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# Safety Assessment of Polyacrylate-13 as Used in Cosmetics

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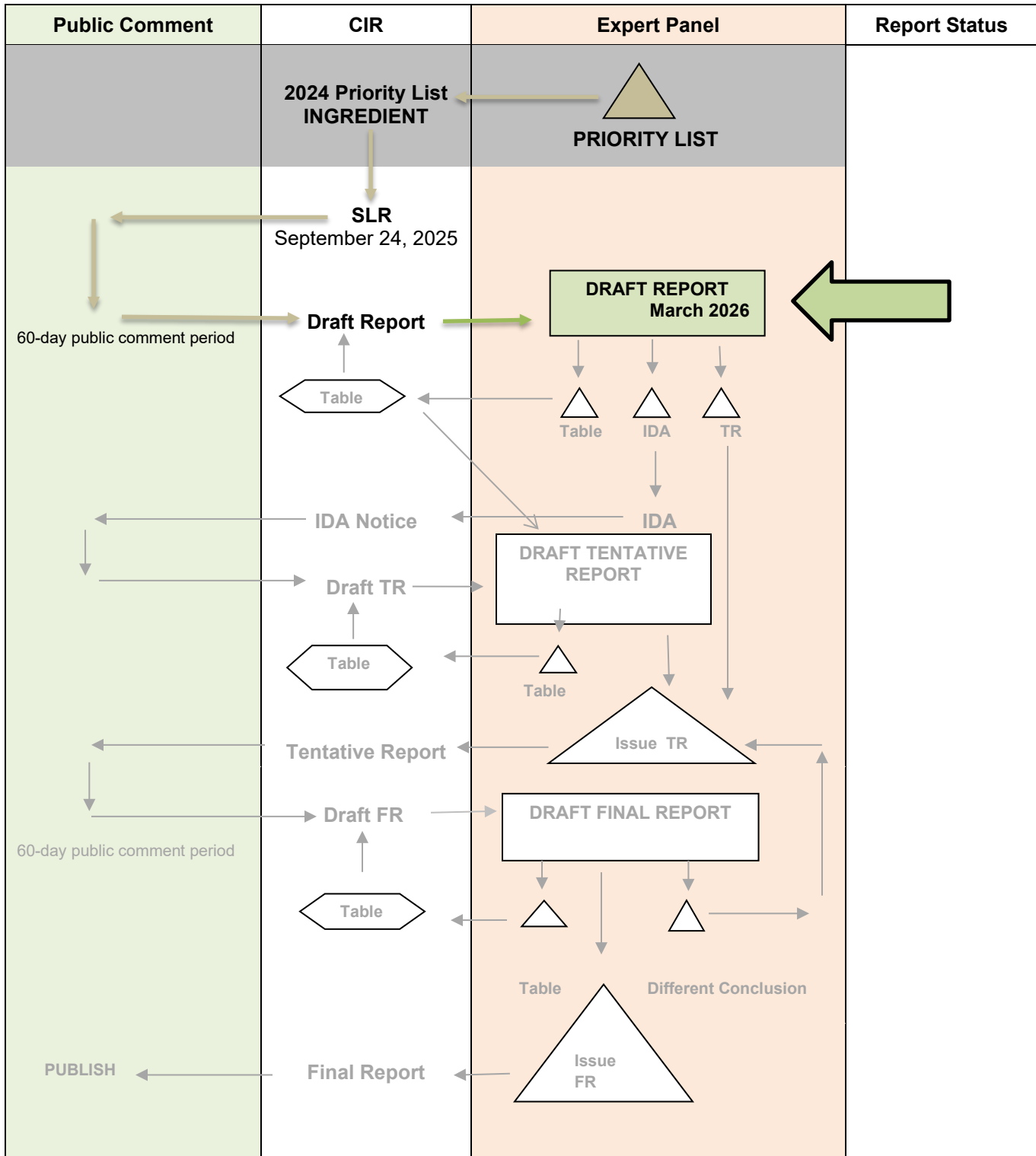
Status: Draft Report for Panel Review  
Release Date: February 17, 2026  
Panel Meeting Date: March 12-13, 2026

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 Temima Nguyen, M.S., Scientific Analyst/Writer, CIR.

# SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY  Polyacrylate-13

MEETING  March 2026



**Memorandum**

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons  
From: Temima Nguyen, M.S., Scientific Analyst/Writer, CIR  
Date: February 17, 2026  
Subject: Safety Assessment of Polyacrylate-13 as Used in Cosmetics

Enclosed is the Draft Report on the Safety Assessment of Polyacrylate-13 as Used in Cosmetics. (It is identified as *report\_Polyacrylate-13\_032026* in the pdf document). This is the first time the Panel is seeing this safety assessment; the Scientific Literature Review (SLR) was issued by CIR on September 24, 2025. Please note, 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. (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.)

The results of a concentration of use survey performed using MoCRA categories were submitted by industry and are included (*data1\_Polyacrylate-13\_032026*). Also, since the issuing of the SLR, data on the method of manufacturing and for a trade name mixture containing Polyacrylate-13 were submitted; this submission also included summary in vitro dermal irritation and sensitization and ocular irritation data on the mixture (*data2\_Polyacrylate-13\_032026*). Additionally, a human repeated-insult patch test (HRIPT) evaluating the irritation and sensitization potential of a leave-on skin care product containing 3.5% Polyacrylate-13 was received and is included in this report document (*data3\_Polyacrylate-13\_032026*).

Other items include:

- Council comments on the SLR and those received on the Draft Report prior to the cancellation of the December meeting (*PCPCcomments1\_Polyacrylate-13\_032026*; *PCPCcomments2\_Polyacrylate-13\_032026*, respectively)
- responses to those PCPC comments (*response-PCPCcomments1\_Polyacrylate-13\_032026*; *response-PCPCcomments2\_Polyacrylate-13\_032026*)
- flow chart (*flow\_Polyacrylate-13\_032026*)
- report history (*history\_Polyacrylate-13\_032026*)
- search strategy (*search\_Polyacrylate-13\_032026*)
- data profile (*datapofile\_Polyacrylate-13\_032026*)

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

### Polyacrylate-13 History

#### **September 24<sup>th</sup>, 2025**

SLR posted.

#### **September 30<sup>th</sup>, 2025**

A summary of an HRIPT on a product containing Polyacrylate-13 was provided.

#### **October 27<sup>th</sup>, 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 2026**

Panel reviews Draft Report with updated RLD.

**Polyacrylate-13 Data Profile\* - March 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 <sub>ow</sub>	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_en) [https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs\\_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](http://www.google.com) <https://scholar.google.com/>



### Memorandum

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

**FROM:** Kimberly Norman, Ph.D., DABT, ERT  
Industry Liaison to the CIR Expert Panel

**DATE:** October 10, 2025

**SUBJECT:** Scientific Literature Review: Safety Assessment of Polyacrylate-13 as Used in Cosmetics (release date September 24, 2025)

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

Introduction – In the Introduction it would be helpful to state that Polyacrylate-13 was notified to NICNAS under the category of polymer of low concern. It would also be helpful to state that the two other components included in the tested trade name mixture, Polyisobutene and Polysorbate 20 have been reviewed by CIR. Polyisobutene has a “safe as used” conclusion (published 2020), and Polysorbate 20 a safe when formulated to be non-irritating conclusion (final in 2015). Although the NICNAS report included a dash in Polysorbate 20, the INCI name has no dash.

Cosmetic Use – It should be made clear that the material listed in Annex III of the EU cosmetics regulation is “Polyacrylamides”. Polyacrylate-13 is not specifically listed in Annex III as implied by the scientific literature review.

<b>Polyacrylate-13 – March 2026 – Temima Nguyen</b>	
<b>Comment Submitter: Kimberly Norman, Personal Care Products Council</b>	
<b>Date of Submission: October 10, 2025</b>	
<b>Comment</b>	<b>Response/Action</b>
<p>Introduction – In the Introduction it would be helpful to state that Polyacrylate-13 was notified to NICNAS under the category of polymer of low concern. It would also be helpful to state that the two other components included in the tested trade name mixture, Polyisobutene and Polysorbate 20 have been reviewed by CIR. Polyisobutene has a “safe as used” conclusion (published 2020), and Polysorbate 20 a safe when formulated to be non-irritating conclusion (final in 2015).</p> <p>Although the NICNAS report included a dash in Polysorbate 20, the INCI name has no dash.</p>	Addressed.
<p>Cosmetic Use – It should be made clear that the material listed in Annex III of the EU cosmetics regulation is “Polyacrylamides”. Polyacrylate-13 is not specifically listed in Annex III as implied by the scientific literature review</p>	Addressed.



