Safety Assessment of Potassium & TEA-Cocoyl Hydrolyzed Collagen as Used in Cosmetics

Status:	Re-Review for Panel Consideration
Release Date:	May 10, 2024
Panel Meeting Date:	June 3-4, 2024

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This safety assessment was prepared by Thushara Diyabalanage, Ph.D., Senior Scientific Analyst/Writer, CIR.

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Thushara Diyabalanage, Ph.D.
Senior Scientific Analyst/Writer, CIR
Date: May 10, 2024
Subject: Re-Review of the Safety Assessment of Potassium and TEA-Cocoyl Hydrolyzed Collagen

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review of the safety of Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein in 1983 (identified as *originalreport_PotassiumCocoylHydrolyzedCollagen_062024* in the pdf). The Panel concluded that Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein are safe as cosmetic ingredients in the present practices of use, as described in that report. The names of these two ingredients as listed in the *International Cosmetic Ingredient Dictionary and Handbook* had subsequently changed, and are now Potassium Cocoyl Hydrolyzed Collagen (CAS no. 68920-65-0) and Triethanolamine Cocoyl Hydrolyzed Collagen (CAS no. 68952-16-9), respectively. The Panel previously considered a re-review of this report in 2002 and reaffirmed the 1983 conclusion, as published in 2005 (*rereview2005_PotassiumCocoylHydrolyzedCollagen_062024*).

Because it has been at least 15 years since the previous safety re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel should consider whether the safety assessment of Potassium and TEA-Cocoyl Hydrolyzed Collagen should be re-opened. In April 2024, an extensive search of the world's literature was performed for studies dated year 2000 forward. All these searches employing many different search strategies clearly indicated that there were no significant scientific developments or changes in safety information that had been reported (*newdata_PotassiumCocoylHydrolyzedCollagen_062024)*. No new, relevant data were found as a result of the literature search.

Also included for your review are current and historical use data *(usetable_PotassiumCocoylHydrolyzedCollagen_062024).* The use of these ingredients has decreased substantially since the last re-review. Based on 2023 FDA VCRP data, Potassium Cocoyl Hydrolyzed Collagen is used in 2 formulations, and TEA-Cocoyl Hydrolyzed Collagen has no reported uses; in 2001, these ingredients were used in 64 and 20 formulations, respectively. According to the Council survey that was conducted in 2022, no concentrations of use were reported for either ingredient; in 2001, Potassium Cocoyl Hydrolyzed Collagen was reported to be used at a maximum concentration of 20% (in non-coloring shampoos) and TEA-Cocoyl Hydrolyzed Collagen was reported to be used at a maximum concentration of 1% (in bubble baths).

If upon review of the new studies and updated use data the Panel determines that a re-review is warranted, a full Draft Amended Report will be presented at an upcoming meeting.

Re-Review - -Potassium and TEA-Cocoyl Hydrolyzed Collagen - History and New Data

Thushara Diyabalanage – June 2024 Metting

Ingredients (# 2)	Citation	Conclusion	Use - New Data	Use -Historical Data	Notes
Potassium and TEA-Cocoyl Hydrolyzed Collagen *ingredients were originally named Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein*	JACT, 2 (7), 1983, 75-86. IJT, 24 (Suppl. 1), 2005, 82-5.	Safe as cosmetic ingredients in the present practices of use as described in that report. Reaffirmed the 1983 conclusion, as published in 2005	Potassium Cocoyl Hydrolyzed Collagen frequency of use (2023): 2 conc of use (2022): Not Reported TEA-Cocoyl Hydrolyzed Collagen frequency of use (2023): not reported conc of use (2022): Not Reported	Potassium Cocoyl Hydrolyzed Collagen frequency of use (2001): 64 conc of use (2002): 0.05-20% TEA-Cocoyl Hydrolyzed Collagen frequency of use (2023): 20 conc of use (2022): 1%	A significant reduction of use is observed

NOTABLE NEW DATA			
Publication	**Study Type**	**Results – Brief Overview**	**Different from Existing Data?**
		There were no new, relevant publications related these two ingredients.	

Search (from 2000 forward):

The search strategy involved a comprehensive literature search using pubmed, google scholar and google. These searches were performed employing the following key search words and respective CAS numbers for each ingredient.
Search terms used: Potassium and TEA Cocoyl Hydrolyzed Collagen, Potassium Cocoyl Hydrolyzed Collagen, TEA Cocoyl Hydrolyzed Collagen, Triethanolamine Cocoyl Hydrolyzed Collagen, CAS number 68920-65-0 and CAS number 68952-16-9.
No published new reports with a relevance to the safety of above these two ingredients were found during this search.

Frequency (2023/2001) and concentration (2023/2001) of use according to likely duration and exposure and by product category

