Amended Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics

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*All interested persons are provided 60 days from the above release date (i.e., by **September 9, 2025**) to comment on this safety assessment, and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth.*

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ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
DBPS	disinfectant by-products
Dictionary	*International Cosmetic Ingredient Dictionary and Handbook*
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FOU	frequency of use
HRIPT	human repeated-insult patch test
l.o.	leave-on
MoCRA	Modernization of Cosmetics Regulation Act
MTT	[3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide
MW	molecular weight
NR	not reported
Panel	Expert Panel for Cosmetic Ingredient Safety
PII	primary irritation index
PUVA	psoralen plus ultraviolet A
RLD	Registration and Listing Data
r.o.	rinse-off
SLS	sodium lauryl sulfate
TEA	triethanolamine
US	United States
UVA	ultraviolet A
UVB	ultraviolet B
VCRP	Voluntary Cosmetic Registration Program

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) reassessed the safety of Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen. Subsequently, the Panel included two structurally-related ingredients, i.e., Cocoyl Hydrolyzed Collagen and Sodium Cocoyl Hydrolyzed Collagen, in this assessment. All 4 cocoyl hydrolyzed collagen ingredients are reported to function in cosmetics as hair conditioning agents, skin-conditioning agents, and surfactants. The Panel reviewed the available data to determine the safety of these ingredients. Industry should minimize impurities that could be present in cosmetic formulations, such as heavy metals and pesticide residues, according to limits set by the US Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), Furthermore, the Panel noted that these ingredients may be derived from animal-sources and stressed the cosmetics industry should continue to use necessary procedures to limit infectious agents, and/or biologically-derived impurities (e.g., nucleic acids, proteins, endotoxins). The Panel issued an amended report reaffirming the original conclusion that cocoyl hydrolyzed collagen ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

This assessment reviews the safety of the following 4 cocoyl hydrolyzed collagen ingredients as used in cosmetic formulations.

Cocoyl Hydrolyzed Collagen	Sodium Cocoyl Hydrolyzed Collagen
Potassium Cocoyl Hydrolyzed Collagen	TEA-Cocoyl Hydrolyzed Collagen

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (*Dictionary*), these ingredients are reported to function in cosmetics as hair conditioning agents, skin conditioning agents, and surfactants - cleansing agents[1] (Table 1).

Two of the 4 ingredients named in this report have been reviewed previously. The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review of the safety of Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen (then called Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein, respectively) in 1983.[2] The Panel concluded that these two ingredients are safe as cosmetic ingredients in the present practices of use, as described in that report. The Panel initially considered a re-review of this report in 2002 and reaffirmed the 1983 conclusion, as published in 2005.[3] In accordance with its Procedures, the Panel evaluates the conclusions of previously issued reports every 15 years, and as it had been at least 15 years since the previous re-review was issued; accordingly, the Panel again considered a re-review of this ingredient at the June 2024 meeting. At that meeting, the Panel determined that this safety assessment should be re-opened to re-evaluate existing endpoints, particularly sensitization and photosensitization. Furthermore, at the December 2024 meeting, the Panel decided to include two structurally-related ingredients, i.e., Cocoyl Hydrolyzed Collagen and Sodium Cocoyl Hydrolyzed Collagen, in this safety assessment.

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an extensive search of the world's literature; a search was last conducted in May 2025. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

Excerpts from the summaries of the 1983 report on Potassium and TEA-Coco-Hydrolyzed Animal Protein are disseminated throughout the text of this re-review document, as appropriate, and are identified by *italicized text*. (This information is not included in the tables or the summary section.) For complete and detailed information, the original 1987 report can be accessed on the CIR website (https://cir-reports.cir-safety.org/).

CHEMISTRY

Definition and Structure

The 4 ingredients named in this report are reviewed together in that they all are formed from the condensation of coconut acid chloride and hydrolyzed collagen.[1] Specifically, Cocoyl Hydrolyzed Collagen (CAS No. 68952-15-8) is the condensation product of coconut acid chloride and hydrolyzed collagen, while Potassium Cocoyl Hydrolyzed Collagen (CAS No. 68920-65-0), Sodium Cocoyl Hydrolyzed Collagen (CAS No. 68188-38-5), and TEA-Cocoyl Hydrolyzed Collagen (CAS No. 68952-16-9) are the potassium, sodium, and triethanolamine (TEA) salts, respectively, of the condensation product (Table 1). The general formula for all these ingredients conforms to Figure 1.

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

Figure 1. Cocoyl hydrolyzed collagen salt ingredients, wherein R-C(O)- represents the acyl moiety of the coconut acid; $NH\text{-}CHR'\text{-}C(O)\text{-}(NH\text{-}CHR''\text{-}C(O))_n\text{-}NH\text{-}CHR'\text{-}C(O)O^-$ represents the mixed peptides and polypeptides resulting from the hydrolysis of collagen; and Y^+ represents either the potassium, sodium, or TEA cation or hydrogen (in the case of Cocoyl Hydrolyzed Collagen).[2]

Coconut acid is a mixture of fatty acids derived from *Cocos nucifera* (coconut) oil, varying in chain length from C6 to C18, but primarily comprising C12 (lauric acid ~44 - 52%), C14 (myristic acid ~13 – 19%), C16 (palmitic acid ~8 – 11%), and C10 (capric acid ~6 – 10%).[4] Coconut acid is first activated by conversion to the acid chloride, prior to amidation with peptides.[2] The hydrolysis of collagen can result in a random assortment of peptide or polypeptide chain lengths, and thus, "n" in Figure 1 may be as small as 2 or much greater.

