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

Status:	Draft Final Amended Report for Panel Review
Release Date:	February 17, 2026
Panel Meeting Date:	March 12-13, 2026

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.; Samuel M. Cohen, M.D., Ph.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., former Scientific Analyst/Writer, CIR.

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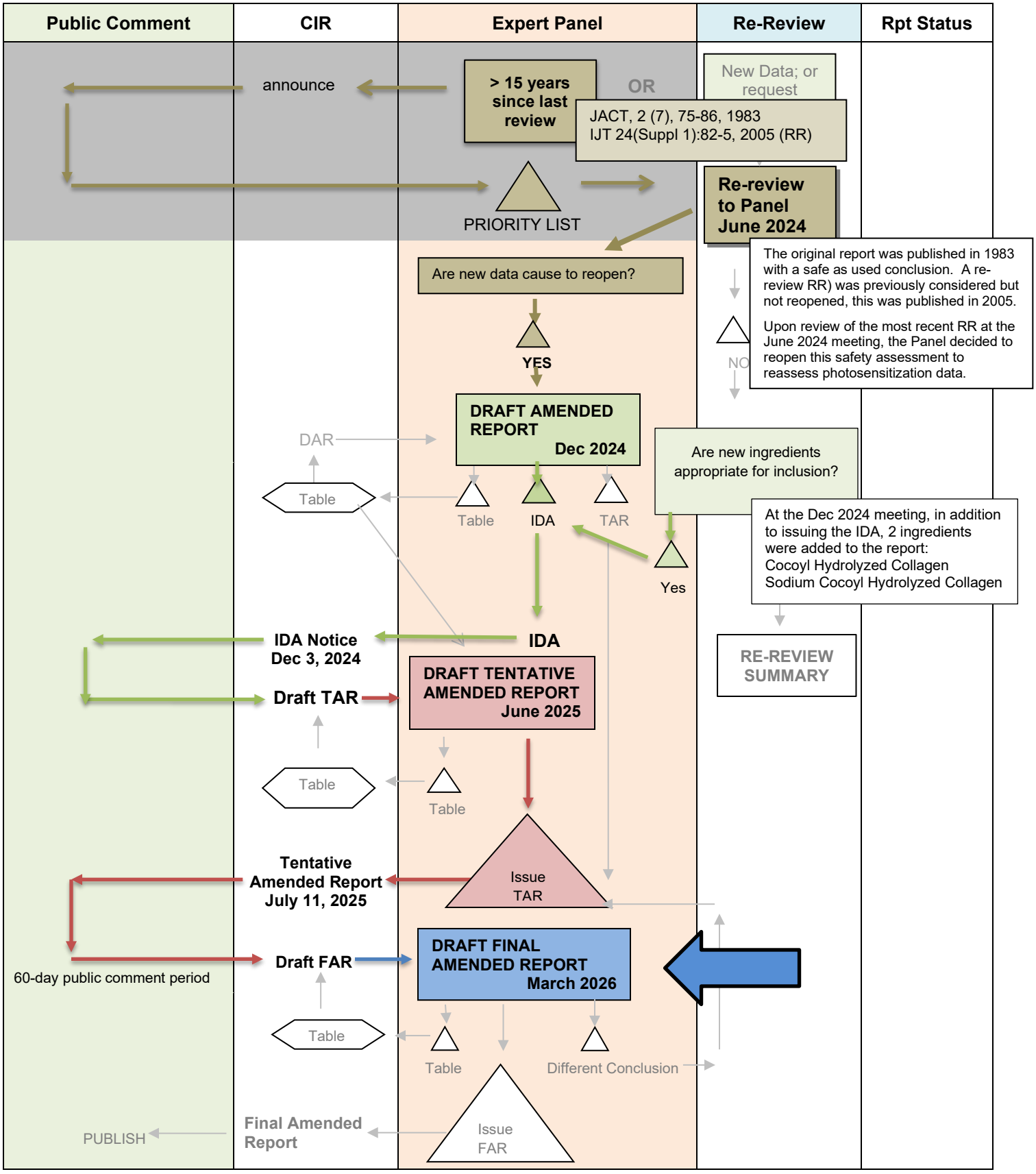
RE-REVIEW FLOW CHART

INGREDIENT/FAMILY Cocoyl Hydrolyzed Collagen Ingredients

MEETING March 2026



Cosmetic Ingredient Review

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice Fiume, M.B.A.
Senior Director, CIR
Date: February 17, 2026
Subject: Draft Final Amended Report on the Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics

Enclosed is the Draft Final Amended Report on the Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics. (It is identified as *report_HydrolyzedCollagens_032026* in the pdf document.) At the June 2025 meeting, the Panel issued a Tentative Amended Report with the conclusion that the 4 cocoyl hydrolyzed collagen ingredients are safe in cosmetics in the present practices of use and concentrations described in this safety assessment. For 2 ingredients, there are currently no concentrations of use reported; therefore, it is noted that the expectation is that they would be used at concentrations comparable to others in this group.

An update to the concentration of use survey was received (*data_HydrolyzedCollagen_032026*). This update was incorporated, and the newly added data are identified with yellow highlighting. Also now included in the March Panel version of the report are updated RLD that were received in 2025; the information added to the text of the Use section in this March version of the report is highlighted in blue for your attention. (Please note that the only changes highlighted in the Use table are the updated total number of uses and any new categories reported to have use in 2025.)

Comments were received from the Council on the Tentative Amended Report (*PCPCcomments_HydrolyzedCollagen_032026*). The comments were editorial in nature and have been addressed (*response-PCPCcomments_HydrolyzedCollagen_032026*).

The original report, the initial re-review summary, and the following supporting documents are included in this report package:

- flow chart (*flow_ HydrolyzedCollagen_032026*)
- history (*history_HydrolyzedCollagen_032026*)
- data profile (*dataprofile_HydrolyzedCollagen_032026*)
- search strategy (*search_HydrolyzedCollagen_032026*)
- transcripts from the meetings discussing the current report (*transcripts_HydrolyzedCollagen_032026*)
- minutes from the past reviews (*originalminutes_HydrolyzedCollagen_032026*)
- original report (*originalreport1983_HydrolyzedCollagen_032026*)
- original re-review summary (*rereview2005_HydrolyzedCollagen_032026*)

The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Amended Report.

CIR History of:

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, as published in 2005.

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.

December 2024

The Panel issued an insufficient data announcement (IDA). The IDA contained data needs for concentration of use, sensitization and UV absorption spectra (if absorbed, phototoxicity and photosensitization data) at maximum use concentrations.

The Panel also decided to add Cocoyl Hydrolyzed Collagen and Sodium Cocoyl Hydrolyzed Collagen to this safety assessment.

June 2025

Unpublished data that were received in response to the IDA have been added to the report. The Panel issued Tentative Amended Report with the conclusion that these ingredients are safe in cosmetics in the present practices of use and concentrations described in this safety assessment.

Cocoyl Hydrolyzed Collagens - Data Profile* – December 2025

					Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	UV Absorption	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	Clinical Report	Case Reports
Cocoyl Hydrolyzed Collagen	X																			X					X		X			
Potassium Cocoyl Hydrolyzed Collagen	X	**XO**	XO	X					O												XO	XO		XO	XO	XO		O	O	
Sodium Cocoyl Hydrolyzed Collagen	X																													
TEA-Cocoyl Hydrolyzed Collagen	X	**O**	O						O												O	O		O	O	O		O		X

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

Cocoyl Hydrolyzed Collagens

Ingredient	CAS #	PubMed	FDA	HPVIS	NIOSH	NTIS	NTP	FEMA	EU	ECHA	ECETOC	SIDS	SCCS	AICIS	FAO	WHO	Web
Cocoyl Hydrolyzed Collagens	68952-15-8	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Cocoyl Hydrolyzed Collagens	68188-38-5	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Potassium 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', Hydrolyzed Collagen Cocoyl and Sodium Cocoyl Hydrolyzed Collagens.

Search Engines Used

- 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/

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

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

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: August 5, 2025

SUBJECT: Tentative Amended Report: Amended Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics (posted July 11, 2025)

The Personal Care Products Council respectfully submits the following comments on the tentative amended report, Amended Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics.

