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

Status:	Draft Amended Report for Panel Review
Release Date:	November 8, 2024
Panel Meeting:	December 2 - 3, 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.; 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, M.B.A. This safety assessment was prepared by Thushara Diyabalanage, Ph.D., Senior Scientific Analyst/Writer, CIR.

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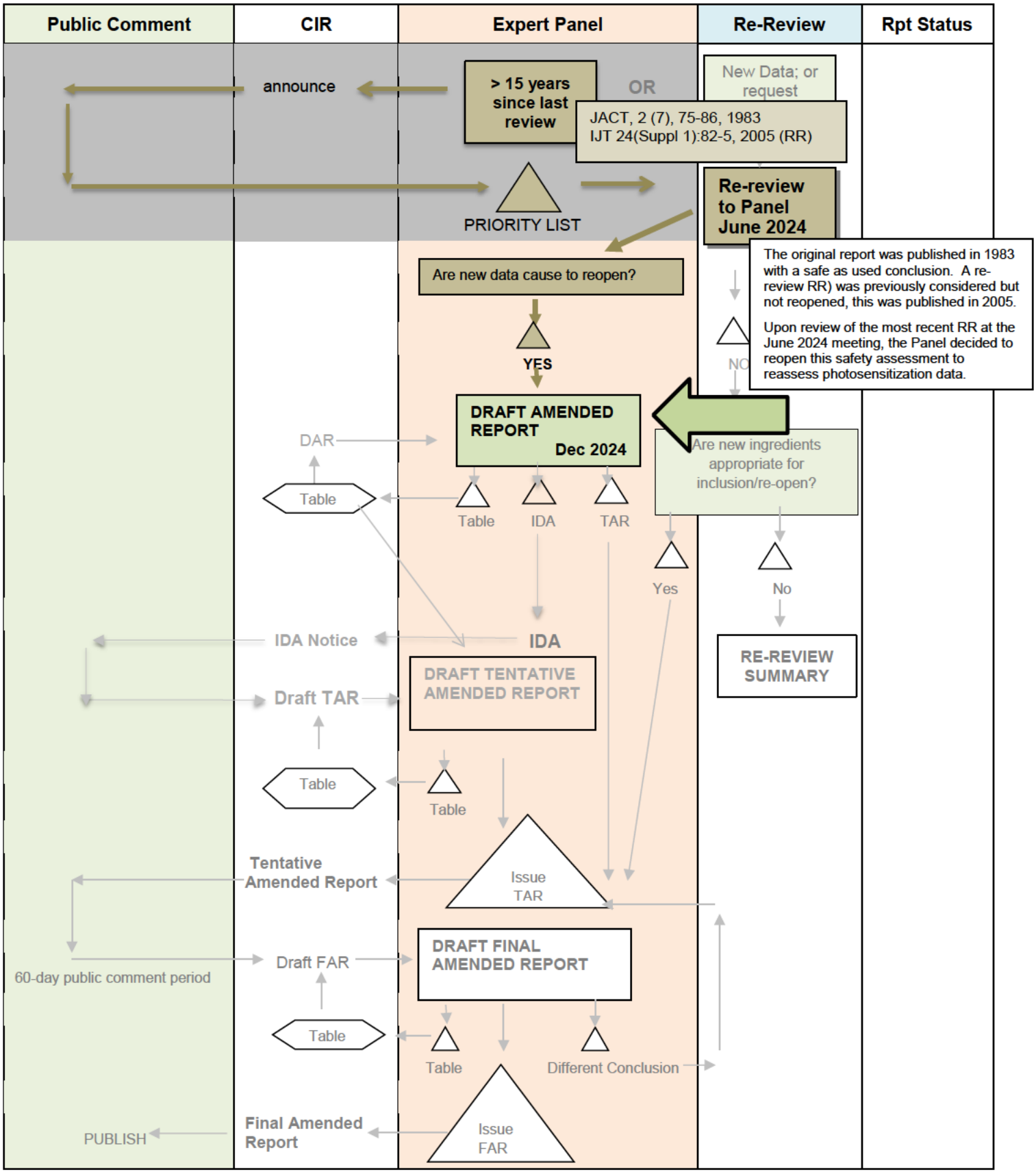
RE-REVIEW FLOW CHART

INGREDIENT/FAMILY Potassium & TEA-Cocoyl Hydrolyzed Collagen

MEETING December 2024



Cosmetic Ingredient Review

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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: November 8, 2024
Subject: Draft Amended Report of the Safety Assessment of Potassium and TEA-Cocoyl Hydrolyzed Collagen

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a Final Report on the Safety Assessment of Potassium-Coco- Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein in 1983 (identified as *originalreport1983_HydrolyzedCollagens_122024* 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* have subsequently changed, and are now Potassium Cocoyl Hydrolyzed Collagen (CAS No. 68920-65-0) and TEA-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_PotassiumCocoylHydrolyzedCollagens_122024*).

