Safety Assessment of Polysilsesquioxanes as Used in Cosmetics

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The 2017 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Executive Director is Bart Heldreth, Ph.D. This report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

1620 L Street, NW, Suite 1200 ♢ Washington, DC 20036-4702 ♢ ph 202.331.0651 ♢ fax 202.331.0088
cirinfo@cir-safety.org

ABSTRACT

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) assessed the safety of 18 polysilsesquioxane ingredients as used in cosmetics. The majority of the ingredients named in this assessment have several functions, with most reported to function as film formers, opacifying agents, and nail conditioning agents. The Panel reviewed relevant data related to these ingredients and concluded that these polysilsesquioxanes are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

This is a safety assessment of 18 polysilsesquioxanes as used in cosmetics. The ingredients in this group comprise the polymers resulting from the hydrolysis and condensation of alkyltrialkoxysilanes or alkyltrichlorosilanes, and typically comprise three-dimensional frameworks. According to the web-based *Cosmetic Ingredient Dictionary and Handbook* (wINCI *Dictionary*), many of the ingredients named in this assessment have several functions, with most reported to function as film formers, opacifying agents, and/or nail conditioning agents (Table 1).[1]

Acryloyloxypropyl Polysilsesquioxane
C26-28 Alkyldimethylsilyl Polypropylsilsesquioxane
C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane
Dimethicone/Silsesquioxane Copolymer
Dimethiconol/Caprylylsilsesquioxane/Silicate Crosspolymer
Ethyl Polysilsesquioxane
Hydrogen Dimethicone/Octyl Silsesquioxane Copolymer
Isobutyl/Methoxy PEG-10 Polysilsesquioxane
Isobutyl Polysilsesquioxane
Methacryloyloxypropyl Polysilsesquioxane
Methoxy PEG-10 Polysilsesquioxane
Polycaprylylsilsesquioxane
Polymethylsilsesquioxane
Polydimethylsiloxy PEG/ PPG-24/19 Butyl Ether Silsesquioxane
Polydimethylsiloxy PPG-13 Butyl Ether Silsesquioxane
Polymethylsilsesquioxane/Trimethylsiloxysilicate
Polypropylsilsesquioxane
Trimethylpentyl Polysilsesquioxane

There are several related polymer ingredients that have been reviewed by the CIR Panel; these ingredients are listed in Table 2. These previously reviewed polymers were all found to be safe as used.[2-4] Some of the manufacturing precursors and monomers were also reviewed by the Panel and are also listed in Table 2.[3,5,6]

CHEMISTRY

Definition and Structure

The ingredients in this group comprise polymers resulting from the hydrolysis and condensation of alkyltrialkoxysilanes or alkyltrichlorosilanes. These polysiloxanes typically comprise, at least in part, extended three-dimensional networks. Under carefully controlled conditions, closed cage structures can be formed (Figure 1). More commonly, however, open chain polysilsesquioxanes composed of partial cages connected to other partial cages via siloxane bonds are formed (Figure 2). These open structures will also contain silanol (SiOH) groups.

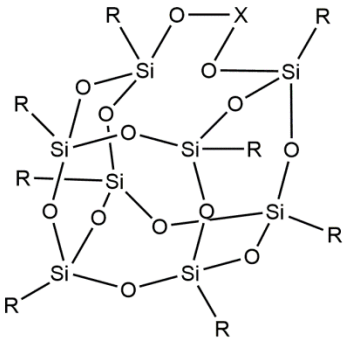


Figure 1. Example of a polysilsesquioxane "closed" framework or cage. "R" represents an alkylalkoxy substituent (or hydroxyl group) and "X" represents a continuation of the siloxy framework.

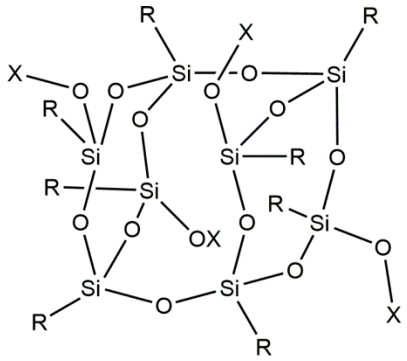


Figure 2. Example of a partial cage. "R" represents an alkylalkoxy substituent (or hydroxyl group) and "X" represents a continuation of the siloxy framework or a hydrogen atom.

Many of the monomers used in the manufacture of these polymeric ingredients are multi-functional, which results in extensive branching, crosslinking, and cage-like structures in the final ingredient product. The degree of polymerization of these ingredients can be controlled to obtain a product having a desired functionality, such as a film former. Accordingly, the molecular weights and molecular volumes of these ingredients can vary widely, unless otherwise noted in use specifications. These polymers, by virtue of their monomers, contain both hydrophilic and hydrophobic groups. The ratio of hydrophilic and hydrophobic groups of the components of each ingredient within a single ingredient name may vary. In the absence of explicit ingredient specifications, estimating some of the chemical and physical properties of these ingredients is challenging.

Polydimethylsiloxy PEG/PPG-24/19 Butyl Ether Silsesquioxane and Polydimethylsiloxy PPG-13 Butyl Ether Silsesquioxane are significantly more linear than the other ingredients in this group, comprising mostly polyol chains with small amounts of silsesquioxane monomers.[7] However, these two ingredients are still likely to have significant molecular volumes, and share much in common, structurally, with previously reviewed ingredients listed in Table 2.

Physical and Chemical Properties

Physical and chemical properties are cited in Table 3.

Dimethicone/Silsesquioxane Copolymer

Dimethicone/Silsesquioxane Copolymer is characterized as having randomly distributed polydimethylsiloxane and Polymethylsilsesquioxane domains with interpenetrating, interlacing networks of differing chemistries.[8,9] A photomicrograph shows a heterogeneous appearance. The average particle size is 7 µm. Dimethicone/Silsesquioxane Copolymer is not soluble in organic solvents, and will not swell or introduce film-forming properties in the presence of organic solvents.

Polymethylsilsesquioxane

One supplier of Polymethylsilsesquioxane reported that it has a bulk density of 0.35 and is stable for 24 months when stored at < 60°C.[10] Another supplier reported that Polymethylsilsesquioxane is available as a powder of spherical-shaped particles, with particle sizes of 2 or 5 µm.[11] A third supplier reported the particle size range as 15 to 30 µm (with 10% ≤ 2.6 µm) and a bulk density of 500 kg/m^3.[12] A fourth supplier reports that Polymethylsilsesquioxane is a powder with a particle size of 5 µm and virtually infinite molecular weight.[13] A fifth supplier reported a particle size range of 1 to 10 µm.[14]

C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane

C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane is stable for 24 months when stored ≤ 32°C, according to one supplier.[15]

Method of Manufacture

These types of polymers typically result from the hydrolysis and condensation of alkylalkoxysilanes. The definitions of several of the polysilsesquioxane polymers in this safety assessment give insight into possible methods of manufacture. For example, the definition for Dimethiconol/Caprylylsilsesquioxane/Silicate Crosspolymer states that this ingredient is a highly crosslinked silicone polymer that is made by the hydrolysis and condensation of tetraethyl orthosilicate (silicic acid tetra-ethyl ester) and triethoxycaprylylsilane with dimethiconol (Table 1).[1]

Dimethicone/Silsesquioxane Copolymer

The starting materials (not specified) of Dimethicone/Silsesquioxane Copolymer are polymerized followed by the removal of excess dimethicone. Each batch is tested for quality and microbial contamination.[16]

Polymethylsilsesquioxane

For the manufacture of Polymethylsilsesquioxane, methyltrimethoxysilane is hydrolyzed at specified temperature and duration followed by condensation. Each batch is tested for quality and microbial contamination.[17]

Impurities/Constituents

Dimethicone/Silsesquioxane Copolymer

The residual monomer content of Dimethicone/Silsesquioxane Copolymer was reported to have a maximum concentration of 100 ppm.[9] It was reported that heavy metals were present at < 20 ppm and arsenic at < 2 ppm. Microbial content was reported to be < 100 organisms/gram (opg).