	Potassium Cocoyl Hydrolyzed Collagen				TEA-Cocoyl Hydrolyzed Collagen			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[1]	**2001[2]**	**2022[3]**	**2001[3]**	**2023[1]**	**2001[2]**	**2022[3]**	**2001[2]**
Totals*	**2**	**64**	**NR**	**0.05-20**	**NR**	**20**	**NR**	**1**
summarized by likely duration and exposure**								
Duration of Use								
Leave-On	*1*	*4*	*NR*	*0.05-0.2*	*NR*	*3*	*NR*	*NR*
Rinse-Off	*1*	*60*	*NR*	*1-20*	*NR*	*13*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*4*	*NR*	*1*
Exposure Type								
Eye Area	1	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	3[a]	NR	0.2[a]	NR	2	NR	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal Contact	1	5	NR	0.2	NR	12	NR	1
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	1	29	NR	1-20	NR	8	NR	NR
Hair-Coloring	NR	30	NR	5	NR	NR	NR	NR
Nail	NR	NR	NR	0.05	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	5	NR	1
Baby Products	NR	NR	NR	NR	NR	1	NR	NR
as reported by product category								
Baby Products								
Baby Shampoos					NR	1	NR	NR
Bath Preparations (diluted for use)								
Bath Oils, Tablets, and Salts					NR	1	NR	NR
Bubble Baths					NR	3	NR	1
Eye Makeup Preparations								
Eye Lotion	1	NR	NR	NR				
Fragrance Preparations								
Perfumes					NR	1	NR	NR
Hair Preparations (non-coloring)								
Hair Conditioner					NR	1	NR	NR
Hair Spray (aerosol fixatives)					NR	1	NR	NR
Hair Straighteners	NR	2	NR	NR				
Permanent Waves	NR	18	NR	1	NR	2	NR	NR
Shampoos (non-coloring)	1	6	NR	1-20	NR	3	NR	NR
Tonics, Dressings, and Other Hair Grooming Aids	NR	2	NR	NR				
Wave Sets								
Other Hair Preparations	NR	1	NR	NR				
Hair Coloring Preparations								
Hair Dyes and Colors (all types requiring caution statements and patch tests)	NR	21	NR	5				
Hair Tints	NR	9	NR	NR				
Makeup Preparations								
Foundations					NR	1	NR	NR
Manicuring Preparations (Nail)								
Nail Creams and Lotions	NR	NR	NR	0.05				
Personal Cleanliness Products								
Other Personal Cleanliness Products					NR	1	NR	NR
Shaving Preparations								
Shaving Cream					NR	1	NR	NR
Other Shaving Preparations	NR	1	NR	NR				
Skin Care Preparations								
Cleansing	NR	3	NR	NR	NR	4	NR	NR
Moisturizing	NR	1	NR	0.2				

NR – not reported

*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

**likely duration and exposure are derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

REFERENCES

1. 1U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition (CFSAN). Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. College Park, MD. 2023. (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2023; received February 2, 2023.)

2. Andersen FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments - 2002/2003. Potassium Cocoyl Hydrolyzed Collagen and Triethanolamine Cocoyl Hydrolyzed Collagen. *Int J Toxicol* 24 (Suppl. 1):82-5, 2005.

3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen. (Unpublished data submitted by the Personal Care Products Council on October 28, 2022.)

JOURNAL OF THE AMERICAN COLLEGE OF TOXICOLOGY
Volume 2, Number 7, 1983
Mary Ann Liebert, Inc., Publishers

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Final Report on the Safety Assessment of Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein

Potassium and TEA-Coco-Hydrolyzed Animal Proteins (PCHAP and TEA-CHAP) are salts of the condensation product of coconut acid and hydrolyzed animal protein. They are used in cosmetic products as detergents, foamers, and levelers.

Acute oral toxicity studies showed that both PCHAP and TEA-CHAP were practically nontoxic when ingested. Both ingredients at concentrations of 10%–100% were practically nonirritating to moderately irritating when instilled in the eyes of rabbits. Both were nonirritating to mildly irritating when applied at concentrations of 10%–50% to the skin of rabbits. Guinea pig sensitization studies with both PCHAP and TEA-CHAP were negative.

PCHAP and TEA-CHAP, at concentrations of 2%–10% were nonirritating to practically nonirritating in humans. In a repeated insult patch test, PCHAP gave a positive sensitization reaction in two of 168 subjects; two additional subjects showed cumulative irritation and one other was reported to have a nonspecific irritation. One subject out of 28 tested did not demonstrate significant irritation or sensitivity to either PCHAP or TEA-CHAP, but was photosensitized to both ingredients.

On the basis of the available information, the Panel concludes that Potassium-Coco-Hydrolyzed Animal Protein and TEA-Coco-Hydrolyzed Animal Protein are safe as cosmetic ingredients in the present practices of use as recorded in this report.

CHEMISTRY

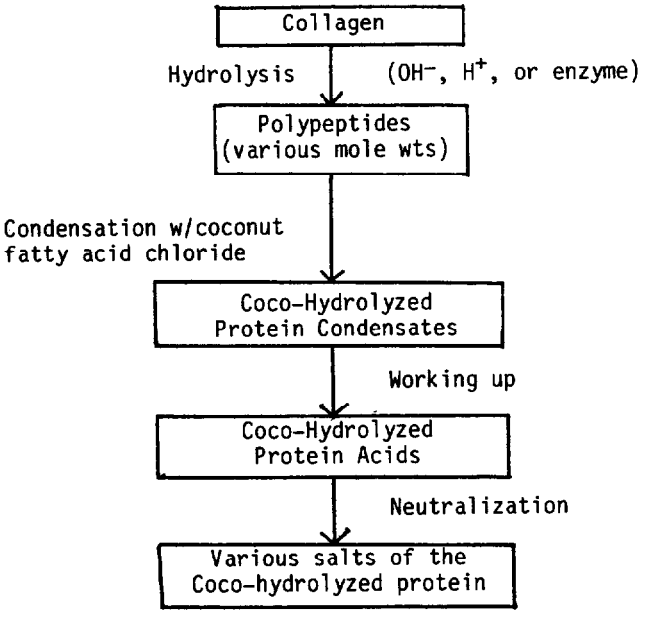
Structure

Potassium and Triethanolamine-Coco-Hydrolyzed Animal Proteins (PCHAP and TEA-CHAP, respectively) are salts of the condensation product of coconut acid and hydrolyzed animal protein. Each conforms to the structure:[1]

$$R\text{-}CO\text{-}NH\text{-}CHR'\text{-}CO\text{-}(NH\text{-}CHR\text{-}CO)_n\text{-}NH\text{-}CHR'\text{-}COO^-Y^+$$

where R-CO represents the acyl moiety of coconut fatty acid; R' represents the carbon chains of the mixed amino acids and polypeptides found in collagen (predominantly glycine, proline, alanine, and hydroxyproline); and Y^+ represents the potassium or TEA cation.