Because it has been at least 15 years since the previous re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety assessment of Potassium and TEA-Cocoyl Hydrolyzed Collagen should be re-opened. A comprehensive literature search conducted in April 2024 and subsequent searches performed in October 2024 did not find any new data. Based on 2023 FDA VCRP data, it is evident that the use of these ingredients has decreased substantially since the last re-review. For instance, according to 2023 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 (*data_HydrolyzedCollagens_122024*); 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). RLD indicate that Potassium Cocoyl Hydrolyzed Collagen has 32 uses and TEA-Cocoyl Hydrolyzed Collagen has 3 applications

However, in June 2024, the Panel concluded that some of the sensitization and photosensitization data included in the original report needs to be re-investigated and decided to re-open the safety assessment of Potassium and TEA-Cocoyl Hydrolyzed Collagen. Therefore, along with a Draft Amended Report, the following documents are included for your review:

- original safety assessment (*originalreport1983_HydrolyzedCollagens_122024)*
- initial rereview (*rereview2005_HydrolyzedCollagens_122024)*
- flow chart (*flow_ HydrolyzedCollagens_122024*)
- report history (*history_HydrolyzedCollagens_122024*)
- search strategy (*search_HydrolyzedCollagens_122024*)
- data profile (*dataprofile_HydrolyzedCollagens_122024*)
- history *(history_HydrolyzedCollagens_122024)*
- transcripts from the meeting at which the re-review was discussed (*trancripts_HydrolyzedCollagens_122024*)
- the minutes from all the meetings at which Potassium and TEA-Cocoyl Hydrolyzed Collagen was discussed during the original review *(originalminutes_HydrolyzedCollagens_122024)*

If no further data are needed, the Panel should formulate an updated Discussion and issue a Tentative Amended Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an Insufficient Data Announcement.

CIR History of:

Potassium Cocoyl Hydrolyzed Collagens

1983

First Safety Assessment- The Panel concluded that both Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagens were safe as used in cosmetics

2002

Re-reviewed, the Panel decided to not to re-open and re-affirmed their earlier conclusion.

June 2024

Panel decided to reopen the safety assessment of these ingredients expecting to revisit some of the safety information related to sensitization and photosensitization.

Potassium and TEA Hydrolyzed Collagen Data Profile* – December 2024 Thushara Diybalanage

				Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	log P/log K_{ow}	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Potassium and TEA Hydrolyzed Collagen	XO	O	O		O	O		O		O			O	O		O	O			O	O		O	O	O		O	O	

* "X" indicates that new data were available in a category for the ingredient. "O" indicates data were reported in the original safety assessment.

Pyrogallol

Ingredient	CAS #	PubMed	FDA	HPVIS	NIOSH	NTIS	NTP	FEMA	EU	ECHA	ECETOC	SIDS	SCCS
Potassium Cocoyl Hydrolyzed Collagen TEA-Cocoyl Hydrolyzed Collagen	68920-65-0	√	√	√	√	√	√	√	√	√	√	√	√
TEA-Cocoyl Hydrolyzed Collagen	68952-16-9	√	√	√	√	√	√	√	√	√	√	√	√

Search Strategy

PubMed

Search included key words 'Potassium Cocoyl Hydrolyzed Collagen', TEA-Cocoyl Hydrolyzed Collagen', and Hydrolyzed Collagen

Typical Search Terms (this is informational – not for inclusion for search strategy that goes to the Panel)

- INCI names
- CAS numbers
- chemical/technical names
- additional terms will be used as appropriate