Chemical Properties

Both Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen are slightly hazy amber liquids.[2] *Each ingredient has its own unique properties based on the size of the polypeptide and fatty acid moieties in the product.* According to a supplier, the number average molecular weight (MW) of Potassium Cocoyl Hydrolyzed Collagen is around 600.[5]

Method of Manufacture

The source of collagen is chrome-leather splitting.[2] *This protein is hydrolyzed into short-chained polypeptides by acids, base or enzymes. The polypeptide chain fragments generated vary in length and MW due to the random nature of this bond breaking process. At the next step, fatty acid chlorides (coconut fatty acids) are added so that an amide linkage is formed between the fatty acid chlorides and the free amino groups in the polypeptide. The polypeptide to the fatty acid ratios vary with the increasing MW of the product. If the MW is less than 600, the fatty acid moiety predominates, whereas when the MW is higher than 600, the polypeptide predominates. At the final step of the production the fatty acid is neutralized with either TEA or potassium to form a salt.*

Potassium Cocoyl Hydrolyzed Collagen

According to a supplier, Potassium Cocoyl Hydrolyzed Collagen Product is prepared by condensation of coconut fatty acid and hydrolyzed collagen derived from fish scale.[5]

Composition/Impurities

Potassium Cocoyl Hydrolyzed Collagen

The impurities reported for Potassium Cocoyl Hydrolyzed Collagen (in order of predominance) include coconut fatty acid, hydrolyzed collagen, and inorganic salts such as sodium chloride, sodium sulfate, potassium chloride, and potassium sulfate.[2]

According to a supplier, Potassium Cocoyl Hydrolyzed Collagen is produced as a 30% solution in water.[5] The heavy metal content was reported as not more than 20 ppm and the content of arsenic was not more than 2 ppm. Another industry submission reported content of Potassium Cocoyl Hydrolyzed Collagen in a product is 20-40% in water.[6] The percentage of the dry substance was reported as 30-33%.

TEA-Cocoyl Hydrolyzed Collagen

The impurities reported for TEA-Cocoyl Hydrolyzed Collagen (in order of predominance) include coconut fatty acid, hydrolyzed collagen, triethanolamine sulfate, sodium chloride, and sodium sulfate.[2]

UV Absorption

Potassium Cocoyl Hydrolyzed Collagen

The ultraviolet (UV) absorption spectra was measured for Potassium Cocoyl Hydrolyzed Collagen (0.1% dilution in purified water).[5] The test material did not have a molar extinction coefficient > 1000 l/mol/cm at any wavelength between 290 - 700 nm.

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of cocoyl hydrolyzed collagens in cosmetics. Data included herein were obtained from the FDA and in response to a survey of maximum use concentrations conducted by the Personal Care Products Council (Council), and it is these values that define the present practices of use and concentration. Frequencies of use obtained from the FDA include data from the Voluntary Cosmetic Registration Program (VCRP) database as well as Registration and Listing Data (RLD). As a result of the Modernization of Cosmetics Regulation Act (MoCRA) of 2022, the VCRP was discontinued in 2023 and, as of 2024, manufacturers and processors are required to register facilities and list their products (and ingredients therein) with the FDA (i.e., RLD). An exception is made for small businesses (average gross annual sales in the US of cosmetic products for the previous 3-yr period is less than $1,000,000, adjusted for inflation), which are exempt from MoCRA reporting for most cosmetic product categories. Eye area products, injected products, internal use products, or products that alter appearance for more than 24 h, and the facilities that manufacture these products, are not included in this exemption.[7] Please note, at this time, it is not appropriate to contrast data from the VCRP and RLD to determine a trend in frequency of use because there are numerous differences in the ways the data for the VCRP and the RLD were collected and processed, and because reporting frequency of use is now mandatory (as opposed to the past practice of voluntary reporting). Although the VCRP program is now defunct, trends in frequency of use from the RLD alone are not yet possible in that a baseline is currently not available.

According to RLD submitted to CIR in 2024, Cocoyl Hydrolyzed Collagen has the most reported uses, in 104 formulations[8] (Table 2; Table 3). However, the results of the maximum concentration of use survey collected by the Council in 2025 only reported use concentrations for Sodium Cocoyl Hydrolyzed Collagen (1.1% in other personal cleanliness rinse-off products) and Potassium Cocoyl Hydrolyzed Collagen (0.01% in face and neck leave-on products).[9] Potassium Cocoyl Hydrolyzed Collagen is reported to be used in a product applied near the eye (an eye lotion; concentration of use not reported). (A concentration of use survey conducted by the Council in 2022 for Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen reported no uses.[10])

In comparing the number of uses reported in the VCRP in 2023 and 2001 for Potassium and TEA-Cocoyl Hydrolyzed Collagen, the frequency of use decreased for both ingredients.[3,11] Potassium Cocoyl Hydrolyzed Collagen was reported to have 64 uses in 2001 but only 2 in 2023; TEA-Cocoyl Hydrolyzed Collagen had 20 reported uses in 2001, but none in 2023.