Abstract – Since the definition of Cocoyl Hydrolyzed Collagen (and its salts) refers to the INCI definition of Hydrolyzed Collagen (which is: "hydrolysate of animal or fish collagen derived by acid, enzyme or other method of hydrolysis"), "may be derived from animal-sources" needs to be revised to "are derived from animal-sources".

Introduction – As there is more than one ingredient in this re-review, "this ingredient" needs to be corrected to "these ingredients".

Dermal Irritation and Sensitization; Summary; Table 4 – Please check table 2 of reference 17. This study did include a challenge exposure with dermal evaluations after challenge (on days 36, 37 and 38) and found that the product containing 3.2% Potassium Cocoyl Hydrolyzed Collagen was not sensitizing. This conclusion should also be added to the description of this study.

Case Reports – Please delete "In" in "In a clinical study was conducted to investigate"

Summary – It is not correct to state that "TEA-Cocoyl Hydrolyzed Collagen is listed in EU Annex IIII". Trialkylamines, trialkanolamines and their salts are listed in EU Annex III and this listing applies to TEA-Cocoyl Hydrolyzed Collagen.

Cocoyl Hydrolyzed Collagens – December 2025	
Comment	**Response/Action**
Abstract – Since the definition of Cocoyl Hydrolyzed Collagen (and its salts) refers to the INCI definition of Hydrolyzed Collagen (which is: "hydrolysate of animal or fish collagen derived by acid, enzyme or other method of hydrolysis"), "may be derived from animal-sources" needs to be revised to "are derived from animal-sources".	Addressed.
Introduction – As there is more than one ingredient in this re-review, "this ingredient" needs to be corrected to "these ingredients".	Addressed.
Dermal Irritation and Sensitization; Summary; Table 4 – Please check table 2 of reference 17. This study did include a challenge exposure with dermal evaluations after challenge (on days 36, 37 and 38) and found that the product containing 3.2% Potassium Cocoyl Hydrolyzed Collagen was not sensitizing. This conclusion should also be added to the description of this study.	Addressed.
Case Reports – Please delete "In" in "In a clinical study was conducted to investigate"	Addressed.
Summary – It is not correct to state that "TEA-Cocoyl Hydrolyzed Collagen is listed in EU Annex IIII". Trialkylamines, trialkanolamines and their salts are listed in EU Annex III and this listing applies to TEA-Cocoyl Hydrolyzed Collagen.	Addressed.

JUNE 2024 PANEL MEETING – INITIAL REVIEW/RE-REVIEW

Belsito Team – June 3, 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?

Cohen Team - [June 3, 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.

Full Panel – June 4, 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.

DECEMBER 2024 MEETING – 2ND REVIEW/DRAFT AMENDED REPORT

Belsito Team – December 2, 2024

DR. BELSITO: Okay. So, when we left off, we were about to start cocoyl hydrolyzed collagen. And basically if you recall that this was up for a re-review because it had been more than 15 years since the last was published and there was a comprehensive literature search that was performed but the real reason for determining to reopen this was that in the original report there were some issues with sensitization and photosensitization that were not dealt with, I thought, at least adequately.

And so, we decided to reopen and take a look at that and also the new data that had come in. So, basically, I think that my take on this was that the data are insufficient, and we don't have a level below which sensitization is not seen. We also don't have a UV spectrum. Looking at the chemical formula I don't think it would absorb but I'll leave that to Allan, perhaps, to discuss. But I think if it does absorb in the A or the B range then we would need additional tests to rule out photosensitization and photo irritation. One of which could be like a ROS assay or other tests.

But that's where I was left with this ingredient that we don't have a level below which we don't have a clear NOAEL for sensitization and I'm not sure about this photosensitization data and it's used up to ten percent, is that correct?

DR. ZHU: Yes.

DR. BELSITO: Yeah. And sensitization and photosensitization were seen at ten percent, and I think the use may be higher than ten percent.

DR. EISENMANN: The current use, I got no concentration of use in 2022.

DR. BELSITO: Okay.

DR. EISENMANN: So that's the old use concentration.

DR. BELSITO: Okay. So then also insufficient for concentration of use. Paul, Curt, Allan?

DR. SNYDER: I agree.

DR. BELSITO: Okay, so we're going to go out with --

DR. RETTIE: I'm good.

DR. BELSITO: -- go ahead, Allan.

DR. KLAASSEN: Under method of manufacture, the last line, a fatty acid is neutralized with either Tea -- I think that should be capital E and capital A, I'd assume, rather than like coffee we want to have a tetraethylammonium.

DR. BELSITO: Where -- I'm sorry, Curt. I couldn't follow you.

DR. KLAASSEN: On methods of manufacture --

DR. BELSITO: What PDF?

DR. KLAASSEN: Last line --

DR. RETTIE: Twenty.

DR. KLAASSEN: -- it's -- what?

DR. RETTIE: PDF 20.

DR. KLAASSEN: Yeah, PDF page 20, methods of manufacture. It's just a small thing but we have tea, T-E-A, that should be a capital E or upper-case E, upper case A.

DR. BELSITO: Right.

DR. KLAASSEN: It should be tetraethylammonium and not --

DR. BELSITO: Yeah. Anything else?

DR. EISENMANN: In the dictionary cocoyl hydrolyzed collagen and sodium cocoyl hydrolyzed collagen are there and we have suppliers listed for all four ingredients so when I'm going out to suppliers I just feel I should do all four rather than just the two whether or not you decide -- because the data -- if somebody has data on the sodium it would support these other two, right?

DR. BELSITO: So, are we bringing these two into the report?

DR. EISENMANN: I don't know if you're going to bring them in or not, but I just feel like it makes sense to bring them in.

DR. BELSITO: Okay.

DR. EISENMANN: If you're going to spend a lot of time doing this report, doesn't it? I mean, that's my question. It's really a question.

DR. BELSITO: Yeah, I wasn't aware of the other two so what were the other two?

DR. EISENMANN: Well, cocoyl hydrolyzed collagen and sodium cocoyl hydrolyzed collagen. Which I don't have concentrations of use for but if I'm going to go out and ask for concentration of use on the two, I might as well add the other two to the survey.

DR. BELSITO: Sure. The more the merrier and there may be data on the other two that would support safety.

DR. EISENMANN: Right.

DR. BELSITO: Okay. So, we're going to add in cocoyl hydrolyzed collagen and sodium cocoyl hydrolyzed collagen to this. Allan, are you okay with that?

DR. RETTIE: I am.

DR. BELSITO: Curt, Paul?

DR. KLAASSEN: Yes.

DR. SNYDER: Yeah, I agree with that.

DR. BELSITO: Okay.

DR. SNYDER: Thank you, Carol for catching that.

DR. BELSITO: We're going to ask for concentration of use and also, we need a sensitization at concentration of use and UV spec and if it absorbs in the A or B range, other tests to evaluate photo irritation and photosensitization. Anything else? Okay, if not --

DR. RETTIE: Actually, one thing. We actually have a phototoxicity section in here. Good, but we don't seem to have --

DR. BELSITO: That's where this report got opened Allan. That was in the old report. That's not new data.

DR. RETTIE: Right. We have DART, genotox, and carcinogenicity tables but we have no sections in the report. Is that right? Yes.

DR. BELSITO: This is -- yeah. But those tables are summarizing old data. This is a report that we're reopening.

DR. RETTIE: Oh, yeah. Right, right, right. Got it.

DR. BELSITO: Anything else, Allan? Allan, anything else?

DR. RETTIE: Nothing.

DR. BELSITO: Okay.

Cohen Team – December 2, 2024

[**DR. COHEN:** Okay, Potassium Cocoyl Hydrolyzed animal protein and Triethanolamine Cocoyl Hydrolyzed animal protein. This was first published in 1983, with the conclusion that they were safe. The names of the ingredients had subsequently changed to what we're using now. The Panel considered a re-review of the report in 2002, and reaffirmed the 1983 conclusion as published in 2005, and it's been 15 years.

