value of 3.0 maximum. It may also contain BHA[18] or mixed tocopherols as antioxidants.[17]

Hydrogenated Tallow Glycerides (CAS no. 68308-54-3) has the following structural formula:



where R, R′, and R″ are either hydrogen or "the hydrogenated acyl residues derived from tallow."[19] Hydrogenated Tallow Glyceride is a waxy beige solid. It is soluble in nonpolar solvents, and has a saponification value of 193–195, an iodine value of 5 maximum, an acid value of 10 maximum, and 1% unsaponifiables.[19]

Tallow may be categorized as edible or inedible;[10] inedible Tallow generally contains greater amounts of free fatty acids.[11]

Following ingestion, fats are hydrolyzed into mono- and diglycerides, and ultimately to fatty acids and glycerol, all of which may be absorbed through the intestinal wall;[20] fatty acids are enzymatically degraded, primarily in the liver, into acetic acid.[21]

IMPURITIES

Samples of various types of Tallow used in making soap and other toiletries were analyzed between 1983 and 1985 for the presence of chlorinated pesticide residues.[22] The three types of Tallow analyzed were bleachable fancy tallow (BFT), top white tallow (TWT), and bleached and filtered bleached fancy tallow (bleached with diatomaceous earth) (BF). The Tallow samples were analyzed for residues of heptachlor epoxide, DDT/DDD/DDE, aldrin/dieldrin, endrin, lindane, chlordane, toxaphene, and methoxychlor. Of nine samples of BFT, six contained detectable levels of DDE. The average level of DDE in these samples was 0.013 ± 0.05 ppm. Of 21 samples of TWT, 20 contained residues of DDE and 2 contained residues of dieldrin. The average level of DDE in these samples was 0.049 ± 0.024 ppm. Dieldrin was detected at a level of 0.010 ppm in one sample and at 0.030 ppm in the other sample. Of 16 samples of BF tested, 15 contained detectable levels of DDE. The average level of DDE in these samples was 0.077 ± 0.035 ppm. The Environmental Protection Agency in 1985[23] proposed action levels for these residues in edible fats from mammals. For DDT, DDD, and DDE the action level is 5 ppm and for aldrin and its metabolite dieldrin, the action level is 0.3 ppm.

COSMETIC USE

United States

Tallow is used in cosmetics as an emollient and as soap stock.[15] Tallow Glyceride is used as an emulsifier,[17] and Hydrogenated Tallow Glycerides are used as lubricants and emollients[19] in cosmetics.

Data submitted to the FDA[24] by cosmetic firms participating in the voluntary registration program indicated that Tallow Glyceride and Tallow Glycerides were used in a total of 10 formulations in the categories of eye makeup products and face and other skin care products in concentrations ranging from 1–>50% (Table 1). Hydrogenated

TABLE 1. Product Formulation Data[24]

Product category	Total no. of formulations in category	Total no. containing ingredient	No. of product formulations within each concentration range (%)						
			>50	>25–50	>10–25	≤10	>5–10	>1–5	>0.1–1
Tallow Glyceride and Tallow Glycerides									
Eye makeup products	1490	8	1		2		3	2	
Face and other skin care products	1816	2				2			
1988 Totals		10	1		2	2	3	2	
Hydrogenated Tallow Glyceride and Hydrogenated Tallow Glycerides									
Eye, lip, and face makeup products	3751	28		2	8		6	8	4
Face and other skin care products	2840	10					1	7	2
1988 Totals		38		2	8		7	15	6

Tallow Glyceride and Hydrogenated Tallow Glycerides were used in a total of 38 formulations in the categories of eye, lip, and face makeup products and face and other skin care products in concentrations ranging from 0.1–50%.

According to more detailed FDA data compiled in 1984,[25] Tallow was used in a total of 22 formulations in eight categories; Tallow Glyceride, in 24 formulations in four categories; Tallow Glycerides, in 73 formulations in six categories; Hydrogenated Tallow Glyceride, in 12 formulations in seven categories; and Hydrogenated Tallow Glycerides, in 50 formulations in 11 categories (Table 2). These ingredients are used mainly in eye makeup preparations, lipsticks, makeup bases and foundations, noncoloring shampoos, in shaving soaps but not other shaving preparations, and in a variety of skin care preparations and moisturizers. Concentrations of use ranged from 0.1–1% to 25–50%.

