Safety Assessment of Polysilicone-11 as Used in Cosmetics

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All interested persons are provided 60 days from the above release date (i.e., November 24, 2020) to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included.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 All unpublished data submitted to the Cosmetic Ingredient Review (CIR) will be discussed in open meetings, will be available at the CIR office for review by any interested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.

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 Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Lisa A. Peterson, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. Previous Panel member involved in this assessment: James G. Marks, Jr., M.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya Cherian, Scientific Analyst/Writer, CIR.

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ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of Polysilicone-11 as used in cosmetic formulations. This ingredient is reported to function as a film former. The Panel considered the available data and concluded that Polysilicone-11 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

This is a safety assessment of Polysilicone-11 as used in cosmetic formulations. According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*), Polysilicone-11 functions as a film former in cosmetics.[1] Polysilicone-11 is the product of a reaction between bis-vinyldimethicone and hydrogen methicone; the Panel has previously evaluated the safety of both bis-vinyldimethicone and hydrogen methicone, and concluded that these ingredients are safe in the present practices of use and concentration in cosmetics.[2,3] The full reports on these ingredients can be accessed on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/ingredients).

This safety assessment includes relevant unpublished data that are available for each endpoint that is evaluated. An exhaustive search of the world's literature was performed, and very little published data were found regarding this ingredient. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints the Panel typically evaluates, is provided on the 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

According to the *Dictionary*, Polysilicone-11 (CAS No: 63394-02-5, 156065-02-0) is a crosslinked dimethyl siloxane formed by the reaction of bis-vinyldimethicone and hydrogen dimethicone.[1]

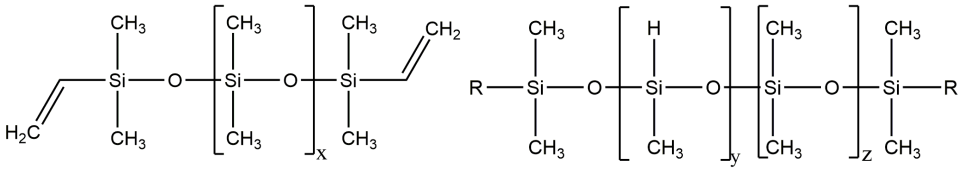

Figure 1. Polysilicone-11 reactants (wherein each instance of R may be hydrogen or methyl; x, y, and z not defined)

For use in cosmetics, copolymers, such as Polysilicone-11, are typically supplied to finishing houses as swollen gels (i.e. trade name mixtures) that contain 1 or more solvents (e.g., cyclopentasiloxane).[4] The addition of the comonomer (i.e. the vinyl-substituted dimethicone) affects both the chemical and the rheological properties of the resultant ingredient. Furthermore, the degree of crosslinking could also significantly affect these properties. Accordingly, this 1 copolymer ingredient theoretically represents a wide variety of materials ranging from liquids to elastomeric solids.

Chemical Properties

While no material properties were found or submitted for this ingredient alone, specifications for tradename mixtures comprising, in part, Polysilicone-11 were found.[5-7] For 3 different tradename mixtures, Polysilicone-11 was stated to comprise 10 – 20% of the mixture composition. The composition remainder of these mixtures (i.e. the other 80 – 90%) was reported to be isododecane, cyclopentasiloxane, or dimethicone. Each of these tradename mixtures is a clear liquid, with a viscosity ranging from 300 to 500 pascal second (Pa·s). The molecular weight of Polysilicone-11 has been reported to be greater than 1 million Da, in the form of an elastomer rubber, amorphous polymer.[8]

Method of Manufacture

According to a supplier, Polysilicone-11 is manufactured in cyclopentasiloxane (D5) solvent, preferable from low cyclotetrasiloxane (D4) feedstock using a hydrosilation catalyst.[8] This is reported to be a pure addition reaction in which no impurities are formed during the reaction and no residual monomers remain after completion.

Impurities

According to a manufacturer, Polysilicone-11 generally contains less than 20 ppm platinum catalyst from hydrosilation.[8] The same manufacturer also reported that heavy metal testing results for Polysilicone-11 typically include: below limits of detection for mercury, and less than 1 ppm for lead and arsenic.

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 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. Use concentration 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 by product category.

According to the 2020 VCRP survey data, Polysilicone-11 is reported to be used in 440 total formulations (432 of which are leave-on formulations; Table 1).[9] The majority of these uses are in face and neck (excluding shave) products, moisturizing products, eye lotions, and foundations. The results of the concentration of use survey conducted by the Council in 2018, and updated in 2019, indicate Polysilicone-11 is used at up to 19.9% in products that have dermal exposure (i.e., other skin care preparations).[10] This ingredient may result in incidental ingestion as it is reported to be used in 8 lipstick formulations at up to 8.8%. In addition, Polysilicone-11 may also be used near the eyes, as it is reported to be used in eyeliner (1 formulation; concentration of use not reported), eye shadows (30 formulations; up to 9.4%), eye lotions (46 formulations; up to 12.2%), mascaras (3 formulations; up to 0.59%), and other eye makeup preparations (19 formulations; up to 0.24%).