Based on the VCRP data, use has substantially decreased with the Potassium Cocoyl, and two formulations in the TEA Cocoyl Hydrolyzed Collagen having no reported uses. In 2001, reported concentration of use was 20 percent in a non-coloring shampoo and for TEA Cocoyl Hydrolyzed Collagen at 1 percent in a bubble bath. The RLD has 32 uses for Potassium Cocoyl Hydrolyzed Collagen and three for TEA Cocoyl Hydrolyzed Collagen.

In June, we reopened this because we wanted to reinvestigate sensitization and photosensitization data. So, this is before us today.

There is a description of the HRIPT at 10 percent for the Potassium Cocoyl Hydrolyzed Collagen and the TEA Cocoyl Hydrolyzed collagen with a few cases having some erythema and then ultimately a couple having some irritation. There was also a UVA study done here for photosensitization with UVA and UVB.

I'll open it up. The first comment was these are pretty large molecular weight products, aren't they? I mean they're mixtures, right, but aren't they pretty large molecular weight?

DR. ROSS: Yeah, I mean there should be -- I'm just looking at the dossier. Do we have that information?

DR. BERGFELD: It's 143.57.

DR. COHEN: Is that right with the collagen? When I looked it up outside I got much larger numbers.

DR. BERGFELD: It's in Table 1.

DR. TILTON: They are mixtures of different chain links, yes.

DR. COHEN: So having reopened this, does anyone have any comments about any data needs that they have?

DR. ROSS: Yeah.

DR. TILTON: We don't have current concentration of use.

DR. COHEN: Right, but --

DR. ROSS: I think we need -- as Susan said, we don't have concentrations of use. We need sensitivity data at the maximum concentration of use. We need photosensitivity data at maximum concentration of use. And I was a bit confused whether the current photosensitivity data was at a frequency of one of 28, or one of 19, or one of 9, which is how they subdivided the groups for the different UVA, UVB?

DR. COHEN: I'm not sure the dose of the light was.

DR. ROSS: Oh, is that right? Okay.

DR. COHEN: It seemed a little low considering like the summer sun can be 6 to 7 microwatts per centimeter squared. But I think under the test conditions it was Okay. What we're getting at here is that we have 10 percent HRIPT and we have 2001 concentration of use of 20 percent in a wash off product. But we don't have a lot of -- there's not much out there that these are problems.

And I thought the molecular weights would be larger. And by the way, what PDF was the molecular weight, again?

DR. BERGFELD: It's Table 1.

DR. ROSS: Yeah, I didn't see it in Table 1.

DR. BERGFELD: Chemical properties.

DR. COHEN: I'm looking at Table 1, it says definitions and reported functions on PDF 24.

DR. BERGFELD: I have it printed out.

DR. COHEN: Am I looking at the wrong thing?

DR. ROSS: I didn't see it there, so maybe I'm looking at the wrong thing.

DR. COHEN: Table 1 is PDF 24, Wilma? Is that what you're talking about?

DR. BERGFELD: I'm not looking at a PDF, I'm looking at print, so I don't have that.

DR. COHEN: Does your Table 1 say definitions and reported functions?

DR. BERGFELD: No, it says chemical properties.

DR. ROSS: If you go to method of manufacture section, there's some discussion there.

DR. COHEN: Okay.

DR. DIYABALANAGE: It's less than 600.

DR. ROSS: Yeah, well, if --

DR. BERGFELD: What did you say it was?

DR. ROSS: It's on PDF 20.

DR. DIYABALANAGE: It's permanently higher than 600.

DR. ROSS: So, yeah, they're pretty big.

DR. BERGFELD: I don't see that. I see under chemical properties on that same area 143.5- --.

DR. DIYABALANAGE: It's under method of manufacture.

DR. ROSS: Yeah, the middle of that method of manufacture paragraph.

MS. FIUME: Can a collagen weight vary?

DR. COHEN: Yeah, depending on the chain, right?

DR. ROSS: Yeah, a lot.

DR. DIYABALANAGE: They have different sizes.

MS. FIUME: Yeah.

DR. ROSS: And they're just talking about the polypeptide here, Thushara, to the fatty acid. No, they're not. Yeah. Nevertheless, to answer your question, they're big.

DR. COHEN: Yeah. Look, I think if this were a new report, I'd be coming at it a little harder. It's been around for a long time; we don't seem to see a lot of issues from them. We have a 10 percent concentration; the max use is on a wash off product. The max use for TEA Cocoyl Hydrolyzed Collagen is 1 percent and we have HRIPT at 10 times of that. I'm just wondering how hard I would of pushed this.

So, we need concentration of use which is old. But, Monice, aren't we going to hear that we got the survey and we didn't get it back, right? So we're not going to get that. And then we're going to say we want irritation and sensitization at a use from 20 some odd years ago, that was reaffirmed after the data that we already have seen.

DR. ROSS: Yeah, that was the concern when, I think, Don drove this, to reopen it. That the historical use was 20 percent and there were some reports of sensitization and photosensitization at 10 percent. So I don't think we need irritation. I think we need sensitivity and photosensitivity at maximum use.

DR. COHEN: Okay. Got it.

DR. BERGFELD: Can I interject? It has no uses now; it says it in the text.

DR. ROSS: Yeah.

DR. BERGFELD: Is that correct? At this point in time there's no use? And it's Annex 2 in Europe.

DR. COHEN: Well, we have uses from the RLD.

DR. DIYABALANAGE: RLD, yeah.

DR. BERGFELD: But the survey showed no uses?

DR. COHEN: Right, but I don't think we can any longer say there's no uses if the RLD is showing a use. Right?

DR. BERGFELD: Okay.

DR. COHEN: And the VCRP, in 2023, show 2 uses for Potassium Cocoyl Hydrolyzed Collagen.

MS. FIUME: David, as far as concentration of use, this was surveyed in 2022. And I don't think Carol is in this team and I don't know if Kim or Kathy can speak to it. I don't know if there are differences in response since the RLD information has become available, it could be higher or lower just because of everything they've had to do to submit to the FDA. So I don't know if something would be expected at this point that didn't come in two years ago as far as concentration of use because the survey is two years old.

DR. ROSS: Did someone say it was Annex 2? I must have missed that.

DR. BERGFELD: Yeah, I did.

DR. TILTON: Not this ingredient.

DR. ROSS: I don't think so, no.

DR. COHEN: I didn't know that.

DR. BERGFELD: I saw it here under uses, I think.

MS. FIUME: I don't think we have any European data for the hydrolyzed collagens.

DR. ROSS: Yeah, I'm not seeing it in here, but.

DR. COHEN: All right, look, we'll see how this is presented tomorrow. But it's been surveyed. We're using 23-year old concentration of use data, and the survey went out two years ago. We have sensitization at 10x the TEA Cocoyl Hydrolyzed Protein, and we have sensitization at half of max use on a wash off product. So we go out with the IDA and probably won't get anything, but we can try. But then we're faced with going out with the IDA having no data, and then what? Going out with an insufficient data conclusion?

DR. ROSS: Yeah.

DR. COHEN: Yes? Based on data that was adjudicated 20 some odd years ago as okay to use and very -- almost -- not zero, but very little data in the literature about this being a problem.

DR. ROSS: I agree there wasn't -- I didn't have too much of an issue with it.

DR. COHEN: I found three articles. By the way, I have three that'll be in my return that I don't think were listed in the report. Maybe they were, but I didn't see, maybe.

MS. FIUME: What wasn't listed, David?

DR. COHEN: A case report of allergic contact dermatitis to TEA Cocoyl Hydrolyzed Protein in the archives of Derm in 1976. Maybe it's there when I search. And that was by Emmett. There's a contact urticaria from protein hydrolysates in hair conditioners and an allergy in 1998. And hydrolyzed protein shampoo additives are not a common contact allergen, by Rycroft and McFadden, in contact dermatitis in 2000.

DR. ROSS: David, I guess the crux of this issue, if I can just ask you a quick question here, is the human HRIPT with 10 percent, we had a frequency of erythema of 5 out of 168. And the photosensitivity, it was 1/28. Or it could be 1/19 or one out of 9. But anyway, are those numbers problems?

DR. COHEN: Maybe we need to report -- maybe we need the raw data?

DR. ROSS: But my question is, would you see those as problems?

DR. COHEN: Yes, they certainly drew attention, but it said erythema no induration.

DR. ROSS: Okay.