International

Tallow and Tallow Glyceride are listed in the *Japanese Cosmetic Ingredient Dictionary* as ingredients previously approved in cosmetic products marketed in Japan.[26]

Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides are not included for use in the European Economic Community (EEC) lists of ingredients which may not be used in cosmetics.[27]

BIOLOGICAL DATA

As previously mentioned, the major constituents of Tallow have been reviewed by CIR or FASEB-FDA. In Table 3, each constituent of Tallow is listed with the CIR report in which it was reviewed and with the conclusion of each report. Table 4 contains a

TABLE 2. Product Formulation Data[25]

Product category	Total no. containing ingredient	Unknown no. of concentrations	No. of product formulations within each concentration range (%)					
			>50	>25–50	>10–25	>5–10	>1–5	>0.1–1
Tallow								
Other baby products	2		1		1			
Shampoos (noncoloring)	1					1		
Foundations	1						1	
Bath soaps/detergents	14		10		4			
Other personal cleanliness products	1					1		
Shaving soap (cakes/sticks)	1			1				
Moisturizing products	1						1	
Other skin care products	1				1			
1984 Totals	22		11	1	6	2	2	
Tallow Glyceride								
Eyebrow pencil	10				10			
Eye shadow	1				1			
Other eye makeup preparations	1					1		
Lipstick	12				12			
1984 Totals	24				23	1		
Tallow Glycerides								
Eyebrow pencil	16	15			1			
Eyeliner	2	2						
Eye shadow	52	52						
Face/body/hand (excluding shaving preparations)	1					1		
Moisturizing products	1					1		
Other skin care preparations	1	1						
1984 Totals	73	70			1	2		
Hydrogenated Tallow Glyceride								
Eyeliner	2				1	1		
Lipstick	3						2	1
Makeup bases	1						1	
Skin cleansing products (cold creams/lotions/liquids/pads)	2						2	
Face/body/hand (exluding shaving preparations)	2						2	
Moisturizing products	1						1	
Other suntan preparations	1							1
1984 Totals	12				1	1	8	2

TABLE 2. *Continued*

Product category	Total no. containing ingredient	Unknown no. of concentrations	No. of product formulations within each concentration range (%)					
			>50	>25–50	>10–25	>5–10	>1–5	>0.1–1
Hydrogenated Tallow Glycerides								
Eyebrow pencil	3					1	2	
Eyeliner	3					1	2	
Eye shadow	2					2		
Other eye makeup preparations	2					2		
Blushers (all types)	1	1						
Lipstick	18	14					1	3
Makeup bases	1	1						
Other makeup preparations	12				3	9		
Skin cleansing products (cold creams/lotions/ liquids/pads)	1	1						
Face/body/hand (exluding shaving preparations)	4					2	1	1
Night preparations	3					2		1
1984 Totals	50	17			3	19	6	5

TABLE 3. The Constituents of Tallow and the CIR Reports in Which They are Reviewed

Constituents of Tallow	% in Tallow	Reference report[a]	Report conclusion
Glycerides of:			
Oleic acid	37–43	Oleic acid[2]	Safe
		Avocado oil[31]	Safe
		Sweet almond oil[32]	Safe
		Tall oil acid[b4]	Safe
Palmitic acid	24–32	Oleic acid[2]	Safe
Stearic acid	20–25	Oleic acid[2]	Safe
Myristic acid	3–6	Oleic acid[2]	Safe
		Coconut oil[33]	Safe
Linoleic acid	2–3	Wheat germ oil[34]	Safe
		Avocado oil[31]	Safe
		Sweet almond oil[32]	Safe
		Safflower oil[35]	Safe
		Tall oil acid[b4]	Safe
Arachidonic acid	Minor	[c]	
Elaidic acid	Minor	[d]	
Vaccenic acid	Minor	[e]	
Cholesterol	Minor	Cholesterol[1]	Safe

[a]Referenced report contains Tallow constituent at a concentration equal or greater than that constituent's concentration in Tallow. Most referenced reports also contain other constituents of Tallow (i.e., palmitic acid), but at concentrations that are lower than those in Tallow (see Table 4).

