Safety Assessment of Polyacrylate-13 as Used in Cosmetics

Status:	Draft Final Report for Panel Review
Release Date:	September 11, 2026
Panel Meeting Date:	October 5-6, 2026

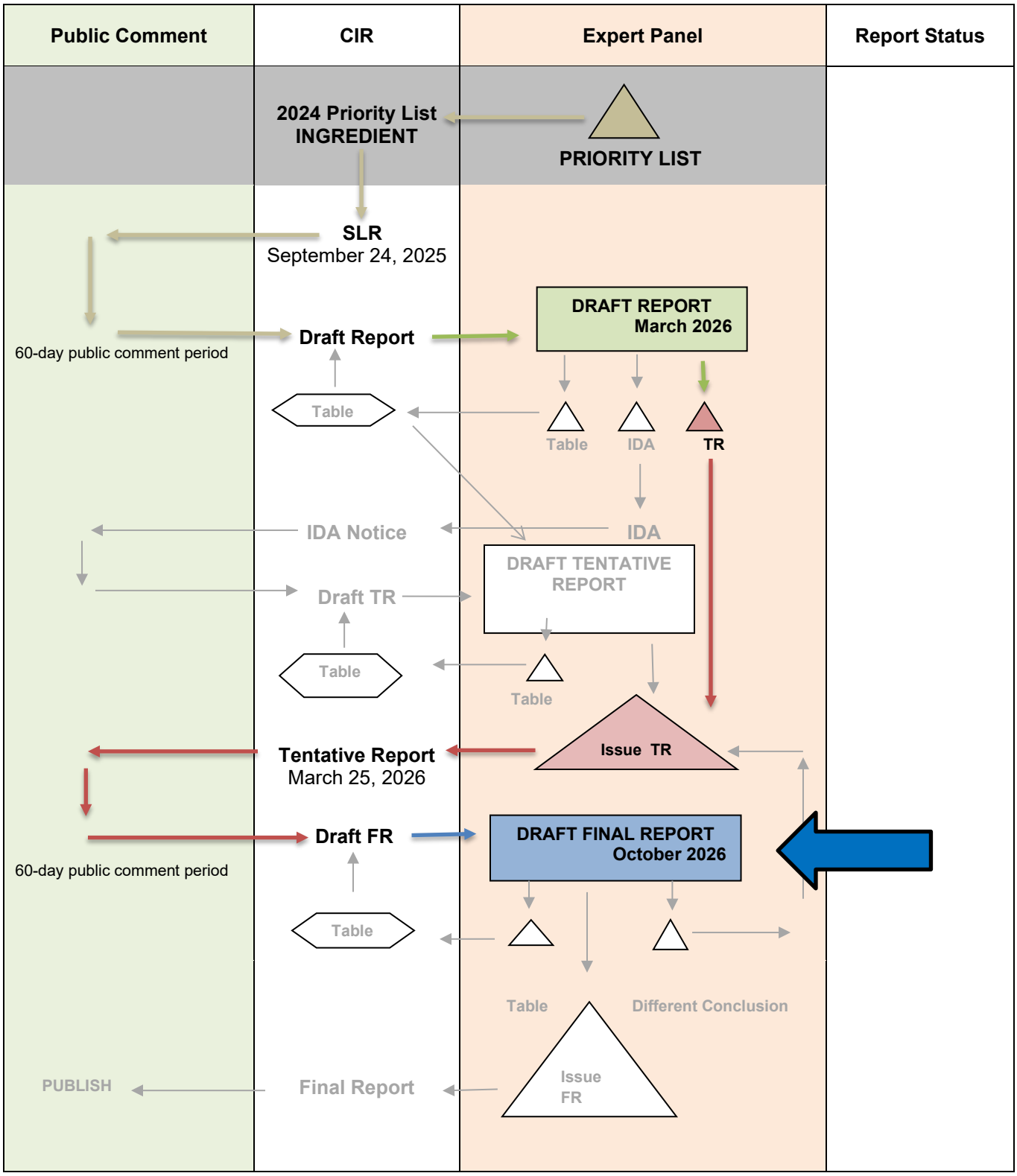
The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Bruce A. Brod, M.D., M.H.C.I., F.A.A.D.; Samuel M. Cohen, M.D., Ph.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. Previous Panel member involved in this assessment: David E. Cohen, M.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 Temima Nguyen, M.S., Scientific Analyst/Writer, CIR.

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SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Polyacrylate-13
MEETING October 2026



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Temima Nguyen, M.S., Scientific Analyst/Writer, CIR
Date: September 11, 2026
Subject: Safety Assessment of Polyacrylate-13 as Used in Cosmetics

Enclosed is the Draft Final Report on the Safety Assessment of Polyacrylate-13 as Used in Cosmetics. (It is identified as *report_Polyacrylate-13_102026* in the pdf document). At the March 2026 meeting, the Panel issued a Tentative Report with the conclusion that Polyacrylate-13 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

No additional data have been received since the March meeting. Comments received from the Council on the Draft Report have been addressed (*PCPCcomments_Polyacrylate-13_102026* and *response-PCPCcomments_Polyacrylate-13_102026*). No comments were submitted on the Tentative Report.

Additional supporting documents for this report package include a flow chart (*flow_Polyacrylate-13_102026*), report history (*history_Polyacrylate-13_102026*), a search strategy (*search_Polyacrylate-13_102026*), a data profile (*dataprofile_Polyacrylate-13_102026*), and meeting transcripts (*transcripts_Polyacrylate-13_102026*).

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

Polyacrylate-13 History

September 24th, 2025

SLR posted.

September 30th, 2025

A summary of a Human Repeat Insult Patch Test (HRIPT) on a product containing Polyacrylate-13 was provided.

October 27th, 2025

A summary of data on Polyacrylate-13 was provided which included method of manufacturing, impurities, a study testing skin sensitization using a Sens-Is assay, and a study testing eye irritation potential using the Isolated Chicken Eye Test (ICE) method.

March 6th, 2026

Comments were received from the Council on the Draft Report.

March 25th, 2026

The Panel reviewed the available data and issued a Tentative Report for public comment with the conclusion that Polyacrylate-13 is safe in cosmetics in the present practices of use and concentration described in the safety assessment.