DR. COHEN: Right. So I'm not sure if I read these as positive. And they were rechallenged. And during the rechallenge, 2 subjects produced allergic contact sensitization. So it went from 5 to 2, I don't know how that happens.

DR. ROSS: Yeah.

DR. COHEN: So, Okay. But the group looked at that and cleared it. Unless it was -- what we're saying, unless it was an error, right? But it's in the report. It's not an error in the report, right? It's not like a typo or something. It's in the report and the conclusion is made.

And then over the -- you know I haven't seen much in 24 years on this, but there was a little action on this, in '98 and '2000, indicating it's not a common sensitizer.

Okay. Look, we need concentration of use, sensitization of photo tox at max use. All right. I think we need to have another discussion about this.

DR. ROSS: Correct.

DR. TILTON: Yeah. You mentioned the fact that the 20 percent was in a rinse off. And I think the max concentration and leave on, the bubble baths was only 0.2 percent. That is much lower than the HRIPT, but it would be good to have current concentrations of use, certainly.

DR. COHEN: We all agree on the data needs. We've just been around the block a few times to fast forward and figure out how this is going to be figured through later on. Okay. There's nothing more to talk about on this. Can I go to Inositol?

DR. ROSS: Absolutely.

Full Panel – December 3, 2024

DR. BELSITO: Yeah. The Potassium Cocoyl Hydrolyzed Collagen and TEA-Cocoyl Hydrolyzed Collagen. We had looked at these in 1983 and concluded that they were safe as cosmetic ingredients in the present practice of use as described in the report. The names have been changed since that time. Then in 2002, we did a re-review and we reaffirmed the 1983 conclusion and that was published in 2005.

Because it was 15 years since the previous re-review was published it is up for re review at this time. A comprehensive literature search was conducted in April of 2024, and performed in October 2024, didn't find any new data. However, in June, we concluded that some of the sensitization and photosensitization data included in the original report needed to be reinvestigated and decided to reopen this.

And so, it has been reopened and I remain concerned about the sensitization and the photosensitization that's reported in this. I thought that this was insufficient for concentration of use, a use level below which sensitization is not seen, UV spectrum and if it absorbs in the A or B range, assays to assess for phototoxicity and photosensitization would be necessary.

And, Carol, I think you mentioned that there were two other ingredients that could be added to this report?

DR. EISENMANN: Yes, the dictionary includes Cocoyl Hydrolyzed Collagen itself and Sodium Cocoyl Hydrolyzed Collagen. And I looked at the suppliers and some of the suppliers have all four, so I feel comfortable going out to the suppliers and asking for data on all of them rather than just two.

DR. BELSITO: Right. So we would recommend that those two ingredients be added to this report.

DR. COHEN: So, Don, you had sensitization at max use was in your IDA?

DR. BELSITO: Yeah, concentration of use and then the use level below which sensitization is not seen. I mean, they could use sensitization at concentration of use or a negative sensitization study above that, I don't care. But they need to show me at what level they can use this product.

DR. COHEN: Okay. Second.

DR. BERGFELD: All right. So we had a second. Any other comments about this insufficient report? I'll call to question. All those opposed to this decision? Abstaining? It goes forward as an insufficient data announcement. Okay. Any comments about the editorials? Okay.

JUNE 2025 MEETING – 3RD REVIEW/DRAFT TENTATIVE AMENDED REPORT

Belsito Twam – June 9, 2025

DR. SNYDER: All right, Cocoyl Hydrolyzed Collagens. It was a Draft Tentative Amended Report. In 1983, we said it was safe as used. In 2002, we re-reviewed it and we reaffirmed the conclusion. In June of 2024, we reopened to re-look at sensitization and photosensitization data, and to add two ingredients. we came out as insufficient data.

We needed maximum concentration of use, dermal irritation and sensitization, UV absorption spectra, and we receive new data that covers all the insufficient needs. Is that not true?

DR. BELSITO: Correct.

DR. SNYDER: So now we're saying safe is used again?

DR. BELSITO: Yep. I think we just need to look at our guidelines for TEA and make sure the Discussion and Conclusion are in agreement with these.

DR. RETTIE: I'd just like to say I really like the IDA --

DR. BELSITO: Allan, microphone.

DR. RETTIE: I'd just like to compliment on the writers and putting together the IDA data needs in a table, the bottom of PDF 4. I've been finding these really useful summaries this go around. So, if that's new, thank you for that.

DR. SNYDER: All right, anything else? All right. The last one is Paeonia suffruticosa. This is a Draft Final Report. In December of 2020.

DR. BELSITO: Oh, wait, can I just add one thing? I'm sorry, Paul, on these Cocoyl Hydrolyzed Collagens.

DR. SNYDER: Yep. That's okay.

DR. BELSITO: I just thought, in the Discussion, that we should add that we noted the hydrolyzed proteins would not absorb into human tissue, reducing the risk of toxicity. And this mitigated the need for systemic tox data. Because we don't have a lot of systemic tox data here.

DR. SNYDER: Okay.

DR. BELSITO: And that we also wanted, since the hydrolyzed collagen should be free of detectable pathogenic viruses, prions, and other pathogenic agents. I mean, all of that was in the original.

DR. SNYDER: Yeah. Got it.

DR. BELSITO: Okay. Sorry.

DR. SNYDER: That's okay. No, that's fine.

Cohen Team – June 9, 2025

DR. DAVID COHEN: Okay. Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein. This is a Final Report. No, it is not?

MS. FIUME: It's a Tentative. It's a Draft Tentative.

DR. ROSS: Second round.

DR. DAVID COHEN: Oh, this is a Draft Final?

MS. FIUME: Draft Tentative Amended.

DR. DAVID COHEN: Draft Tentative Amended.

DR. ROSS: We added two ingredients.

MS. FIUME: And it went IDA at the last -- in December, and two ingredients were added.

DR. ROSS: Yeah.

DR. DAVID COHEN: Okay, hold on. All right. We had some name changes that are described. At the June meeting we reopened the assessment for Potassium and TEA-Cocoyl Hydrolyzed Collagen, concluding that some of the sensitization and photosensitization data included in the original report needed to be reinvestigated, right?

After reviewing the Draft Amended Report in December 2024, the Panel decided to add two ingredients: Cocoyl Hydrolyzed Collagen and Sodium Cocoyl Hydrolyzed Collagen.

All right. Let me just make some changes here. All right. So we had the review in December and issued an Insufficient Data Announcement requesting the following for the four ingredients: max use concentration, dermal irritation and sensitization at maximum concentration of use, and UV absorption spectrum, if absorbed, phototox and photosensitization.

We received data on dermal irritation and sensitization and photosensitivity. I think that's where I want to stop for a moment and open for comments.

DR. TILTON: So we --

DR. DAVID COHEN: Yeah, thank you, Susan.

DR. TILTON: The report was primarily reopened to assess the potential for sensitization and photosensitization, even prior to the two ingredients being added. And so, we had received data for the Potassium Collagen with no UV absorption, lack of dermal irritation and sensitization in animals, and in HRIPT, lack of ocular irritation in vivo up to 10 percent.

And although there's no concentration of use reported in products around the eye, the overall max use concentration is 0.1 percent. So that would be well below the 10 percent tested that caused ocular toxicity in vivo.

So, I didn't have any concerns with the Potassium Collagen. And then, it looked like for the Collagen overall, the data was consistent with that that we had already seen, including dermal irritation and sensitization and HRIPT under occlusive conditions. I would be okay with safe as used for the group.

DR. SAM COHEN: I just had the question, what's the issue with the triethanolamine in Annex III in Europe as a source for nitrosation? And is that an issue that we need to worry about that says that there are no products in 2023, with DEA salt? So it wouldn't be an issue if we're not even addressing that salt.

DR. DIYABALANAGE: I think it's related to the possibility of formation of indigenous nitrosation.

DR. ROSS: Yeah.

DR. DIYABALANAGE: Yeah.

DR. ROSS: So they just want to minimize that.

DR. DAVID COHEN: So how are we concluding?

DR. SAM COHEN: If you have to avoid nitrosation, you can't use the Triethanolamine salt at all. So that one we wouldn't approve then, right?

MS. FIUME: We do have boilerplate language for nitrosation.