### Memorandum

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

**FROM:** Jaap Venema, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** November 26, 2025

**SUBJECT:** Draft Report: Safety Assessment of Polyacrylate-13 as Used in Cosmetics  
(December 2025 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.

Dermal Irritation and Sensitization; Summary; Table 3 – The description of the HRIPT in 108 subjects is misleading. The first paragraph of the submission, (pdf page 23 of the Panel book) states: “A leave-on skin care product used as spot treatment containing the ingredient Polyacrylate-13 at 3.5% was tested for its potential to induce irritation and sensitization in healthy human subjects using HRIPT procedure, as described below.” Rather than being tested “individually”, a skin care product containing 3.5% Polyacrylate-13 was tested. The CIR report should be corrected in the Dermal Irritation and Sensitization section, the Summary and in Table 3.

Summary – Please correct “polyglyceryl” (should be “polyglyceryl”)

<b>Polyacrylate-13 – March 2026 – Temima Nguyen</b>	
<b>Comment Submitter: Jaap Venema, Personal Care Products Council</b>	
<b>Date of Submission: November 26, 2025</b>	
<b>Comment</b>	<b>Response/Action</b>
Dermal Irritation and Sensitization; Summary; Table 3 – The description of the HRIPT in 108 subjects is misleading. The first paragraph of the submission, (pdf page 23 of the Panel book) states: “A leave-on skin care product used as spot treatment containing the ingredient Polyacrylate-13 at 3.5% was tested for its potential to induce irritation and sensitization in healthy human subjects using HRIPT procedure, as described below.” Rather than being tested “individually”, a skin care product containing 3.5% Polyacrylate-13 was tested. The CIR report should be corrected in the Dermal Irritation and Sensitization section, the Summary and in Table 3.	Addressed.
Summary – Please correct “polyglyceryl” (should be “polyglyceryl”)	Addressed.

# Safety Assessment of Polyacrylate-13 as Used in Cosmetics

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**ABBREVIATIONS**

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
<i>Dictionary</i>	<i>International Cosmetic Ingredient Dictionary and Handbook</i>
FDA	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 <sub>50</sub>	median lethal dose
MoCRA	Modernization of Cosmetics Regulation Act
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

## INTRODUCTION

This assessment reviews the safety of Polyacrylate-13 as used in cosmetic formulations. According to the web-based *International Cosmetic Ingredient Dictionary and Handbook (Dictionary)*, Polyacrylate-13 is reported to function as a film former in cosmetic products.<sup>1</sup>

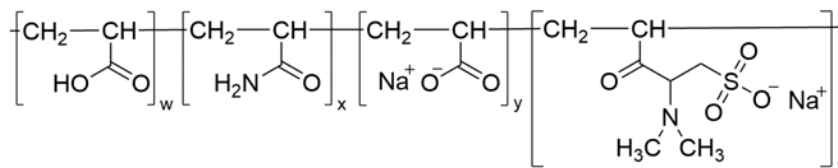
This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an extensive search of the world's literature; a search was last conducted October 2025. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the 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.<sup>2</sup> (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 report in 2020 stating that polyisobutene is safe in cosmetics in the present practices of use and concentration described in the safety assessment<sup>3</sup> 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.<sup>4</sup>

## CHEMISTRY

### Definition and Structure

According to the *Dictionary*, Polyacrylate-13 is a copolymer consisting of acrylic acid, acrylamide, sodium acrylate, and sodium acryloyldimethyltaurate monomers.<sup>1</sup> This ingredient has the following chemical structure as shown in Figure 1.<sup>CIR Staff</sup>



**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.<sup>2</sup> 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.<sup>5</sup> 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.<sup>5</sup> 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 (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.<sup>6</sup>

According to RLD obtained from the FDA in 2025, Polyacrylate-13 was reported to be used in 1807 formulations (Table 2).<sup>7,8</sup> 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).<sup>9</sup>

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 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.

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 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 this ingredient as listed in the RLD do require designation if airbrush application is used (e.g., makeup bases), but no airbrush use was indicated. Additionally, 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.

In the European Union, polyacrylamides are currently listed on Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions.<sup>10</sup> Polyacrylate-13 is listed as one of the ingredients underneath this regulation which states that it 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.

#### **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.<sup>2</sup> 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<sub>50</sub>) 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**

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.<sup>2</sup> 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).<sup>2</sup> 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<sup>2</sup> patch area (Polyacrylate-13 dose per unit area was 3.11 mg/cm<sup>2</sup>).<sup>11</sup> 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.<sup>5</sup> When tested at 10%, 50%, and undiluted (100%), the mixture was non-irritating and concluded to be a non-sensitizer.

