Safety Assessment of Glyceryl Acrylates as Used in Cosmetics

Status: Tentative Report for Public Comment
Release Date: March 11, 2022
Panel Meeting Date: June 16-17, 2022

All interested persons are provided 60 days from the above release date (i.e., May 10, 2022) to comment on this safety assessment, and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to the Cosmetic Ingredient Review (CIR) will be discussed in open meetings, will be available for review by any interested party, and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth

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ABBREVIATIONS

aq.	aqueous
CFR	Code of Federal Regulations
CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
CPSC	Consumer Product Safety Commission
FDA	Food and Drug Administration
FHSLA	Federation of Health Science Library Associations
HRIPT	human repeated insult patch test
NR	not reported
Panel	Expert Panel for Cosmetic Ingredient Safety
PII	primary irritation index
SIOPT	single-insult occlusive patch test
SLS	sodium lauryl sulfate
VCRP	Voluntary Cosmetic Registration Program
wINCI	web-based *International Cosmetic Ingredient Dictionary and Handbook*
US	United States

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 4 glyceryl acrylates as used in cosmetic formulations. Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer and Glyceryl Acrylate/Acrylic Acid Copolymer are both reported to function in cosmetics as skin-conditioning agents, and Glyceryl Polyacrylate and Glyceryl Polymethacrylate as film formers. The Panel considered the available data and concluded that these ingredients are safe in cosmetics in the present practices of use and concentrations described in this safety assessment

INTRODUCTION

The safety of the following 4 glyceryl acrylates as used in cosmetics is reviewed in this safety assessment:

Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer
Glyceryl Acrylate/Acrylic Acid Copolymer
Glyceryl Polyacrylate
Glyceryl Polymethacrylate

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*), Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer and Glyceryl Acrylate/Acrylic Acid Copolymer are both reported function in cosmetics as a skin-conditioning agents; Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer is also reported to function as a humectant, and Glyceryl Acrylate/Acrylic Acid Copolymer as a viscosity increasing agent (Table 1).[1] Glyceryl Polyacrylate and Glyceryl Polymethacrylate are both reported to function in cosmetics as a film former.

The safety of Glyceryl Polyacrylate as used in cosmetics was previously reviewed by the Expert Panel for Cosmetic Ingredient Safety (Panel). In 2004, the Panel published a report, concluding that Glyceryl Polyacrylate is safe as a cosmetic ingredient in the present practices of use and concentration [described in that report].[2] Additionally, in 2018, the Panel issued a final amended report on 126 acrylates copolymers (not glyceryl) with the following conclusion, "Acrylates copolymers are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating."[3]

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 exhaustive search of the world's literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

CHEMISTRY

Definition and Structure

Two ingredients defined as copolymers, i.e., Caprylyl Glycol/Glycerin/ Polyacrylic Acid Copolymer and Glyceryl Acrylate/Acrylic Acid Copolymer, and two esters of glycerin, i.e., Glyceryl Polyacrylate and Glyceryl Polymethacrylate, are reviewed in this safety assessment.[1] These ingredients are each vinyl-type polymers, resulting from the esterification of acrylic acid or methacrylic acid with glycerin. The figure for Glyceryl Polymethacrylate, an ester of glycerin and polymethacrylic acid, is depicted in Figure 1.

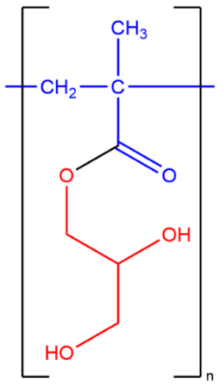


Figure 1. Glyceryl Polymethacrylate

The definitions, idealized structures, and available CAS Nos. of the glyceryl acrylates included in this safety assessment are presented in Table 1.