Additionally, Polysilicone-11 is used in cosmetic sprays and could possibly be inhaled; for example, it is reported to be used in suntan pump sprays at up to 0.04%. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters > 10 μm, with propellant sprays yielding a greater fraction of droplets/particles < 10 μm compared with pump sprays.[11,12] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e. they would not enter the lungs) to any appreciable amount.[13,14] Polysilicone-11 was reportedly used in face powders at concentrations up to 3.5%, and could possibly be inhaled. 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 air.[15-17]

Polysilicone-11 is not restricted from use in any way under the rules governing cosmetic products in the European Union.[18]

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 toxicity study was performed on Sprague Dawley rats (5/sex) using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane.[19] The test substance was administered undiluted. The LD_{50} was reported to be > 5 g/kg. No other details regarding this study were provided.

Short-Term, Subchronic, and Chronic Toxicity

Short-term, subchronic, and chronic toxicity studies on Polysilicone-11 were neither found in the published literature, nor were these data submitted.

GENOTOXICITY

The genotoxic potential of a mixture consisting of 14% Polysilicone-11, 47% dimethicone, and 39% cyclopentasiloxane, was evaluated in an Ames assay.[19] Bacterial cell lines (*Salmonella typhimurium* strains TA98 and TA100) were tested with and without metabolic activation. The test substance was tested at concentrations of 50, 100, 500, 1000, and 5000 μg/plate, and was considered to be non-mutagenic.

CARCINOGENICITY STUDIES

Data on the carcinogenicity of Polysilicone-11 were neither found in the published literature, nor were these data submitted.

OTHER RELEVANT STUDIES

Cytotoxicity

An agar diffusion test was performed in vitro to determine the biological reactivity of a mammalian cell culture (not specified) following indirect contact with the test substance (a trade name mixture containing 12 - 16% Polysilicone-11, 43 -

50% dimethicone, and 36 - 42% cyclopentasiloxane). The test substance exhibited no reactivity after the 24-hour observation period, and did not induce cytotoxicity.

DERMAL IRRITATION AND SENSITIZATION

Details of the dermal irritation and sensitization studies summarized below are provided in Table 2.

Irritation

A skin irritation study was performed on 6 New Zealand white albino rabbits.[19] The test substance (6% Polysilicone-11 and 94% cyclotetrasiloxane) was applied, undiluted, under a patch (type of patch not specified), on intact and abraded skin. The test substance was not considered to be a primary irritant. A 48-h patch test was performed on 50 subjects using a lipstick containing 1.8% Polysilicone-11 under semi-occlusive conditions.[20] No dermal irritation was observed. Similarly, a 7-d dermal irritation study was performed on 38 subjects using a face cream containing 1.6% Polysilicone-11 under semi-occlusive conditions.[21] On day 1, patches were applied for 24 h and removed. After evaluation of the site, identical patches were applied to the same site, and the process was repeated for 7 d. The subjects showed no evidence of irritation to the test substance.

Sensitization

A human repeated insult patch test (HRIPT) was performed to evaluate the sensitization potential of a product containing 1.45% Polysilicone-11.[22] The test article was placed on the skin of 54 subjects, under an occlusive patch. No evidence of irritation or sensitization was observed. No sensitization was observed in an HRIPT performed on 51 subjects using a facial product containing 9.68% Polysilicone-11.[23] The product was applied neat, under semi-occlusive conditions. An HRIPT was performed on 50 subjects using a test substance consisting of 11% Polysilicone-11 and 89% cyclopentasiloxane.[19] All applications were performed neat (type of patch used not specified). The test substance was considered to be non-irritating and non-sensitizing. Another HRIPT was performed, according to the same procedure, on 110 subjects using a facial product containing 19.83% Polysilicone-11. Applications were made using a 10% dilution of the test substance (2% Polysilicone-11) under a semi-occlusive patch. No sensitization was observed. The amount of test substance used was not stated in either study. A maximization assay was performed on 17 subjects to evaluate the sensitization potential of a test substance containing 24.625% Polysilicone-11 (applied undiluted).[24] No instances of contact allergy were recorded at either 48 or 72 h after the application of the challenge patch. The test substance was not considered to possess a detectable contact-sensitizing potential. No signs of sensitization were observed when an HRIPT was performed on 51 subjects using a trade name mixture consisting of 98% Polysilicone-11 and 2% laureth-12.[25]

OCULAR IRRITATION STUDIES

In Vitro

A tissue equivalent assay was performed with EpiOcular™ cultures to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11.[26] The face cream was tested neat (100 µl), the test samples were treated in duplicate, and the exposure periods were 8, 16, 20, and 24 h. Appropriate negative and positive controls were used. The ET_{50}s (i.e., the time at which the tissue viability was reduced 50% compared to negative control tissues) for Polysilicone-11 and the positive control were 18.2 h and 30.3 min, respectively.