[b]Final Report available from CIR: Director, Cosmetic Ingredient Review, 1110 Vermont Ave., N.W., Suite 810, Washington, D.C. 20005.

[c]Synthesized in the body from linoleic acid, required for production of prostaglandins and thromboxanes.[28,29]

[d]Stereoisomer of oleic acid.[14]

[e]Chain length equal to linoleic acid, but with one less double bond.[30]

TABLE 4. CIR Reports in Which the Constituents of Tallow Have Been Reviewed

Report		*Concentration of use (%)*
Wheat germ oil[34]		≤0.1-50
Palmitic acid	11-16%	
Stearic acid	1-6%	
Oleic acid	8-30%	
Linoleic acid	44-65%	
Avocado oil[31]		≤0.1-50
(free fatty acid only)		
Palmitic acid	20.3%	
Stearic acid	0.4%	
Oleic acid	43.7%	
Linoleic acid	22.5%	
Sweet almond oil[32]		≤0.1-50
Palmitic acid	5.7-7.9%	
Stearic acid	0.5-1.2%	
Oleic acid	66.3-72.4%	
Linoleic acid	18.4-22.3%	
Safflower Oil[35]		≤0.1->50
Palmitic acid	2%	
Oleic acid	26%	
Linoleic acid	68%	
Coconut oil[33]		≤0.1->50
Palmitic acid	8-11%	
Stearic acid	1-3%	
Oleic acid	5-8%	
Linoleic acid	trace-2.5%	
Myristic acid	13-19%	
Tall oil acid[4]		≤10-25
Oleic acid	49%	
Linoleic acid	38%	
Oleic acid[2]		
(cosmetic-grade fatty acid)		
Oleic acid		≤0.1-50
Palmitic acid		>0.1-25
Stearic acid		≤0.1->50
Myristic acid		>0.1-50
Cholesterol[1]		≤0.1-5

detailed list of the constituents reviewed in each report referenced in Table 3 as well as the concentrations of use of the cosmetic ingredient reviewed in each report.

Of the constituents of Tallow, linoleic acid (a major constituent) is an essential nutrient.[28–30] Arachidonic acid, a minor constituent of Tallow, can be synthesized only from linoleic acid,[28,29] is a necessary lipid component of biological membranes,[28] and is a required precursor for the production of prostaglandins and thromboxanes.[29] Scaly dermatitis in rats results from the lack of linoleic acid in the diet.[29] Vaccenic acid, another minor constituent of Tallow, contains 18 carbon atoms, as does linoleic acid, but has a lesser degree of unsaturation, containing one double bond (with *cis* and *trans* isomers), whereas linoleic acid contains two.[30] Another minor constituent of Tallow, elaidic acid, is a stereoisomer of oleic acid.[14]

The concentrations of use of the cosmetic ingredients listed in Table 4, ranging from ≤0.1% to >50%, are comparable to the concentrations of use of Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides. All of the oils listed in Table 4 are edible oils.

All of the cosmetic ingredients containing various constituents of Tallow have been found safe in the present practices of use.[31–36]

ABSTRACTS OF REPORTS ON THE CONSTITUENTS OF TALLOW

Wheat Germ Oil

Wheat germ oil is used in a wide variety of cosmetic formulations at concentrations ranging from less than 0.1 to 50%.

The results of tests on laboratory animals and humans for the safety of wheat germ oil and the numerous cosmetic products containing this material confirmed the safety of wheat germ oil as presently used in such products.

Avocado Oil

Toxicological test data from human and animal studies using avocado oil, as well as cosmetic formulations containing avocado oil were reviewed. Skin irritation and sensitization results, as well as general toxicity test data in animals and humans, were presented in support of the conclusion that avocado oil, as currently used in cosmetic formulations, is safe.