LINKS

Search Engines

- Pubmed - http://www.ncbi.nlm.nih.gov/pubmed
  - appropriate qualifiers are used as necessary
  - search results are reviewed to identify relevant documents
- Connected Papers - https://www.connectedpapers.com/
- DeepDyve - https://www.deepdyve.com/

Pertinent Websites

- wINCI - https://incipedia.personalcarecouncil.org/winci/ingredient-custom-search/
- FDA Cosmetics page - https://www.fda.gov/cosmetics
- eCFR (Code of Federal Regulations) - https://www.ecfr.gov/
- FDA search databases: https://www.fda.gov/industry/fda-basics-industry/search-databases
- Substances Added to Food (formerly, EAFUS): https://www.fda.gov/food/food-additives-petitions/substances-added-food-formerly-eafus
- GRAS listing: https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras
- SCOGS database: https://www.fda.gov/food/generally-recognized-safe-gras/gras-substances-scogs-database
- Inventory of Food Contact Substances Listed in 21 CFR: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives
- Drug Approvals and Database: https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases
- FDA Orange Book: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book
- OTC Monographs - https://dps.fda.gov/omuf
- Inactive Ingredients Approved For Drugs: https://www.accessdata.fda.gov/scripts/cder/iig/
- FEMA (Flavor & Extract Manufacturers Association) GRAS: https://www.femaflavor.org/fema-gras
- HPVIS (EPA High-Production Volume Info Systems) - https://iaspub.epa.gov/oppthpv/public_search.html_page
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
  - technical reports search page: https://ntrl.ntis.gov/NTRL/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/

- EUR-Lex - https://eur-lex.europa.eu/homepage.html
- Scientific Committees (SCCS, etc) opinions: https://health.ec.europa.eu/scientific-committees_en https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en
- ECHA (European Chemicals Agency – REACH dossiers) – https://echa.europa.eu/
- European Medicines Agency (EMA) - http://www.ema.europa.eu/ema/
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- http://webnet.oecd.org/hpv/ui/Search.aspx
- EFSA (European Food Safety Authority) - https://www.efsa.europa.eu/en
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - http://www.ecetoc.org
- AICIS (Australian Industrial Chemicals Introduction Scheme)- https://www.industrialchemicals.gov.au/
- International Programme on Chemical Safety http://www.inchem.org/
- Office of Dietary Supplements https://ods.od.nih.gov/
- FAO (Food and Agriculture Organization of the United Nations) - http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/
- WHO (World Health Organization) IRIS library - https://apps.who.int/iris/
- a general Google and Google Scholar search should be performed for additional background information, to identify references that are available, and for other general information - www.google.com https://scholar.google.com/

POTASSIUM COCOYL HYDROLYZED COLLAGEN (BELSITO GROUP)

3RD JUNE 2024

DR. BELSITO: So, hydrolyzed animal protein and triethanolamine-coco-hydrolyzed animal protein in 1983 was reviewed. We concluded that they were safe as cosmetic ingredients in the present practice of use as described in the report. Since 1983, the names for the two ingredients have been changed. They are now potassium cocoyl hydrolyzed collagen and triethanolamine cocoyl hydrolyzed collagen, respectively. We reviewed these in 2002, reaffirmed the '83 conclusion.

So, it's been 15 years, and we're being asked to look at any new data, determine whether it needs to be reopened. An extensive scouring of the literature was done in April of 2024. No new relevant data were found in the literature.

Don't worry, Preethi, we moved on to a re-review.

And also is a current and historical use data. Basically, 2023 VCRP data, potassium cocoyl hydrolyzed collagen in two formulation, TEA-cocoyl hydrolyzed collagen, no reported uses. 2001, the ingredients were

used in 64 and 20 formulations, respectively. Council survey in 2022, there were no concentrations of use reported. 2001, 20 percent non-coloring shampoo for the potassium cocoyl hydrolyzed, and TEA-cocoyl hydrolyzed, maximum of one percent in bubble baths. And so, that's our status.

The original report had sensitization at 10 percent and HR (inaudible) -- no other studies (inaudible). Okay.

So, my concern in not reopening it is that we will continue with the prior conclusion on this. And when I looked at the original report, there were reports of sensitization at 10 percent, and an HRIPT, and also positive photosensitization. There were no other studies to determine a non-sensitizing level. We have no concentration of use in this report, but prior uses of up to 20 percent in rinse-offs. I guess it's 0.2. I think I missed a decimal point. Or it's 0.02 in leave-ons. So, do we want to let that safety assessment sit out there?