Chemical Properties

According to one supplier, Glyceryl Polyacrylate has a molecular weight > 500,000 Da.[4] Properties data on a Glyceryl Acrylate/Acrylic Acid Copolymer trade name mixture, but not on the ingredient alone, were found and are presented in Table 2. This mixture (which contains 1.71 – 2.09% Glyceryl Acrylate/Acrylic Acid Copolymer, 36.5 – 44.6% glycerin, 50- 62% water, and 0.85 – 1.1% propylene glycol) is water-soluble and has a relative density of 1.15 g/ml.[5]

Method of Manufacture

Glyceryl Polymethacrylate

According to one paper, the mixing of 4-aminocarbonylazo-2-pyrimidinone with mildly acidic solutions of 1-glyceryl methacrylate resulted in polymerization to Glyceryl Polymethacrylate.[6]

Method of manufacture data on glyceryl acrylates for use in cosmetics were not found in the published literature, and unpublished data were not provided.

Impurities

Glyceryl Acrylate/Acrylic Acid Copolymer

Potential impurities of Glyceryl Acrylate/Acrylic Acid Copolymer include acrylic acid (< 5 ppm), methyl vinyl ether (< 0.5 ppm), and maleic acid (< 5 ppm).[7]

Glyceryl Polyacrylate

Glyceryl Polyacrylate may contain < 5 ppm residual acrylic acid.[4]

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in the FDA Voluntary Cosmetic Registration Program (VCRP) database. The cosmetic product categories named in the VCRP database indicate the intended uses of cosmetic ingredients, and are identified in 21 CFR Part 720. Data are submitted by the cosmetic industry in response to a survey conducted by the Personal Care Products Council (Council) of maximum reported use concentrations, also by product category. Neither the categories provided by the VCRP, nor those provided by the Council survey, include a designation for use via airbrush application. Airbrush devices, alone, are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients used in airbrush devices are within the jurisdiction of the FDA. As airbrush technology use for cosmetics has neither been evaluated by the CPSC, nor the use of cosmetic ingredients in airbrush technology by the FDA, no US regulatory authority has evaluated the safety of this delivery methodology for cosmetic ingredients. Moreover, no consumer habits and practices data are available to evaluate the risks associated with this use type.

According to 2022 FDA VCRP data, Glyceryl Acrylate/Acrylic Acid Copolymer has the greatest frequency of use; it is reported to be used in 295 cosmetic products, 288 of which are leave-on products (Table 3).[8] The results of concentration of use surveys conducted by the Council, and provided to CIR in 2021, indicate that Glyceryl Polymethacrylate has the highest concentration of use; it is used at maximum use concentrations up to1.9% in leave-on products (body and hand products).[9,10] The frequency of use of Glyceryl Polyacrylate has increased since it was originally reviewed by the Panel; in 1998, 1 use was reported,[2] and in 2022, 119 uses are reported[8] (Table 4). The maximum reported concentration of use of Glyceryl Polyacrylate has decreased slightly since the original review; in 1999, this ingredient was reported to be used at a maximum of 2% in face and neck creams, lotions, powders, and sprays,[2] and in 2021, it was reported to have a maximum use concentration of 0.99% in face and neck products (not sprays).[10]

Cosmetic products containing glyceryl acrylates may incidentally come in contact with the eyes (e.g., Glyceryl Acrylate/ Acrylic Acid Copolymer at concentrations up to 0.62% in eye lotions), and 3 of these 4 ingredients are also used in products are reported to be used in formulations that come in contact with mucous membranes (concentrations not stated). Additionally, the potential for incidental ingestion exists with these ingredients; Glyceryl Acrylate/Acrylic Acid Copolymer is reported to be used in 12 lipstick formulations (concentration not stated). Use in baby products is also reported (e.g., Glyceryl Polyacrylate is used at up to 0.09% in baby lotions, oils, and creams.)

Some of these ingredients are used in cosmetic products that could possibly be inhaled. For example, Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer is reported to be used at a maximum concentration of 0.2% in perfumes, and Glyceryl Polymethacrylate (concentration not reported) is reported to be used in face powders. In practice, most droplets/ particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[13,14] 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.[15-17]

Additionally, although products containing some of these ingredients may be marketed for use with airbrush technology, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients (and without consumer habits and practices data related to this use technology), the data are insufficient to evaluate the safety thereof in airbrush applications.