No comments were issued on the Tentative Report after the 60 day public comment period.

October 2026

The Panel reviews Draft Final Report

Polyacrylate-13 Data Profile* – October 2026 – Writer, Temima Nguyen																														
				Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	log P/log K_{ow}	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Polyacrylate-13	X	X	X					X							X						X	X		X		X			

* "X" indicates that data were available in a category for the ingredient

Polyacrylate-13

Ingredient	CAS #	PubMed	FDA	CompTox	ChemPort	NIOSH	NTIS	NTP	FEMA	EU	ECHA	SIDS	SCCS	AICIS	FAO	WHO	Web
Polyacrylate-13	N/A	NR	√*	NR	NR	NR	NR	NR	NR	√	NR	NR	NR	√	NR	NR	√

NR- not reported; √* - data is available, but is not new or relevant

Search Strategy

Pubmed

(Polyacrylate-13) – 0 hits / 0 useful

Web

Polyacrylate-13 toxicity – 1,040,000 hits/ 1 useful
Polyacrylate-13 irritation – 791,000 hits/ 0 useful

LINKS

Search Engines

- Pubmed - http://www.ncbi.nlm.nih.gov/pubmed
  - appropriate qualifiers are used as necessary
  - search results are reviewed to identify relevant documents
- CompTox: https://comptox.epa.gov/dashboard/chemical/pubmed-abstract-sifter/DTXSID3039242; https://www.epa.gov/comptox-tools/downloadable-computational-toxicology-data#LM
- eChemPortal: https://www.echemportal.org/echemportal/
- DeepDyve: https://www.deepdyve.com/
- Connected Papers - https://www.connectedpapers.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; https://dps.fda.gov/omuf/monographsearch
- 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
- 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

Memorandum

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

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: March 6, 2026

SUBJECT: Draft Report: Safety Assessment of Polyacrylate-13 as Used in Cosmetics (March 2026 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft report, Safety Assessment of Polyacrylate-13 as Used in Cosmetics.

Definition and Structure – Please revise the following sentence so that it is consistent with the information associated with Figure 1. "This ingredient has the following chemical structure as shown in Figure 1." (it should be revised so it is not as definitive, e.g., "One possible structure of Polyacrylate-13 is shown in Figure 1").

Cosmetic Use – It should be made clear that the EU limits for residual acrylamide refer to finished products.

Table 2 – Please revise Table 2 to be consistent with the memo from PCPC concerning tattoo preparations (memo dated February 26, 2026).

Polyacrylate-13 – October 2026 – Temima Nguyen	
Comment Submitter: Jaap Venema, Ph.D., Personal Care Products Council **Date of Submission: March 6, 2026**	
Comment	**Response/Action**
Definition and Structure – Please revise the following sentence so that it is consistent with the information associated with Figure 1. "This ingredient has the following chemical structure as shown in Figure 1." (it should be revised so it is not as definitive, e.g., "One possible structure of Polyacrylate-13 is shown in Figure 1").	Addressed.
Cosmetic Use – It should be made clear that the EU limits for residual acrylamide refer to finished products	Addressed.
Table 2 – Please revise Table 2 to be consistent with the memo from PCPC concerning tattoo preparations (memo dated February 26, 2026).	Addressed.

MARCH 2026 PANEL MEETING – INITIAL REVIEW

Belsito Team – March 12, 2026

DR. BELSITO: Okay, if not, Polyacrylate 13. It's nice to review a single ingredient, but I guess my first question is, are there any other related ingredients that could be added, like Polyacrylate 14 or 15 that we haven't reviewed?

DR. HELDRETH: Although the names sound a lot alike, the additional co-monomers vary quite a bit. And so, that's why it wasn't proposed to be reviewed with anything else.

DR. BELSITO: Okay. So, Polyacrylate. This is the first time that we're looking at this safety assessment. The SLR was announced, or issued, in September of 2025. We do have updated RLD data for 2025, and that's been added to the text. We have very little data, but in my opinion, it appears sufficient because this is unlikely to be absorbed, so the systemic endpoints, I think, are less important. And in terms of the acrylamide, we can put that in the Discussion, that it should be limited, minimized.

Incidental ingestion, there are 265 uses but no concentration in the mucous membrane; 274 uses with no concentration. I thought sensitization, irritation, ocular irritation were covered. And just to comment in the sensitization, the one paragraph, the last sentence, it says, when tested at 10 percent, 50 and undiluted, the mixture, it says, when non-irritating, concluded to be a non-sensitizer with Sens-Is assay. Sens-Is measures sensitization, it doesn't measure irritation. So, the mixture was concluded to be a non-sensitizer.

Because Sens-Is is a gene array and you put the mixture in, and you look at the expression of genes, and it tells you sensitizer and non-sensitizer. It does not tell you irritant. So, yeah, it's greater than 10,000 Daltons; so, Discussion: greater than 10,000 Daltons not absorbed, obviating the systemic needs, manufactured to minimize acrylamide. Dermal sensitization irritation negative, ocular irritation negative.

I guess the only question is since we're saying that it's large and not absorbed, since there is mucosal and membrane use without concentrations, are we concerned about that? I wasn't, but.

DR. KLAASSEN: No.

DR. SNYDER: I'm not either.

DR. KLAASSEN: It's not going to be absorbed by the GI tract either.

DR. BELSITO: Okay. So safe as used.

DR. RETTIE: That's what I had.

DR. BELSITO: Any other comments on the report?

DR. SNYDER: None for me.

DR. BELSITO: Okay.

DR. RETTIE: Nice one to end on.

DR. HELDRETH: Anything for the Discussion for Temima? This is one of her first reports.

DR. BELSITO: Greater than 10,000 Daltons, so not absorbed, obviating the need for systemic exposure. Manufactured to minimize acrylamide, and the dermal sensitization, irritation, ocular irritation and concentrations of use were negative.

DR. HELDRETH: Perfect. Thank you.

MS. NGUYEN: Thank you.

DR. BELSITO: Okay. Wow, I thought we were going to be going to 6:00 p.m.