Some products containing cocoyl hydrolyzed collagen ingredients may be marketed for use with airbrush delivery systems. With the advent of MoCRA and the current product categories outlined by the FDA, it is now mandatory that cosmetic products used in airbrush delivery systems be reported as such for some, but not all, product categories in the RLD. In other words, a reliable source of frequency of use data regarding the use of cosmetic ingredients in conjunction with airbrush delivery systems is now available, in some instances. Some of the reported product categories for these ingredients as listed in the RLD do require designation if airbrush application is used (e.g., foundations), but no airbrush use was indicated. Additionally, the Council currently surveys the cosmetic industry for maximum reported use concentrations of ingredients in products which may be used in conjunction with an airbrush delivery system; thus, this type of data may also be available, when submitted. Please note that no concentration of use data were provided indicating airbrush application. Nevertheless, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety. Without information regarding the consumer habits and practices data or product particle size data (or other relevant particle data, e.g., diameter) related to this use technology, the data profile is incomplete, and the Panel is not able to determine safety for use in airbrush formulations. Accordingly, the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

The cocoyl hydrolyzed collagen ingredients named in this report, except TEA-Cocoyl Hydrolyzed Collagen, are not restricted from use in any way under the rules governing cosmetic products in the European Union (EU).[12,13] Because TEA-Cocoyl Hydrolyzed Collagen contains TEA, it is listed in EU Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions;, therefore, it must conform to the restrictions listed for trialkylamines, trialkanolamines, and their salts. In leave-on products, the maximum concentration allowed for trialkylamines, trialkanolamines, and their salts is 2.5%. Restrictions for both leave-on and rinse-off products include not to be used with nitrosating systems; must have a minimum purity of 99%; a maximum secondary amine content of 0.5% (applies to raw materials); a maximum nitrosamine content of 50 µg/kg; and is to be kept in nitrite-free containers.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

Potassium Cocoyl Hydrolyzed Collagen

The oral LD_{50} of Potassium Cocoyl Hydrolyzed Collagen was 18.2 g/kg in rats.[2] In other studies, a single dose of 10 g/kg or up to 20 ml did not result in any deaths in rats.

TEA-Cocoyl Hydrolyzed Collagen

The oral LD_{50} of TEA-Hydrolyzed Collagen was 27.3 g/kg in rats.[2] In other studies, a single dose of up to 20 ml did not result in any deaths in rats.

Repeated-Dose Toxicity Studies

Repeated-dose toxicity studies on the cocoyl hydrolyzed collagen ingredients were not included in the original report, were not found in the updated literature search, and unpublished data were not submitted.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Developmental and reproductive toxicity studies on the cocoyl hydrolyzed collagen ingredients were not included in the original report, were not found in the updated literature search, and unpublished data were not submitted.

GENOTOXICITY STUDIES

Genotoxicity studies on the cocoyl hydrolyzed collagen ingredients were not included in the original report, were not found in the updated literature search, and unpublished data were not submitted.

CARCINOGENICITY STUDIES

Carcinogenicity studies on the cocoyl hydrolyzed collagen ingredients were not included in the original report, were not found in the updated literature search, and unpublished data were not submitted.

DERMAL IRRITATION AND SENSITIZATION STUDIES

The dermal irritation potential of Potassium and TEA-Cocoyl Hydrolyzed Collagen was evaluated in rabbits.[2] Potassium Cocoyl Hydrolyzed Collagen was non- to slightly irritating to rabbit skin at a concentration of 10%, and was mildly irritating when tested undiluted. TEA-Cocoyl Hydrolyzed Collagen was non-irritating to rabbit skin at a concentration of 10%, and was mildly/slightly irritating in 2 studies when tested undiluted, but was severely irritating in a third study. In clinical studies, Potassium Cocoyl Hydrolyzed Collagen (2 and 20%; 24-h occlusive patches) was not an irritant in 33 subjects. Potassium and TEA-Cocoyl Hydrolyzed Collagen (24-h occlusive patch; 1.5 mg/cm^2) were not irritating in single-insult patch tests at 10%; of the 50 subjects tested, 29 were considered healthy and 8 had skin disease.

In guinea pigs, Potassium and TEA-Cocoyl Hydrolyzed Collagen were not sensitizers when tested at 10%. In a human repeated-insult patch test (HRIPT) in168 subject with 10% aq. Potassium and TEA-Cocoyl Hydrolyzed Collagen, 5 subjects challenged with Potassium Cocoyl Hydrolyzed Collagen were reported to have significant erythema, and were rechallenged at concentrations of 2.5, 5.0, and 10.0%. The results of both the initial challenge and subsequent rechallenge indicated that Potassium Cocoyl Hydrolyzed Collagen produced allergic contact sensitization in 2 subjects, cumulative irritation in 2 additional subjects, and a mild non-specific irritation in a fifth subject. The 2 subjects who were sensitized to Potassium Cocoyl Hydrolyzed Collagen were also sensitized to TEA-Cocoyl Hydrolyzed Collagen.