The glyceryl acrylates reviewed in this safety assessment are not restricted from use in any way under the rules governing cosmetic products in the European Union.[18]

Non-Cosmetic

Glyceryl Polymethacrylate–collagen composite hydrogels have been developed for implantation in surgical lesions of the rat brain. Such materials provide porous matrices that can serve as support systems for growth of scar tissue and axonal growth.[19,20] It has been noted that this technology has considerable potential for basic as well as for clinical research in central nervous system regeneration. Other reported uses of Glyceryl Polymethacrylate include autoclavable lubricant and moisturizer for medical and surgical use.[21]

TOXICOKINETIC STUDIES

Toxicokinetic data on glyceryl acrylates were not found in the published literature, and unpublished data were not provided.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

Glyceryl Acrylate/Acrylic Acid Copolymer

The acute oral toxicity of Glyceryl Acrylate/Acrylic Acid Copolymer was evaluated in rats (number of animals not provided). [7] Fasted animals were dosed by gavage with up to 5 g/kg, and observed fore 14 d; no mortality was reported. The oral LD_{50} of Glyceryl Acrylate/Acrylic Acid Copolymer was > 5 g/kg in rats.

Short-Term, Subchronic, and Chronic Toxicity Studies

Repeated dose toxicity studies on glyceryl acrylates were not found in the published literature, and unpublished data were not provided.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Developmental and reproductive toxicity data on glyceryl acrylates were not found in the published literature, and unpublished data were not provided.

GENOTOXICITY STUDIES

In Vitro

Glyceryl Acrylate/Acrylic Acid Copolymer

The mutagenic potential of Glyceryl Acrylate/Acrylic Acid Copolymer was evaluated in an Ames test using *Salmonella typhimurium* TA97a, T98, TA100, and TA102, and TA1535.[7] A concentration of 5000 µg/plate was tested with and without metabolic activation. Vehicle and positive controls were used; however, the control substances were not identified. Glyceryl Acrylate/Acrylic Acid Copolymer was not mutagenic.

Glyceryl Polyacrylate

An Ames test was conducted on 1.9% Glyceryl Polyacrylate.[4] The test substance was not mutagenic. No details were provided.

CARCINOGENICITY STUDIES

Carcinogenicity data on glyceryl acrylates were not found in the published literature, and unpublished data were not provided.

OTHER RELEVANT STUDIES

Effect on Burn-Wound Healing

Glyceryl Polymethacrylate

Eight domestic pigs were subjected to burn wounds in the paravertebral area. Some wounds were exposed to an experimental cream, and other wounds served as air-exposed controls.[22] The cream consisted of Glyceryl Polymethacrylate in an oil-in-water emulsion with the following components: fibronectin (40 ppm), proline, arginine, and glycine. Beginning on day 0 (day of wounding), the wounds were treated once daily with the cream (~ 0.2 g/wound site) to completely cover the wound until healing was complete. The wounds treated with the cream developed a soft eschar, when compared to air-exposed control wounds. Erythema was not observed after application of the cream.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Dermal irritation and sensitization studies are described in Table 5, and summarized below.

In rabbits, application of an occlusive patch of 1.3 – 2% Glyceryl Acrylate/Acrylic Acid Copolymer in a water and glycerin solution for 24 h was not irritating.[7] In clinical single insult occlusive patch tests (SIOPT), a product containing 0.586% Glyceryl Acrylate/Acrylic Acid Copolymer (23 subjects)[23] and a product containing 7.7% Glyceryl Polymethacrylate (19 subjects)[24] were non-irritating; the primary irritation index (PII) in each study was 0 and 0.05, respectively.

Glyceryl Acrylate/Acrylic Acid Copolymer (1.3 – 2% in a water and glycerin solution; 55 subjects; occlusive patch),[7] a product containing 0.5% Glyceryl Polyacrylate (100 subjects; semi-occlusive patch),[25] and Glyceryl Polyacrylate (1.9%; 51 subjects; patch type not specified)[4] were not irritants or sensitizers in human repeated insult patch tests (HRIPT). Sensitization also was not observed in maximization assays with a product containing 0.586% Glyceryl Acrylate/Acrylic Acid Copolymer (25 subjects)[26] and a product containing 7.7% Glyceryl Polymethacrylate (17 subjects).[27]

OCULAR IRRITATION STUDIES

Animal

Glyceryl Acrylate/Acrylic Acid Copolymer

The ocular irritation potential of 1.3 – 2% Glyceryl Acrylate/Acrylic Acid Copolymer in a water and glycerin solution was evaluated following instillation of 0.1 ml of the test substance into the conjunctival sac of one eye of each of 6 albino rabbits; the eyes were not rinsed.[7] The contralateral eye served as a control. Each eye was evaluated after 24, 48, and 72 h, and no signs of irritation were observed. Glyceryl Acrylate/Acrylic Acid Copolymer (1.3 – 2% in a water and glycerin solution) was not irritating to the eyes of rabbits.