Cohen Team – March 12, 2026

DR. DAVID COHEN: Let's open up with Polyacrylate-13. I'm presenting this tomorrow. This is a Draft Report on Polyacrylate-13, a high-molecular-weight, film-forming polymer used primarily in leave-on skincare, eye area products and hairstyling formulations. According to the 2025 Use report, there are 1,807 reported formulations containing it. The highest

reported leave-on concentration is 3.4 percent in face and neck products, and 1.8 percent in eyelash and eyebrow preparations, and hair grooming products use up to 1.2 percent.

There are some additional reported uses in lip products, eye areas, sprays, powders. We already have an airbrush notation. We have a fair amount of data on genotox, oral tox. We have an HRIPT at 3.5 percent, with no irritation and sensitization.

The principal questions here are, do we have any data needs here? Or is this an early but sufficient report? I'll open it up for commentary to everyone. Anyone want to start?

DR. ROSS: I had one thing, I guess. You summarized it nicely. I didn't have really any concerns with the genotox, the dermal, the ocular, et cetera. I guess it was a couple of things. The major one for me was impurities. All we have is a limit on acrylamide of less than 1 ppm in this dossier. And the EU Annex III, for example, limits leave-on to acrylamide less than 0.1 ppm, and other products to 0.5. All the data we have is still maybe tenfold above that EU limit. So, I just felt we needed more data on the acrylamide levels in some of these products, which would give us confidence that these products didn't contain excess levels of acrylamide.

The other issue, it's not likely to get across the skin. It has a molecular weight in the area of, 10,000. But there is no data, but I just felt that it really wasn't likely to get absorbed. And other people can weigh in on that if they wish, but I had no other concerns. They were my two things.

DR. SAM COHEN: With regard to the acrylamide, the Germans, a year or two ago, reviewed that and came up with a much lower risk assessment than had originally been done in Europe. There was all that hullabaloo ten years ago about acrylamide being on French fries and everything else. And they took a more careful look at it and came to the conclusion that it's not quite as dangerous as once considered.

DR. ROSS: Well, that may be true, but we've got the EU regulatory out there, Sam; so, I just think that we probably need more data in our dossier with respect to levels so we can compare it to that. And again, I wasn't really concerned for the lack of DART data, but I just wanted to make the point that this isn't likely to get absorbed; but others may have other opinions. I don't know.

DR. SAM COHEN: I agree entirely.

DR. TILTON: Yeah, Dave, I agree, too. I didn't have a lot of concerns. I did notice that for some of the use categories we didn't have concentration of use, but the report itself then would just cover max concentration of use, I guess, at 3.4 percent, which is in the leave-on products. And so, if that's where the report would cover, then I didn't have any concerns with that.

DR. ROSS: That's a great point, actually. It's on my list; I didn't get to it, but we don't have concentrations of use in lipsticks and body washes. So, if you're going out for more acrylamide information on an insufficiency, you could ask for concentrations of use in those product areas. Otherwise, as you point out, it would revert back to the 3.4 percent.

DR. DAVID COHEN: So, in my assessment, I had a comment that I want the Discussion to clearly reflect the safety contingent upon appropriate control of residual monomers and impurity, particularly acrylamide. That was going to be an editorial thing. We're going to go out with an IDA on this, right? What is our ask? Am I correct, we want to go out with an IDA?

DR. ROSS: I don't know how you want to handle it. I would just like more information on acrylamide levels in some of these products. I guess it would have to be an IDA if you wanted new data to come in.

DR. SAM COHEN: Acrylamide levels and use levels?

DR. ROSS: Yeah.

DR. DAVID COHEN: You mean use levels on the lips or something?

DR. ROSS: Well, it would be lipsticks and body washes. We don't have that in the dossier.

DR. DAVID COHEN: If the lipsticks were 3.4 percent, tell me, how would we change our conclusion?

DR. TILTON: It would not change.

DR. ROSS: It wouldn't change our conclusion. No, I agree with Susan, yeah.

DR. DAVID COHEN: Right. So, I don't want to ask for IDA materials that, one, may not come back, or, two, won't change our ultimate conclusion. And so, we're asking -- we have impurities less than 1 ppm of acrylamide. What is our ask? And by the way, less than 1 ppm -- what's EU at?

DR. ROSS: 0.1.

DR. DAVID COHEN: 0.1 ppm?

MS. FIUME: And to clarify, that's in finished product. That acrylamide level is in finished product.

DR. ROSS: Yeah, I'm not sure how we'd -- maybe Monice can comment. I'm not sure how we'd get that information, Monice, if we don't ask for it, you know?

DR. DAVID COHEN: No, but that's really interesting. It's less than 1 ppm in a finished product, not in the raw Polyacrylate-13 material going into the product.

DR. ROSS: That may make a difference, you're right. Yeah.

DR. DAVID COHEN: David, do we know what the EU's 0.1 ppm is for finished product, or cosmetic-grade raw material?

DR. ROSS: I don't know that offhand.

MS. FIUME: When I say in finished product, the value given in the report from the EU for the maximum residual acrylamide content, that's in finished product. That's how much is allowed in the finished product.

DR. DAVID COHEN: Okay. So, we're still getting back to finished product, ultimately. Now, is there a basis for us changing present practices of use at less than 1 ppm? Like, so, if they're telling us it's less than 1 ppm, and we get data 0.9, 0.7, 0.01, like, a couple -- we get some data on that. What are we doing with the conclusion? Like, Dave, what if you got back 0.95?

DR. ROSS: Yeah, I know what you're saying.

DR. DAVID COHEN: In a lipstick. Okay? I'm just running the hypotheticals out.

DR. SAM COHEN: Just because the EU is at 0.1, is there any reason why we can't make it at 0.1 ppm of what we have?

DR. ROSS: No, there's not. We don't have to be at the same level as EU.

DR. SAM COHEN: So, we don't need the information.

DR. ROSS: Well, we don't, but I guess my point is I'd like more information around that; is that 1 ppm just a single report, for example, or are we dealing with products here that have 0.9, 0.951; or are we dealing with a lot more products that have 0.1, 0.05? I mean, it seems like a minor point, and I think --

DR. DAVID COHEN: It's not a minor point. I'm just asking if you got -- if 70 percent of the products came back at 0.095 ppm.

DR. ROSS: How would you split it out, yeah.

