Safety Assessment of Polyacrylate-13 as Used in Cosmetics

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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

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 use good manufacturing practices to minimize the presence of residual acrylamide monomer 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This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated.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 Unpublished data are provided by the cosmetics industry, as well as by other interested parties.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]

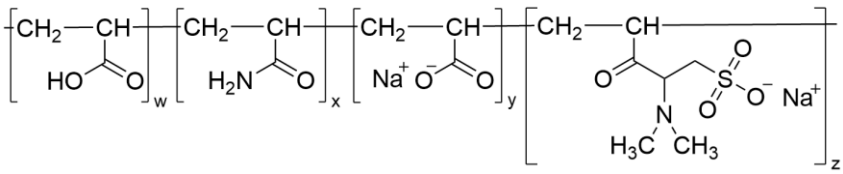


Figure 1. Polyacrylate-13 (This idealized structure is merely 1 generalized depiction of this copolymer. Although the above monomer residues are drawn sequentially, for convenience, this by no means implies that this ingredient comprises a block-type copolymer. Instead, this structure is meant to represent 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), in products that are used near mucous membranes (e.g., bath soaps and body washes), and in baby products (e.g., baby lotions/oils/powders/creams); concentrations of use were not reported for any of these product types. 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.

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). 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), 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, the present practices of use for these products remain unknown and the Panel's safety assessment conclusion does not apply to these preparations.

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 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.

Use in baby products has been reported, but concentration of use data were not available. The Panel noted that due to the large average formula weight of this ingredient (>10,000 Da), Polyacrylate-13 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) and for the lack of concentration of use data for baby products 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. In an industry submission, a tradename mixture (aq.) comprising Polyacrylate-13 (up to 70%), polyisobutene, and polysorbate 20 was reported to contain < 1 ppm acrylamide. Accordingly, the Panel stated that industry should use good manufacturing practices to minimize the presence of residual acrylamide monomer 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.

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 conclusion, therefore, does not apply to these preparations.

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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