DR. SAM COHEN: Okay, good.

MS. FIUME: I will find it. It basically says to -- rather than paraphrase, let me find it.

DR. TILTON: I think it says not to be used with nitrosamines systems.

MS. FIUME: Nitrosating agents. Yeah.

DR. SAM COHEN: Yeah.

DR. TILTON: That would have been how it was -- is that how it was approved before?

DR. ROSS: I think it's just to minimize – obviously, the nitrosamines in the product. I think it's fine if we have that in.

MS. FIUME: Right.

DR. SAM COHEN: Yeah, it says that one of the criteria is that the secondary amine be low and less than 50 micrograms per kilogram of nitrosamine content in the product. But I'm just wondering if the low nitrosating ability, does that exclude TEA as one of the components? Was that one of the things that just led to the Annex III classification in Europe?

DR. ROSS: I think they were concerned with the nitrosating systems, weren't they? It says not to be used with nitrosating systems in the Annex III.

MS. FIUME: All the cosmetic ingredients that have TEA have the same caveat under their entry. They're all reflected back to the TEA restrictions. And so, the boilerplate language in the discussion, we would say it should not be used in cosmetic products in which N-nitroso compounds can be formed. And then you discuss the rationale behind it.

And then, in the Conclusion in the past it's stated, "The Panel cautions that ingredients should not be used in cosmetic products in which N-nitroso compounds can be formed." So it's been done in both the Discussion and the Conclusion before.

DR. SAM COHEN: Then, for these substances, there's really no tox data at all. There's no genotox, DART, carci data, repeat-dose tox?

DR. ROSS: Well, there's no systemic toxicity concerns that I saw with Potassium and TEA. They're practically non-toxic orally. No dermal or toxicity data with the Cocoyl or the Sodium derivative.

DR. SAM COHEN: Yeah, but in the table it doesn't have any boxes checked for the various toxic endpoints.

DR. ROSS: Yeah, I saw that.

DR. DAVID COHEN: Yeah the table is devoid of any Xs or Os.

DR. SAM COHEN: Yeah.

DR. ROSS: Well, that's why I mentioned this.

DR. DAVID COHEN: We have no hugs or kisses in any of those sections.

DR. SAM COHEN: It just worried me that how can we evaluate a --

DR. DIYABALANAGE: (Inaudible) after the last meeting. (Inaudible).

DR. DAVID COHEN: Right.

DR. DIYABALANAGE: And for them, like -- so there's no old report. So therefore, there are no rules. So, unless we find excerpts, like --

DR. SAM COHEN: You know, in the data summary here, under DART, genotox, carcinogenicity and repeat dose studies, there's nothing listed. All we have is a little bit of acute toxic- -- I doubt if there's any toxicity of these substances, but it would be nice to have some data indicating there's no toxicity.

MS. FIUME: So that is totally up to the purview of the Panel. In the past, if those data were lacking but they're either based on personal experience or what you've seen as far as composition, or anything like that, that you don't feel is a concern, it's been explained in the Discussion. And that would be language we would be asking for after this meeting.

If upon further review, that there is great concern, we could go out with a second Insufficient Data Announcement asking for additional data.

DR. SAM COHEN: I don't have any concern; it's just that it bothered me that there wasn't any there.

DR. DAVID COHEN: Would you predict any?

DR. SAM COHEN: No. I mean, I -- but I've been surprised in the past.

DR. DIYABALANAGE: It does have --

DR. DAVID COHEN: We have oral tox on Cocoyl Hydrolyzed animal protein, right?

DR. ROSS: It says we got DART and genotox here.

DR. SAM COHEN: Just the acute tox.

DR. DAVID COHEN: We have the acute oral tox?

DR. SAM COHEN: Yeah. And it's -- you know, it's not toxic at all, I mean.

DR. ROSS: It's practically non-toxic.

DR. SAM COHEN: Yeah.

DR. BERGFELD: Is it food? It's collagen.

DR. DAVID COHEN: But is it hydrolyzed the same way?

DR. BERGFELD: I don't know.

MS. FIUME: Hydrolysis of collagen to short-chained polypeptides, with the addition of coconut fatty acid. This is from the original Summary of the original report.

DR. DIYABALANAGE: So it's pretty much polypeptides with coconut oil.

DR. BERGFELD: Yeah.

DR. ROSS: I think last time we –

DR. BERGFELD: You know, coconut oil is also food now. It's also a cosmetic, as are the proteins.

DR. ROSS: Last time we weren't that concerned with the tox based on, you know, those very high concentrations where there's sort of no toxicological relapse.

DR. SAM COHEN: Okay. That's fine.

DR. BERGFELD: They always have the toxicology statement regarding animal proteins and also the other -- I guess you should put it in the Discussion, though, that you don't have it, but you didn't think it was going to be important in this setting.

DR. SAM COHEN: That the very high acute tox levels indicates a lack of toxicity or something.

DR. ROSS: Yeah. I didn't go for clearing these, actually.

DR. DAVID COHEN: What was your insufficiency?

DR. ROSS: You know, I thought -- because we have the new data on the potassium derivative, you know, you can essentially read across here, because they're basically solids, right? So you're not too worried about the rest of them, so you can read across for the (inaudible), the Cocoyl. But we have 104 uses; that's the one we added. That's one of the newest ones. It's the most used of the four. We have no concentration of use.

So I wasn't going to clear him based on that. I feel that it's the most frequently used compound, and I think we need a concentration of use?

DR. DIYABALANAGE: I think too big concentration of use for two ingredients, I guess.

DR. BERGFELD: I didn't hear you. For what?

DR. DIYABALANAGE: I think we need concentration of use data for two ingredients.

DR. BERGFELD: Both of them.

DR. ROSS: Well, it's TEA, that one. But you know that was anchored back to 1 percent in 2001. And I went through all the data here on TEA. And actually, if you wanted to, you could clear it at 1 percent. But, you know, if you're asking for concentration of use of Cocoyl, you may as well ask for concentration of TEA.

MS. FIUME: Well -- oh.

DR. DAVID COHEN: No, go ahead.

MS. FIUME: I was going to say, so you have in the IDA you did ask for concentration of use, so this is now -- and it said for all four ingredients.

DR. DAVID COHEN: So it's an Insufficient Data Conclusion.

MS. FIUME: Right. It would be moving on to the Tentative Report stage at this point.

DR. ROSS: If people agree with that, I think it a valid question, the most frequently used member of this class wants the concentration used.

DR. DAVID COHEN: And so, if you don't get that, you're not going to clear this in the final report?

DR. ROSS: You get it? There's 104 uses; just someone hasn't reported it.

DR. TILTON: And because it wasn't included before, we don't have historical data. Is that right?

MS. FIUME: Correct.

DR. TILTON: So we don't have anything to anchor it on.

DR. ROSS: Correct.

MS. FIUME: No. And the concentration of use survey results were received March 27th of this year for all four ingredients.

DR. ROSS: And equals 1 of 104. It has a concentration out there, we just need to know what it is.

DR. DIYABALANAGE: I have a question, actually, after listening to these talks. So the only difference between all these ingredients is just the (inaudible)?

DR. DAVID COHEN: Correct.

DR. DIYABALANAGE: Right. And one is (inaudible), the other one sodium and the other TEA, and the other one is (inaudible).

DR. ROSS: Yeah. They're all fine, but we just don't know if the Cocoyl is being used at 1.1 percent or .01 percent or 10 percent. Just tell us what it is.

DR. TILTON: Based on our prior discussion, would it be just anchored to the max concentration reported for the group, then?

DR. DAVID COHEN: Yes.

DR. ROSS: Which would be the max in the group.

DR. DAVID COHEN: Which is --

DR. ROSS: 1.1 percent for the sodium.

DR. DAVID COHEN: 1.1 percent. So, I think coming with an Insufficient Data Conclusion on this would change -- I don't know -- the way we've been doing things.

DR. ROSS: Is that a good thing or a bad thing?

DR. DAVID COHEN: I don't know. I don't know.

DR. TILTON: You mean based on concentration?

DR. DAVID COHEN: Because if I told you the max concentration for the Cocoyl was 1.1 percent, would you clear it?

DR. ROSS: I would have to check the data first, yeah. That's what I would do.