DR. DAVID COHEN: It's less than 1 ppm. Like, you can't have 1 ppm, it's got to be less than 1 ppm.

DR. ROSS: We're not setting a regulatory limit here, we're just looking at what is in these products so we have a better sense of the risk coming out the other end. I'm not proposing we do a risk assessment on 1 ppm acrylamide versus 0.1 ppm acrylamide, I'd just like to see what level the acrylamide products actually come in at here. Is it closer to 0.1, or is it 1, or is it higher than that? And maybe we won't get any information, I don't know.

DR. DAVID COHEN: No, no, but I'm just getting at, when we put an IDA in, it's presumably to inform us of a conclusion. Right? And so, the question is, in present practices, the impurities anchor to less than 1 ppm. We're saying present practices of use is impurities less than 1 ppm of acrylamide. If everyone comes in at 0.99, they're within present practices of use.

Will that change our conclusion, right? Because that's the worst case scenario in your mind, I'm assuming, right? We're not going to get -- we shouldn't get them back at 1.5 because that would be not present practices at that point. I'm sorry, Monice, did you have your hand up?

MS. FIUME: I do. I just wanted to point out that in the Acrylamide Acrylate Copolymers Report, in the Discussion -- that went final in March of 2022. In the Discussion, it said to ensure the concentration of acrylamide monomer in cosmetic formulations does not exceed 5 parts per million. So, at that time you handled it, in the Discussion, saying that it has to be below a certain level; but at that time it was 5 parts per million.

I'd have to look back to the minutes to see why it was 5 and not 1. Maybe the Panel had its own thoughts on the acceptable amount. But that's what was done in the Acrylamide Acrylates Copolymer Report.

DR. ROSS: Well, maybe we handle it editorially, that's another option. And we say as low as possible, but with a limit of -- in this case we have one, Monice, in this report.

MS. FIUME: And that's the EU. I can try and look back at the minutes to see why the Panel went with 5 parts per million and not 1. It was only four years ago.

DR. ROSS: But this report is 1, right, we have in here?

DR. DAVID COHEN: 1 ppm.

DR. SAM COHEN: Or was that 5 in finished product or in the raw material?

MS. FIUME: It was limiting residual monomer level of, I believe, in the ingredient for that report.

DR. SAM COHEN: Yes, it's different.

DR. DAVID COHEN: In the ingredient?

DR. SAM COHEN: Yes, it's different than what we're talking about now.

MS. FIUME: No, I'm sorry, in cosmetic formulations.

DR. DAVID COHEN: Yeah.

MS. FIUME: That the concentration of acrylamide monomer in cosmetic formulations in it exceed 5 parts per million.

DR. TILTON: Should we reference the report in this report?

DR. DAVID COHEN: Well, if we reference that report it increases the impurity level. Like, why would we want to anchor to a lower acrylamide impurity level, which is already a clear statement in the dossier now? I mean, we could reference it, but then might it add confusion? Well, you're referencing this one that says 5 parts per million, and this more modern one is 1 part per million.

DR. ROSS: If I could just get back to this. The impurity section says it is according to an industry submission. So it's a single submission.

DR. BERGFELD: They usually are.

DR. DAVID COHEN: We're going to anchor to that single submission because it's the only thing we have. And in the Discussion, we can anchor to agreeing with the less than 1 part per million of acrylamide.

DR. BERGFELD: It'll go out for public, so they can correct that later if they feel it's worthwhile doing.

DR. ROSS: Can we put some verbiage in there as low as practically possible -- as low as reasonably exp- -- it's like a LARA methodology.

DR. BERGFELD: Wait, we've done that before with animal protein, insecticides, contaminants of other -- from soil.

DR. DAVID COHEN: Yeah, that's a Discussion issue.

DR. SAM COHEN: Do we have any information as to why the Europeans set it at 0.1 instead of 1?

DR. ROSS: We'd have to go in and look at that risk assessment. I didn't do that.

DR. BERGFELD: So, your action is going to be putting this into the Discussion, or is it action to go insufficient until you review the European dossier?

DR. ROSS: No, I think you could probably put it in the Discussion. As I said, I think it's a relatively minor point. I don't know about others' opinions here.

DR. SAM COHEN: Question is, do we have any safety concern? And personally, I don't. So, I would rather just see it in the Discussion and not do an IDA.

DR. ROSS: Okay, that would work for me, as long as there's some --

DR. BERGFELD: And you're going to hold the concentration at 3.4 percent?

DR. DAVID COHEN: Well, yeah, I think in present practices of use, yeah.

DR. BERGFELD: Okay.

DR. DAVID COHEN: Susan, are you okay with a safe as used?

DR. TILTON: Yes, I am. I support that.

DR. DAVID COHEN: Will you support that, Dave? And then we can open it up for discussion.

DR. ROSS: Yeah, I'll support that, sure.

DR. DAVID COHEN: Okay. Thank you on that.

Full Panel – March 13, 2026

So this is a Draft Report for Polyacrylate-13. This is a high molecular weight, film former polymer reported in 1807 formulations with a maximum reported concentration of 3.5 in leave-on face and neck products, and up to 1.8 percent in eyelash and eyebrow preparations.

This is a well-attended report with a lot of data. And other than some discussion points we could bring up after the motion, we move for a conclusion that it's safe as used in present practices.

DR. BELSITO: Second.

DR. BELSITO: Any further discussion regarding this ingredient?

DR. BELSITO: Yeah, greater than 10,000 Daltons not absorbed, so that obviates our need for systemic, and just one correction. For the Sens-Is -- this is PDF Page 16 -- the last sentence says, when tested at 10, 50 (undiluted), the mixture was nonirritating. Sens-Is does not measure irritation it measures sensitization. So, it should simply say the mixture was concluded to be non-sensitizing.

DR. BERGFELD: Okay. Any other comments. David?

DR. DAVID COHEN: Yeah, for the Discussion, we have to reinforce that residual monomers need to be minimized. And I think this is the report where we had lower monomer concentration than the acrylate dossier itself.

DR. BELSITO: Yeah, minimize the level of acrylamides.

DR. DAVID COHEN: Yeah, acrylamides.