Details of the irritation, sensitization, and photosensitization studies summarized below can be found in Table 4.

Undiluted Cocoyl Hydrolyzed Collagen was predicted to be non-irritating in an EpiDerm™ dermal irritation test; tissue viability was approximately 90%.[14] In rabbits, Potassium Cocoyl Hydrolyzed Collagen (as a 30% aq. solution) was non-irritating when tested as 10% active matter (24-h occlusive patch) and was a mild irritant when applied neat under occlusive patches for 4 or 24 h.[5,6] A 24-h occlusive patch of undiluted Potassium Cocoyl Hydrolyzed Collagen (30% aq. solution) did not cause an irritation reaction in 25 subjects.[5]

In a Buehler guinea pig test for sensitization conducted with 15 Pirbright guinea pigs, no contact hypersensitivity was observed with Potassium Cocoyl Hydrolyzed Collagen (30% active matter).[6] In HRIPTs, a formulation containing 0.1% Cocoyl Hydrolyzed Collagen (102 subjects),[15] an emulsion containing 0.058% Potassium Cocoyl Hydrolyzed Collagen (51 subjects),[16] and Potassium Cocoyl Hydrolyzed Collagen (as a 30% aq. solution) [5] did not produce irritation or sensitization. Additionally, a formulation containing 3.2% Potassium Cocoyl Hydrolyzed Collagen (50 subjects) did not produce a significant cutaneous reaction in a primary and accumulated dermic irritation evaluation.[17]

Photosensitization

Potassium and TEA-Cocoyl Hydrolyzed Collagen, as 1% aq. solutions, did not result in UVB or UVA phototoxicity when the treated skin of 10 subjects was exposed to 7.5 J/cm^2 (15 min PUVA 6001).[2] In a phototoxicity study with 28 subjects (randomly chosen from the 168 subjects that participated in the previously-described HRIPT), Potassium and TEA-Cocoyl Hydrolyzed Collagen was applied to the forearm, and 19 subject were irradiated with UVA only and 9 with UVA and UVB, One subject included in the photosensitization subgroup was sensitized to both Potassium and TEA-Cocoyl Hydrolyzed Collagen, and one additional subject was considered by the investigator to be photosensitized by both at the original challenge site at 72 h; only TEA-Cocoyl Hydrolyzed Collagen gave a similar value for this subject when challenged at a virgin site.

The photosensitization potential of Potassium Cocoyl Hydrolyzed Collagen (9% active matter) was evaluated using Pirbright guinea pigs (10 males and 10 females/group).[6] The skin was assessed 2, 6, and 24 h after retesting and 2, 6, 24, and 48 h after depilation. Potassium Cocoyl Hydrolyzed Collagen was not a photosensitizer in guinea pigs.

OCULAR IRRITATION STUDIES

In Vitro

Cocoyl Hydrolyzed Collagen

An EpiOcular™ assay was performed to determine the ocular irritation potential of undiluted Cocoyl Hydrolyzed Collagen.[14] Deionized water was used as the negative control, and methyl acetate as the positive control. Tissue viability was approximately 85%; Cocoyl Hydrolyzed Collagen was considered to be non-irritating.

Animal

Potassium and TEA-Cocoyl Hydrolyzed Collagen

The ocular irritation of Potassium and TEA-Cocoyl Hydrolyzed Collagen was evaluated in rabbit eyes at concentrations of 10, 25, 50, and 100%.[2] In one study, both ingredients were minimally irritating at 10%, mildly irritating at 25 and 50%, and moderately irritating at 100%. In another study, concentrations of 10% were practically non-irritating to rabbit eyes, and the undiluted test material caused severe irritation,

CLINICAL STUDIES

A "large number" of healthy subjects and patients suffering from dermatitis used a 5% solution of a soap containing 41- 43% Potassium Cocoyl Hydrolyzed Collagen over a 10 – 48-d period.[2] Histological examinations of the treated area displayed a low irritation frequency, and no signs of sensitivity were observed.

Case Reports

Researchers stated there are occasional reports of contact urticaria to protein hydrolysate ingredients that are added to hair care products, soaps, bath gels, and creams.[18] Four different samples of commercial hydrolyzed proteins (5% aq.) from bovine collagen elastin and keratins (not identified) were sequentially patch-tested in 500 patients of the clinic; no positive reactions were noted. Additionally, 25 patients with scalp dermatitis to these allergens (i.e., hydrolyzed proteins) were prick-tested (0.1% aq.); again, the results were negative. The researchers stated that although there was no evidence of hydrolyzed protein acting as a common contact allergen, it is recognized as being capable of producing reactions through a Type 1 mechanism.

In a clinical study was conducted to investigate the potential for the protein hydrolysates added to hair-care products to cause contact urticaria, 22 protein hydrolysates used in hair-care products (one of which was TEA-Cocoyl Hydrolyzed Collagen) were tested in scratch and patch tests in 11 hairdressers with hand dermatitis.[19] While some positive results were observed in the tests, none were seen with TEA-Cocoyl Hydrolyzed Collagen.