Polymethylsilsesquioxane

Polymethylsilsesquioxane is reported to be 100% pure by a supplier.[10]

A supplier reported that analysis of three batches of Polymethylsilsesquioxane showed no Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cu, Fe, Hg, Mn, Mo, Ni, Pb, Sb, Sn, Sr, V, W, Zn, and Zr (< 2 ppm).[12] The sum of the heavy metal content was < 20 ppm. There was a trace of toluene at < 0.1%.

Another supplier reported that there are no detectible residual silane monomers in Polymethylsilsesquioxane.[13]

It was reported by another supplier that heavy metals were present at < 20 ppm, lead at < 20ppm, and arsenic at < 5 ppm.[14] Microbial content was reported to be < 100 opg.

Polymethylsilsesquioxane/Trimethylsiloxysilicate

Polymethylsilsesquioxane/Trimethylsiloxysilicate is supplied at 50% in cyclopentasiloxane.[18] It is reported to contain no residual monomers.

USE

Cosmetic

The safety of the cosmetic ingredients included in this assessment is evaluated based on data received from the U.S. Food and Drug Administration (FDA) and the cosmetic 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 FDA's Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by the cosmetic industry in response to surveys, conducted by the Personal Care Products Council (Council), of maximum reported use concentration by product category.

According to VCRP survey data received in 2017, Polymethylsilsesquioxane was reported to be used in 397 formulations, i.e., 374 in leave-on formulations, 22 in rinse-off formulations, and 1 diluted for the bath (Table 4).[19] All other in-use ingredients were reported to be used in 14 formulations or fewer.

The results of the concentration of use survey conducted by the Council in 2016 indicate Polymethylsilsesquioxane has the highest reported maximum concentration of use; it is used at up to 55.2% (highest in the category of other eye preparations).[20,21] The rest of the in-use ingredients are reported to be used at 4.9% (C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane in foundations) or less.

In some cases, reports of uses were received in the VCRP, but concentration of use data were not provided. For example, Dimethicone/Silsesquioxane Copolymer was reported to be used in 7 cosmetic formulations, but no use concentration data were reported. In other cases, no uses were reported in the VCRP, but concentration of use data were received from the Council; Polydimethylsiloxy PEG/PPG-24/19 Butyl Ether Silsesquioxane had no reported uses in the VCRP, but a use concentration in the category of hair spray was provided in the Council survey. Therefore, it should be presumed there is at least one use in every category for which a concentration is reported.

The ingredients not in use according to the VCRP and industry survey are listed in Table 5.

Some of the polysilsesquioxanes are used in products that are used near the eye (e.g., Polymethylsilsesquioxane in the category of other eye makeup preparations at up to 55.2%), products that could possibly be ingested, or products that come in contact with mucus membranes (e.g., Polymethylsilsesquioxane in lipstick at up to 20.7%).

Additionally, some of the polysilsesquioxanes are used in cosmetic sprays and could possibly be inhaled; for example, Polymethylsilsesquioxane was reported to be used at 52% in perfumes and Polydimethylsiloxy PEG/PPG-24/19 Butyl Ether Silsesquioxane is used up to 0.023% in aerosol hair sprays. 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.[22,23] 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.[24,25] There is some evidence indicating that deodorant spray products (e.g., Polymethylsilsesquioxane at up to 4%) can release substantially larger fractions of particulates having aerodynamic equivalent diameters in the range considered to be respirable.[24] However, the information is not sufficient to determine whether significantly greater lung exposures result from the use of deodorant sprays, compared to other cosmetic sprays. Polymethylsilsesquioxane was reported to be used in face powders at concentrations up to 49.8%. Conservative estimates of inhalation exposures to respirable particles during the use of loose-

powder cosmetic products are 400- to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.[26-28]

None of the polysilsesquioxanes named in the report are restricted from use in any way under the rules governing cosmetic products in the European Union.[29]

Non-Cosmetic

Polymethylsilsesquioxane may be used as a surface lubricant or anti-blocking agent in films as basic components of single and repeated use food contact surfaces. [21CFR177.1520]

TOXICOKINETIC STUDIES

Dermal Penetration

Data on dermal penetration of polysilsesquioxanes ingredients were not found in the published literature and no unpublished data were submitted. However, the cage-like structures of many of these ingredients encompass large molecular volumes, which likely decrease the potential for these ingredients to penetrate the skin significantly.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Data on the ADME of polysilsesquioxane ingredients were not found in the published literature and no unpublished data were submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Data on acute dermal or inhalation toxicity studies of polysilsesquioxane ingredients were not found in the published literature and no unpublished data were submitted.

Oral

Summaries of acute oral studies of polysilsesquioxanes in this safety assessment are presented in Table 6.

The reported LD_{50} for Isobutyl/Methoxy PEG-10 Polysilsesquioxane, Isobutyl Polysilsesquioxane, Methacryloyl-oxypropyl Polysilsesquioxane, Methoxy PEG-10 Polysilsesquioxane, and Trimethylpentyl Polysilsesquioxane was > 5000 mg/kg. [30-35] Two of five rats treated with 5000 mg/kg Isobutyl/Methoxy PEG-10 Polysilsesquioxane died; none of the rats treated with 5000 mg/kg of the other polymers tested died.

Short-Term Toxicity Studies

Dermal

A Polymethylsilsesquioxane emulsion (0 or 200 mg/kg/day; concentration of solids not specified; not known if it is a grade that is used in cosmetics) was dermally administered to rabbits (n=10) for 28 days.[36] The rabbits were weighed prior to study initiation and on days 7, 14, 21, and 28. The rabbits were observed for mortality, behavioral changes, and adverse skin reactions throughout the study period and were killed on day 28 for gross necropsy and histopathological examination. The testes were weighed at necropsy and testes to body weight ratios were calculated. There were no statistically-significant treatment-related changes in mortality, body weight, behavior, or gross pathology. In addition, there were no changes in mean testes weight or testes to body weight ratio. No abnormal histopathological findings were reported.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Data on the DART of polysilsesquioxane ingredients were not found in the published literature and no unpublished data were submitted.