Sweet Almond Oil

Sweet almond oil is used as an emollient and emulsifier in cosmetic products.

Results of pharmacological studies have indicated that sweet almond oil was absorbed slowly through intact skin, whereas it was easily absorbed and digested following oral administration. It was nontoxic when ingested, and products containing up to 25% sweet almond oil were practically nonirritating to rabbit skin and only minimally irritating to rabbit eyes. In subchronic studies, sweet almond oil at 100% concentrations was only slightly irritating to rabbit skin.

In clinical studies, undiluted sweet almond oil and products containing up to 25% sweet almond oil were practically nonirritating and nonsensitizing. On the basis of the available data and clinical experience, it was concluded that sweet almond oil is safe for topical application to humans in the present practices of use and concentration.

Safflower Oil

Safflower oil is a polyunsaturated seed oil consisting primarily of triglycerides of linoleic acid. The oil is used in cosmetics as an emollient in topical lotions and creams at concentrations normally between 0.1 and 5%. The pure oil produced slight to moderate comedogenicity. However, products containing up to 5% safflower oil were not comedogenic in rabbits. Results of animal tests indicated that safflower oil was not an ocular or skin irritant or contact sensitizer.

Safflower oil has been used to treat human essential fatty acid deficiencies via oral and topical administration, and is often applied to abraded and irritated skin. Products containing up to 5% safflower oil were negative for human skin irritation, sensitization, or photosensitization.

It was concluded that safflower oil is safe as a cosmetic ingredient in the present practices of use.

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 indicated that coconut oil and hydrogenated coconut oil were nontoxic. Neither product produced significant skin or ocular irritation in laboratory animals. No sensitization was reported. Clinical assessment of cosmetic products containing coconut oil produced minimal skin irritation reactions. There was no indication that these ingredients were primary irritants, sensitizers, or phototoxic compounds following human testing. It was concluded that coconut oil, coconut acid, hydrogenated coconut oil, and hydrogenated coconut acid are safe for use as cosmetic ingredients.

Tall Oil Acid

Tall oil acid is a mixture of oleic, linoleic, and rosin acids derived from the hydrolysis of tall oil, a byproduct of wood pulp. Cosmetics formulated with tall oil acid include hair dyes and bleaches, shampoos, skin cleansing preparations, and a shaving cream. Tall oil acid is approved for use as an indirect food additive.

When fed to rats at 15% of the total caloric intake, tall oil acid was nontoxic; however, it had a growth-retarding effect. No treatment-related effects were observed in rats fed diets containing 5% and 10% tall oil acid over two generations.

Liquid soap containing up to 12% tall oil acid did not cause dermal irritation, sensitization, or photosensitization in human subjects.

On the basis of data included in the report on tall oil acid, and the available data on oleic acid, it was concluded that tall oil acid is safe for use in cosmetic products.

Oleic Acid

Oleic, lauric, palmitic, myristic, and stearic acids are fatty acids with hydrocarbon chains ranging in length from 12 to 18 carbons and with a terminal carboxyl group. These fatty acids are absorbed and metabolized or stored as glycerides in animals and humans. Little acute toxicity was observed when oleic, lauric, palmitic, myristic, and stearic acid or formulations containing these fatty acids were given to rats orally at doses of 15–19 g/kg body weight. Feeding of 15% dietary oleic acid to rats in a chronic study resulted in normal growth and health, but reproductive capacity of female rats was impaired. The topical application of oleic, palmitic, and stearic acid to the skin of mice, rabbits, and guinea pigs produced little or no apparent toxicity. Results of studies using formulations containing oleic and stearic acids indicated that these compounds were neither sensitizers nor photosensitizing agents. Results of animal studies also indicated that these fatty acids were not ocular irritants. Lauric, stearic, and oleic acids were noncarcinogenic in separate animal tests. In primary and cumulative clinical studies,

oleic, myristic, and stearic acids at high concentrations were nonirritating. Cosmetic product formulations containing oleic, lauric, palmitic, and stearic acids at concentrations ranging up to 13% were neither primary nor cumulative irritants, nor sensitizers. On the basis of animal studies and clinical data, it was concluded that oleic, lauric, palmitic, myristic, and stearic acids are safe in present practices of use and concentration in cosmetics.