A 21-yr-old woman developed a severe dermatitis of the face after using a proprietary skin cleanser.[20] Patch testing showed delayed hypersensitivity to TEA-Cocoyl Hydrolyzed Collagen, but not to other ingredients of the cleanser. Further patch testing revealed positive results with other condensates of fatty acids and protein hydrolysates.

SUMMARY

The Panel first published a safety assessment on Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen (then called Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein, respectively) in 1983 and concluded that these two ingredients are safe as cosmetic ingredients in the present practices of use, as described in that report. Subsequently, the Panel considered the initial re-review of these ingredients in 2002 and reaffirmed the 1983 conclusion, as published in 2005. In June 2024, since more than 15 years have passed since the last review, the Panel considered another re-review and determined to reopen the safety assessment to re-evaluate existing endpoints, particularly sensitization and photosensitization. Subsequently, the Panel decided to add two structurally-related ingredients, Cocoyl Hydrolyzed Collagen and Sodium Cocoyl Hydrolyzed Collagen, to this safety assessment.

According to RLD submitted to CIR in 2024, Cocoyl Hydrolyzed Collagen has the most reported uses, in 104 formulations. However, the results of the maximum concentration of use survey collected by the Council in 2025 only reported use concentrations for Sodium Cocoyl Hydrolyzed Collagen (1.1% in other personal cleanliness rinse-off products) and Potassium Cocoyl Hydrolyzed Collagen (0.01% in face and neck leave-on products; a concentration of use survey conducted by the Council in 2022 for Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen reported no uses TEA-Cocoyl Hydrolyzed Collagen is listed in EU Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions because it contains TEA, and therefore must conform to the restrictions listed for trialkylamines, trialkanolamines, and their salts.

Undiluted Cocoyl Hydrolyzed Collagen was predicted to be non-irritating in an EpiDerm™ dermal irritation test; tissue viability was approximately 90%. In rabbits, Potassium Cocoyl Hydrolyzed Collagen (as a 30% aq. solution) was non-irritating when tested as 10% active matter (24-h occlusive patch) and was a mild irritant when applied neat under occlusive patches for 4 or 24 h. A 24-h occlusive patch of undiluted Potassium Cocoyl Hydrolyzed Collagen (as a 30% aq. solution) did not cause an irritation reaction in 25 subjects.

In a Buehler guinea pig test for sensitization conducted with 15 Pirbright guinea pigs, no contact hypersensitivity was observed with Potassium Cocoyl Hydrolyzed Collagen (30% active matter). In HRIPTs, a formulation containing 0.1% Cocoyl Hydrolyzed Collagen (102 subjects), an emulsion containing 0.058% Potassium Cocoyl Hydrolyzed Collagen (51 subjects), and undiluted Potassium Cocoyl Hydrolyzed Collagen (as a 30% aq. solution) did not produce irritation or sensitization. Additionally, a formulation containing 3.2% Potassium Cocoyl Hydrolyzed Collagen (50 subjects) did not produce a significant cutaneous reaction in a primary and accumulated dermic irritation evaluation. Potassium Cocoyl Hydrolyzed Collagen (9% active matter) did not produce a photosensitizing effect in Pirbright guinea pigs. The UV absorption spectra obtained for Potassium Cocoyl Hydrolyzed Collagens did not indicate absorption at any wavelength between 290 - 700 nm.

In an EpiOcular™ assay, undiluted Cocoyl Hydrolyzed Collagen was considered to be non-irritating. Tissue viability was approximately 85%.

Patch testing of commercial hydrolyzed proteins (5% aq.) from bovine collagen elastin and keratins in patients did not report positive results. In a study investigating the potential for the protein hydrolysates added to hair-care products to cause contact urticaria, a trade product containing TEA-Cocoyl Hydrolyzed Collagen did not produce positive results in scratch and patch tests in 11 hairdressers with hand dermatitis.

DISCUSSION

In accordance with its Procedures, the Panel re-evaluates the conclusions of previously issued reports approximately every 15 years. In 1983, the Panel evaluated the safety of Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen (then called Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein, respectively) and concluded that these two ingredients are safe as cosmetic ingredients in the present practices of use, as described in that report. The Panel considered the initial re-review of these ingredients in 2002 and

reaffirmed the 1983 conclusion, as published in 2005. In June 2024, since more than 15 years have passed since the last review, the Panel considered another re-review and determined to reopen the safety assessment to re-evaluate existing endpoints, particularly sensitization and photosensitization. Subsequently, the Panel decided to add two structurally-related ingredients, Cocoyl Hydrolyzed Collagen and Sodium Cocoyl Hydrolyzed Collagen, to this safety assessment.

Accordingly, the Panel reviewed the safety of 4 cocoyl hydrolyzed collagen ingredients as used in cosmetic formulations, in accordance with the product categories and concentration of use identified in the Use Section and Use table. The Panel determined that the data are sufficient to conclude that these cocoyl hydrolyzed collagen ingredients are safe in cosmetics in the present practices of use and concentrations, thereby reaffirming the original conclusion.