GENOTOXICITY STUDIES

Genotoxicity studies of polysilsesquioxanes are presented in Table 7.

Methacryloyloxypropyl Polysilsesquioxane, Methoxy PEG-10 Polymethylsilsesquioxane, Polymethylsilsesqui-oxane, and Trimethylpentyl Polymethylsilsesquioxane were not genotoxic in bacterial reverse mutation assays at up to 5000 µg/plate. [13,37-39,39]

CARCINOGENICITY STUDIES

Data on the carcinogenicity of polysilsesquioxane ingredients were not found in the published literature and no unpublished data were submitted.

OTHER RELEVANT STUDIES

Cytotoxicity

An agar diffusion test was conducted on Polymethylsilsesquioxane (65% in water) to determine the biological activity of this ingredient on mammalian cell cultures following indirect contact with the test substance.[13] The test was run

on three plates with an exposure period of 24 h. There was no reactivity observed. This test suggests that this ingredient does not have a toxic diffusible (low molecular weight) fraction.[40]

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

In Vitro

In an EpiDerm™ assay, reconstructed human epidermis was exposed to Polymethylsilsesquioxane (neat, 25 mg) for 60 min. The negative control was sterile deionized water and the positive control was sodium dodecyl sulfate (5%). The test substance had similar results as the negative control and was predicted to be non-irritating.[41]

Animal

Dermal irritations studies of polysilsesquioxanes using rabbits are summarized in Table 8.

The Primary Irritation Index (PII) was 0.05 out of 8 for Isobutyl Polysilsesquioxane (100%) administered to the intact and abraded skin of New Zealand White rabbits.[42] The PII was 0.55 for Methacryloyloxypropyl Polysilsesquioxane, 0.40 for Methoxy PEG-10 Polysilsesquioxane (100%), 0.30 for Trimethylpentyl Polysilsesquioxane (100%), and 0.78 for another form of Trimethylpentyl Polysilsesquioxane (100%).[35,43,44]

A Polymethylsilsesquioxane emulsion (200 mg/kg/day) dermally administered to rabbits for 28 days caused slight local erythema and dryness following 7 to 14 dermal applications.[36] Isobutyl/Methoxy PEG-10 Polysilsesquioxane (100%) caused very slight to well defined, transient erythema after dosing in rabbits, which resolved by day 7.[45]

Sensitization

In Vitro

Polymethylsilsesquioxane

In an in vitro dermal sensitization assay of Polymethylsilsesquioxane conducted in accordance with the Organisation for Economic Co-operation and Development Test Guideline (OECD TG) 442C (in chemico Skin Sensitization, Direct Peptide Reactivity Assay [DPRA]), the incubation with the test substance for approximately 24 h resulted in a mean percent depletion of the peptides of 3.22%, which is within the range of non-sensitization prediction model. Therefore, Polymethylsilsesquioxane was predicted to be a non-sensitizer.[46]

In an in vitro dermal sensitization assay conducted in accordance with OECD TG 442D (in vitro Skin Sensitization, ARE-Nrf2 Luciferase Test Method), the IC_{50} (the concentration at which inhibition is 50%) for Polymethylsilsesquioxane was > 1000 µM, there was no luciferase induction, and the I_{max} was 0.36.[47] The criteria for a positive prediction include an IC_{50} greater than 70% the lowest luciferase induction concentration and an I_{max} greater than 1.5-fold (and statistically-significantly different from) the I_{max} of the negative control (solvent; 0.16). This ingredient was predicted to be a non-sensitizer.

Human

Summaries of human repeated insult patch tests (HRIPT) of polysilsesquioxanes are presented in Table 9.

In HRIPTs of makeup products that contain C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane (4.337%)[48] or Polymethylsilsesquioxane (50% or 22.0%),[49,50] there was no evidence of sensitization. Polymethylsilsesquioxane (100%)[13] and Polymethylsilsesquioxane/Trimethylsiloxysilicate (50%)[18] were not sensitizing in HRIPTs.

Photosensitization/Phototoxicity

A phototoxicity test was conducted on a foundation product containing Polymethylsilsesquioxane (5%) using subjects (n = 20) with Fitzpatrick skin types of I, II, or III.[13] The test material (0.2 g) was applied to the inner surface of both arms of the subjects after tape stripping 3 times. The right arm was irradiated at a distance of 10 cm resulting in a UV-A light dosage of > 4.4 J/cm^2 (spectrum range 320 to 400 nm with peak at 365 nm). After irradiation, the test site was covered with an occlusive patch containing an additional 0.2 g of the test material. The test sites were scored immediately after irradiation and at 24 and 48 h and 1 week after patch removal. There were no adverse effects or reactions of any kind observed.

OCULAR IRRITATION STUDIES

In Vitro

In an EpiOcular™ assay, human-derived epidermal keratinocytes cultured to form cornea epithelium were exposed to Polymethylsilsesquioxane for 90 min. The negative control was sterile deionized water and the positive control was methyl acetate. The test substance had similar results as the negative control and was predicted to be non-irritating.[41]

SUMMARY

This is a safety assessment of 18 polysilsesquioxanes as used in cosmetics. The ingredients in this group comprise the polymers resulting from the hydrolysis and condensation of alkylalkoxysilanes. These siloxy polymers typically comprise three-dimensional frameworks. Many of the ingredients named in this assessment have several functions, with most reported to function as film formers and/or nail conditioning agents.

Polymethylsilsesquioxane was reported to be used in 397 formulations (e.g., 374 in leave-on formulations, 22 in rinse-off formulations, and 1 diluted for the bath). All other in-use ingredients were reported to be used in 14 formulations or fewer. Polymethylsilsesquioxane has the highest reported maximum concentration of use; it is used at up to 55.2% in the category of other makeup preparations. The rest of the in-use ingredients are reported to be used at 4.9% (C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane in foundations) or less.

In acute oral studies of Isobutyl/Methoxy PEG-10 Polysilsesquioxane, Isobutyl Polysilsesquioxane, Methacryloyloxypropyl Polysilsesquioxane, Methoxy PEG-10 Polysilsesquioxane, and Trimethylpentyl Polysilsesquioxane, the LD_{50} was reported to be > 5000 mg/kg.

In a 28-day dermal toxicity study of a Polymethylsilsesquioxane emulsion at 200 mg/kg/day using rabbits, there were no remarkable toxicological findings. Slight local erythema and dryness were observed following 7 to 14 dermal applications.

Methacryloyloxypropyl Polysilsesquioxane, Methoxy PEG-10 Polymethylsilsesquioxane, Polymethylsilsesquioxane, and Trimethylpentyl Polymethylsilsesquioxane were not genotoxic in bacterial reverse mutation assays at up to 5000 µg/plate.

There was no biological activity from Polymethylsilsesquioxane (65%) in an agar diffusion test.