Chrome-leather splittings are used as a collagen source.[2] This protein material is hydrolyzed by acid, base, or enzymes into short-chained polypeptides. Due to random bond breaking during this step, polypeptide chains vary in length and molecular weight. Fatty acid chlorides (i.e., coconut fatty acid) are then added, forming amide linkages with the free amino groups on the polypeptide chain. The ratio of polypeptide to fatty acid changes with increasing molecular weight of the product. For molecular weights less than 600, fatty acids predominate, whereas at molecular weights greater than 600, the polypeptide predominates. In the final step of production, the terminal carboxyl group of the fatty acid is neutralized with either potassium or TEA ions to form a salt. The reaction temperature for preparing this ingredient varies between 60° and 100°C.[2] A typical manufacturing process of coco-hydrolyzed animal proteins is shown below.[3,4]



Properties

PCHAP and TEA-CHAP are clear to slightly hazy amber liquids. Table 1 lists some chemical and physical properties of these coco-hydrolyzed animal proteins. Each ingredient has unique properties which are dependent upon the proportions of polypeptide and fatty acid in the product.[4]

Viscosity of fatty acid hydrolyzed animal proteins is dependent on various conditions. Viscosity is high under conditions of low pH and low molecular weight (lower fatty acid content) and increases with time which may be a result of the orientation of the fatty acid.[4]

Coco-hydrolyzed animal proteins exhibit good foaming and detergent properties. As anionic tensides, their cleansing effect is dependent on low molecular weight and low pH conditions.[4]

These ingredients increase the skin and eye compatibility of anionic-active tensides (i.e., sodium laureth sulfate) without interfering with the cosmetic properties. The foaming and cleansing properties of sodium laureth sulfate were undisturbed by the addition of fatty acid hydrolyzed animal protein.[4]

Impurities and Additives

The impurities reported in PCHAP (in order of predominance) include: coconut fatty acid, hydrolyzed animal protein (collagen) and inorganic salts (sodium chloride, sodium sulfate, potassium chloride, and potassium sulfate).[1]

Impurities reported in TEA-CHAP (in order of predominance) include: coconut fatty acid, hydrolyzed animal protein (collagen), triethanolamine sulfate, sodium chloride, and sodium sulfate.[1] There were no reports of potential chemical interactions of either PCHAP or TEA-CHAP with other cosmetic ingredients. It is suspected that in the presence of nitrite and other nitrosating agents cosmetic preparations containing TEA-CHAP may give rise to N-nitrosodiethanolamine.

COSMETIC USE

Coco-hydrolyzed animal proteins are used in cosmetics as detergents, foamers, and levelers. In shampoos, the protective colloidal action of the

TABLE 1. Properties.

Property	*PCHAP*	*TEA-CHAP*
Solids (%)[a]	30%–38%	32%–40%
Ash (%)	7% maximum	0.8% maximum
Water (%)	70% maximum	60%–62%
pH	6.0–7.5	6.7–7.3
Possible additives	Ethylparaben, formaldehyde, sodium polyphosphate	Ethylparaben, formaldehyde, sodium polyphosphate

[a]Of the two suppliers of PCHAP and TEA-CHAP, the American manufacturer lists percent solids as 30%–38% and 32%–40%, respectively, while the German tab states that both ingredients contain 32% solids.

Data from Refs. 1,3.

polypeptide moiety prevents excessive defatting while the detergent activity produces good cleansing action.[3]

According to the industry's voluntary submissions to the Food and Drug Administration (FDA) in 1981, PCHAP is used in 251 cosmetic formulations. A concentration range of >25%–50% was reported for two shampoos and one skin

TABLE 2. Product Formulation Data.

Product category	Total no. of formulations in category	Total no. containing ingredient	No. product formulations within each concentration range (%)					
			>25–50	>10–25	>5–10	>1–5	>0.1–1	≤0.1
PCHAP								
Bubble baths	475	6	–	–	–	6	–	–
Other bath preparations	132	1	–	–	–	1	–	–
Hair conditioners	478	4	–	–	1	2	1	–
Hair straighteners	64	12	–	–	–	–	3	9
Permanent waves	474	55	–	–	–	6	48	1
Hair shampoos (noncoloring)	909	33	2	1	8	13	7	2
Tonics, dressings, and other hair grooming aids	290	6	–	–	–	2	3	1
Wave sets	180	1	–	–	–	1	–	–
Other hair preparations (noncoloring)	177	3	–	–	–	3	–	–
Hair dyes and colors (all types requiring caution statement and patch test)	811	43	–	–	5	38	–	–
Hair lighteners with color	2	1	–	–	–	1	–	–
Hair bleaches	111	1	–	–	–	1	–	–
Nail polish and enamel	767	74	–	–	–	–	–	74
Other manicuring preparations	50	6	–	–	–	3	–	3
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	680	3	1	–	–	2	–	–
Face, body, and hand skin care preparations (excluding shaving preparations)	823	1	–	–	–	1	–	–
Other skin care preparations	349	1	–	–	–	–	1	–
1981 TOTALS		251	3	1	14	80	63	90
TEA-CHAP								
Hair conditioners	478	3	–	–	–	3	–	–
Hair shampoos (noncoloring)	909	11	1	–	1	1	7	1
Tonics, dressings, and other hair grooming aids	290	1	–	–	–	1	–	–
Cuticle softeners	32	1	–	–	–	–	–	1
Bath soaps and detergents	148	1	–	–	–	1	–	–
Other skin care preparations	349	1	–	–	–	1	–	–
1981 TOTALS		18	1	–	1	7	7	2

Data from Ref. 5.

cleansing cream. PCHAP is most commonly used in hair preparations. TEA-CHAP was reported in 18 formulations, usually in concentrations of up to 5%. Like PCHAP, it is generally found in hair preparations. A concentration range of >25%–50% was reported for one shampoo. Table 2 summarizes product formulation data for these two ingredients.[5]

The cosmetic product formulation computer printout which is made available by the FDA is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations (1979). 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 concentration in such a case would be a fraction of that reported to the FDA. The fact that data are submitted only 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 two- to 10-fold error in the assumed ingredient concentration.