Cholesterol

Cholesterol occurs in the nonsaponifiable fraction of fats and oils. It is used as an emulsifier in cosmetic skin and hair care products and eye and makeup formulations at concentrations up to 5%.

The synthesis, metabolism, and excretion of cholesterol is well documented in humans and experimental animals. Cholesterol was neither a significant dermal nor ocular irritant. Cholesterol was not genotoxic in bacterial or mammalian cell *in vitro* mutagenic and transformation assays. Large doses of cholesterol were teratogenic in rats. Cholesterol has not been established as a promoter, cocarcinogen, or complete carcinogen.

Clinical studies evaluating the safety of topically applied cholesterol were restricted to products formulated with the ingredient. Most products were moisturizers containing 1.4% cholesterol. The highest concentration of cholesterol tested (6%) was evaluated in a modified prophetic patch test (110 subjects) and an RIPT (45 subjects); both assays had UVA and UVB exposure incorporated into the protocols. The cholesterol-containing products were minimal to mild primary and cumulative skin irritants but were neither sensitizers nor photosensitizers.

SUMMARY

Tallow is the fat of beef or mutton. Hydrogenation of Tallow results in a greater degree of saturation of the fatty acid chains of the glycerides of Tallow. Hydrogenation of the glycerides may be used to obtain the corresponding fatty acid alcohols.

Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides are used in eye and face cosmetic preparations and in skin care preparations. Concentrations of use range from $\leq 0.1\%$ to $>50\%$.

Tallow and Tallow Glyceride are approved in Japan for use in cosmetics. The members of the Tallow group are not listed in the restricted annexes of the EEC Cosmetics Directive.

Tallow, hydrogenated tallow, beef fat, the fatty acid constituents of Tallow, and some of the corresponding fatty acid alcohols have been evaluated for safety by FASEB and FDA and by CIR. In all cases, the ingredients were found safe in present practices of use.

DISCUSSION

In view of the extent to which Tallow and its various constituents and metabolites have been reviewed by both CIR and FASEB-FDA, the Expert Panel refers to Section

30(e)VIII(i)(4) of the CIR Procedures, which states that "to minimize the duplication of effort" ingredients which are subject to other existing safety reviews may be deferred by the Expert Panel. Specifically in the case of GRAS food ingredients, once the ingredient(s) has received a final ruling from the FDA, the CIR Expert Panel may determine whether the safety data used by FASEB-FDA are also relevant to that ingredient's cosmetic use. "The Expert Panel shall adopt those conclusions of the FASEB-FDA review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the FASEB-FDA review."

The Expert Panel concludes that the existing safety evaluations are adequate to determine the safety of Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides for use as cosmetic ingredients. Tallow contains the glycerides of oleic, palmitic, stearic, myristic and linoleic acids, and cholesterol. None of these constituents of Tallow were toxic through oral and dermal exposure, they were not ocular or dermal irritants, and they were neither dermal sensitizers nor photosensitizers. The same was true for other oils which contain varying concentrations of the constituents of Tallow. Although it is unlikely that these cosmetic ingredients contain impurities at toxic concentrations, the lack of data on traces of hormones, pesticides, and halogenated hydrocarbons is nevertheless recognized. While there is some concern with the irritant and sensitization potential of Tallow, if the Tallow is purified sufficiently so that there is no free protein, test results on Tallow would not be expected to differ from those of the various constituents.

CONCLUSION

Based on the CIR safety evaluations of the individual constituents of Tallow and of cosmetic ingredients containing the constituents of Tallow, and on the approval of Tallow for use in foods and other consumer products, the Expert Panel concludes that Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides are safe as cosmetic ingredients in the present practices of use.

ACKNOWLEDGMENT

Julie K. Poudrier, Scientific Analyst and Writer, prepared this report.

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