Polymethylsilsesquioxane (neat) was predicted to be a non-irritant in an EpiDerm™ assay. Polysiloxanes were not dermally irritating to rabbits. The PII was 0.05 out of 8 for Isobutyl Polysilsesquioxane (100%) administered to the intact and abraded skin of New Zealand White rabbits. The PII was 0.55 for Methacryloyloxypropyl Polysilsesquioxane, 0.40 for Methoxy PEG-10 Polysilsesquioxane (100%), 0.30 for Trimethylpentyl Polysilsesquioxane (100%), and 0.78 for Trimethylpentyl Polysilsesquioxane (100%).

Isobutyl/Methoxy PEG-10 Polysilsesquioxane (100%) caused very slight to well defined, transient erythema in rabbits, which resolved by day 7.

Polymethylsilsesquioxane (neat) was predicted to be a non-sensitizer in two in vitro assays conducted in accordance with OECD TGs 442C and 442D. In HRIPTs of polysilsesquioxanes and products containing polysilsequioxanes, there were no signs of irritation or sensitization. In HRIPTs of makeup products that contain C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane (4.337%), Polymethylsilsesquioxane (50%), or Polymethylsilsesquioxane (22.0%), there was no evidence of sensitization. Polymethylsilsesquioxane (100%) and Polymethylsilsesquioxane/Trimethylsiloxysilicate (50%) were not sensitizing in HRIPTs.

A product containing 5% Polymethylsilsesquioxane was not phototoxic.

Polymethylsilsesquioxane (neat) was predicted to be a non-irritant in an EpiOcular™ assay.

DISCUSSION

The Panel examined the available data for these 18 polysilsesquioxane cosmetic ingredients, including physical and chemical properties, dermal and oral toxicity, genotoxicity, and dermal irritation and sensitization. The majority of these data were on a few ingredients (i.e., Polymethylsilsesquioxane and Dimethicone/Silsesquioxane Copolymer) with some data on a few of the other ingredients (i.e., C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane, Methacryloyloxypropyl Polysilsesquioxane, and Polymethylsilsesquioxane/Trimethylsiloxysilicate). The Panel noted a lack of systemic toxicity data (i.e., reproductive and developmental toxicity and carcinogenicity data), but agreed that these ingredients are large, insoluble molecules that share dominant features/structures, and are not expected to penetrate the skin. The Panel also agreed that the weight of the evidence alleviated concerns about the potential for local effects, such as dermal irritation and sensitization.

The available data show that the concentrations of monomer impurities are low or below detection. The monomers of these ingredients are highly reactive in the context of the synthetic process and are unlikely to survive hydrolysis in biological systems if absorbed. However, manufacturers should use current good manufacturing practices (cGMP) to ensure that monomers and source materials are limited.

The Panel discussed the issue of incidental inhalation exposure from hair sprays and perfumes. There were no inhalation toxicity data available. However, the particle sizes of these ingredients were reported to range from 2 to 30 µm. The Panel believes that the sizes of a substantial majority of the particles of these ingredients, as manufactured, are larger than the respirable range and/or aggregate and agglomerate to form much larger particles in formulation. Polymethylsilsesquioxane is reportedly used at concentrations up to 52% in cosmetic products that may be sprayed and up to 49.8% in loose powder products that may become airborne. The Panel noted that droplets/particles from cosmetic products would not be respirable to any appreciable amount. Furthermore, these ingredients are not likely to cause any direct toxic effects in the upper respiratory tract, based on the properties of the polysilsesquioxanes and on data that shows that these ingredients are not expected to be irritants. 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. Polysilsesquioxanes are large macromolecules and insoluble in water, which supports the view that they are unlikely to be absorbed or cause local effects in the respiratory tract. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at http://www.cir-safety.org/cir-findings.

CONCLUSION

The CIR Expert Panel concluded that the following polysilsesquioxane ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment:

Acryloyloxypropyl Polysilsesquioxane*
C26-28 Alkyldimethylsilyl Polypropylsilsesquioxane*
C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane
Dimethicone/Silsesquioxane Copolymer
Dimethiconol/Caprylylsilsesquioxane/Silicate Crosspolymer*
Ethyl Polysilsesquioxane*
Hydrogen Dimethicone/Octyl Silsesquioxane Copolymer
Isobutyl/Methoxy PEG-10 Polysilsesquioxane*
Isobutyl Polysilsesquioxane*
Methacryloyloxypropyl Polysilsesquioxane*
Methoxy PEG-10 Polysilsesquioxane*
Polycaprylylsilsesquioxane
Polymethylsilsesquioxane
Polydimethylsiloxy PEG/ PPG-24/19 Butyl Ether Silsesquioxane
Polydimethylsiloxy PPG-13 Butyl Ether Silsesquioxane*
Polymethylsilsesquioxane/Trimethylsiloxysilicate*
Polypropylsilsesquioxane
Trimethylpentyl Polysilsesquioxane*

* Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.

TABLES

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.(1; CIR Staff)

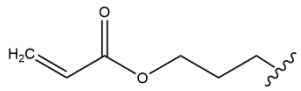
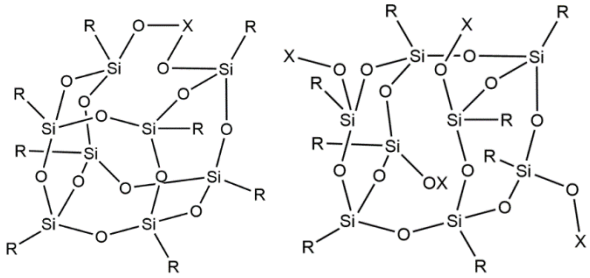
Ingredient CAS No.	Definition & Monomer Structures[a]	Function(s)
Acryloyloxypropyl Polysilsesquioxane 1204591-17-2	Acryloyloxypropyl Polysilsesquioxane is a resinous material composed of a mixture of three-dimensional siloxane polymers and oligomers with cage structures. For the oligomers, each silicon atom in the polysilsesquioxane is connected via oxygen atoms to three other silicon atoms and can be represented by the empirical formulation $RSiO_{3/2}$ where R represents the acryloxypropyl group. For the larger polymeric polysilsesquioxanes, some of the ~~silicon atoms~~ [siloxy groups (SiO)] are not connected [through the oxygen atom] to other silicon atoms and instead [terminate as] ~~have a~~ silanol (SiOH) groups. [Silicon atoms that do not have silanol groups connect to other partial cage structures via siloxane linkages.] Acryloxypropyl Polysilsesquioxane is prepared by the hydrolysis and condensation of acryloyloxy propyltrimethoxysilane.   "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is methacryloxypropyl or OH, and X is a continuation of the polymer.]	Nail conditioning agent
C26-28 Alkyldimethylsilyl Polypropylsilsesquioxane	C26-28 Alkyldimethylsilyl Polypropylsilsesquioxane is the silicone compound that conforms generally to the formula: $[CH_3CH_2CH_2SiO_{3/2}]_x\,[R(CH_3)_2SiO_{1/2}]_y$ where R is $-(CH_2)_nCH_3$ where n has a value between 25 and 27 [x and y are not defined].	Film former; viscosity increasing agent – nonaqueous
C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane	C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane is the silicone compound that conforms generally to the formula: $[CH_3CH_2CH_2SiO_{3/2}]_x\,[R(CH_3)_2SiO_{1/2}]_y$ where R is $-(CH_2)_nCH_3$ where n has a value between 29 and 44 [x and y are not defined].	Film former
Dimethicone/Silsesquioxane Copolymer 68440-84-6	Dimethicone/Silsesquioxane Copolymer is a siloxane polymer consisting of methyl trimethoxysilane and dimethylsiloxane.	Film former; hair conditioning agent; hair fixative
Dimethiconol/ Caprylylsilsesquioxane/Silicate Crosspolymer 1802406-18-3	Dimethiconol/Caprylylsilsesquioxane/Silicate Crosspolymer is a highly crosslinked silicone polymer that is made by the hydrolysis and condensation of tetraethyl orthosilicate [(silicic acid (H_4SiO_4) tetra-ethyl ester)] and triethoxycaprylylsilane with dimethiconol.	Opacifying agent