Formulations which contain PCHAP or TEA-CHAP may come into contact with the face, hair and scalp, nails, axillae, and skin. These products are used daily or occasionally and their use may extend over years. Contact with formulations containing PCHAP or TEA-CHAP may last from seconds to several days.[5]

BIOLOGICAL PROPERTIES

General Effects

Collagen is often the protein used for hydrolysis in the preparation of these ingredients. This is partly because of its nonantigenic properties. Topical, intradermal, and subcutaneous sensitivity tests using collagen polypeptides (MW 110–1400) were performed on 50 male and 50 female guinea pigs. No antigenic responses or sensitivity resulted.[4]

Various ratios of sodium laureth sulfate to protein fatty acid condensates were tested for sucrase inhibition. Inhibition was nearly 100% for pure sodium laureth sulfate; however, when diluted to 60% or less with protein fatty acid condensate, there was no inhibition. Additionally, protein fatty acid condensates (at various molecular weights) were tested alone for sucrase inhibition. At molecular weights of 550 and 650, inhibition was negligible (3.5% and 0.5%, respectively) and nonexistent at molecular weights of 750, 900, and 1200.[4]

The adverse biological properties of protein fatty acid condensates include diminution of alkaline neutralization power of the skin, alteration of epidermal pH and eye irritation. Eye irritation appears to be inversely proportional to the molecular weight of the condensate and to the ratio of polypeptides in the product.[4]

Animal Toxicology

Acute Oral Toxicity

PCHAP and TEA-CHAP were tested for acute oral toxicity. Data are presented in Table 3. These studies indicate that PCHAP and TEA-CHAP are practically nontoxic when administered orally at the dosages specified.[6-8]

Acute Irritation

Ocular

Both PCHAP and TEA-CHAP were tested for rabbit eye irritation. Each ingredient was tested at 10%, 25%, 50%, and 100% concentrations. One-tenth ml of the test material at each dilution was instilled into one eye of six rabbits; the contralateral eye served as the control. Observations were made at 1, 2, and 8 h and each day for one week. Solutions containing 10% TEA-CHAP or PCHAP were reported to be minimally irritating with the most irritation (conjunctival only) subsiding by the second day of testing. Solutions containing 25% TEA-CHAP or PCHAP were defined as mildly irritating. Irritation disappeared after the second day. At a concentration of 50%, TEA-CHAP and PCHAP also caused mild irritation; however, irritation (corneal and conjunctival) lasted the duration of the experiment. Undiluted PCHAP and TEA-CHAP caused moderate irritation which also lasted the duration of the testing. Table 4 summarizes the results.[9-12]

In other studies, both PCHAP and TEA-CHAP were tested at concentrations of 10% and 100% for eye irritation. The Draize method was used as the test procedure, but an unknown method was used for scoring irritation. Each ingredient, at a concentration of 10%, caused minor conjunctival irritation which cleared by 72 h. The authors concluded that these materials were "practically nonirritating" at the concentration tested.[13,14] When the undiluted ingredient was instilled

TABLE 3. Acute Oral Toxicity of Coco-Hydrolyzed Animal Proteins.

Ingredient	*Dose (per kg)*	*No. of rats*	*Oral LD50 (per kg)*	*Ref.*
PCHAP	10.0 g	10	No deaths	6
PCHAP	10.4–29.5 g	20	18.2 g[a]	7
PCHAP	10 or 20 ml	10	No deaths	8
PCHAP	10 or 20 ml	10	No deaths	8
TEA-CHAP	15.89–44.9 g	20	27.3 g[b]	7
TEA-CHAP	10 or 20 ml	20	No deaths	8
TEA-CHAP	10 or 20 ml	20	No deaths	8

[a]Of the dead animals, the following observations were made: hyperemic lungs; "bleached" liver, kidneys and spleen; gastrointestinal tracts distended with sample; bloody nasal discharge; diuresis; hyperemic gastrointestinal tract and hardened sample in stomach. Of the survivors: five with red spotted lungs at dosage 10.4 ml/kg. Organs of the thorax and abdomen normal in others.

[b]Of the dead animals, the following observations were made: hyperemic lungs; "bleached liver and kidneys"; hyperemic gastrointestinal tract distended with sample; darkened spleen; hemorrhage of the gastrointestinal tract; bloody nasal discharge; diureseis and darkened liver.

TABLE 4. Eye Irritation.

Ingredient	*Concentration (%)*	*1 h*	*2 h*	*8 h*	*1 day*	*2 days*	*3 days*	*4 days*	*5 days*	*6 days*	*7 days*	*Area(s) affected*
PCHAP	10	7.33	9.33	9.33	3.00	0.67	0	0	0	0	0	Conjunctivae
PCHAP	10	6.33	8.00	5.67	0.67	0	0	0	0	0	0	Conjunctivae
PCHAP	25	12.00	14.33	10.67	2.33	0	0	0	0	0	0	Conjunctivae
PCHAP	25	17.33	18.67	16.00	10.67	0.67	0	0	0	0	0	Cornea and conjunctivae
PCHAP	50	11.33	14.33	14.67	4.83	4.33	1.17	0	0	0	0	Cornea and conjunctivae
PCHAP	50	15.33	15.67	15.00	14.50	7.50	1.33	0	0	0	0	Cornea and conjunctivae
PCHAP	100	10.33	13.33	11.33	8.83	3.33	0.33	0.33	0	0	0	Iris and conjunctivae
PCHAP	100	16.67	17.00	16.00	13.00	18.00	26.17	21.17	24.50	14.17	2.83	All
TEA-CHAP	10	7.33	8.33	6.67	2.00	1.00	0	0	0	0	0	Conjunctivae
TEA-CHAP	10	5.00	7.67	5.33	0	0	0	0	0	0	0	Conjunctivae
TEA-CHAP	25	12.67	14.33	13.00	6.00	0	0	0	0	0	0	Conjunctivae
TEA-CHAP	25	14.33	16.00	14.67	5.67	1.00	0	0	0	0	0	Conjunctivae
TEA-CHAP	50	10.67	13.00	12.00	1.67	0.33	0.33	0.33	0	0	0	Conjunctivae
TEA-CHAP	50	13.33	16.33	15.00	18.50	9.00	2.67	2.67	1.00	0.67	0.67	Cornea and conjunctivae
TEA-CHAP	100	13.67	17.00	29.50	12.50	5.33	3.33	3.00	3.00	2.17	1.50	Cornea and conjunctivae
TEA-CHAP	100	14.66	15.33	16.00	22.83	16.33	2.67	1.33	0.33	0.67	0	Cornea and conjunctivae