I guess I wasn't on the Panel then, but I don't like having something, data, out there that says it photosensitizes and was a sensitizer at 10 percent; and

it's being used in a bubble bath at 20 percent; and even though low concentration of leave-on, we don't a safe level of use in terms of sensitization, but photosensitizers are even of greater concern.

DR. EISENMANN: I wouldn't expect any data on these.

DR. BELSITO: I wouldn't either.

DR. EISENMANN: So, that's gonna be the problem.

DR. BELSITO: But then we would go insufficient rather than currently we say it's safe as used, based upon that old report. Right. If we don't reopen it, that's safe-as-use conclusion is out there with data giving percentages of how it was used in 2002. And I'm not sure that if I reviewed even the old data I would say that it's safe at those levels of use. I would want additional studies; in which case, it would go insufficient. Then per our ruling in two years, the conclusion would be whatever it is now. It's not --

DR. HELDRETH: Use not supported.

DR. BELSITO: Use not supported. Which I would prefer rather than having a document out there saying that this is safe as used, and we didn't reopen it when I looked

at the old data and I wasn't so happy with the data that I saw, even though the use concentrations and the number of uses have declined.

DR. HELDRETH: Between now and when we would look at it again, we'll likely have Cosmetics Direct data. If that shows that there really are no reported uses at all, then when it was concluded, it would immediately go to insufficient data conclusion, zero use, as the conclusion instead of use not supported.

DR. BELSITO: Right. I think just for that reason -- again, looking at the old reports --

DR. SNYDER: Don, I support that motion to reopen and bring it up to date regarding the sensitization data.

DR. BELSITO: Yeah. And the photosensitization.

DR. SNYDER: Correct.

DR. BELSITO: Okay. Okay. So, now we can break for lunch. Allan, you have the report. You have the data that I need for the reports when my computer was down?

DR. RETTIE: Yes, I think we have --

DR. BELSITO: Can we meet now and do that? Shouldn't take long.

DR. RETTIE: Sure, assuming I have them. Maybe we

need Curt as well. He'd been making notes.

DR. BELSITO: I thought you were writing it down. Curt took --

DR. KLAASSEN: Not me, but I'll listen.

DR. RETTIE: So, where we starting?

DR. KLAASSEN: I think it was -- Don, did you do the first two?

POTASSIUM COCOYL HYDROLYZED COLLAGEN (COHEN GROUP)

JUNE 3RD 2024

DR. COHEN: Yeah. Potassium-coco-hydrolyzed animal protein and triethanolamine-coco-hydrolyzed animal protein. This was first published in 1983 with a safe as used conclusion. The names of the two ingredients have subsequently changed and now are potassium cocoyl hydrolyzed collagen and triethanolamine cocoyl hydrolyzed collagen respectively. The Panel considered re-review in 2002 and reaffirmed the 1983 conclusion.

It's been some time, over 15 years, so we're looking at it again. Based on the VCRP, potassium cocoyl

hydrolyzed collagen is used in two formulations and the TEA cocoyl hydrolyzed collagen has no reported use. These had much more reported use in 2001. According to a council survey, no concentration of use were reported. In the past, it was used up to 20 percent in some shampoo and the TEA one percent in bubble bath.

The question to us is do we reopen? There didn't seem to be a lot of additional data to warrant a reopening.

DR. TILTON: I agree.

DR. ROSS: Agreed.

DR. COHEN: We're not going to reopen. As far as we can tell. Should we break before we go to the next one?

DR. BERGFELD: Yeah.

DR. ROSS: We can do the next one of these.

DR. COHEN: Okay.

POTASSIUM COCOYL HYDROLYZED COLLAGEN (Full panel)

4th June 2024

DR. COHEN: Yes, so this group, Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-

Hydrolyzed Animal Protein, was published in 1983 with a conclusion of safe as used in the present practice. The name on the two ingredients had subsequently changed to Potassium Cocoyl Hydrolyzed Collagen and Triethanolamine-Cocoyl Hydrolyzed Collagen respectively.

The Panel considered rereview in 2002 and reaffirmed the 1983 conclusion. The use of these ingredients has decreased substantially since the last review. And based on the data that we were presented, our motion was to not reopen.