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

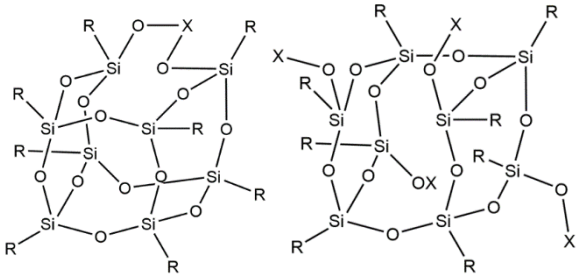
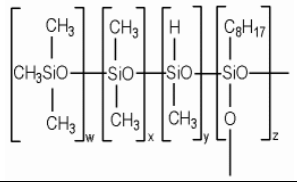
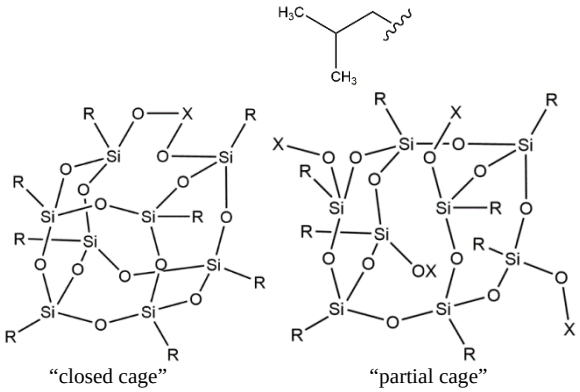
Ingredient CAS No.	Definition & Monomer Structures[a]	Function(s)
Ethyl Polysilsesquioxane	Ethyl Polysilsesquioxane is a resinous material composed of a mixture of three-dimensional siloxane polymers and oligomers with cage structures. For the oligomers, each silicon atom in the polysilsesquioxane is connected via oxygen atoms to three other silicon atoms and can be represented by the empirical formulation $RSiO_{3/2}$, where R represents the ethyl group. For the larger polymeric polysilsesquioxanes, some of the ~~silicon atoms~~ [siloxy groups (SiO)] are not connected [through the oxygen atom] to other silicon atoms and instead [terminate as] ~~have a~~ silanol (SiOH) group. [Silicon atoms that do not have silanol groups connect to other partial cage structures via siloxane linkages.] Ethyl Polysilsesquioxane is prepared by the hydrolysis and condensation of ethyl trimethoxysilane.*  "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is ethyl, and X is a continuation of the polymer.]	Nail conditioning agent
Hydrogen Dimethicone/Octyl Silsesquioxane Copolymer	Hydrogen Dimethicone/Octyl Silsesquioxane Copolymer is the silicone polymer that conforms generally to the formula: 	Surface modifier
Isobutyl Polysilsesquioxane 221326-46-1	Isobutyl Polysilsesquioxane is a resinous material composed of a mixture of three-dimensional siloxane polymers and oligomers with cage structures. For the oligomers, each silicon atom in the polysilsesquioxane is connected via oxygen atoms to three other silicon atoms and can be represented by the empirical formulation $RSiO_{3/2}$ where R represents the isobutyl group. For the larger polymeric polysilsesquioxanes, some of the ~~silicon atoms~~ [siloxy groups (SiO)] are not connected [through the oxygen atom] to other silicon atoms and instead [terminate as] ~~have a~~ silanol (SiOH) groups. [Silicon atoms that do not have silanol groups connect to other partial cage structures via siloxane linkages.] Isobutyl Polysilsesquioxane is prepared by the hydrolysis and condensation of 2-methylpropyl trimethoxysilane.*  "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is isobutyl or OH, and X is a continuation of the polymer.]	Nail conditioning agent

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

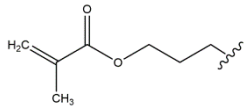
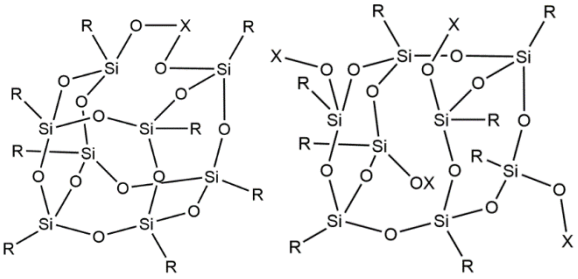
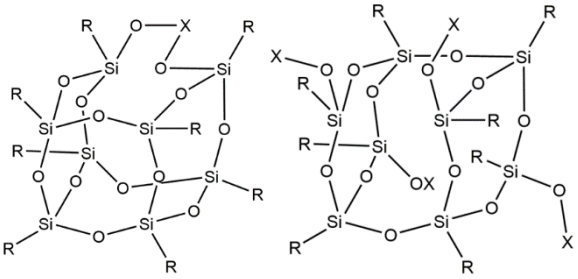
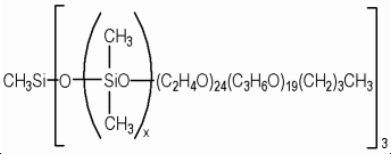
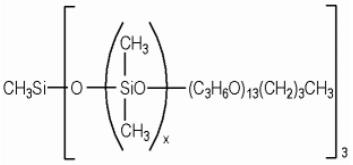
Ingredient CAS No.	Definition & Monomer Structures[a]	Function(s)
Methacryloyloxypropyl Polysilsesquioxane 160185-24-0	Methacryloyloxypropyl Polysilsesquioxane is a resinous material composed of a mixture of three-dimensional siloxane polymers and oligomers with cage structures. For the oligomers, each silicon atom in the polysilsesquioxane is connected via oxygen atoms to three other silicon atoms and can be represented by the empirical formulation $RSiO_{3/2}$ where R represents the methacryloxypropyl group. For the larger polymeric polysilsesquioxanes, some of the ~~silicon atoms~~ [siloxy groups (SiO)] are not connected [through the oxygen atom] to other silicon atoms and instead [terminate as] ~~have a~~ silanol (SiOH) groups. [Silicon atoms that do not have silanol groups connect to other partial cage structures via siloxane linkages.] Methacryloyloxypropyl Polysilsesquioxane is prepared by the hydrolysis and condensation of methacryloyl propyltrimethoxysilane.*   "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is methacryloxypropyl or OH, and X is a continuation of the polymer.]	Abrasive
Polycaprylylsilsesquioxane 1385031-14-0	Polycaprylylsilsesquioxane is a polymer formed by the hydrolysis and condensation of triethoxycaprylylsilane.  "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is caprylyl or OH, and X is a continuation of the polymer.]	Anticaking agent; binder; opacifying agent; surface modifier
Polydimethylsiloxy PEG/ PPG-24/19 Butyl Ether Silsesquioxane 68554-65-4	Polydimethylsiloxy PEG/PPG-24/19 Butyl Ether Silsesquioxane is the silicone polymer that conforms generally to the formula: 	Skin-conditioning agent – humectant; surfactant-cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent
Polydimethylsiloxy PPG-13 Butyl Ether Silsesquioxane	Polydimethylsiloxy PPG-13 Butyl Ether Silsesquioxane is the silicone polymer that conforms generally to the formula: 	Hair conditioning agent; humectant; surfactant – cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent

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

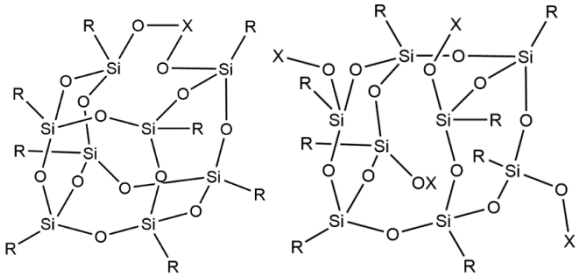
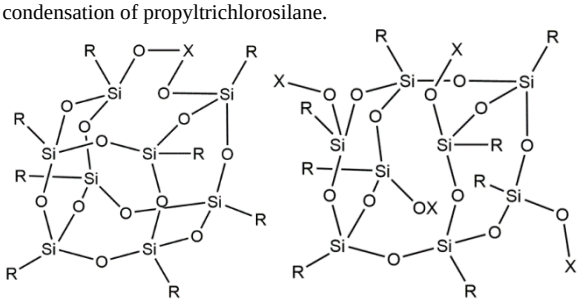
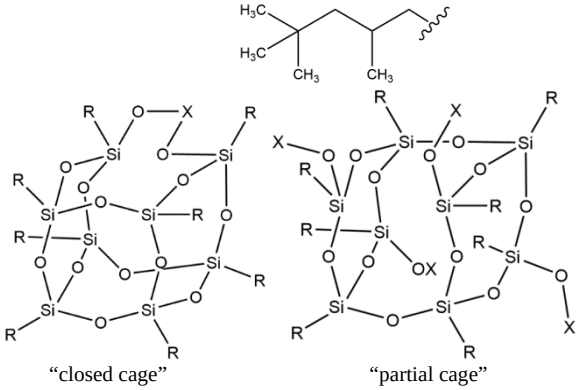
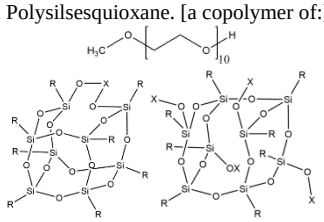
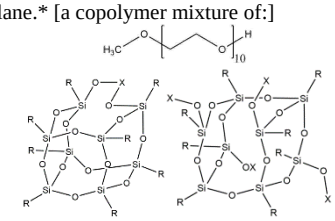
Ingredient CAS No.	Definition & Monomer Structures[a]	Function(s)
Polymethylsilsesquioxane 68554-70-1	Polymethylsilsesquioxane is a polymer formed by the hydrolysis and condensation of methyltrimethoxysilane.  "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is methyl or OH, and X is a continuation of the polymer.]	Opacifying agent
Polymethylsilsesquioxane/ Trimethylsiloxysilicate 1402155-47-8	Polymethylsilsesquioxane/Trimethylsiloxysilicate is the product of the hydrolysis and subsequent condensation polymerization of trialkoxymethylsilane, alkylorthosilicate and trimethylchlorosilane.	Film former
Polypropylsilsesquioxane 36088-62-7	Polypropylsilsesquioxane is a polymer formed by the hydrolysis and condensation of propyltrichlorosilane.  "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is propyl or OH, and X is a continuation of the polymer.]	Binder; film former
Trimethylpentyl Polysilsesquioxane 190732-67-3 444619-08-3	Trimethylpentyl Polysilsesquioxane is a resinous material composed of a mixture of three-dimensional siloxane polymers and oligomers with cage structures. For the oligomers, each silicon atom in the polysilsesquioxane is connected via oxygen atoms to three other silicon atoms and can be represented by the empirical formulation $RSiO_{3/2}$ where R represents the trimethylpentyl group. For the larger polymeric polysilsesquioxanes, some of the ~~silicon atoms~~ [siloxy groups (SiO)] are not connected [through the oxygen atom] to other silicon atoms and instead [terminate as] ~~have a~~ silanol (SiOH) groups. [Silicon atoms that do not have silanol groups connect to other partial cage structures via siloxane linkages.] Trimethylpentyl Polysilsesquioxane is prepared by the hydrolysis and condensation of 2,4,4-trimethylpentyl trimethoxysilane.*  "closed cage" "partial cage" [Polymethylsilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is Trimethylpentyl or OH, and X is a continuation of the polymer.]	Nail conditioning agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.(1; CIR Staff)

Ingredient CAS No.	Definition & Monomer Structures[a]	Function(s)
Isobutyl/Methoxy PEG-10 Polysilsesquioxane	Isobutyl/Methoxy PEG-10 Polysilsesquioxane is the Methoxy PEG-10 derivative of Isobutyl Polysilsesquioxane. [a copolymer of:]  "closed cage" "partial cage" [Isobutyl Polysilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is isobutyl, and X is a continuation of the polymer.]	Viscosity decreasing agent
Methoxy PEG-10 Polysilsesquioxane 1838163-04-4	Methoxy PEG-10 Polysilsesquioxane is a resinous material composed of a mixture of three-dimensional siloxane polymers and oligomers with cage structures. For the oligomers, each silicon atom in the polysilsesquioxane is connected via oxygen atoms to three other silicon atoms and can be represented by the empirical formulation $RSiO_{3/2}$ where R represents the methoxy PEG-10 propyl moiety. For the larger polymeric polysilsesquioxanes, some of the ~~silicon atoms~~ [siloxy groups (SiO)] are not connected [through the oxygen atom] to other silicon atoms and instead [terminate as] ~~have a~~ silanol (SiOH) groups. [Silicon atoms that do not have silanol groups connect to other partial cage structures via siloxane linkages.] Methoxy PEG-10 Polysilsesquioxane is prepared by the hydrolysis and condensation of methoxy PEG-10 propyltrimethoxysilane.* [a copolymer mixture of:]  "closed cage" "partial cage" [Polysilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is methoxy PEG-10 propyl, methyl, or OH, and X is a continuation of the polymer.]	Skin-conditioning agent – humectant; surfactant – cleansing agent; surfactant – solubilizing agent

[a] Some of the definitions and structures were edited by CIR staff for clarity. Words that are to be removed have a ~~strike through~~ and added language is in [brackets].