MUCOUS MEMBRANE IRRITATION STUDIES

Animal

Glyceryl Acrylate/Acrylic Acid Copolymer

The vaginal mucosal irritation potential of 1.3 – 2% Glyceryl Acrylate/Acrylic Acid Copolymer in a water and glycerin solution was evaluated using groups of 6 albino rabbits.[7] The test material (0.1 ml) was applied to the vaginal orifice of the animals, and the animals were observed 5x/d for 7 d for gross signs of edema, erythema, and excretion. For the negative controls, the tip of an empty 1.0 ml syringe was inserted. Glyceryl Acrylate/Acrylic Acid Copolymer (1.3 – 2% in a water and glycerin solution) was not irritating to the vaginal mucosa of rabbits; the mucosal irritation index was 0.

SUMMARY

The safety of 4 glyceryl acrylates as used in cosmetics is reviewed in this safety assessment. According to the *Dictionary*, Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer and Glyceryl Acrylate/Acrylic Acid Copolymer are both reported to function in cosmetics as skin-conditioning agents, and Glyceryl Polyacrylate and Glyceryl Polymethacrylate as film formers.

The mixing of 4-aminocarbonylazo-2-pyrimidinone with mildly acidic solutions of 1-glyceryl methacrylate was reported to result in polymerization to Glyceryl Polymethacrylate. According to data submitted by industry, both Glyceryl Acrylate/ Acrylic Acid Copolymer and Glyceryl Polyacrylate may contain < 5 ppm residual acrylic acid. Glyceryl Acrylate/Acrylic Acid Copolymer may also contain methyl vinyl either (< 0.5 ppm) and maleic acid (< 5 ppm).

According to 2022 FDA VCRP data, Glyceryl Acrylate/Acrylic Acid Copolymer has the greatest frequency of use; it is reported to be used in 295 cosmetic products (288 leave-on products and 7 rinse-off products). The results of a concentration of use surveys provided by the Council in 2021 indicate Glyceryl Polymethacrylate has the highest concentration of use; it is used at maximum use concentrations up to1.9% in leave-on products.

The acute oral toxicity of Glyceryl Acrylate/Acrylic Acid Copolymer was evaluated in rats; the test article was administered by gavage. The oral LD_{50} was > 5 g/kg.

The mutagenic potential of Glyceryl Acrylate/Acrylic Acid Copolymer and 1.9% Glyceryl Polyacrylate were evaluated in the Ames test. Neither substance was mutagenic.

Eight domestic pigs were subjected to burn wounds in the paravertebral area. The wounds were exposed to an experimental cream that consisted of Glyceryl Polymethacrylate in an oil-in-water emulsion. Daily treatment with the cream (~ 0.2 g/wound site) was continued until wound healing was complete. Application of the cream resulted in a soft eschar, but erythema was not observed.

In rabbits, application of an occlusive patch of 1.3 – 2% Glyceryl Acrylate/Acrylic Acid Copolymer in a water and glycerin solution for 24 h was not irritating. In clinical SIOPTs, a product containing 0.586% Glyceryl Acrylate/Acrylic Acid Copolymer (23 subjects) and a product containing 7.7% Glyceryl Polymethacrylate (19 subjects) were non-irritating; the PII in each study was 0 and 0.05, respectively.