DR. BERGFELD: Response?

DR. BELSITO: We didn't agree with that.

DR. BERGFELD: Okay.

DR. COHEN: Okay.

DR. BELSITO: If you look at the original report, there was sensitization at 10 percent and an HRIPT, and also a report of photosensitization. We had no information as to how to determine a non-sensitizing level for these. We have no concentration of use in this report, but the prior uses that would be referred to if we don't reopen it would be 20 percent in rinse-offs and I think 0.2 percent in leave-ons. I think we need to reopen it to reassess

that photosensitization report. They report some sensitization at 10 percent. And, perhaps, again, with the new FDA reporting, get a sense of where these are being used. And if they are not being used, then we can accept the fact we have no concentration of use. If they are being used, then I think we need a concentration of use given the sensitization that was in the initial reports. I don't know how that got through, quite honestly.

DR. COHEN: Okay, so you want a re-adjudication of the conclusion from the last report, because it's not that long ago we have no concentration of use from the survey, right. So, you're hoping to get concentration of use from the survey, what if we don't have that?

DR. BELSITO: Well, then I think we have an issue with sensitization and photosensitization, don't we?

DR. COHEN: Okay, so, no reason not to amend my motion to reopen.

DR. BERGFELD: Is there a second to reopen?

DR. BELSITO: Second.

DR. BERGFELD: Any further discussion? Seeing none, call the question, all those in favor raise your hand, please.

DR. SNYDER: I agree.

DR. BERGFELD: Thank you. Thank you, Paul. Unanimous. And moving on to the last item is Dr. Belsito's group for MoS vs MoE.

DRAFT

MINUTES OF THE TWENTY-SECOND MEETING OF THE EXPERT PANEL

December 12-13, 1983

Olde Town Holiday Inn

Alexandria, Virginia

Expert Panel Members

Karl H. Beyer, Jr., M.D., Ph.D., Chairman

Wilma F. Bergfeld, M.D.

William O. Berndt, Ph.D.

Roswell K. Boutwell, Ph.D.

William W. Carlton, D.V.M., Ph.D.

Dietrich K. Hoffmann, Ph.D.

Arnold L. Schroeter, M.D.

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Robert L. Elder, Sc.D., Director

Teresa Crawford, Administrator

Liaison Representatives

Consumer

Ms. Anne Averyt

Industry

Gerald N. McEwen, Jr., Ph.D.

FDA Contact Person

Heinz Eiermann

Adopted _____
(Date)

_____

Karl H. Beyer, Jr., M.D., Ph.D.

Chairman

[redacted]

2. Hydrolyzed Animal Protein

The following conclusion of the report was unanimously approved:

"On the basis of the available animal and clinical data presented in this report, the Panel concludes that Hydrolyzed Animal Protein is safe as a cosmetic ingredient in the present practices of use and concentration."

Subject to minor revisions, the document will shortly be announced as a Tentative Report. Dr. McEwen said the CTFA adopted name for this ingredient has been changed to Hydrolyzed Collagen. Once this is confirmed in writing, the change will be incorporated into the report.

[redacted]

INTRODUCTION

This assessment reviews the safety of Potassium and TEA-Cocoyl Hydrolyzed Collagen as used in cosmetic formulations. The two ingredients are salts of the condensation products of coconut fatty acids and hydrolyzed collagen. According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (*Dictionary*), these ingredients are reported to function as hair and skin conditioning agents and as a surfactant - cleansing agent (Table 1).[1]

The Expert Panel for Cosmetic Ingredient Safety (Panel) conducted a review of the safety of Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein 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 names of these two ingredients as listed in the *Dictionary* had subsequently been changed and are now Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen , respectively. The Panel previously considered a re-review of this report in 2002 and reaffirmed the 1983 conclusion, as published in 2005.[3] Since it has been at least 15 years since the last review, the Panel decided to undertake a rereview of these ingredients and decided to re-open the safety assessment to re-evaluate existing endpoints, particularly sensitization and photosensitization.

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 October 2024. All these searches employing many different search strategies indicated that there were no significant scientific developments or changes in safety information. 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.