The Panel noted that concentrations of use for Cocoyl Hydrolyzed Collagen, the ingredient with the highest number of uses, were not reported. It is presumed that this ingredient will be used in the same manner and at the same concentration as the other ingredients in this report.

The Panel remarked on the absence of systemic toxicity data for these ingredients. However, concern was mitigated by the fact that the hydrolyzed proteins have low absorption.

Tertiary alkyl amines, such as TEA, do not react with *N*-nitrosating agents to directly form nitrosamines. However, tertiary amines can act as precursors in nitrosamine formation by undergoing nitrosative cleavage. The resultant secondary amine (i.e., diethanolamine) can then be *N*-nitrosated to products that may be carcinogenic. Because of the potential for this process to occur, TEA-containing ingredients should not be used in cosmetic products in which *N*-nitroso compounds can be formed.

The Panel was also concerned with the risks inherent in using animal-derived ingredients, namely the transmission of infectious agents and biologically-derived impurities (e.g., nucleic acids, proteins, endotoxins). They stressed that these ingredients must be free of detectible pathogenic viruses, infectious agents or biologically-derived impurities.

Additionally, the Panel expressed concern regarding heavy metals and pesticides that may be present in these ingredients. It was stressed that the cosmetics industry should continue to use the necessary procedures to minimize impurities in cosmetic formulations according to limits set by the US FDA and EPA.

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush technology presents a potential safety concern. Although frequency and/or concentration of use data are now available (and in some cases mandated) for ingredients marketed for use with airbrush delivery systems in certain product categories, no data are available for consumer habits and practices thereof, product particle size, or other relevant particle data (e.g., diameter). As a result of deficiencies in these critical data needs, the data profile is incomplete, and the safety of cosmetic ingredients applied by airbrush delivery systems cannot be determined by the Panel. Accordingly, the Panel has concluded the data are insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that following 4 cocoyl hydrolyzed collagen ingredients are safe in cosmetics in the present practices of use and concentrations described in this safety assessment.

Cocoyl Hydrolyzed Collagen*
Potassium Cocoyl Hydrolyzed Collagen
Sodium Cocoyl Hydrolyzed Collagen
TEA-Cocoyl Hydrolyzed Collagen*

** There are currently no concentrations of use reported for these ingredients. The expectation is that they would be used at concentrations comparable to others in this group.*

TABLES

Table 1. Definitions and reported functions[1]

Ingredient/CAS No	Definition	Reported Functions
Cocoyl Hydrolyzed Collagen (CAS No. 68952-15-8)	Cocoyl Hydrolyzed Collagen is the condensation product of coconut acid chloride and hydrolyzed collagen	hair conditioning agents skin-conditioning agents – misc. surfactants-cleansing agents
Potassium Cocoyl Hydrolyzed Collagen (CAS No. 68920-65-0)	Potassium Cocoyl Hydrolyzed Collagen is the potassium salt of the condensation product of coconut acid chloride and hydrolyzed collagen.	hair conditioning agents; skin-conditioning agents – misc; surfactants - cleansing agents
Sodium Cocoyl Hydrolyzed Collagen (CAS No. 68188-38-5)	Sodium Cocoyl Hydrolyzed Collagen is the sodium salt of the condensation product of coconut acid chloride and hydrolyzed collagen	hair conditioning agents skin-conditioning agents – misc surfactants-cleansing agents
TEA-Cocoyl Hydrolyzed Collagen (CAS No. 68952-16-9)	TEA-Cocoyl Hydrolyzed Collagen is the triethanolamine salt of the condensation product of coconut acid chloride and hydrolyzed collagen.	hair conditioning agents; skin-conditioning agents – misc; surfactants - cleansing agents

Table 2. Historical and updated frequency (RLD/VCRP) and concentration 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*	
	RLD (2024)[8]	VCRP (2023)[11]	VCRP (2001)[3]	% (2025)[9]	% (2001)[3]	RLD (2024)[8]	VCRP (2023)[11]	VCRP (2001)[3]	% (2025)[9]	% (2001)[3]
Totals*	**32**	**2**	**64**	**0.01**	**0.05-20**	**3**	**NR**	**20**	**NR**	**1**
summarized by likely duration and exposure**										
Duration of Use										
Leave-On	***	*1*	*4*	*0.01*	*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	0.01	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	NR	1	NR	NR
Bath Preparations										
Bath Oils, Tablets, and Salts						NR	NR	1	NR	NR
Bubble Baths						NR	NR	3	NR	1
Eye Makeup Preparations (not children's)										
Eye Lotion	NR	1	NR	NR	NR					
Fragrance Preparations										
Perfumes						NR	NR	1	NR	NR
Hair Preparations (non-coloring)	***17***					***1***				
Hair Conditioners						NR	NR	1	NR	NR
Hair Sprays (aerosol fixatives)						NR	NR	1	NR	NR
Hair Straighteners	NR	NR	2	NR	NR					
Permanent Waves	12	NR	18	NR	1	NR	NR	2	NR	NR
Rinses (non-coloring)	2	NR	NR	NR	NR					
Shampoos (non-coloring)	1 (r.o.)	1	6	NR	1-20	NR	NR	3	NR	NR
Tonics, Dressings, and Other Hair Grooming Aids	2	NR	2	NR	NR					
Other Hair Preparations	NR	NR	1	NR	NR	1	NR	NR	NR	NR
Hair Coloring Preparations	***5***									
Hair Dyes and Colors (all types requiring caution statements and patch tests)	NR	NR	21	NR	5					
Hair Tints	NR	NR	9	NR	NR					
Hair Shampoos (coloring)	4 (r.o.)									
Other Hair Coloring Preparation	1 (l.o.)	NR	NR	NR	NR	1 (l.o.)	NR	NR	NR	NR
Makeup Preparations (not eye; not children's)										
Blushers and Rouges (all types)										
Foundations						NR	NR	1	NR	NR
Lipstick and Lip Glosses										
Makeup Bases										