In an HRIPT, Glyceryl Acrylate/Acrylic Acid Copolymer (1.3 – 2% in a water and glycerin solution; 55 subjects; occlusive patch), a product containing 0.5% Glyceryl Polyacrylate (tested neat; 100 subjects; semi-occlusive patch), and Glyceryl Polyacrylate (1.9%; 51 subjects; patch type not specified) were not irritants or sensitizers. Sensitization also was not observed in maximization assays with a product containing 0.586% Glyceryl Acrylate/Acrylic Acid Copolymer (25 subjects) and a product containing 7.7% Glyceryl Polymethacrylate (17 subjects).

Glyceryl Acrylate/Acrylic Acid Copolymer (1.3 – 2% in a water and glycerin solution) was not irritating to rabbit eyes. It also was non-irritating when applied to the vaginal mucosa of rabbits.

DISCUSSION

This assessment reviews the safety of 4 glyceryl acrylates as used in cosmetic formulations. The Panel reviewed the available data and concluded that these ingredients are safe in cosmetics in the present practices of use and concentration described in the safety assessment.

The Panel determined that the available data were sufficient to support the safety of all 4 glyceryl acrylates. Representative data on method of manufacturing and impurities were adequate for evaluating the entire group of ingredients. Safety was further supported by the large molecular weights of these ingredients. Glyceryl Polyacrylate, for example, has a molecular weight greater than 500,000 Da. The other polymers are also very large, which precludes dermal absorption.

The Panel discussed the issue of incidental inhalation exposure that could result with the use of formulations that contain these ingredients (e.g., Caprylyl Glycol/ Glycerin/Polyacrylic Acid Copolymer is reported to be used at up to 0.2% in perfumes, and Glyceryl Polymethacrylate (concentrations unavailable) is reported to be used in face powders). 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 bronchial 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 in the respiratory exposure resource document at https://www.cir-safety.org/cir-findings.

The Panel acknowledged that some cosmetic ingredients are used in products marketed for airbrush application. However, the available data are insufficient to make a determination of safety for use of these ingredients in products that may be incidentally inhaled when applied using airbrush devices. The Panel's respiratory exposure resource document (see link above) notes that airbrush technology presents a potential safety concern, and that no data are available for consumer habits and practices thereof. Thus, the data do not support the safety the ingredients named in this report if applied via airbrush technology.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that the following 4 glyceryl acrylates are safe in cosmetics in the present practices of use and concentration described in this safety assessment:

Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer
Glyceryl Acrylate/Acrylic Acid Copolymer
Glyceryl Polyacrylate
Glyceryl Polymethacrylate

TABLES

Table 1. Definitions, reported functions, and idealized structures of the ingredients in this safety assessment.[1, CIR Staff]

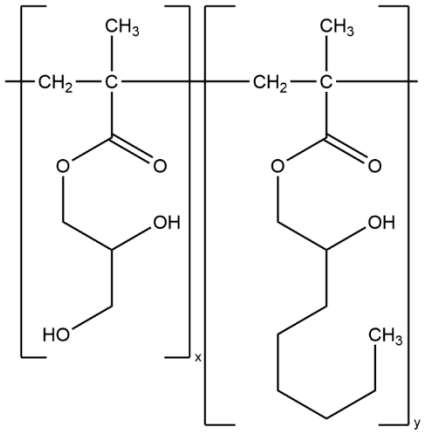
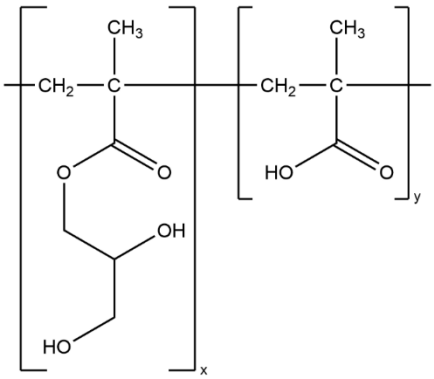
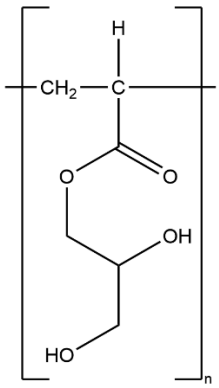
Ingredient/CAS No.	Definition & Structures	Function(s)
Caprylyl Glycol/Glycerin/ Polyacrylic Acid Copolymer	Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer is a copolymer of caprylyl glycol, glycerin, and polyacrylic acid monomers  *Drawn as a simple block-type copolymer for demonstration; other monomer connectivity patterns possible.*	humectant; skin-conditioning agent - emollient
Glyceryl Acrylate/Acrylic Acid Copolymer	Glyceryl Acrylate/Acrylic Acid Copolymer is a copolymer of glyceryl acrylate and acrylic acid  *Drawn as a simple block-type copolymer for demonstration; other monomer connectivity patterns possible.*	skin-conditioning agent - humectant; viscosity increasing agent - aqueous
Glyceryl Polyacrylate 104365-75-5	Glyceryl Polyacrylate is the ester of glycerin and polyacrylic acid 	film former