CHEMISTRY

Definition and Structure

Potassium Cocoyl Hydrolyzed Collagen (CAS No. 68920-65-0) is the potassium salt of the condensation product of coconut acid chloride and hydrolyzed collagen, whereas TEA-Cocoyl Hydrolyzed Collagen (CAS No. 68952-16-9) is the triethanolamine salt of the condensation product of coconut acid chloride and hydrolyzed collagen.[2] (Table 1.) The general formula for both of 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 or TEA cation.[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. 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.[2]

Method of Manufacture

The source of collagen is chrome-leather splitting. This protein is hydrolyzed into short chained polypeptides by acids, base or enzymes[2]. The polypeptide chain fragments generated vary in length and molecular weight 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 ratio vary with the increasing molecular weight of the product. If the molecular weight is less than 600, the fatty acid moiety predominates whereas when the molecular weight 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 from a salt.

Composition/Impurities

The impurities reported for Potassium Cocoyl Hydrolyzed Collagen include the unreacted starting materials; coconut fatty acid, hydrolyzed collagen and inorganic salts such as sodium chloride, sodium sulfate, potassium chloride and potassium sulfate.[2] The impurities reported for TEA-Cocoyl Hydrolyzed Collagen include coconut fatty acid, hydrolyzed collagen, triethanolamine sulfate, sodium chloride, and sodium sulfate.

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 these ingredients 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). 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 terminated in 2023, and as of 2024, manufacturers and processors have been mandated to register and list their products (and ingredients therein) with the FDA (i.e., RLD). Consequently, RLD are product-centric, whereas VCRP data were ingredient-centric. However, because there are numerous differences in the ways the data for the VCRP and the RLD were collected and processed, it is not appropriate to contrast data from the VCRP and RLD to determine a trend in frequency of use.

The use of these ingredients has decreased substantially since the last re-review. Based on 2023 FDA VCRP data, Potassium Cocoyl Hydrolyzed Collagen was reported to be used in 2 formulations and TEA-Cocoyl Hydrolyzed Collagen has no reported use;[5] in 2001, these ingredients were used in 64 and 20 formulations, respectively[3] (Table 2). According to the Council survey that was conducted in 2022, no concentrations of use were reported for either ingredient;[6] 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).[3] According to RLD received in 2024, Potassium Cocoyl Hydrolyzed Collagen has 32 uses whereas TEA-Cocoyl Hydrolyzed Collagen has 3 reported uses.[7]

Some products containing these ingredients may be marketed for use with airbrush delivery systems; however, this information is not available from the VCRP, RLD, or the Council survey. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. The airbrush delivery system used for cosmetic application has not been evaluated by the CPSC, nor has the use of cosmetic ingredients in airbrush technology been evaluated by the FDA. Moreover, 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 frequency and concentrations of use of these ingredients, and without consumer habits and practices data or particle size data related to this use technology, 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.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Both Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen were tested for acute oral toxicity using rats.[2 3] *According to these studies, Potassium Cocoyl Hydrolyzed Collagen was orally administered to 20 rats at 10.4-29.5 g/kg and an LD_{50} value of 18.2 g/kg observed. Administration of TEA-Cocoyl Hydrolyzed Collagen at a dose of 15.89-44.9 g/kg indicated an LD_{50} value of 27.3 g/kg. These results showed that both ingredients are practically nontoxic when administered orally at the specified dosage.*

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

Animal

Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen were tested for potential skin irritancy in rabbits.[2] *The Draize method was used in all studies. Potassium Cocoyl Hydrolyzed Collagen was reported to be non-irritating to slightly irritating when applied at a 10% concentration and undiluted Potassium Cocoyl Hydrolyzed Collagen was mildly irritating; erythema was the only skin response observed. At a concentration of 10%, TEA-Cocoyl Hydrolyzed Collagen was determined to be non-irritating to rabbit skin, and without dilution, it was found to be slightly to mildly irritating in two studies. One study reported erythema, edema, and eschar formation and concluded that undiluted TEA-Cocoyl Hydrolyzed Collagen is severely irritating (PII = 3.05; maximum score = 8).*

Human

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

Sensitization

Animal

Potassium Cocoyl Hydrolyzed Collagen (0.1 ml of a 0.1% solution) was administered intracutaneously to the shaved skin of two white male guinea pigs [2] *The injections were made every other day, 3 times weekly, until a total of 10 injections*

were administered.[2] *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, challenge scores were compared with induction scores. Because Potassium Cocoyl Hydrolyzed Collagen elicited no response to neither induction nor challenge injections it was considered to be non-sensitizing under the test conditions.*

In order to determine potential sensitization, two samples of each of Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen at 10% were tested according to Buehler method. None of the guinea pigs (20 per ingredient) showed reactions to test or challenge patches. Therefore, both ingredients were considered to be non-sensitizing in all four tests at the given concentration.