Based on the method of Draize (total possible score = 110).
Data from Refs. 9–12.

into eyes of rabbits, severe irritation developed in the cornea, iris, and/or conjunctiva. Irritation persisted throughout the 72 h observation period. These ingredients were considered to be eye irritants.[7,15]

Skin

Primary Irritation: PCHAP and TEA-CHAP were tested for potential skin irritancy in rabbits. The Draize method was used in all studies. PCHAP was reported to be nonirritating to slightly irritating when applied at a 10% concentration. Undiluted PCHAP was mildly irritating; erythema was the only skin response observed. At a concentration of 10%, TEA-CHAP was determined to be nonirritating to rabbits' skin. Undiluted TEA-CHAP was found to be slightly to mildly irritating in two studies; however, erythema, edema, and eschar formation were reported in one study which concluded that undiluted TEA-CHAP is severely irritating (PII = 3.05; maximum score = 8). Results of these tests are summarized in Table 5.[6-9,13]

Sensitization: PCHAP (0.1 ml of a 0.1% solution) was administered intracutaneously to the shaved skin of two white male guinea pigs. The injections were made every other day, three times weekly, until a total of 10 injections had been administered. Two weeks after the final induction injection, a challenge injection of 0.05 ml of the solution was made. Skin sites were scored 24 h following every injection and challenge scores were compared with induction scores. PCHAP elicited no responses to either induction or challenge injections and was considered to be nonsensitizing under the test conditions.[6]

Two samples each of PCHAP and TEA-CHAP at 10% were tested for potential sensitization according to the Buehler method. No reactions to test or challenge patches occurred in any of the guinea pigs (20 per ingredient). Both ingredients were considered to be nonsensitizing in all four tests at the given concentration.[9]

TABLE 5. Primary Skin Irritation.[a]

Ingredient	*No. of rabbits*	*Concentration (%)*	*PII*[b]	*Reactions*	*Comment*	*Ref.*
PCHAP	6	10	0.00	–	Nonirritating	8
PCHAP	6	10	0.50	erythema	Slightly irritating	8
PCHAP	6	100	1.59	erythema	Mildly irritating	9
PCHAP	6	100	1.26	erythema	Mildly irritating	9
PCHAP	6	100	1.04	erythema	Mildly irritating	6
PCHAP	6	100	1.88	eschar formation	Mildly irritating	7
TEA-CHAP	6	10	0.00	–	Nonirritating	8
TEA-CHAP	6	10	0.00	–	Nonirritating	8
TEA-CHAP	6	100	1.21	edema and erythema	Mildly irritating	9
TEA-CHAP	6	100	0.50	erythema	Slightly irritating	9
TEA-CHAP	6	100	3.05	eschar formation, edema, erythema	Severely irritating	7

[a]Method and scoring according to Draize.
[b]Primary Irritation Index (Maximum Score = 8).

CLINICAL ASSESSMENT OF SAFETY

Single Insult Patch Test

Patch tests were performed on 33 subjects using PCHAP at concentrations of 2% and 20%. Occlusive patches containing PCHAP at each concentration were applied to the chest or arm, and left in place for 24 h. Sites were scored upon patch removal and at 48 and 72 h. No reactions occurred.[16]

In another study, PCHAP and TEA-CHAP were simultaneously tested on 50 subjects. Two samples of each ingredient were tested at a concentration of 10%. Of the 50 subjects tested, at least eight had skin diseases (psoriasis and eczema) and many were being treated for illnesses (i.e., migraines, allergies, diabetes). There were 29 healthy subjects. Approximately 1.5 mg/cm^2 of each ingredient were applied under patches and left in place for 24 h. Sites were scored upon removal and at 48 and 72 h. One reaction (slight erythema at 24 h from a patch containing 10% PCHAP) occurred in a patient with psoriasis.[17] Table 6 summarizes the results of these studies.

Sensitization

A 5% solution of a soap containing 41%–43% PCHAP was used by a "large number of healthy subjects and people suffering from dermatitis" over a 10- to 48-day period. Histological examinations of the treated area indicated a low irritation frequency and no signs of sensitivity.[18]

A repeated insult patch test was performed on 168 subjects (115F, 53M) using 0.1 ml of a 10% water solution of PCHAP and TEA-CHAP. The test material was applied at 48 h intervals, three times per week for three weeks on the subjects' backs. The test area was occluded for 24 h, removed, and washed with distilled water. The test sites were read at 48 h, after which fresh test material and the occlusive patch were reapplied. After a three-week rest period, the test area, as well as a virgin site, were challenged using the same procedure as previously noted. The sites were scored for sensitization at 24, 48, and 72 hours. Five subjects challenged with PCHAP were reported to have significant erythema, and were rechallenged at concentrations of 2.5%, 5.0%, and 10.0%. The rechallenge was scored at 24, 48, and 72 h. The results of both the initial challenge and subsequent rechallenge indicated that PCHAP produced allergic contact sensitization in two subjects, cumulative irritation in two additional subjects, and a mild

TABLE 6. Single Insult Patch Test (Human).