DR. DAVID COHEN: Well, you've reviewed it. Like, is there a reason you wouldn't clear it at 1.1 percent? Is this going to come back as a Draft Final -- as a Final?

MS. FIUME: A Daft final, yeah.

DR. DAVID COHEN: This comes back as a Draft Final.

MS. FIUME: Yeah.

DR. ROSS: No dermal irritation or sensitization as used in humans: 0.1 percent for the Cocoyl.

DR. DAVID COHEN: So you don't want to read across on any?

DR. ROSS: Well, no, we would read across to the Potassium.

DR. DAVID COHEN: Huh? You could not read across?

DR. ROSS: We could.

DR. DAVID COHEN: For what?

DR. ROSS: Because they're salts so you could presumably read across some of them all. You could read across from the –

DR. DAVID COHEN: The TEA-Coco?

DR. ROSS: Or from the Potassium. So you could go up to 1.1 percent. Because there with the Potassium you've got no irritation at neat in 25 subjects, and no irritation or sensitization at neat with 50 subjects, so you could.

DR. BERGFELD: And it has 3.2.

MS. FIUME: In vitro for undiluted Cocoyl Hydrolyzed Collagen, in the in vitro studies.

DR. DAVID COHEN: In the in vitro studies, yeah. If we have the human studies why not --

MS. FIUME: Yeah.

DR. BERGFELD: That's in human.

MS. FIUME: Oh, we do have the Cocoyl and it was neat. It's 0.1 percent.

DR. ROSS: That's what Wilma pointed out, that's the 3.2 percent.

DR. DAVID COHEN: We have 0.1 on the Cocoyl, right?

DR. ROSS: Yeah, but if you can read across to the Potassium --

DR. DAVID COHEN: Then we have 3.2 percent.

DR. ROSS: Yeah. Then you're good to go, I would agree.

DR. DAVID COHEN: I just haven't come across, clinically, anything related to these things.

DR. ROSS: Okay.

DR. DAVID COHEN: So I was leaning towards clearing the Root.

DR. ROSS: I just thought, particularly, as this one was the most frequently used --

DR. SAM COHEN: If you got a stated level for the group and assuming that (inaudible) would be no higher than that, you've got a level of use.

DR. ROSS: Yeah. Monice, we don't do that, though, we wouldn't put the actual highest concentration of the group in?

DR. BERGFELD: Maximum use we would, probably.

MS. FIUME: The only thing -- you're talking in the Conclusion?

DR. BERGFELD: No, you do it in the Discussion.

DR. ROSS: As Sam said, you know, would you say, well, you know, the whole group the maximum concentration is the 1.1 percent, so we're approving under those conditions, not higher than that.

MS. FIUME: We've done that when there's been concern at higher concentrations.

DR. ROSS: Yeah.

MS. FIUME: If you say it's used at up to X concentration, and we're reviewing it at that, that is sort of like putting a limit on the concentration?

DR. ROSS: It is.

DR. DAVID COHEN: Well, we are, because isn't the max use always the limit of concentration, as approved in this report?

MS. FIUME: It is, but it's viewed -- it's viewed differently.

DR. BERGFELD: They have to hunt it out.

MS. FIUME: Like, it's viewed as an absolute versus as used and being able to take that information in all the different parts. I mean, I know it's the same thing, but it's just --

DR. DAVID COHEN: No, no, our conclusions have stated resolutely a concentration limit on some chemicals where we really had an issue with toxicity.

MS. FIUME: That, and when we didn't have concentrations of use reported. That was years ago.

DR. DAVID COHEN: Yeah, okay. Right. You used to use concentrations in the Conclusion, in the old days, a lot, right? But technically, that shouldn't make a difference. If safe is used as in this report, the max use is the limit.

DR. SAM COHEN: Yeah. That's my understanding.

DR. DAVID COHEN: How is it any different? If someone interprets it under their own -- I mean, how would you interpret a concentration higher than used in the report when it says, as described in this report?

DR. BERGFELD: You have to hunt it out, though. Other than put it in the Discussion as an absolute, you're hunting it out. It's a little more work, a little bit more loosey-goosey.

MS. FIUME: And then we refer them back --

DR. DAVID COHEN: To the use statements, right?

DR. ROSS: You're presenting this tomorrow, so I guess you have to come down one way or the other.

MS. FIUME: But you're going to need consistency, right? So if you go -- if I were looking at it, right, from the outside looking in, if you go insufficient for this one, for one ingredient, because it doesn't have concentration of use, rather than anchoring it to the highest concentration of use, then why was it okay in Lactobacillus to anchor it to the other ingredients?

DR. DAVID COHEN: That's the issue.

DR. ROSS: Yeah, that's a really good point. I'm fine if we anchor it, because I think we can clear it. Wilma pointed out that you've got data up to 3.2 percent with this stuff.

DR. DAVID COHEN: We're going clear as used?

MS. FIUME: And I guess, thinking about it a little bit more, the reason we don't put an absolute maximum concentration is because as used there are many different uses, right, with different concentrations in it that you need to look at. If you do a maximum concentration, even though you sort of are clearing it across the board, you're really clearing it across the board rather than saying, okay, in the eyes -- I mean, now if you're saying as used, if it's only used at 0.2 in an eye product, but it's used at 10 percent in a skin product, and you say it's safe at 10 percent, that's saying it's safe at 10 percent in the eye product even though you're not evaluating it at that percentage in the eye product.

DR. DAVID COHEN: Yeah, I get that.

DR. SAM COHEN: So just saying as used as described in the report is fine.

DR. DAVID COHEN: Use tables. You okay with clear as used?

DR. ROSS: It's still a little irritating -- pun very much intended -- that we don't have a maximum use concentration on the product that is used more frequently in the group. But I'm fine going with the anchoring back to highest concentration of use.

DR. BERGFELD: Do you want to put that in the Discussion to have that clarification?

DR. ROSS: That's what we've been discuss- -- I mean, I don't know what the editorial niceties are here, but it would be great to have it in.

MS. FIUME: We'll look back and make sure we word it as we have in the past. But the other thing we can do is when we put out the post-meeting announcement, we can add a statement saying that the report would benefit from the actual maximum concentration of use for the ingredient that has the highest number of uses. And include that in our post-meeting announcement.

DR. DAVID COHEN: That's somewhat satisfying, right?

DR. BERGFELD: That's great.

DR. ROSS: It works for me.

DR. DAVID COHEN: Sam, you're okay with that?

DR. SAM COHEN: So, maybe they'll put it in.

DR. ROSS: Maybe, maybe not.

DR. DAVID COHEN: Susan, this was your original conclusion anyway.

DR. TILTON: Yeah.

DR. DAVID COHEN: Okay. We'll go out as safe as used. Can I, um, call just a five-minute break?

DR. SAM COHEN: I was going to ask.

DR. DAVID COHEN: Yes. Five minutes.

[BREAK]

MS. FIUME: I'm sorry, before you go on. For the last one with the hydrolyzed collagens, is the Discussion going to have anything about the TEA ingredient with the nitrosation? Is it the Discussion, Conclusion?

DR. SAM COHEN: I think that there was enough there. You guys clarified it enough for me, at least.

MS. FIUME: I didn't know if it was just in the Discussion or if it's also in the Conclusion.

DR. SAM COHEN: It's just in the Discussion.

MS. FIUME: Discussion? Okay, I just wanted to make sure.

DR. BERGFELD: I think that we've tried not to put that sort of thing in the Conclusion and just put it all in the Discussion.

MS. FIUME: Yeah.

DR. DAVID COHEN: I mean, from a practical standpoint, how is avoiding nitrosation possible if you have an isolated product when you don't know what the person is using collateral to that?

DR. SAM COHEN: Yeah.

DR. DAVID COHEN: You have no idea.

DR. BERGFELD: Well, it's the manufacturer of the formulation that has to pay attention to it.

DR. DAVID COHEN: Right, but that doesn't avoid the fact that someone may use a nitrosating product.

DR. BERGFELD: Well, if you're under a million dollars in value, you don't have to even report with the new reg.

DR. DAVID COHEN: No, no. What I mean is just using two or three hair products. How do you know what the second product and the third product have in them?