A MatTek EpiOcular™ methyl thiazole tetrazolium (MTT) viability assay was also performed to evaluate the ocular irritation potential of a test substance containing 98.5% Polysilicone-11.[27] The chemical was tested neat (100 µl), the test samples were treated in duplicate, and the exposure periods were 64, 256, and 1200 min. Appropriate negative and positive controls were used. The ET_{50} was 12 h, and the ocular irritancy classification for this test substance was "non-irritating, minimal."

Animal

An acute eye irritation study was performed on 6 New Zealand albino rabbits using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane.[19] Approximately 0.1 ml of the test substance was applied to the eye, undiluted. No other details regarding this study were provided. The test substance was reported to be minimally irritating.

SUMMARY

This is a safety assessment of Polysilicone-11 as used in cosmetics. According to the *Dictionary*, Polysilicone-11 is a crosslinked dimethyl siloxane formed by the reaction of bis-vinyldimethicone and hydrogen dimethicone, and is reported to function as a film former in cosmetics.

According to 2020 VCRP data, Polysilicone-11 is reported to be used in 440 formulations, 432 of which are leave-on formulations. The majority of these uses are in face and neck (excluding shave) products, moisturizing products, eye lotions, and foundations. Results of the concentration of use survey conducted by Council in 2018, and updated in 2019, indicate Polysilicone-11 is used at a maximum concentration of up to 19.9% in other skin care preparations.

An LD_{50} of > 5 g/kg was established in an acute oral toxicity study performed on Sprague-Dawley rats given a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane.

No mutagenicity was reported in an Ames assay performed using a mixture consisting of 14% Polysilicone-11, 47% dimethicone, and 39% cyclopentasiloxane. The test substance was tested on *S. typhimurium* (TA98 and TA100) at concentrations of up to 5000 µg/plate.

No cytotoxicity was observed in an agar diffusion test using a test substance consisting of 12 - 16% Poylsilicone-11, 43 - 50% dimethicone, and 36 - 42% cyclopentasiloxane.

No irritation was observed in a skin irritation study performed on New Zealand white albino rabbits using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane. A 48-h patch test was performed on 50 subjects using a lipstick containing 1.8% Polysilicone-11. No irritation was observed. In addition, no dermal irritation was observed in a 7-d dermal irritation study (24-h patches) performed on 38 subjects using a face cream containing 1.6% Polysilicone-11.

No sensitization was observed in multiple HRIPTs using the following test materials: a facial product containing 9.68% Polysilicone-11, a 10% dilution of a facial product containing 19.83% Polysilicone-11 (2% Polysilicone-11 as actual test concentration), a mixture of 11% Polysilicone-11 and 89% cyclopentasiloxane, a product containing 1.45% Polysilicone-11, or a trade name mixture containing 98% Polysilicone-11 and 2% laureth-12. In a maximization assay performed on 27 subjects using a pre-treatment with SLS, the test substance (containing 24.625% Polysilicone-11) was considered to be non-sensitizing.

An in vitro tissue equivalent assay was performed in order to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11. The ET_{50}s for Polysilicone-11 and the positive control were 18.2 h and 30.3 min, respectively. A MatTek EpiOcular™ MTT viability assay was also performed to evaluate the ocular irritation potential of a test substance containing 98.5% Polysilicone-11. The ET_{50} was 12 h, and the ocular irritancy classification for this test substance was "non-irritating, minimal." In an ocular irritation study in New Zealand white rabbits, a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane applied to the eyes was considered to be minimally irritating.

DISCUSSION

The Panel determined that the available acute toxicity, genotoxicity, irritation, and sensitization data were adequate for assessing the safety of Polysilicone-11 as used in cosmetics. There was a lack of chronic toxicity and mammalian genotoxicity data in this safety assessment. However, the Panel was not concerned about these gaps because Polysilicone-11 is reported to have a large molecular weight, therefore it is unlikely that skin penetration would occur. Concern for a lack of impurities and residual monomer data was mitigated as this ingredient is reported to be the product of a pure addition reaction, forming no impurities and resulting in residual monomers. In addition, safety of this ingredient was supported by the lack of systemic toxicity in an acute oral exposure assay, no instances of dermal or ocular irritation, no evidence of sensitization in an assay using Polysilicone-11 at 98%, the absence of genotoxicity in an Ames assay, and lack of adverse clinical reports.