Ingredient	*Concentration (%)*	*No. of subjects*	*Subject ages (yrs)*	*M/F*	*No. of reactions*	*Comments*	*Ref.*
PCHAP	2	33	20–76	18/15	0	nonirritating	16
PCHAP	20	33	20–76	18/15	0	nonirritating	16
PCHAP	10	50	15–59	22/28	0	nonirritating	17
PCHAP	10	50	15–59	22/28	1	1+ erythema at 24 h, 0 at 48 h	17
TEA-CHAP	10	50	15–59	22/28	0	nonirritating	17
TEA-CHAP	10	50	15–59	22/28	0	nonirritating	17

nonspecific irritation in a fifth subject. The two subjects who were sensitized to PCHAP were also sensitized to TEA-CHAP.[19]

Phototoxicity

One percent water solution of PCHAP and TEA-CHAP was tested on ten subjects under the regulations of the German Association for Light Research.[20] The investigator reported no UVB phototoxicity and no UVA phototoxicity when the treated skin was exposed to 7.5 J/cm^2 (15 min PUVA 6001).

Twenty-eight of the 168 subjects tested for irritation and sensitization discussed above were randomly selected to test the ability of PCHAP and TEA-CHAP to induce a phototoxic or photosensitive reaction following ultraviolet exposure. The test protocols were the same except that the forearm was used as a test site. The 28 subjects were divided into two groups; 19 received only UVA and 9 received both UVA and UVB. The UVA (320–400 nm) light was applied for 15 min to the 19 subjects (4.4 μW/cm^2 at the skin surface measured at a 360 nm wavelength peak). The UVB was applied at two times Mean Erythema Dose (MED) to nine subjects from a 150 watt Xenon Arc Solar Simulator emitting at 280–320 nm. The subjects receiving the UVB exposure were also exposed for 5 min to UVA as previously described. One subject included in the photosensitization subgroup reported above was sensitized to both PCHAP and TEA-CHAP. One additional subject who was considered by the investigator to be photosensitized by both PCHAP and TEA-CHAP at the original challenge site at 72 h. Only TEA-CHAP gave a similar value for this subject when challenged at a virgin site.[19]

Worker/Consumer Experiences

A chemical manufacturer has stated that he and his predecessor have produced protein derivatives for 40 years. During that time, there has been no case of sensitization or allergenic reaction by workers involved in the handling of these products.[21]

Approximately 600,000 units of a shampoo containing 1% TEA-CHAP have been sold without report of consumer complaint.[22]

SUMMARY

Potassium and TEA-Coco-Hydrolyzed Animal Proteins are salts of the condensation product of coconut acid and hydrolyzed animal protein. These two ingredients are prepared by the hydrolysis of collagen to short-chained polypeptides, then addition of coconut fatty acid and finally neutralization of the terminal carboxyl group of the fatty acid with either potassium or TEA. These ingredients have chemical and physical properties which are dependent upon their ratios of fatty acid to polypeptides. PCHAP is used in 251 and TEA-CHAP is used in 18 cosmetic products as detergents, foamers and levelers. Both ingredients are reported to be used primarily in rinse-off products, with one exception being a skin cleansing preparation.

Acute oral toxicity studies reveal that both PCHAP and TEA-CHAP are practically nontoxic when ingested. Both ingredients at concentrations of 10%–100% were practically nonirritating to moderately irritating when instilled in the eyes of rabbits. Both were nonirritating to mildly irritating when applied at concentrations of 10%–50% to the skin of rabbits. Guinea pig sensitization studies concluded that PCHAP and TEA-CHAP are nonsensitizing.

PCHAP and TEA-CHAP, at concentrations of 2%–10%, were nonirritating to practically nonirritating (one reaction in 50 subjects) when tested using a single insult patch test and a total of 266 patches.

In a repeated insult patch test PCHAP gave a positive sensitization reaction in two of 168 subjects; two additional subjects showed cumulative irritation and one other was reported to have a nonspecific irritation. The two subjects reported to be sensitized to PCHAP were also sensitized to TEA-CHAP. One subject out of 28 tested did not demonstrate significant irritation or sensitivity to either PCHAP or TEA-CHAP, but was photosensitized to both ingredients.

CONCLUSION

On the basis of the available information, the Panel concludes that Potassium-Coco-Hydrolyzed Animal Protein and TEA-Coco-Hydrolyzed Animal Protein are safe as cosmetic ingredients in the present practices of use as recorded in this report.

ACKNOWLEDGMENT

Mr. Kevin Fisher, Scientific Analyst and writer, prepared the technical analysis used by the Expert Panel in developing this report.

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TABLE 20
Historical and current cosmetic product uses and concentrations for Polybutene

Product type	1976 uses (Elder 1982)	2001 uses (FDA 2001)	1976 use concentrations (Elder 1982) (%)	2001 uses concentrations (CTFA 2001) (%)
Bath preparations (other)	—	—	—	0.002
Eyebrow pencil	—	3	—	3
Eyeliner	—	3	—	4
Eye shadow	10	8	>1–5	8.4–36
Mascara	—	51	—	2–5
Eye makeup (other)	—	6	—	2–36
Fragrance preparations (other)	—	—	—	14
Noncoloring shampoos	2	—	>5–10	0.9
Blushers	—	—	—	10
Face powders	—	1	—	2–3
Foundations	—	5	—	8
Lipstick	70	151	>1–>50	0.6–92
Makeup preparations (other)	—	19	>10–25	6–87
Personal cleanliness products (other)	—	—	—	16
Moisturizers	1	3	>1–5	—
Night skin care preparations	1	—	>10–25	—
Skin care preparations (other)	—	2	—	6–16
Suntan preparations (other)	—	1	—	—
Total uses/ranges for Polybutene	**84**	**253**	**>1–>50**	**0.002–92**

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POLYQUATERNIUM-11

In 1983, CIR issued a Final Report that Polyquaternium-11 is safe as a cosmetic ingredient in the present practices of use (Elder 1983). A review of the recent literature on Polyquaternium-11 uncovered no new studies. Updated information below regarding types and concentrations of use were considered by the CIR Expert Panel. The Panel determined not to reopen this safety assessment.