Table 1. Definitions, reported functions, and idealized structures of the ingredients in this safety assessment.[1, CIR Staff]

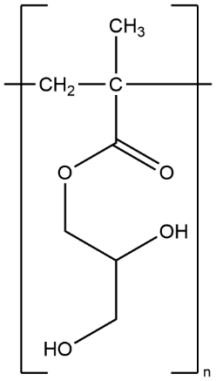
Ingredient/CAS No.	Definition & Structures	Function(s)
Glyceryl Polymethacrylate 146126-21-8 28474-30-8	Glyceryl Polymethacrylate is the ester of glycerin and polymethacrylic acid 	film former

Table 2. Chemical properties

Property	Value/Results	Reference
Glyceryl Acrylate/Acrylic Acid Copolymer trade name mixture (also containing glycerin, water, and propylene glycol)		
Form	Clear, colorless viscous gel	
Solubility	Water-soluble	
Relative density (g/ml)	1.15	
Viscosity (cps)	250,000 – 350,000	
Melting point (ºC)	< 0	
Boiling point (ºC)	> 100	

Table 3. Frequency (2022)[8] and concentration (2020)[9,10] of use according to duration and type of exposure.

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Caprylyl Glycol/Glycerin/ Polyacrylic Acid Copolymer		Glyceryl Acrylate/Acrylic Acid Copolymer		Glyceryl Polymethacrylate	
Totals*/Conc. Range	**NR**	**0.2**	**295**	**0.00001-0.62**	**142**	**0.048 – 1.9**
Duration of Use						
Leave-On	*NR*	*0.2*	*288*	*0.00001-0.62*	*138*	*0.048 – 1.9*
Rinse off	*NR*	*NR*	*7*	*0.012-0.42*	*4*	*NR*
Diluted for (bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	24	0.035-0.62	9	NR
Incidental Ingestion	NR	NR	12	NR	NR	NR
Incidental Inhalation- Sprays	NR	0.2	88[a];131[b]	0.012-0.62[a]	54[a];49b	NR
Incidental Inhalation- Powders	NR	NR	131[b]; 1[c]	0.02-0.1[c]	1;40[b]	0.08-1.9[c]
Dermal Contact	NR	0.2	278	0.00001-0.62	142	0.08-1.9
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	1	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	4	NR	NR	NR
Mucous Membrane	NR	NR	13	NR	1	NR
Baby Products	NR	NR	1	NR	NR	NR

NR = Not Reported

* Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

[a] It is possible that these products may be sprays, but it is not specified whether the reported uses are sprays

[b] Not specified these products are sprays or powders, but it is possible the use can be as a spray or powder, therefore the information is captured in both categories

[c] It is possible that these products may be powders, but it is not specified whether the reported uses are powders

Table 4. Current and historical frequency and concentration of use of Glyceryl Polyacrylate

	# of Uses		Max Conc of Use (%)	
	2022[8]	**1998[2]**	**2021[10]**	**1999[2]**
Totals*/Conc. Range	**119**	**1**	**0.008 – 0.99**	**0.2 – 2**
Duration of Use				
Leave-On	*110*	*1*	*0.0099 – 0.99*	*0.2 – 2*
Rinse-Off	*9*	*NR*	*0.008 – 0.4*	*0.4*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*
Exposure Type				
Eye Area	15	NR	0.25 – 0.5	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	47[a]; 19[b]	1[b]	0.01[a]	0.2[a]; 2[b]
Incidental Inhalation-Powder	19[b]	1[b]	0.09[c]	2[b]
Dermal Contact	118	1	0.008 – 0.99	2
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	1	NR	0.01	0.2 – 0.4
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR
Baby Products	NR	NR	0.0099 – 0.09	NR