Human

Involving a group of 168 subjects, a human-repeated insult patch test (HRIRT) was performed using 0.1 ml of 10% aq. Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen.[2] *Occlusive patches (24-h) were applied to the back of each subject, 3 times/wk for 3 wk. . After a 3-wk period, the test areaans a previously untreated site, were challenged using the same procedure. The sites were scored for sensitization at 24, 48, and 72 h. Five subjects challenged with Potassium Cocoyl Hydrolyzed Collagen were reported to have significant erythema, and were challenged at concentrations of 2.4, 5, and 10%. During a rechallenge, scores were obtained at 24, 48, 72 h. The results of both the initial and subsequent challenge indicated that Potassium Cocoyl Hydrolyzed Collagen produced allergic contact sensitization in 2 subjects, cumulative irritation in 2 additional subjects, and a mild nonspecific irritation in a fifth subject. The 2 subjects who were sensitized to Potassium Cocoyl Hydrolyzed Collagen were also sensitized to TEA-Cocoyl Hydrolyzed Collagen.*

Phototoxicity

Under the regulations of the German Association for Light Research, 1% aq. solutions of Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen were tested on 10 subjects.[2] *The investigators reported no UVB phototoxicity and no UVA phototoxicity when the treated skin was exposed to 7.5 J/cm^2 (15 min PUVA 6001).*[2] *A group of 28 of the original 168 subjects tested for irritation and sensitization discussed above were randomly selected to test the ability of Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen to induce phototoxic or photosensitive reaction following ultraviolet exposure. The test protocols were the same apart from the fact 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 (4.4μW/cm^{2}at the skin surface measured at 360nm wavelength peak). The UVB applied at 2 times the minimal erythema dose (MED) to 9 subjects from a 150-W 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 ingredients. There was one additional subject who was considered by the investigators to be photosensitized by both ingredients at the original challenge site at 72 h. Only TEA-Cocoyl Hydrolyzed Collagen gave similar value for this subject when challenged at a previously untreated site.*

OCULAR IRRITATION STUDIES

Both Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen were tested for eye irritation in rabbits at 10, 25, 50, and 100% concentrations.[2] *One-tenth (0.1) ml of each test material was instilled into one eye of 6 rabbits with the contralateral eye serving as the control. Observations were made after 1, 2, and 8 h and each day for 1 wk. The solutions containing 10% Potassium or TEA-Cocoyl Hydrolyzed Collagen were minimally irritating, with the most irritation (conjunctional only) subsiding by the second day of testing. The solutions containing 25% Potassium or TEA-Cocoyl Hydrolyzed Collagen were defined as mildly irritating, and the irritation disappeared after the second day. At a second concentration of 50%, Potassium and TEA-Cocoyl Hydrolyzed Collagen also caused mild irritation; however, irritation (corneal and conjunctival) lasted during the duration of the experiment. Undiluted Potassium and TEA-Cocoyl Hydrolyzed Collagen caused moderate irritation, which also lasted the duration of the test.*

In other studies, both Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen were tested at concentration of 10 and 100% for eye irritation. The Draize method was used as the procedure, but an unknown method was used for scoring irritation. Each ingredient at a concentration at 10% caused minor conjunctival irritation which cleared by 72 h. The researchers concluded that these materials were "practically nonirritating' at the concentration tested. When the undiluted ingredient was instilled into the eyes of the rabbits, severe irritation developed in the cornea, iris and/or conjunctiva. Irritation persisted throughout the 72-h period, and therefore, these ingredients were considered eye irritants.