DR. ROSS: That was the discussion, yeah, particularly given the EU highlight. But I think, yeah, minimizing the acrylamide would be a good comment in there. And I think someone came up with some verbiage for that. Maybe it was Monice, I don't know.

DR. BELSITO: I think the typical verbiage goes around, manufacturers should continue to minimize the presence of acrylamide in final product or something like that.

DR. ROSS: Yeah.

DR. BELSITO: There's language that we have for these impurities.

DR. BERGFELD: Priya can look at those Conclusions.

MS. FIUME: Yeah.

DR. BELSITO: Well, the Discussions, not Conclusions.

DR. DAVID COHEN: You know what it was? In this dossier, acrylamides were less than one ppm. So, if it's in present practices in this dossier, this less than one ppm is lower than some of the others we've spoken about with acrylamide, right? And so, I like this, because it anchors to a lower acrylamide level.

DR. ROSS: One of the previous dossiers had 5 ppm. This one had 1 ppm. The EU has 0.1 to 0.5 ppm. So, I think, yeah, keeping it as low as possible, Don, would be the right verbiage, yeah.

DR. BELSITO: Yeah, I mean, and don't eat French fries tonight.

DR. ROSS: I was going to, actually, but there you go.

DR. DAVID COHEN: You're taking the fun out of everything, Don.

DR. BERGFELD: I'm going to call the question. All those approving of this complete, safe ingredient. I'm going to call it by reverse. Those against? Abstaining? It's approved.

Safety Assessment of Polyacrylate-13 as Used in Cosmetics

Status:	Draft Final Report for Panel Review
Release Date:	September 11, 2026
Panel Meeting Date:	October 5-6, 2026

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ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
Dictionary	*International Cosmetic Ingredient Dictionary*
FDA	US Food and Drug Administration
HET-CAM	hen's egg test on the chorioallantoic membrane
HRIPT	human repeated-insult patch test
ICE	isolated chicken eye
l.o.	leave-on
LD_{50}	median lethal dose
MoCRA	Modernization of Cosmetics Regulation Act of 2022
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NR	not reported
OECD	Organisation for Economic Co-operation and Development
Panel	Expert Panel for Cosmetic Ingredient Safety
RBCA	red blood cell aggregation
RLD	Registration and Listing Data
r.o.	rinse-off
SIOPT	single-insult occlusive patch test
TG	test guideline
US	United States
WoE	weight-of-evidence

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of Polyacrylate-13, which is reported to function as a film former in cosmetic products. The Panel reviewed the available data to determine the safety of this ingredient, and stated that industry should continue to use good manufacturing practices to minimize the presence of residual acrylamide in final formulations. The Panel concluded that Polyacrylate-13 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

This assessment reviews the safety of Polyacrylate-13 as used in cosmetic formulations. According to the *International Cosmetic Ingredient Dictionary* (*Dictionary*), Polyacrylate-13 is reported to function as a film former in cosmetic products.[1]

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 September 2026. 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 Expert Panel for Cosmetic Ingredient Safety (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.

Much of the data included in this safety assessment was found on the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) website.[2] (Please note that the NICNAS website provides summaries of information generated by industry, and it is those summary data that are reported in this safety assessment when NICNAS is cited.) The test chemical evaluated in the NICNAS paper was categorized as a polymer of low concern and is a tradename mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20. The Panel has reviewed the safety of both of these two additional ingredients, issuing a published a report in 2020 stating that polyisobutene is safe in cosmetics in the present practices of use and concentration described in the safety assessment[3] and a final amended report on polysorbate 20 in 2015 with the conclusion that this ingredient is safe in cosmetics when formulated to be non-irritating.[4]

CHEMISTRY

Definition and Structure

According to the *Dictionary*, Polyacrylate-13 is a copolymer consisting of acrylic acid, acrylamide, sodium acrylate, and sodium acryloyldimethyltaurate monomers.[1] One possible structure of Polyacrylate-13 is shown in Figure 1.[CIR Staff]

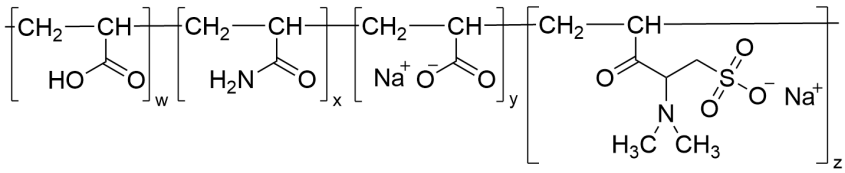


Figure 1. Polyacrylate-13 (This idealized structure is merely 1 generalized depiction of this copolymer. Although the above monomer residues are drawn sequentially, for convenience, this by no means implies that this ingredient comprises a block-type copolymer. Instead, this structure is meant to represent only 1 example of the multitude of potentially produced connectivities found within these macromolecules.)

Chemical Properties

One tradename mixture that includes Polyacrylate-13 is reported to be a translucent to opaque, white-to-pale yellow viscous emulsion.[2] The number average formula weight of the tradename mixture is > 10,000 Da. Other chemical properties of this tradename mixture can be found in Table 1.

Methods of Manufacture

Unpublished data submitted by industry stated Polyacrylate-13 is produced by polymerization in inverse emulsion.[5] No further details were provided.

Impurities

According to an industry submission, a tradename mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 contains < 1 ppm acrylamide.[5] No further details were provided.

USE

Cosmetic

The safety of the cosmetic ingredient 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 Polyacrylate-13 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 of 2022 (MoCRA), 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.[6] Another change resulting from MoCRA is the addition of tattoo preparations (permanent tattoo inks, temporary tattoo inks, and other tattoo products) to the product categories for which companies need to list their products with FDA. However, evaluating the safety of ingredients as used in tattoo preparations is not within the purview of the Panel; accordingly, such use is not included as part of the present practices of use that are assessed by the Panel.

According to RLD obtained from the FDA in 2025, Polyacrylate-13 was reported to be used in 1807 formulations (Table 2).[7,8] The results of the most recent concentration of use survey, which was conducted in 2025 using MoCRA product categories, reported the highest reported concentration of use resulting in leave-on exposure was 3.4% in leave on face and neck products (not spray).[9]

Polyacrylate-13 is used in products that are applied near the eye (e.g., eyelash and eyebrow preparations up to 1.8%), that can be incidentally ingested (e.g., lipsticks and lip glosses; concentration of use not reported), and in products that are used near mucous membranes (e.g., bath soaps and body washes; concentration of use not reported). Additionally, Polyacrylate-13 is reported to be used in sprays (e.g., perfumes; concentration of use not reported) and powders (e.g., face powders; concentration of use not reported) and could therefore be incidentally inhaled. In practice, as stated in the Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings), most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.