Table 2. Historical and updated frequency (RLD/VCRP) and concentration 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*	
	RLD (2024)[8]	**VCRP (2023)[11]**	**VCRP (2001)[3]**	**% (2025)[9]**	**% (2001)[3]**	**RLD (2024)[8]**	**VCRP (2023)[11]**	**VCRP (2001)[3]**	**% (2025)[9]**	**% (2001)[3]**
Manicuring Preparations										
Nail Creams and Lotions	NR	NR	NR	NR	0.05					
Personal Cleanliness	***1***									
Other Personal Cleanliness Products	1 (r.o.)	NR	NR	NR	NR	NR	NR	1	NR	NR
Shaving Preparations										
Shaving Creams (aerosol, brushless, lather)						NR	NR	1	NR	NR
Other Shaving Preparation Products	NR	NR	1	NR	NR					
Skin Care Preparations	***9***					***2***				
Cleansing	NR	NR	3	NR	NR	NR	NR	4	NR	NR
Face and Neck (excluding shaving preparations)	9 (l.o.)	NR	NR	0.01	NR					
Body and Hand (excluding shaving preps)										
Moisturizing	NR	NR	1	NR	0.2	2	NR	NR	NR	NR
Other Skin Care Preparations										
Other Preparations (i.e., those preparations that do not fit another category)										

NR – not reported; l.o. – leave-on; r.o. – rinse-off

*The total FOU provided for RLD refers to the ingredient count supplied by FDA, and is not a summation of the number of uses per category because each product may be categorized under multiple ***product*** categories. For data supplied via the VCRP or by the Council survey, the sum of all exposure types may not equal the sum of total uses because each ingredient may be used in cosmetics with multiple ***exposure*** types.

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

***Because RLD are product-centric and not ingredient-centric, each ingredient may be reported under several product categories, making a summation of RLD misleading in comparison to VCRP data. Accordingly, RLD are presented below by product category (as supplied by FDA), but are not summarized by likely duration and exposure.

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

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	Cocoyl Hydrolyzed Collagen			Sodium Cocoyl Hydrolyzed Collagen		
	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use
	RLD (2024)[8]	VCRP (2023)[11]	% (2025)[9]	RLD (2024)[8]	VCRP (2023)[11]	% (2025)[9]
Totals*	**104**	**2**	**NR**	**1**	**NR**	**1.1**
summarized by likely duration and exposure**						
Duration of Use						
Leave-On	***	*2*	*NR*	***	*NR*	*NR*
Rinse-Off	***	*NR*	*NR*	***	*NR*	*1.1*
Diluted for (Bath) Use	***	*NR*	*NR*	***	*NR*	*NR*
Exposure Type						
Eye Area	***	NR	NR	***	NR	NR
Incidental Ingestion	***	NR	NR	***	NR	NR
Incidental Inhalation-Spray	***	NR	NR	***	NR	NR
Incidental Inhalation-Powder	***	NR	NR	***	NR	NR
Dermal Contact	***	2	2	***	NR	1.1
Deodorant (underarm)	***	NR	NR	***	NR	NR
Hair - Non-Coloring	***	NR	NR	***	NR	NR
Hair-Coloring	***	NR	NR	***	NR	NR
Nail	***	NR	NR	***	NR	NR
Mucous Membrane	***	NR	NR	***	NR	NR
Baby Products	***	NR	NR	***	NR	NR
as reported by product category						
Bath Preparations	***1***					
Bath Oils, Tablets, and Salts	1	NR	NR			
Eye Makeup Preparations (not children's)						
Eye Lotion						
Hair Preparations (non-coloring)	***14***					
Hair Conditioners	2 (r.o)	NR	NR			
Permanent Waves						
Rinses (non-coloring)						
Shampoos (non-coloring)	4 (r.o)	NR	NR			
Tonics, Dressings, and Other Hair Grooming Aids						
Other Hair Preparations	4 (l.o): 4 (r.o)	NR	NR			
Hair Coloring Preparations						
Hair Shampoos (coloring)						
Other Hair Coloring Preparation						
Makeup Preparations (not eye or children's)	***42***					
Blushers and Rouges (all types)	11	NR	NR			
Lipstick and Lip Glosses	30	NR	NR			
Makeup Bases	1	NR	NR			
Personal Cleanliness				***1***		
Other Personal Cleanliness Products				1 (r.o)	NR	1.1
Skin Care Preparations	***46***					
Cleansing	9	NR	NR			
Face and Neck (excluding shaving preps)	14 (l.o); 10 (r.o)	2	NR			
Body and Hand (excluding shaving preps)	10 (l.o)	NR	NR			
Moisturizing	12	NR	NR			
Night	1	NR	NR			
Other Skin Care Preparations	8 (l.o)	NR	NR			
Other Preparations (i.e., those preparations that do not fit another category)	***1***					