Table 2. Related cosmetic ingredients and precursors that have been reviewed by CIR.

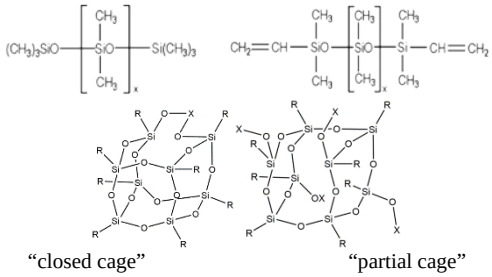
Ingredient	Conclusion[a] and structures	Reference
Related Ingredients		
Dimethicone/Divinyldimethicone/ Silsesquioxane Crosspolymer	Safe in the practices of use and concentration as given in this safety assessment. [a crosspolymer mixture of:]  "closed cage" "partial cage" [Polysilsesquioxane is a mixture of closed and partial caged structures, wherein "R" is methyl, and X is a continuation of the polymer.]	2

Table 2. Related cosmetic ingredients and precursors that have been reviewed by CIR.

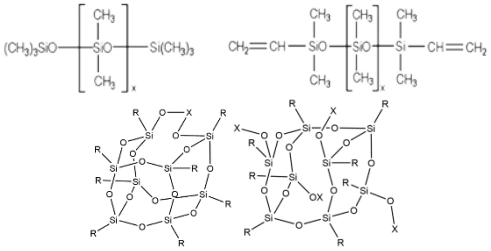
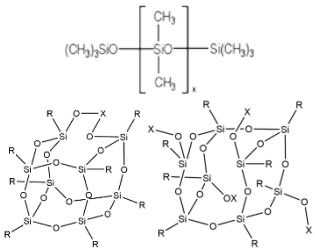
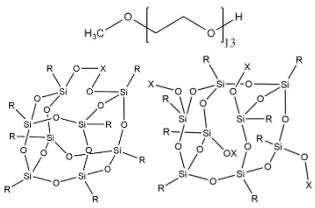
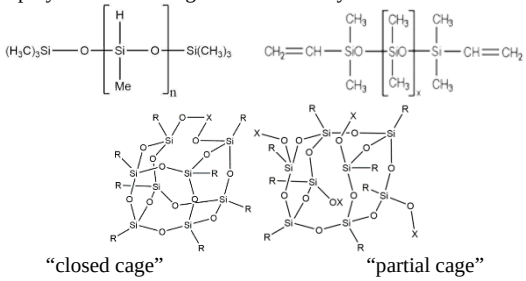
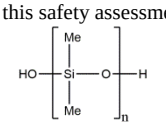
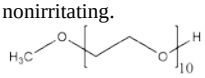
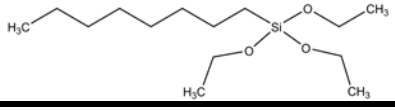
Ingredient	Conclusion[a] and structures	Reference
Dimethicone/ Bis-Vinyldimethicone/ Silsesquioxane Crosspolymer	Safe in the practices of use and concentration as given in this safety assessment. [a crosspolymer mixture of:]  “closed cage” “partial cage” [Polysilsesquioxane is a mixture of closed and partial caged structures, wherein “R” is methyl, and X is a continuation of the polymer.]	2
Dimethiconol/Silsesquioxane Copolymer	Safe as cosmetic ingredients in the present practices of use and concentration described in this safety assessment. [a copolymer mixture of:]  “closed cage” “partial cage” [Polysilsesquioxane is a mixture of closed and partial caged structures, wherein “R” is methyl, and X is a continuation of the polymer.]	3
Methoxy PEG-13 Ethyl Polysilsesquioxane	Safe in cosmetics in the practices of use and concentration of this safety assessment. [a copolymer mixture of:]  “closed cage” “partial cage” [Ethyl Polysilsesquioxane is a mixture of closed and partial caged structures, wherein “R” is ethyl, and X is a continuation of the polymer.]	4
Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer	Safe in the practices of use and concentration as given in this safety assessment.  “closed cage” “partial cage” [Polysilsesquioxane is a mixture of closed and partial caged structures, wherein “R” is methyl, and X is a continuation of the polymer.]	2

Table 2. Related cosmetic ingredients and precursors that have been reviewed by CIR.

Ingredient	Conclusion[a] and structures	Reference
Monomers/Precursors		
Dimethiconol	Safe as cosmetic ingredients in the present practices of use and concentration described in this safety assessment. 	3
Methoxy PEG-10	Safe as used when formulated to be nonirritating. 	6
Triethoxycaprylylsilane	Safe as cosmetic ingredients in the practices of use and concentration described in this safety assessment. 	5

[a] Please see the original reports for details (http://www.cir-safety.org/ingredients).

Table 3. Chemical and physical properties of polysilsesquioxanes.

Property	Value	Reference
C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane		
Physical Form	Solid, flakes	15
	Wax	51
Color	White to off-white	15,51
Odor	Characteristic	15
Specific Gravity	0.8	15
Melting Point °C	66	15
	63-71	51
Dimethicone/Silsesquioxane Copolymer		
Physical Form	Powder	9
Color	Off white	9
Odor	Characteristic	9
Other Solubility		
Organic solvents	Not soluble	8
Isobutyl/Methoxy PEG-10 Polysilsesquoxane		
Physical Form	Semi-solid	52
Color	Clear, pale yellow/orange	52
Molecular Volume m^3/kmol	1330.13	52
Melting Point °C	65	52
Water Solubility	Insoluble	52
Other Solubility		
Ethanol (95%)	Soluble	52
Hexane (aliphatics)	Soluble	52
Mineral Oil	Soluble	52
Petrolatum	Dispersible	52
Isobutyl Polysilsesquioxane		
Physical Form	Powder	53
Color	White	53
Formula Weight g/mol	873.60	53
Density	1.13	53
Water Solubility	Not Soluble	53
Other Solubility		
Ethanol (95%)	Dispersible	53
Hexane (aliphatics)	Mostly Soluble	53
Mineral Oil	Soluble	53
Petrolatum	Soluble	53

Table 3. Chemical and physical properties of polysilsesquioxanes.