DR. BERGFELD: No, it's cumulative.

DR. DAVID COHEN: You can't know.

DR. BERGFELD: We have addressed that in cumulative effect multiple times. And the FDA person this morning, Jennifer, pointed out what she did, and that was amazing, because she didn't look like she did a whole lot. You know, by the time she got here she used ten different products.

DR. DAVID COHEN: Oh, yeah, yeah, yeah. Okay.

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DR. DAVID COHEN: Okay. Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein. At the June 2024 meeting, the Panel decided to reopen the safety assessment of potassium and TEA-Coco-Hydrolyzed Collagen, concluding that some of the sensitization of photosensitization data in the original report needed to be reinvestigated. After reviewing the Draft Amended Report in December, the Panel decided to add two ingredients, Coco-Hydrolyzed Collagen and Sodium Coco-Hydrolyzed Collagen to this assessment, and issued an Insufficient Data Announcement requesting the following information for all four ingredients: Max concentration of use, dermal irritation and sensitization, UV absorption spectrum. We received data on much of this and our motion is safe as used.

DR. SNYDER: Second.

DR. BERGFELD: Very nicely done. Any other comments?

DR. SNYDER: We just had a comment to note in the Discussion that it would not be absorbed, to mitigate the need for systemic tox.

DR. DAVID COHEN: Yeah. And I have to say yesterday we had a number of conversations through a number of the dossiers. When we don't have concentration of use for a product, we would anchor to the concentration of use within the report for an item that doesn't have a concentration of use. And that seemed obvious to everyone, but I don't know if it's always so obviously articulated in the report, right? Because it's as described in this report. And if there's no concentration of use as described in this report, does 99 percent count, right? Instead, it's got to be clear it's anchored to the max use concentration of one of the other ingredients, and that's the best we can do.

DR. SNYDER: We would agree.

DR. BERGFELD: And you will put that in the Discussion?

DR. DAVID COHEN: So the question is, do we need a boilerplate for that? Because it's always going to be an issue, right? And we think maybe a boilerplate for something like that makes sense or at least we could discuss it further at another meeting.

DR. BELSITO: And I think that's fine, David. It is collagen, right? So in Discussion, free of detectable pathogenic viruses, prions and other pathogenic agents needs to go in, correct?

DR. SNYDER: That's correct.

DR. ROSS: Did you make the conclusion that it wasn't absorbed or not likely to be absorbed? I would prefer the latter, I think.

DR. BELSITO: Right, not likely.

DR. ROSS: Yeah.

DR. BERGFELD: Any other comments, Bart?

DR. HELDRETH: Yeah. So historically, we've had a situation where we included as part of the Conclusion, we will add an asterisk on ingredients where we don't have either frequency of use, or concentration of use, or both. And we'll have that language of the expectation is that these ingredients that do not have reported concentration or frequency of use will be used in the same way as those other ingredients in the report. And so that it limits the conclusion essentially to what the other ones have?

DR. DAVID COHEN: So yeah, we've had concentrations in our Conclusion. We don't do it often, right? It was the old report.

DR. BELSITO: No, what Bart is saying is that there's an asterisk to the Conclusion that says that the Panel assumes that ingredients without concentrations of use would be used in the same concentration. It's not actually in the Conclusion. Right, Bart?

DR. DAVID COHEN: Is it in all reports that have a missing concentration of use?

DR. HELDRETH: It hasn't been in all, but it's been in many of the reports. And typically what we'll do is we'll have --

DR. BELSITO: Bart, is your mic on?

DR. HELDRETH: I'm sorry. Typically, we'll have our Conclusion. So, in this example, we're saying safe as used in the present practices of use and concentration, and then on those ingredients, since there's just four here, we could list them all in the Conclusion and put an asterisk on those where we don't have concentration of use. And then that caveat would be below it explaining what the asterisk is.

DR. ROSS: There's only one here where we don't have either concentration of use or historical concentration of use. And that's the one that's most frequently used.

DR. DAVID COHEN: That's what sparked the conversation. The most common one we didn't have a concentration of use on. The question is, well, if we don't have a boilerplate, will we always catch it? Will we always create that in the Conclusion? I can imagine it could slip by.

DR. HELDRETH: I mean, we could certainly make that part of our internal SOP to say, hey, look here in the in the memo we don't have concentration of use for this one, do you want to include that in your Conclusion. We'd be happy to raise that flag for you every time.

DR. DAVID COHEN: Yeah. Okay.

DR. BERGFELD: Sort of administrative guidelines for writers. Yeah.

DR. DAVID COHEN: Exactly. That makes sense. Okay. Is that okay with you, Don?

DR. SNYDER: Yeah, I think we're good with that.

DR. DAVID COHEN: Okay.

DR. BERGFELD: Okay. I'm going to call the question then. All those in favor of the conclusion of safe in this ingredient, please indicate by raising your hands. I had in my notes that -- had we addressed the nitrosation Annex II comments by the European Group at all? Are we satisfied with that? You are okay with that? Okay.

DR. DAVID COHEN: This was the TEA issue?

DR. BERGFELD: Yeah.

DR. DAVID COHEN: Yeah.

DR. BERGFELD: Okay.

suggests the possibility that upon absorption BNPD may contribute to the endogenous formation of nitrosamines in man."

Dr. Beyer suggested writing a letter to Dr. Holland of Boots Co. Ltd. expressing the Panel's appreciation for his comments, and inviting him to submit the results of Boots' research on human skin absorption after the study is completed.

The Addendum to the Final Report on 2-Bromo-2-Nitropropane-1,3-Diol will shortly be announced as Final.

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.

3. Stearyl Alcohol

The following conclusion of the report was unanimously approved:

"Based on the available data, Stearyl Alcohol, Oleyl Alcohol, and Octyl Dodecanol are safe as currently used in cosmetics."

Dr. Carlton suggested changing the title of section "Anti-Tumor Effect" to "Test for Anti-Tumor Effect." The group concurred. Dr. Carlton further stated the standard paragraph used in the Cosmetic Use section to qualify the

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

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ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
Da	Daltons
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
UV	ultraviolet light
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 are 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 with the 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 these ingredients 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 October 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.

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

Figure 1. Cocoyl hydrolyzed collagen salt ingredients, wherein R-C(O)- represents the acyl moiety of the coconut acid; NH-CHR′-C(O)-(NH-CHR'-C(O))$_n$-NH-CHR′-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 Da.[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 Da, the fatty acid moiety predominates, whereas when the MW is higher than 600 Da, 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 collagen ingredients in cosmetics. Registration and Listing Data (RLD) obtained from the FDA report frequency of use, and responses to a survey conducted by the Personal Care Products Council (Council) indicate maximum reported concentrations of use; it is these values that define the present practices of use and concentration that are assessed by the Panel. Since 2024, as a result of the Modernization of Cosmetics Regulation Act (MoCRA) of 2022, 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]

According to RLD obtained from the FDA in 2025, Cocoyl Hydrolyzed Collagen has the most reported uses, in 133 formulations[8,9] (Table 2). Although all 4 ingredients have use reported in the RLD, the results of the maximum concentration of use survey conducted by the Council in 2025 only reported use concentrations for Sodium Cocoyl Hydrolyzed Collagen (up to 1.1%, in other personal cleanliness rinse-off products) and Potassium Cocoyl Hydrolyzed Collagen (up to 0.01%, in leave-on face and neck products and moisturizing products).[10]

When determining whether to re-open this safety assessment, the Panel considered FDA Voluntary Cosmetic Registration Program (VCRP) data submitted to CIR in 2023 for Potassium and TEA-Cocoyl Hydrolyzed Collagen as compared to that stated in the previous report.[3,11] The frequency of use decreased for both ingredients. 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.

This group of ingredients are reported to be used in formulations that are applied near the eyes and in those that can result in incidental ingestion and mucous membrane exposure. 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. Additionally, the concentration of use surveys are conducted based on product categories as stated in the RLD. Some of the reported product categories for these ingredients as listed in the RLD do require designation if airbrush application is used (e.g., make-up bases), 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 must conform to the restrictions listed for trialkylamines, trialkanolamines, and their salts, as listed in EU Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions. 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 3.