## **OCULAR IRRITATION STUDIES**

### **In Vitro**

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).<sup>2</sup> 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.<sup>5</sup> 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<sub>50</sub> 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<sup>2</sup> patch area (Polyacrylate-13 dose per unit area was 3.11 mg/cm<sup>2</sup>). 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 nonirritating and concluded to be a non-sensitizer.

A trade name mixture comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 was predicted not to be an ocular irritant at 3% in an in vitro HET-CAM or at 5% in a RBCA assay. When a different trade mixture comprising Polyacrylate-13 (up to 70%), hydrogenated polyisobutene, and polyglyceryl-10 laurate was tested using an ICE test method according to OECD TG 438, the mixture was "not predicted as causing serious eye damage or not predicted as not classified."

## **DISCUSSION**

To be developed.

## **CONCLUSION**

To be determined.

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

Property	Value	Reference
Physical Form (@ 20 °C 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 <sup>3</sup> @ 20 °C)	100	2
Glass Transition Temperature (°C)	> 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) <sup>7,8</sup>	% (2025) <sup>9</sup>
<b>Totals*</b>	<b>1807</b>	<b>0.16-3.4</b>
<b>summarized by likely duration and exposure**</b>		
<b>Duration of Use</b>		
Leave-On	1944	0.16 - 3.4
Rinse-Off	242	0.3
Diluted for (Bath) Use	1	NR
Permanent Tattoo Ink	NR	NR
Unknown	21	NR
<b>Exposure Type</b>		
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 <sup>a</sup> ; 990 <sup>b</sup>	0.81 - 1.2 <sup>b</sup>
Incidental Inhalation-Airbrush	NR	NR
Incidental Inhalation-Powder	2; 990 <sup>b</sup> ; 1 <sup>c</sup>	0.81 - 1.2 <sup>b</sup> ; 0.16 - 3.4 <sup>c</sup>
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
Tattoo Preparations	NR	NR
Other Preparations (Unknown Exposure Type)	21	NR
<b>as reported by product category</b>		
<b>Baby Products</b>		
Baby Lotions/Oils/Powders/Creams	1	NR
<b>Bath Preparations</b>		
Bath Oils, Tablets, and Salts	1	NR
<b>Eye Makeup Preparations (other than children's eye makeup preparations)</b>		
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
<b>Fragrance Preparations</b>		
Perfumes	1	NR
<b>Hair Preparations (non-coloring)</b>		
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
<b>Hair Coloring Preparations</b>		
Hair Dyes and Colors (all types requiring caution statements and patch tests)	10	NR
Other Hair Coloring Preparation	10 (r.o.)	NR
<b>Makeup Preparations (not eye; not children's)</b>		
Blushers and Rouges (all types)	2	NR
Face Powders	2	NR
Foundations	2 (traditional application)	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) <sup>7,8</sup>	% (2025) <sup>9</sup>
Lipsticks and Lip Glosses	265	NR
Makeup Bases	6 (traditional application)	0.96
Makeup Fixatives	6	NR
Other Makeup Preparations	14 (traditional application)	NR
<b>Manicuring Preparations</b>		
Nail Creams and Lotions	1	NR
Nail Polishes and Enamels	2	NR
<b>Personal Cleanliness</b>		
Bath Soaps and Body Washes	6	NR
Deodorants (underarm)	4	NR
Other Personal Cleanliness Products	1 (l.o.); 1 (r.o.)	NR
<b>Shaving Preparations</b>		
Aftershave Lotions	5	NR
<b>Skin Care Preparations (creams, lotions, powder, and sprays)</b>		
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
<b>Suntan Preparations</b>		
Suntan Gels, Creams, and Liquids	10	NR
Indoor Tanning Preparations	11	NR
Other Suntan Preparations	3	NR
<b>Other Preparations (i.e., those preparations that do not fit another category)</b>	<b>21</b>	<b>NA</b>

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>)

<sup>a</sup> It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

<sup>b</sup> 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.