For Polyacrylate-13 reported use in baby products is identified in the RLD; however, concentration of use data are not available for this category of baby product. In cases where a baby product category is reported without an associated concentration, but an analogous adult product category with reported concentration data is available, the adult product use level may be considered informative for exposure characterization. In such cases, concentrations in the corresponding baby product category are not expected to exceed those reported for the analogous adult product category. For example, Polyacrylate-13 has no reported concentration of use in baby lotions, oils, powders, and creams but it is reported in leave-on body and hand products (not spray) at a maximum concentration of 0.74% accordingly, concentrations in baby lotions, oils, powders, and creams are not expected to exceed this value. The category "other baby products" represents a miscellaneous grouping of reported uses not assigned to specific baby product subcategories. Given its broad and non-specific nature, it does not correspond to a single analogous adult product category; therefore, the adult-product concentration bridging approach is not applied to this category.

Following the passage of MoCRA, the FDA created a number of new product categories, including "(17) Other preparations (i.e., those preparations that do not fit another category)" (Category 17). CIR and the Panel utilize these product categories to inform, in part, the weight-of-evidence (WoE) in exposure and risk analyses. However, citation of Category 17, alone, as the product use category is uninformative. When a product is co-categorized with both Category 17 and one or more common product use categories (e.g., eye makeup preparations), or other information in the RLD such as the product name are indicative of use type (e.g., "lip balm" is part of the product name), then those uses are accounted for and may be considered to be part of the "the present practices of use" for those products; as such, the Panel's safety conclusion may be inclusive thereon. Conversely, for instances wherein the use of an ingredient in a cosmetic product is only categorized as Category 17 and other information in the RLD is not indicative of use type, the present practices of use for these products remain unknown and the Panel's safety assessment conclusion, therefore, does not apply thereon.

It is possible that some products containing Polyacrylate-13 may be marketed for use with airbrush delivery systems. With the advent of MoCRA and the current product categories outlined therein, 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. None of the reported product categories for this ingredient as listed in the RLD include a designation using airbrush application, so it is possible that this ingredient is used with airbrush delivery systems, but not reported as such. Additionally, the concentration of use surveys are conducted based on product categories as stated in the RLD, but airbrush use was not reported in response to the survey. No consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with airbrush technology, 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. If this ingredient was to be used in airbrush formulations, the data are insufficient to evaluate the exposure resulting from cosmetics applied in such a manner.

In the European Union, polyacrylamides are listed on Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions.[10] Polyacrylate-13 is included under this entry. The restrictions/conditions of use state polyacrylamides can be used in body leave-on products and other products up to a maximum residual acrylamide content of 0.1 and 0.5 mg/kg, respectively, in finished products.

Non-Cosmetic

Non-cosmetic uses were not found in the published literature, and unpublished data were not submitted.

TOXICOKINETIC STUDIES

Toxicokinetics studies were not found in the published literature, and unpublished data were not submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

An acute oral study was completed in rats using a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20.[2] The study followed Organisation for Economic Co-operation and Development (OECD) test guideline (TG) 423. There were no effects observed and the median lethal dose (LD_{50}) was > 2000 mg/kg bw. No additional information was given.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Developmental and reproductive toxicity studies were not found in the published literature, and unpublished data were not submitted.

GENOTOXICITY STUDIES

In Vitro

Gene Mutation

A bacterial reverse mutation test was conducted using a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 according to OECD TG 471.[2] The substance was considered non-mutagenic. No additional information was provided.

CARCINOGENICITY STUDIES

Carcinogenicity studies were not found in the published literature, and unpublished data were not submitted.

DERMAL IRRITATION AND SENSITIZATION STUDIES

The dermal irritation and sensitization studies summarized herein are described in Table 3. The dermal irritation of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 was tested in 20 subjects in a 48-h single-insult occlusive patch test (SIOPT).[2] The study concluded that the trade mixture was non-irritating at 3%. The same trade mixture was evaluated for sensitization potential using a human repeated-insult patch test (HRIPT) in 49 subjects. The researchers concluded that the trade mixture did not have evidence of sensitization at 5%. In a different study, a skin care product containing 3.5% Polyacrylate-13 was tested in an HRIPT in 108 subjects; 50 mg of the formulation were applied over a 7.5 mm^2 patch area (Polyacrylate-13 dose per unit area was 3.11 mg/cm^2).[10] The substance yielded similar results where no dermal irritation or allergic contact sensitization was observed under occlusion or in open application. A Sens-Is assay was performed on a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), hydrogenated polyisobutene, and polyglyceryl-10 laurate.[5] When tested at 10, 50, and 100% (undiluted), the mixture was concluded to be non-sensitizing.

OCULAR IRRITATION STUDIES

Details of the ocular irritation studies summarized below are described in Table 4.

A study evaluated the ocular irritation potential of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 in vitro using the hen's egg test on the chorioallantoic membrane (HET-CAM).[2] At 3%, the test was negative, and the trade mixture was considered to be non-irritating. In a different study, the ocular irritation potential of the same trade mixture was evaluated using the in vitro red blood cell aggregation (RBCA) method. The trade mixture is expected to be non-irritating at 5%. The ocular irritation potential of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), hydrogenated polyisobutene, and polyglyceryl-10 laurate was tested undiluted using the isolated chicken eye (ICE) test.[5] This method is used to determine whether a substance is categorized as a "chemical inducing serious eye damage" or a "chemical not requiring classification for eye irritation or serious eye damage" according to OECD TG 438. The mixture was "not predicted as causing serious eye damage or not predicted as not classified."

SUMMARY

The safety of Polyacrylate-13 as used in cosmetics is reviewed in this safety assessment. Polyacrylate-13 is reported to function in cosmetics as a film former.