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 dermic irritation and sensitization 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 ultraviolet B (UVB) or ultraviolet A (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 2025, Cocoyl Hydrolyzed Collagen has the most reported uses, in 133 formulations. Although all 4 ingredients have use reported in the RLD, the results of the maximum concentration of use survey conducted by the Council in 2025 only reported use concentrations for Sodium Cocoyl Hydrolyzed Collagen (up to 1.1%, in other personal cleanliness rinse-off products) and Potassium Cocoyl Hydrolyzed Collagen (up to 0.01%, in leave-on face and neck products and moisturizing products). Trialkylamines, trialkanolamines and their salts are listed in EU Annex III and this listing applies to TEA-Cocoyl Hydrolyzed Collagen; therefore, it 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. Frequency and concentration of use according to likely duration and exposure and by product category

	Cocoyl Hydrolyzed Collagen		Potassium Cocoyl Hydrolyzed Collagen		Sodium Cocoyl Hydrolyzed Collagen		TEA- Cocoyl Hydrolyzed Collagen	
	# of Uses	Max Conc of Use	# of Uses	Max Conc of Use	# of Uses	Max Conc of Use	# of Uses	Max Conc of Use
	RLD (2025)[8,9]	% (2025)[10]	RLD (2025)[8,9]	% (2025)[10]	RLD (2025)[8,9]	% (2025)[10]	RLD (2025)[8,9]	% (2025)[10]
Totals*	**133**	**NR**	**62**	**0.01**	**1**	**1.1**	**5**	**NR**
summarized by likely duration and exposure**								
Duration of Use								
Leave-On	*107*	*NR*	*19*	*0.01*	*NR*	*NR*	*4*	*NR*
Rinse-Off	*39*	*NR*	*45*	*NR*	*1*	*1.1*	*1*	*NR*
Diluted for (Bath) Use	*1*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Permanent Tattoo Ink	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Unknown	*1*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
Children's Makeup	NR	NR	NR	NR	NR	NR	NR	NR
Eye Area	1	NR	4	NR	NR	NR	1	NR
Incidental Ingestion	37	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	39	NR	1	NR	1	1.1	NR	NR
Incidental Inhalation-Spray	36[a]; 37[b]	NR	3[a]; 19[b]	NR	NR	NR	3[a]; 1[b]	NR
Incidental Inhalation-Airbrush	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	37[b]	NR	19[b]	0.01[c]	NR	NR	1[b]	NR
Dermal Contact	95	NR	23	0.01	1	1.1	4	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	14	NR	36	NR	NR	NR	1	NR
Hair-Coloring	NR	NR	5	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Tattoo Preparations	NR	NR	NR	NR	NR	NR	NR	NR
Other Preparations (Unknown Exposure Type)	1	NR	NR	NR	NR	NR	NR	NR
as reported by product category								
Bath Preparations (diluted for use)								
Bath Oils, Tablets, and Salts	1	NR						
Eye Makeup Preparations (other than children's)								
Eye Makeup Removers			4	NR				
Mascaras	1	NR						
Other Eye Makeup Preparations							1	NR
Hair Preparations (non-coloring)								
Hair Conditioners	2 (r.o.)	NR	2 (r.o.)	NR				
Hair Straighteners			4	NR				
Permanent Waves			15	NR				
Rinses (non-coloring)			2	NR				
Shampoos (non-coloring)	4 (r.o.)	NR	5 (r.o.)	NR				
Tonics, Dressings, Other Hair Grooming Aids			3	NR				
Wave Sets			2	NR				
Other Hair Preparations	4 (l.o.) 4 (r.o.)	NR	2 (r.o.)	NR			1 (l.o.)	NR
Hair Coloring Preparations								
Hair Shampoos (coloring)			4 (r.o.)	NR				
Other Hair Coloring Preparation			1	NR				
Makeup Preparations (not eye or children's)								
Blushers and Rouges (all types)	13	NR						
Lipsticks and Lip Glosses	37	NR						
Makeup Bases	1 (traditional)	NR						

Table 2. Frequency and concentration of use according to likely duration and exposure and by product category

	Cocoyl Hydrolyzed Collagen		Potassium Cocoyl Hydrolyzed Collagen		Sodium Cocoyl Hydrolyzed Collagen		TEA- Cocoyl Hydrolyzed Collagen	
	# of Uses	Max Conc of Use	# of Uses	Max Conc of Use	# of Uses	Max Conc of Use	# of Uses	Max Conc of Use
	RLD (2025)[8,9]	% (2025)[10]	RLD (2025)[8,9]	% (2025)[10]	RLD (2025)[8,9]	% (2025)[10]	RLD (2025)[8,9]	% (2025)[10]
Personal Cleanliness								
Other Personal Cleanliness Products	1	NR	1 (r.o.)	NR	1 (r.o.)	1.1 (r.o.)		
Skin Care Preparations								
Cleansing	14	NR	2	NR				
Depilatories								
Face and Neck (excluding shaving preps)	18 (l.o.); 14 (r.o.)	NR	14 (l.o.); 1 (r.o.)	0.01 (l.o.; not spray)				
Body and Hand (excluding shaving preps)	7 (l.o.)	NR					1 (r.o.)	NR
Moisturizing	17	NR	NR	0.01 (not spray)			2	NR
Night	1	NR						
Other Skin Care Preparations	8	NR	1	NR				
Other Preparations (i.e., those that do not fit another category)	1	NR						

NR – not reported
l.o. – leave-on; r.o. – rinse-off
*The sum of the counts given for duration of use and by exposure type, and the sum of the frequency reported by product category, may not equal the sum of total uses because each ingredient may be used in cosmetic formulations that are reported under more than one product category
**Likely duration and exposure are derived from survey data based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)
[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b] 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
[c] It is possible these products are powders, but it is not specified whether the reported uses are powders.

Table 3. 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)	water	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)	water	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 and sensitization evaluation.	No significant cutaneous reaction observed.	17
Potassium Cocoyl Hydrolyzed Collagen 30% aq, solution (number average MW, 600)	water	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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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.

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CHEMISTRY

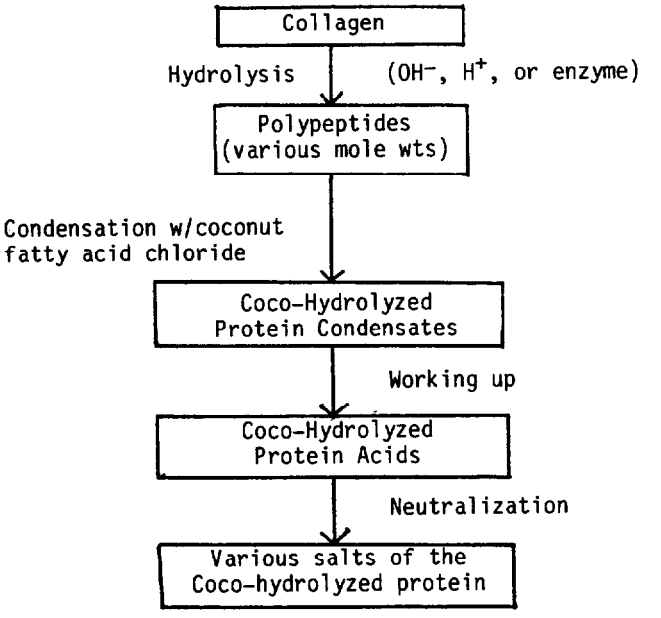
Structure

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]



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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.

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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.

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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).

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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

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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.

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

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

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

CONCLUSION

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

ACKNOWLEDGMENT

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

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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.

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

Concentration of Use by FDA Product Category[1]*

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

Ingredient	Product Category	Maximum Concentration of Use
Potassium Cocoyl Hydrolyzed Collagen	Face and neck products (not spray) – leave-on	0.01%
Potassium Cocoyl Hydrolyzed Collagen	Moisturizing products (not spray)	0.01%
Sodium Cocoyl Hydrolyzed Collagen	Other personal cleanliness products – rinse-off	1.1%

*The ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

Information collected in 2025
Table prepared: March 27, 2025
Table updated June 30, 2025 added moisturizing products for Potassium Cocoyl Hydrolyzed Collagen

[1] The new FDA cosmetic product categories under MoCRA were used for this survey.