NR – not reported; NA – not applicable (this category was not part of the VCRP)
l.o. – leave-on; r.o. – rinse-off
*The total FOU provided for RLD refers to the ingredient count supplied by FDA, and is not a summation of the number of uses per category because each product may be categorized under multiple ***product*** categories. For data supplied via the VCRP or by the Council survey, the sum of all exposure types may not equal the sum of total uses because each ingredient may be used in cosmetics with multiple ***exposure*** types.
**Likely duration and exposure are derived from VCRP and survey data based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)
*** In the RLD each ingredient may be reported under several product categories, making a summation of RLD misleading in comparison to VCRP data. Accordingly, RLD are presented below by product category (as supplied by FDA), but are not summarized by likely duration and exposure.
[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b] It is possible these products are powders, but it is not specified whether the reported uses are powders.
[c] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

Table 4. Dermal irritation and sensitization studies

Test Article	Vehicle	Concentration/Dose	Test Population/System	Protocol	Results	Reference
IRRITATION						
IN VITRO						
Cocoyl Hydrolyzed Collagen	none	undiluted	EpiDerm™ human epidermal model, developed with human epidermal keratinocytes	EpiDerm™ dermal irritation test DBPS was used as the negative control, SLS was the positive control	Nonirritating tissue viability was approximately 90% Controls gave expected results	14
ANIMAL						
Potassium Cocoyl Hydrolyzed Collagen (30% active matter)	distilled water	10% active matter	6 New Zealand White rabbits	24-h occlusive patch (2.5 cm x 2.5 cm) on shaved abraded and non-abraded skin. Untreated control sites were shaved abraded and non-abraded skin	Non-irritating; PII = 0	6
Potassium Cocoyl Hydrolyzed Collagen; 30% aq. solution (number average MW, 600)	none	neat; 0.5 ml	3 male New Zealand White rabbits	4-h occlusive patch applied to clipped intact and abraded skin of the back (2.5 x 2.5 cm)	mild irritant; PII = 1.7 Very slight to well-defined erythema and very slight edema,	5
Potassium Cocoyl Hydrolyzed Collagen (% active matter not specified)	water	neat; 0.5 ml	6 New Zealand White rabbits,	24-h occlusive patch (2.5 cm x 2.5 cm) on shaved abraded and non-abraded skin. Untreated control sites were shaved abraded and non-abraded skin	mild irritant; PII = 1.59 Pronounced erythema on both test sites of all animals at 24 h after application; the effect was diminished but present in 5 animals at 72 h.	6
HUMAN						
Potassium Cocoyl Hydrolyzed Collagen; 30% aq. solution (number average MW, 600)	none	neat	25 female subjects	24-h occlusive patch test on the back of the subjects	No reaction at 30-60 min or 24 h after patch removal	5
SENSITIZATION						
ANIMAL						
Potassium Cocoyl Hydrolyzed Collagen (30% active matter)	distilled water	10% dilution of 30% active matter	15 Pirbright guinea pigs 10 treated, 5 control	Buehler method; test article was applied 1x/wk for 3 wk. Challenge was performed after 14 d (6-h patch)	No contact hypersensitivity was observed	6
HUMAN						
formulation containing 0.1% Cocoyl Hydrolyzed Collagen	none	neat	102 subjects	HRIPT; occlusive patches	Not an irritant or sensitizer	15
emulsion containing 0.058% Potassium Cocoyl Hydrolyzed Collagen	none	tested neat; 0.2 ml	51 subjects	HRIPT Induction consisted of 3, 24-h occlusive patches/wk for 3 wk Challenge was performed following a 2-wk non-treatment period	Not an irritant or sensitizer	16
formulation containing 3.2% Potassium Cocoyl Hydrolyzed Collagen,	NR	undiluted	50 subjects	Primary and accumulated dermic irritation evaluation.	No significant cutaneous reaction observed.	17
Potassium Cocoyl Hydrolyzed Collagen 30% aq, solution (number average MW, 600)	none	neat; 0.2 ml	50 subjects	HRIPT Induction consisted of 3, 24-h occlusive patches/wk for 3 wk Challenge was performed following a 2-wk non-treatment period	Not an irritant or sensitizer	5
PHOTOSENSITIZATION						
ANIMAL						
Potassium Cocoyl Hydrolyzed Collagen (9% active matter)	not provided	not provided	Pirbright guinea pigs 10 males and 10 females/group	The skin was assessed 2, 6, and 24 h after retesting and 2, 6, 24 and 48 h after depilation.	No photosensitizing effect	6

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