According to RLD obtained from the FDA in 2025, Polyacrylate-13 is reported to be used in 1807 formulations. In response to a Council survey conducted in 2025, Polyacrylate-13 was reported to be used at up to 3.4% in leave on face and neck products (not spray).

The toxicity of a trade name mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 was evaluated in several studies. The mixture had an oral LD_{50} of > 2000 mg/kg bw in rats. It was non-mutagenic in an Ames test (concentrations tested not stated).

The dermal irritation of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 was tested in 20 subjects in a 48-h SIOPT. The study concluded that the trade mixture was non-irritating at 3%. The same trade mixture was evaluated for sensitization potential using an HRIPT in 49 subjects. The researchers concluded that the trade mixture did not have evidence of sensitization at 5%. In a different study, a skin care product containing 3.5% Polyacrylate-13 was tested in an HRIPT in 108 subjects; 50 mg of the formulation was applied to a 7.5 mm^2 patch area (Polyacrylate-13 dose per unit area was 3.11 mg/cm^2). The substance yielded similar results where no dermal irritation or allergic contact sensitization was observed under occlusion or in open application. A Sens-Is assay was performed on a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), hydrogenated polyisobutene, and polyglyceryl-10 laurate. When tested at 10%, 50%, and undiluted (100%), the mixture was concluded to be non-sensitizing.

A study evaluated the ocular irritation potential of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 in vitro using the hen's egg test on the chorioallantoic membrane (HET-CAM). At 3%, the test was negative, and the trade mixture was considered to be non-irritating. In a different study, the ocular irritation potential of the same trade mixture was evaluated using the in vitro red blood cell aggregation (RBCA) method. The trade mixture is expected to be non-irritating at 5%. The ocular irritation potential of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), hydrogenated polyisobutene, and polyglyceryl-10 laurate was tested undiluted using the isolated chicken eye (ICE) test. This method is used to determine whether a substance is categorized as a "chemical inducing serious eye damage" or a "chemical not requiring classification for eye irritation or serious eye damage" according to OECD TG 438. The mixture was "not predicted as causing serious eye damage or not predicted as not classified."

DISCUSSION

This assessment reviews the safety of Polyacrylate-13 as used in cosmetic formulations, in accordance with the product categories and concentrations of use identified in the Use section and Use table. The Panel concluded that Polyacrylate-13 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

The Panel noted that due to the large average formula weight of this ingredient (>10,000 Da), it is unlikely to be absorbed through the skin, thereby limiting systemic exposure. Consequently, concern for the lack of additional toxicity data (e.g. developmental and reproductive toxicity studies) was mitigated. The Panel did note that Polyacrylate-13 is not an irritant or a sensitizer.

The Panel recognized that residual acrylamide monomer may be present. In the European Union, polyacrylamides (including Polyacrylate-13) are listed on Annex III, and the restrictions/conditions of use state polyacrylamides can be used in body leave-on products and other products up to a maximum residual acrylamide content of 0.1 and 0.5 mg/kg, respectively, in finished products. Accordingly, the Panel stated that industry should continue to use good manufacturing practices to minimize the presence of residual acrylamide in final formulations.

The Panel discussed the issue of incidental inhalation exposure resulting from this ingredient. Inhalation toxicity data were not available. However, the Panel noted that the majority of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or tracheobronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the low concentrations at which these ingredients are used (or expected to be used) in potentially inhaled products, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at https://www.cir-safety.org/cir-findings.

The Panel's respiratory exposure resource document (see link above) notes that airbrush technology presents a potential safety concern. Although frequency and 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 that if this ingredient is used in airbrush formulations, the data are insufficient to support safe use when applied with such delivery system.

Use in baby products has been reported, but concentration of use data were not available. When use in a baby product category is reported without an associated concentration, and an analogous adult product category with reported concentration data is available, the adult product concentration is considered informative for exposure characterization. Accordingly, concentrations in the corresponding baby product categories are not expected to exceed those reported for the analogous adult product categories. Thus, although no concentration of use is reported for Polyacrylate-13 in baby lotions, oils, powders, and creams, this ingredient is reported in leave-on body and hand products (not spray) at a maximum concentration of 0.74%, and concentrations in baby lotions, oils, powders, and creams are not expected to exceed this value. The category "other baby products" represents a miscellaneous grouping of reported uses not assigned to specific baby product subcategories; given its broad and non-specific nature, an analogous adult product category could not be identified, and the adult-product bridging is not applied.

Additionally, at least 1 use for the ingredient reviewed in this assessment is reported in the RLD under Category 17, "other preparations." For instances wherein the use of an ingredient in a cosmetic product is only categorized as Category 17, and other information in the RLD is not indicative of use type, the present practices of use for such products remain unknown and the Panel's safety assessment conclusion, therefore, does not apply thereon.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that Polyacrylate-13 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

TABLES

Table 1. Chemical properties of a tradename mixture (aq.) comprising Polyacrylate-13, polyisobutene, and polysorbate 20

Property	Value	Reference
Physical Form (@ 20 ºC and 101.3 kPa)	Viscous emulsion	[2]
Color	Translucent to opaque, white to pale yellow	[2]
Formula Weight (number average; Da)	> 10,000	[2]
Density (kg/m^3 @ 20 ºC)	100	[2]
Glass Transition Temperature (ºC)	> 200 (decomp.)	[2]
Water Solubility	Insoluble, but when dispersed in water, it forms a gel	[2]