<sup>c</sup> 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
<b>IRRITATION</b>						
<b>HUMAN</b>						
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
<b>SENSITIZATION</b>						
<b>IN VITRO</b>						
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 both a non-irritant and non-sensitizer.	5
<b>HUMAN</b>						
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 <sup>2</sup> patch area Polyacrylate-13 dose per unit area = 3.11 mg/cm <sup>2</sup>	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.	11

HRIPT - human repeated-insult patch test; SIOPT - single-insult occlusive patch test

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## Concentration of Use by FDA Product Category<sup>1</sup>

### Polyacrylate-13

<b>Product Category</b>	<b>Maximum Concentration of Use</b>
Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers)	1.8%
Tonics, dressings, and other hair grooming aids	0.9-1.2%
Makeup bases Traditional	0.96%
Face and neck products (not spray) Leave-on	0.24-3.4%
Body and hand products (not spray) Leave-on	0.16-0.74%
Moisturizing products (not spray)	0.72-0.9%
Night products (not spray)	0.32%
Paste masks and mud packs	0.3%
Other skin care preparations Leave-on	0.81%

Information collected in 2025  
Table prepared: October 20, 2025

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<sup>1</sup> The new FDA cosmetic product categories under MoCRA were used for this survey.



**Memorandum**

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

**FROM:** Carol Eisenmann, Ph.D.  
Personal Care Products Council

**DATE:** October 27, 2025

**SUBJECT:** Polyacrylate-13

Anonymous. 2025. Summary information – Polyacrylate-13.

October 2025

### Summary Information – Polyacrylate-13

Polyacrylate-13 is only sold as part of an aqueous mixture (with Polyisobutene and Polysorbate 20) as described in the 2006 NICNAS assessment cited in the CIR Scientific Literature Review.

- Method of manufacturing data

Polymerization in inverse emulsion

- Impurities data

For the trade mixture (aq) containing Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20, the impurities are as follows:

Acrylamide <1ppm

- Dermal irritation and sensitization data at maximum concentration of use

The skin sensitization potential of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), hydrogenated polyisobutene, and polyglyceryl-10 laurate was evaluated in a Sens-Is assay (draft OECD guideline <https://www.oecd.org/content/dam/oecd/en/events/public-consultations/2024/7/draft-test-guidelines-sens-is-assay.pdf>). The mixture was tested undiluted and at 50% and 10% in DMSO. The mixture was concluded as non irritant and non sensitizer.

- Ocular irritation data at maximum concentration of use

The eye irritation potential of a trade mixture (aq.) comprising Polyacrylate-13 (up to 70%), hydrogenated polyisobutene, and polyglyceryl-10 laurate was tested undiluted in the Isolated Chicken Eye Test (ICE) Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring classification for Eye Irritation or Serious Eye Damage according to OECD 438. The mixture was not predicted as “causing serious eyes damage” or not predicted as “not classified” (tested pure, score = 3 x II).



**Memorandum**

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

**FROM:** Carol Eisenmann, Ph.D.  
Personal Care Products Council

**DATE:** September 30, 2025

**SUBJECT:** Polyacrylate-13

Anonymous. 2025. HRIPT on a Product Containing Polyacrylate -13.

**September 29, 2025**

### **HRIPT on a product containing Polyacrylate-13**

A leave-on skin care product used as spot treatment containing the ingredient Polyacrylate-13 at 3.5% was tested for its potential to induce irritation and sensitization in healthy human subjects using HRIPT procedure, as described below.

#### **HRIPT procedure**

- Completed in November 2007
- 108 subjects completed the study
- Approximately 0.05 g of the test product was applied to the 7.5 mm x 7.5 mm paper disk of the Finn Chamber. 50% of participants had the application under occlusive conditions and the other 50% of participants had the open application. The upper back between the scapulae was served as the treatment area.
- Induction phase consisted of a series of 9 x 24-hour applications over 3 consecutive weeks (Monday, Wednesday and Friday of each week); approximately 2 weeks after the final induction patch application, challenge patch was applied on a virgin test site adjacent to the original induction patch site. The patch was removed 24 hours after application and the site was scored at Day 2 and Day 3 post-application.
- No adverse reactions scored during the process. Test material considered as non-primary irritant and non-primary sensitizer.

#### **Calculations for dose/cm<sup>2</sup>**

Amount of product applied = 50 mg (0.05 g)

Concentration of ingredient = 3.5%

Amount of ingredient applied = 1.75 mg

Applied area = 0.563 cm<sup>2</sup>

Dose per unit area = 3.11 mg/cm<sup>2</sup>

#### **Conclusion**

Under the conditions of the test, the product (containing Polyacrylate-13 at 3.5%, applied at 3.11 mg/cm<sup>2</sup>) did not show potential to induce dermal irritation or allergic contact sensitization.