CLINICAL STUDIES

A large number of healthy subjects and people 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.*

In another study, Potassium and TEA-Cocoyl Hydrolyzed Collagen 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 8 had skin diseases (psoriasis and eczema) and many were being treated for illness (i.e. migraines, allergies, diabetes). There were 29 healthy

subjects. Approximately 1.5 mg/cm^2 of each ingredient was 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% Potassium Cocoyl Hydrolyzed Collagen occurred in patients with psoriasis.[2]

SUMMARY

The Panel conducted a safety assessment on Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen 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, as published in 2005, the Panel reviewed the safety information related to the these two ingredients and decided to not re-open a safety assessment, re-affirmed the 1983 conclusion. In June 2024, since more than 15 years have passed since the last review, the Panel decided to reopen the safety assessment to re-evaluate existing endpoints, particularly sensitization and photosensitization.

The use of these ingredients has decreased substantially since the last re-review. Based on 2023 FDA VCRP data, Potassium Cocoyl Hydrolyzed Collagen was reported to be used in 2 formulations and TEA-Cocoyl Hydrolyzed Collagen has no reported use; in 2001, these ingredients were used in 64 and 20 formulations, respectively,

DISCUSSION

To be developed.

CONCLUSION

To be determined.

TABLES

Table 1. Definitions and reported functions of Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen

Ingredient/CAS No	Definition	Reported Functions
Potassium Cocoyl Hydrolyzed Collagen CAS No. 68920-65-0	the potassium salt of the condensation product of coconut acid chloride and hydrolyzed collagen. The general formula is provided in Figure 1.	hair conditioning agents; skin-conditioning agents – miscellaneous; surfactants - cleansing agents
TEA-Cocoyl Hydrolyzed Collagen CAS No. 68952-16-9	is the triethanolamine salt of the condensation product of coconut acid chloride and hydrolyzed collagen. The general formula is provided in Figure 1.	hair conditioning agents; skin-conditioning agents – miscellaneous; surfactants - cleansing agents

Table 2. 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)[7]	VCRP (2023)[5]	VCRP (2001)[3]	% (2022)[6]	% (2001)[3]	RLD (2024)[7]	VCRP (2023)[5]	VCRP (2001)[3]	% (2022)[6]	% (2001)[3]
Totals*	**32**	**2**	**64**	**NR**	**0.05-20**	**3**	**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	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*									
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					
Hair Coloring Preparations	*5*					*1*				
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.)					1 (l.o.)	NR	NR	NR	NR
Makeup Preparations (not eye; not children's)										
Foundations						NR	NR	1	NR	NR
Manicuring Preparations										
Nail Creams and Lotions	NR	NR	NR	NR	0.05					

Table 2. 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)[7]	VCRP (2023)[5]	VCRP (2001)[3]	% (2022)[6]	% (2001)[3]	RLD (2024)[7]	VCRP (2023)[5]	VCRP (2001)[3]	% (2022)[6]	% (2001)[3]
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	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.)									
Moisturizing	NR	NR	1	NR	0.2	2	NR	NR	NR	NR

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.

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5

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

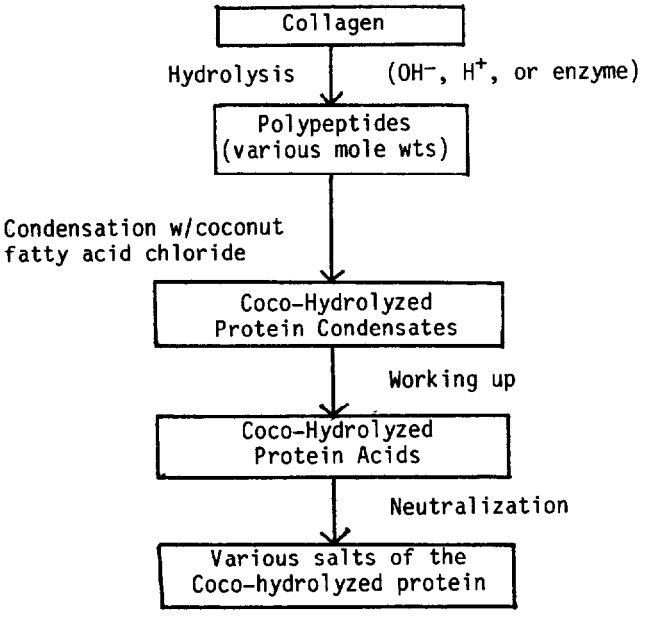
Structure

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.

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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.

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.

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Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council (PCPC)

DATE: October 28, 2022

SUBJECT: Concentration of Use by FDA Product Category: Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen

Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen were included in a PCPC concentration of use survey. No uses were reported.