Table 2. Frequency and concentration of use of Polyacrylate-13 according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use
	RLD (2025) [7,8]	% (2025)[9]
Totals*	**1807**	**0.16-3.4**
summarized by likely duration and exposure**		
Duration of Use		
Leave-On	*1944*	*0.16 - 3.4*
Rinse-Off	*242*	*0.3*
Diluted for (Bath) Use	*1*	*NR*
Unknown	*21*	*NR*
Exposure Type		
Baby Products	1	NR
Children's Makeup	NR	NR
Eye Area	60	1.8
Incidental Ingestion	265	NR
Mucous Membrane	274	NR
Incidental Inhalation-Spray	1; 682[a]; 990[b]	0.81 - 1.2[b]
Incidental Inhalation-Airbrush	NR	NR
Incidental Inhalation-Powder	2; 990[b] ; 1[c]	0.81 - 1.2[b]; 0.16 - 3.4[c]
Dermal Contact	1856	0.16 – 3.4
Deodorant (underarm)	4 (not spray)	NR
Hair - Non-Coloring	41	0.9 - 1.2
Hair-Coloring	20	NR
Nail	3	NR
Other Preparations (Unknown Exposure Type)	21	NR
as reported by product category		
Baby Products		
Baby Lotions/Oils/Powders/Creams	1	NR
Bath Preparations		
Bath Oils, Tablets, and Salts	1	NR
Eye Makeup Preparations (other than children's eye makeup preparations)		
Eyebrow Pencil	4	NR
Eye Lotion	34	NR
Eye Makeup Remover	1	NR
Mascara	2	NR
Eyelash and Eyebrow Adhesives, Glues, and Sealants	6	NR
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)	8	1.8
Other Eye Makeup Preparations	5	NR
Fragrance Preparations		
Perfumes	1	NR
Hair Preparations (non-coloring)		
Hair Conditioners	10 (l.o); 3 (r.o.)	NR
Shampoos (non-coloring)	2 (r.o.)	NR
Tonics, Dressings, and Other Hair Grooming Aids	4	0.9 - 1.2
Other Hair Preparations	22	NR
Hair Coloring Preparations		
Hair Dyes and Colors (all types requiring caution statements and patch tests)	10	NR
Other Hair Coloring Preparation	10 (r.o.)	NR
Makeup Preparations (not eye; not children's)		
Blushers and Rouges (all types)	2	NR
Face Powders	2	NR
Foundations	2 (traditional application)	NR
Lipsticks and Lip Glosses	265	NR
Makeup Bases	6 (traditional application)	0.96
Makeup Fixatives	6	NR

Table 2. Frequency and concentration of use of Polyacrylate-13 according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use
	RLD (2025) [7,8]	**% (2025)**[9]
Other Makeup Preparations	14 (traditional application)	NR
Manicuring Preparations		
Nail Creams and Lotions	1	NR
Nail Polishes and Enamels	2	NR
Personal Cleanliness		
Bath Soaps and Body Washes	6	NR
Deodorants (underarm)	4	NR
Other Personal Cleanliness Products	1 (l.o.); 1 (r.o.)	NR
Shaving Preparations		
Aftershave Lotions	5	NR
Skin Care Preparations (creams, lotions, powder, and sprays)		
Cleansing (cold creams, cleansing lotions, liquids, and pads)	67	NR
Depilatories	2	NR
Face and Neck (excluding shaving preparations)	674 (l.o.); 63 (r.o.)	0.24 - 3.4 (l.o.; not spray)
Body and Hand (excluding shaving preparations)	152 (l.o.); 10 (r.o.)	0.16 - 0.74 (l.o.; not spray)
Moisturizing	506	0.72 - 0.9 (not spray)
Night	29	0.32 (not spray)
Paste Masks (mud packs)	28	0.3
Skin Fresheners	12	NR
Other Skin Care Preparations	160 (l.o.); 17 (r.o.)	0.81
Suntan Preparations		
Suntan Gels, Creams, and Liquids	10	NR
Indoor Tanning Preparations	11	NR
Other Suntan Preparations	3	NR
Other Preparations (i.e., those preparations that do not fit another category)	**21**	NA

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	Protocol	Results	Reference
IRRITATION						
HUMAN						
Polyacrylate-13 (up to 70%) in a trade mixture with hydrogenated polyisobutene, and polysorbate 20	NR	3% (no further information given)	20 subjects	48-h SIOPT; no further information given	2 subjects experienced very slight to slight erythema after patch removal at 48 h. However, after 48 h, the effects were reversed. Mixture was non-irritating at 3%.	[2]
SENSITIZATION						
IN VITRO						
Polyacrylate-13 (up to 70%) in a trade mixture with hydrogenated polyisobutene and polyglyceryl-10 laurate	Undiluted & in DMSO	10% (in DMSO) 50% (in DMSO) 100% (undiluted) No further information given.	NR	Sens-Is assay performed following a draft OECD guideline; no further information given	Mixture was concluded to be non-sensitizing.	[5]
HUMAN						
Polyacrylate-13 (up to 70%) in a trade mixture with hydrogenated polyisobutene, and polysorbate 20	NR	5% (no further information given)	49 subjects	HRIPT was completed; no further information given	Induction phase: slight erythema in 1 subject on days 5, 8, and 10 and at induction site immediately after challenge phase. Challenge site: no reactions. No evidence of sensitization at 5%.	[2]
leave-on skin care product containing 3.5% Polyacrylate-13	NR	neat 50 mg of formulation applied to 7.5 mm^2 patch area Polyacrylate-13 dose per unit area = 3.11 mg/cm^2	108 subjects	HRIPT was completed with an induction period lasting 3 wk consisting of three 24-h applications/wk. A challenge patch was applied to a previously untested site following a 2-wk non-treatment period. The subjects were split 50/50 and either had an occlusive application or open application.	No allergic contact sensitization or dermal irritation observed.	[10]

HRIPT - human repeated-insult patch test; NR – not reported; SIOPT - single-insult occlusive patch test

Table 4. Ocular irritation studies

Test Article	Vehicle	Concentration/Dose	Test Population	Protocol	Results	Reference
IN VITRO						
Polyacrylate-13 (up to 70%) in a trade mixture with hydrogenated polyisobutene, and polysorbate 20	NR	3%	NR	HET-CAM test was completed; no further information given	At 3%, test was negative, so the mixture was non-irritating.	[2]
Polyacrylate-13 (up to 70%) in a trade mixture with hydrogenated polyisobutene, and polysorbate 20	NR	5%	NR	RBCA was completed; no further information given	At 5%, the mixture was non-irritating.	[2]
Polyacrylate-13 (up to 70%) in a trade mixture with hydrogenated polyisobutene and polyglyceryl-10 laurate	NR	100% (undiluted)	NR	ICE test following OECD TG 438; no further information given	The mixture was "not predicted as causing serious eye damage or not predicted as not classified."	[5]

HET-CAM - hen's egg test on the chorioallantoic membrane; ICE - isolated chicken eye; RBCA – red blood cell aggregation

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