The Panel discussed the issue of incidental inhalation exposure from powders and suntan pump sprays. The Council survey results indicate that Polysilicone-11 is being used in face powders at concentrations up to 3.5%. In addition, Polysilicone-11 is used in spray suntan products at up to 0.04%. The Panel noted that in aerosol products, 95% – 99% 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 concentrations at which the ingredients are used, 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.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that Polysilicone-11 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

TABLES

Table 1. Frequency and concentration of use of Polysilicone-11[9,10]

	# of Uses	*Max Conc. of Use (%)*
Totals*	***440***	***0.025 – 19.9***
Duration of Use		
Leave-On	412	0.025 – 19.9
Rinse-Off	8	0.061 – 5.8
Diluted for (Bath) Use	NR	NR
Exposure Type		
Eye Area	94	0.24 – 12.2
Incidental Ingestion	8	7.2 – 8.8
Incidental Inhalation-Spray	100[a]; 90[b]	0.04; 0.47 – 0.48[b]
Incidental Inhalation-Powder	8; 100[a]	0.025 – 3.5; 0.08 – 14.6[c]
Dermal Contact	407	0.025 – 19.9
Deodorant (underarm)	NR	NR
Hair - Non-Coloring	1	0.48
Hair-Coloring	NR	NR
Nail	1	NR
Mucous Membrane	8	7.2 – 8.8
Baby Products	NR	NR

*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] 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
[b] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[c] It is possible these products are powders, but it is not specified whether the reported uses are powders
NR – no reported use

Table 2. Dermal irritation and sensitization

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
			ANIMAL		
6% Polysilicone-11 and 94% cyclotetrasiloxane	100%; 0.5 g	6 New Zealand White Rabbits	The test substance was applied under a 2.5 cm^2 patch on intact and abraded skin (type of patch not specified)	Non-irritating	[19]
			HUMAN		
Product containing 1.45 % Polysilicone-11	100%; 0.1 – 0.15 g	54	HRIPT; The test substance was applied neat, under an occlusive patch, 3 times per week during the induction period. The amount of test substance used was not reported. Patches were removed 24 h after each application. After a 2-wk rest period, a challenge patch was applied to a previously untreated test site. Patches were removed and the site was scored 24 and 72 h post-application.	Non-irritating; Non-sensitizing	[22]
Lipstick containing 1.8% Polysilicone-11	100%; 0.2 ml	50	The test material was applied to a 1" x 1" absorbent pad portion of a clear adhesive dressing, and placed on the back. This dressing formed a semi-occlusive patch. The material remained on the skin for 2 d.	Non-irritating	[20]
Face cream containing 1.6% Polysilicone-11	100%; 0.2 g	38	On day 1, the undiluted test substance (0.2 g) was applied to the back, under semi-occlusive conditions. After approximately 24 h, patches were removed. Twenty to 40 minutes after patch removal, sites were evaluated, and identical patches were applied to the same site. This process was repeated daily for a total of 7 d. Distilled water and 0.75% sodium lauryl sulfate (SLS) served as the negative and positive controls, respectively.	Non-irritating	[21]
Facial product containing 9.68% Polysilicone-11	100%; amount of test substance not reported	51	HRIPT (same procedure as above); semi-occlusive patch	Non-sensitizing	[23]
11% Polysilicone-11 and 89% cyclopentasiloxane	100%; amount of test substance not reported	50	HRIPT (same procedure as above); patch type not specified	Non-irritating; Non-sensitizing	[19]
Facial product containing 19.83% Polysilicone-11	10% dilution (actual test concentration 2% Polysilicone-11); amount of test substance not reported	110	HRIPT (same procedure as above); semi-occlusive patch	Non-sensitizing	[23]
Liquid blend containing 24.625% Polysilicone-11	100%; 0.05 ml	17	Maximization assay. Approximately 0.05 ml of aqueous SLS was applied to the skin of each subject under occlusive conditions for 24 h. After 24 h, patches were removed and 0.05 ml of the test material was applied to the same site, and covered with occlusive tape. This induction patch was left in place for 48 or 72 h. After removal of the induction patches, if no irritation was present, a 0.25% SLS aqueous patch was again reapplied to the same site for 24 h, followed by reapplication of a fresh induction patch with the test material. This sequence of SLS pre-treatment followed by 48 h of test material application continued for a total of 5 induction exposures. The induction phase was followed by a 10-d rest period. After the rest period, subjects were challenged with a single, 48-h application of the test material to a previously untreated site. Pre-treatment with SLS was performed prior to challenge. Evaluations were performed 48 and 72 h after application of challenge patch.	Non-sensitizing	[24]
Trade name mixture containing 98% Polysilicone-11 and 2% laureth-12	100%; 0.2 g	51	HRIPT (same procedure as above); occlusive patch	Non-irritating; Non-sensitizing	[25]

HRIPT = human repeated insult patch test; SLS = sodium lauryl sulfate

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