In 1976 Polyquaternium-11 was reported to be used in 131 cosmetic preparations with the largest single use occurring in hair conditioners at concentrations of ≤25%. As reported to the FDA (FDA, 2001), Polyquaternium-11 is currently used in 254 products, with hair tonics, dressings, etc., as the largest category with a concentration range of 0.05–10%, according to an industry survey (CTFA 2001). Table 21 presents the available use information.

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POTASSIUM COCOYL HYDROLYZED COLLAGEN AND TRIETHANOLAMINE COCOYL HYDROLYZED COLLAGEN

A Safety Assessment of Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein was published in 1983 (Elder 1983). Based on the data available at that time, the Panel concluded that these compounds were "safe as cosmetic ingredients in the present practices of use."

The names these two compounds as listed in the *International Cosmetic Ingredient Dictionary and Handbook* have been

[22]Available from the Director, Cosmetic Ingredient Review, 1101 17th Street NW, Suite 310, Washington, DC 20036, USA.

TABLE 21
Historical and current cosmetic product uses and concentrations for Polyquarternium-11

Product type	1976 uses (Elder 1983)	2001 uses (FDA 2001)	1976 use concentrations (Elder 1983) (%)	2001 uses concentrations (CTFA 2001) (%)
Baby products (other)	1	—	1–5	—
Bath preparations (other)	—	1	—	—
Mascara	—	1	—	—
Hair conditioners	49	69	0–25	0.8–3
Hair sprays (aerosol fixatives)	2	—	1–5	2
Permanent waves	7	14	0.1–10	—
Rinses (noncoloring)	5	1	0–5	0.8
Shampoos (noncoloring)	8	24	0.1–5	0.05–4
Hair tonics, dressings, etc.	3	88	1–5	0.05–10
Wave sets	23	8	0.1–50	2–3
Hair preparations (other noncoloring)	12	37	0–25	0.1–4
Hair dyes and colors	5	—	0.1–1	—
Hair tints	—	4	—	—
Hair rinses (coloring)	4	—	0.1–1	—
Hair-bleaches	1	3	0.1–1	—
Hair-coloring preparations (other)	1		0.1–1	0.3
Personal cleanliness products (other)	—	1	—	12
Shaving cream	5	2	0.1–1	—
Skin-cleansing creams, lotions, liquids, and pads	—	—	—	0.4
Face and neck skin care preparations		—	—	0.05
Moisturizers	1	—	0.1–1	—
Night skin care preparations	1	—	0.1–1	0.05
Paste masks (mud packs)	1	—	10–25	4
Skin fresheners	2	1	0–0.1	—
Total uses/ranges for Polyquaternium-11	**131**	**254**	**$\leq$25**	**0.05–10**

changed to Potassium Cocoyl Hydrolyzed Collagen (CAS no. 68920-65-0) and Triethanolamine Cocoyl Hydrolyzed Collagen (CAS no. 68952-16-9), respectively (Pepe et al. 2002).

A search of the scientific literature databases to identify any new safety data relevant to the cosmetic use of Potassium Cocoyl Hydrolyzed Collagen and Triethanolamine Cocoyl Hydrolyzed Collagen yielded no new safety or toxicity data on either compound. The only new information related to these compounds is the updated frequency of use, as voluntarily reported by the industry to the FDA and shown in Table 22. The CIR Expert Panel considered these new uses and determined to not reopen this safety assessment.

Potassium-Coco-Hydrolyzed Animal Protein was used in 251 cosmetic products in 1981, with the highest concentration at 50% in non-coloring shampoos. In 2002, Potassium Cocoyl Hydrolyzed Collagen was used in 64 cosmetic products, with the highest concentration at 20% in noncoloring shampoo.

Triethanolamine-Coco-Hydrolyzed was used in 18 cosmetic products in 1981, with the highest concentration at 50% in noncoloring shampoos. In 2002, Triethanolamine Cocoyl Hydrolyzed Collagen was reported to FDA as used in 21 cosmetic products (FDA 2002), but an industry survey of current use concentrations did not provide any information (CTFA 2002).

The CIR Expert Panel acknowledged the new use of Triethanolamine Cocoyl Hydrolyzed Collagen in aerosol hair sprays. The effects of inhaled aerosols depend on the specific chemical species, the concentration, the duration of exposure, and site of deposition within the respiratory system. Particle size is the most important factor affecting the location of deposition (Jensen and O'Brien 1993). The mean aerodynamic diameter of pump hair spray particles is $\geq$80 μ, and the diameter of anhydrous hair spray particles is 60 to 80 μ. Typically less than 1% are below 10 μ, which is the upper limit for respirable particles (Bower 1999). Based on the particle size, Triethanolamine Cocoyl Hydrolyzed Collagen would not be respirable in formulation. Therefore, the Panel was not concerned about the lack of inhalation toxicity data.

The Panel also noted that the hydrolyzed protein would not absorb into human tissues, thus further reducing the risk of toxicity.