NR = Not Reported

* Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

[a] It is possible that these products may be sprays, but it is not specified whether the reported uses are sprays

[b] Not specified these products are sprays or powders, but it is possible the use can be as a spray or powder, therefore the information is captured in both categories

[c] It is possible that these products may be powders, but it is not specified whether the reported uses are powders

Table 5. Dermal irritation and sensitization studies

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
ANIMAL					
Irritation					
Glyceryl Acrylate/Acrylic Acid Copolymer	1.3-2% in a water-glycerin solution 0.5 ml or 0.5 g	6 rabbits	Primary skin irritation testing conducted according to FHSLA, 16 CFR 1500.41. The trunk of each animal was clipped free of hair, and 2.5 cm^2 patches were placed on intact and abraded skin. The trunk of each animal was wrapped with rubberized elastic cloth, and neck collars were placed on the animals. All test sites were evaluated 24 and 72 h after application.	PII = 0.0 not a primary irritant	7
HUMAN					
Irritation					
product containing 0.586%Glyceryl Acrylate/Acrylic Acid Copolymer	tested neat	23 subjects	SIOPT (24 h); a reference control was used (no additional details provided)	PII = 0 no irritation reported for any of the subjects	23
product containing 7.7% Glyceryl Polymethacrylate	tested neat	19 subjects	SIOPT (24 h); a reference control was used (no additional details provided)	PII = 0.05 no irritation in 18 subjects; score of 1 observed for 1 subject	24
Sensitization					
product containing 0.586% Glyceryl Acrylate/Acrylic Acid Copolymer	0.05 ml; tested neat	25 subjects	maximization assay. During induction, an occlusive patch with 0.25% aq. SLS was applied for 24 h; upon removal, an occlusive patch with test article was applied to the same site for 48 h (72 h on weekends). This sequence was repeated for a total of 5 induction exposures. After a 10-d non-treatment period, a previously-untreated site was pretreated with 1% SLS for1 h under an occlusive patch; upon removal, a challenge patch containing the test material was applied to the site for 48 h. The challenge site was scored upon patch removal, and 24 h after removal. Protocol deviations included no SLS pretreatment prior to the last induction patch, due to a scheduling issue.	not a sensitizer; no adverse reactions were observed during the study	26
Glyceryl Acrylate/Acrylic Acid Copolymer	1.3-2% concentration in a water- glycerin solution 0.2 g	55 subjects	HRIPT. During induction, nine 24-h occlusive patches were applied (3x/wk for 3 wk). After a 2-wk non-treatment period, challenge patches were applied for 24 h to a previously untreated site on the back of each subject, and the challenge sites were evaluated 24 and 72 h after patching.	not an irritant or a sensitizer; no significant dermal reactions were observed.	7
product containing 0.5% Glyceryl Polyacrylate	0.2 ml; tested neat	100 subjects	HRIPT. Same HRIPT protocol as described above, with the exception that the patches (2 cm^2) were semi-occlusive, and challenge sites were evaluated 48 and 72h after patching	not a sensitizer During induction: 1 subject discontinued due to experiencing definite erythema and edema after the 5th induction patch; definite erythema, no edema was reported for .9% of the subjects; minimal or doubtful response was recorded for 9.6% of the subjects	25
Glyceryl Polyacrylate	1.9%	51 subjects	HRIPT (details were not provided)		4
product containing 7.7% Glyceryl Polymethacrylate	0.05 ml; tested neat	27 subjects	maximization assay. Same maximization assay protocol as described above, with the exception that 5% SLS was used for pre-treatment at challenge, and no protocol deviations occurred	not a sensitizer; no adverse reactions were observed during induction	27

Abbreviations: aq. – aqueous; CFR – Code of Federal Regulations: FHSLA - Federation of Health Science Library Associations; HRIPT – human repeated insult patch test; PII – primary irritation index; SIOPT – single-insult occlusive patch test; SLS – sodium lauryl sulfate.

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