TABLE 22
Historic and current use of Potassium Cocoyl Hydrolyzed Collagen and Triethanolamine (TEA) Cocoyl Hydrolyzed Collagen

Product type	1976 uses (Elder 1983)	2001 uses (FDA 2001)	1976 use concentrations (Elder 1983) (%)	2001 uses concentrations (CTFA 2002) (%)
Potassium Cocoyl Hydrolyzed Collagen				
Bubble baths	6	—	>1–5	—
Bath preparations (other)	1	—	>1–5	—
Hair conditioners	4	—	>1–10	—
Hair straighteners	12	2	≤0.1–1	—
Permanent waves	55	18	≤0.1–5	1
Shampoos (noncoloring)	33	6	≤0.1–50	1–20
Hair tonics, dressings, etc.	6	2	≤0.1–5	—
Wave sets	1	—	>1–5	—
Hair preparations (other noncoloring)	3	1	>1–5	—
Hair dyes and colors	43	21	>1–10	5
Hair tints	—	9	—	—
Hair lighteners with color	1	—	>1–5	—
Hair bleaches	1	—	>1–5	—
Nail creams and lotions	—	—	—	0.05
Nail polish and enamel	74	—	≤0.1	—
Manicuring preparations (other)	6	—	≤0.1–5	—
Shaving preparations (other)	—	1	—	—
Skin cleansing creams, lotions, liquids, and pads	3	3	>1–50	—
Face and neck skin care preparations	1*	—	>1–5*	—
Body and hand skin care preparations		—		—
Moisturizers	—	1	—	0.2
Skin care preparations (other)	1	—	>0.1–1	—
Total uses/ranges for Potassium Cocoyl Hydrolyzed Collagen	**251**	**64**	**≤0.1–50**	**0.05–20**
Triethanolamine (TEA) Cocoyl Hydrolyzed Collagen				
Baby shampoos	—	1	—	—
Bath oils, tablets, and salts	—	1	—	—
Bubble Baths	—	3	—	1
Perfumes	—	1	—	—
Hair conditioners	3	1	>1–5	—
Hair sprays (aerosol fixatives)	—	1	—	—
Permanent waves	—	2	—	—
Shampoos (noncoloring)	11	3	≤0.1–50	—
Hair tonics, dressings, etc.	1	—	>1–5	—
Foundations	—	1	—	—
Cuticle softeners	1	—	≤0.1	—
Bath soaps and detergents	1	—	>1–5	—
Personal cleanliness products (other)	—	1	—	—
Shaving cream	—	1	—	—
Skin-cleansing creams, lotions, liquids, and pads	—	4	—	—
Skin care preparations (other)	1	—	>1–5	—
Total uses/ranges for Triethanolamine (TEA) Cocoyl Hydrolyzed Collagen	**18**	**20**	**0.1–50**	**—**

*This category was combined when the original safety assessment was performed and is now two separate categories.

As with all cosmetic ingredients derived from animal tissues, Potassium Cocoyl Hydrolyzed Collagen and Triethanolamine Cocoyl Hydrolyzed Collagen, as used in cosmetic products, must be free of detectable pathogenic viruses, prions, or other pathogenic agents.

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PROPYLENE GLYCOL STEARATE/PROPYLENE GLYCOL STEARATE SE

A Safety assessment of Propylene Glycol Stearate/Propylene Glycol Stearate Self-Emulsifying was published in 1983 (Elder 1983). Only one new study has been reported since then. This new study, along with the updated information below regarding types and concentrations of use, was considered by the CIR Expert Panel. After this review, the Panel determined that there was no need to reopen the safety assessment.

Data from the 1983 report on frequency of use and concentration of use (circa, 1976) is provided in Table 23, along with current frequency of use and total products in each category as provided by the FDA (FDA, 2002). An industry survey (CTFA 2002) uncovered no current concentrations of use of these ingredients.

In 1976, Propylene Glycol Stearate was used in 401 cosmetic preparations; currently Propylene Glycol Stearate is used in 193 cosmetic preparations. Eleven new product categories appeared in 2002.

Concentration of use in 1976 for Propylene Glycol Stearate ranged from 0.1% to 25%. In 1976, Propylene Glycol Stearate SE was reported in 131 cosmetic formulations; currently Propylene Glycol Stearate SE is used in 60 cosmetic formulations. Eight new product use categories appeared in 2002. Concentrations of use in 1976 for Propylene Glycol Stearate SE ranged from less than or equal to 0.1% to 25%.

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SODIUM LAURETH SULFATE AND AMMONIUM LAURETH SULFATE

A Safety assessment of Sodium Laureth Sulfate and Ammonium Laureth Sulfate was published in 1982 (Elder 1982). New studies since then are listed at the end of this review. These new studies along with the updated information below regarding types and concentrations of use were considered by the CIR Expert Panel. After this review, the Panel determined that there was no need to reopen the safety assessment.

Data from the 1983 report on frequency of use and concentration of use (circa 1976) is provided in Table 24, along with current frequency of use and total products in each category as provided by the FDA (FDA 2002). Current concentration of use data from an industry survey are also provided (CTFA 2002).

In 1976, Sodium Laureth Sulfate was used in 282 cosmetic preparations, with the largest use in noncoloring shampoos at concentrations ranging from >1% to >50%. According to reports to FDA, Sodium Laureth Sulfate is reportedly now used in 952 cosmetic preparations (FDA 2002), with the largest use in shampoos at 11% to 50% (CTFA 2002). This ingredient is used in 23 product categories in 2002 that were not in the 1976 FDA data.

In 1976, Ammonium Laureth Sulfate was used in 63 cosmetic preparations, with the largest use in hair dyes and colors at >5% to 25%. Currently Ammonium Laureth Sulfate is used in 244 cosmetic preparations, with the largest use in shampoos at >0.1% to >50%. This ingredient was used in 11 product categories in 2002 that were not in the 1976 FDA data.

The Panel reiterated that the previously existing and the new data demonstrate the irritancy of Sodium Laureth Sulfate and Ammonium Laureth Sulfate in leave on products. The available data do suggest that these ingredients are toxic in animal tests via inhalation exposure and they are used in products that may be aerosolized.

The effects of inhaled aerosols in humans depend on the specific chemical species, the concentration, the duration of

[23]Available from the Director, Cosmetic Ingredient Review, 1101 17th Street NW, Suite 310, Washington, DC 20036, USA.

[24]Available from the Director, Cosmetic Ingredient Review, 1101 17th Street NW, Suite 310, Washington, DC 20036, USA.