Property	Value	Reference
Methacryloyloxypropyl Polysilsesquioxane		
Physical Form	Liquid Oil	[54]
Color	Clear, colorless	[54]
Formula Weight	1433.97	[54]
Density	1.20	
Viscosity kg/(s*m)	1.8	[54]
Water Solubility	Not soluble	[54]
Other Solubility		
Ethanol (95%)	Soluble	[54]
Isopropyl Propanol (99%)	Soluble	[54]
Hexanes (aliphatics)	Unstable	[54]
Glycerin	Soluble	[54]
Parafin Wax	Stable	[54]
Methoxy PEG-10 Polysilsesquioxane		
Physical Form	Liquid	[55]
Color	Clear/colorless	[55]
Formula Weight g/mol	4525.83	[55]
Density	1.09	[55]
Water Solubility	Soluble	[55]
Other Solubility		
Ethanol (95%)	Soluble	[55]
Isopropyl Propanol (99%)	Soluble	[55]
Hexanes (aliphatics)	Not Soluble	[55]
Glycerin	Soluble	[55]
Parafin Wax	Stable	[55]
Polymethylsilsesquioxane		
Physical Form	Solid; powder	[10,11,14,56]
Color	White	[10,11,14,56]
Odor	Characteristic	[56]
	Odorless	[14]
Specific Gravity @ 25°C	1.3	[56]
	1.32	[10,11]
Water Solubility	Insoluble	[56]
Trimethylpentyl Polysilsesquioxane[a]		
Physical Form	Liquid	[57,58]
	Liquid	[59]
Color	Colorless to pale yellow	[57,58]
	Colorless to pale yellow	[59]
Molecular Weight g/mol	1322.46	[58]
Formula Weight	1184.16	[57]
Density	0.97	[57]
	1.01	[59]
Viscosity kg/(s m)	27.5	[57]
	1.9	[59]
Water Solubility	Not soluble	[57]
	Not soluble	[59]
Other Solubility		
Ethanol (95%)	Soluble	[57]
Isopropyl Propanol (99%)	Soluble	[57]
Hexanes (aliphatics)	Soluble	[57]
Glycerin	Not Soluble	[57]
Parafin Wax	Soluble	[57]
Isopropyl Propanol (99%)	Soluble	[59]
Hexanes (aliphatics)	Soluble	[59]
Glycerin	Soluble	[59]
Parafin Wax	Soluble	[59]

[a] These are the chemical and physical properties of two different forms of Trimethylpentyl Polysilsesquioxane.

Table 4. Frequency of use according to duration and exposure of polysilsequioxanes.[19-21]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane		Dimethicone/ Silsesquioxane Copolymer		Hydrogen Dimethicone/Octyl Silsesquioxane Copolymer		Polycaprylylsilsesquioxane	
Total/range	**12**	**0.2-4.9**	**7**	**NR**	**3**	**NR**	**3**	**0.0025-0.005**
Duration of use[a]								
Leave-on	12	0.2-4.9	7	NR	3	NR	3	0.0025-0.005
Rinse-off	NR	NR	NR	NR	NR	NR	NR	0.0025
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	8	0.2-3.9	1	NR	NR	NR	3	0.005
Incidental ingestion	3	1	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	NR	NR	NR	NR	3[b]	NR	NR	NR
Incidental inhalation-powders	NR	4.6	1	NR	NR	NR	NR	NR
Dermal contact	9	0.2-4.9	7	NR	3	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	NR	0.0025
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	3	1	NR	NR	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	Polymethylsilsesquioxane		Polydimethylsiloxy PEG/PPG-24/19 Butyl Ether Silsesquioxane		Polypropylsilsesquioxane		
Total/range	**397**	**0.00001-55.2**	NR	**0.023**	**14**	**0.8-2.4**	
Duration of use							
Leave-on	374	0.00001-55.2	NR	0.023	14	0.8-2.4	
Rinse-off	22	0.01-7.5	NR	NR	NR	NR	
Diluted for (bath) use	1	NR	NR	NR	NR	NR	
Exposure type							
Eye area	87	0.02-55.2	NR	NR	8	2	
Incidental ingestion	17	0.03-20.7	NR	NR	4	NR	
Incidental Inhalation-sprays	4; 60[b]; 65[c]	0.08-52; 1.3-5.5[b]	NR	0.023	NR	NR	
Incidental inhalation-powders	38; 65[c]	0.1-49.8; 0.01-28[d]	NR	NR	NR	NR	
Dermal contact	342	0.001-55.2	NR	NR	9	0.8-2.4	
Deodorant (underarm)	NR	4[e]	NR	NR	NR	NR	
Hair-noncoloring	27	0.11-7	NR	0.023	NR	NR	
Hair-coloring	NR	NR	NR	NR	NR	NR	
Nail	NR	0.00001-0.77	NR	NR	NR	NR	
Mucous Membrane	20	0.03-20.7	NR	NR	4	NR	
Baby	NR	NR	NR	NR	NR	NR	

NR = Not Reported; Totals = Rinse-off + Leave-on + Diluted for Bath Product Uses.

[a] 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.

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

[c] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

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

[e] Spray products.

Table 5. Polysilsesquioxane ingredients that have no reported uses in the VCRP or the Council survey.[19-21]

Acryloyloxypropyl Polysilsesquioxane	C26-28 Alkyldimethylsilyl Polypropylsilsesquioxane
Dimethiconol/Caprylylsilsesquioxane/Silicate Crosspolymer	Ethyl Polysilsesquioxane
Isobutyl/Methoxy PEG-10 Polysilsesquioxane	Isobutyl Polysilsesquioxane
Methacryloyloxypropyl Polysilsesquioxane	Methoxy PEG-10 Polysilsesquioxane
Polydimethylsiloxy PPG-13 Butyl Ether Silsesquioxane	Polymethylsilsesquioxane/Trimethylsiloxysilicate
Trimethylpentyl Polysilsesquioxane	

Table 6. Acute oral toxicity studies of polysilsesquioxanes in this safety assessment.

Ingredient (concentration)	Animal (n)	Methods	Results	Reference
Isobutyl/Methoxy PEG-10 Polysilsesquioxane (5000 mg/kg)	Female Sprague Dawley albino rats (5)	Single oral dose after fasting. Rats observed first 30 min and 1, 3, 6, and 24 h after dosing; then daily for 14 days. Results were scored according to U.S. Environmental Protection Agency (EPA) established four Toxicity Categories for acute hazards of pesticide products [40 CFR 156.62]	Two rats died. Clinical signs included foaming of the mouth, red nasal discharge, dehydration, and slight depression. Two necropsies were unremarkable; masses were attached to the uterine horn in two necropsies (one rat died), blanching on the lungs, reddened small intestine and black spleen were observed in one rat (this rat died); and white matter in the thoracic cavity and portions of stomach appeared slightly reddened were observed in the fifth rat. LD_{50} = > 5000 mg/kg, Toxicity Category III (slightly toxic and slightly irritating)	30
Isobutyl Polysilsesquioxane (5000 mg/kg)	Female Wistar albino rats (10)	Single oral dose after fasting. Rats observed first 30 min and 1, 3, 6, and 24 h after dosing; then daily for 14 days	There were no mortalities. Clinical signs included: moist, matted hair, probable inner ear infection, diarrhea, dehydrated appearance, convulsions, muscle tremors, and rales. LD_{50} = > 5000 mg/kg, Toxicity Category III	31
Methacryloyloxypropyl Polysilsesquioxane (5000 mg/kg)	Female Sprague Dawley albino rats (3)	Single oral dose after fasting. Rats observed first 30 min and 1, 3, 6, and 24 h after dosing; then daily for 14 days	There were no mortalities. All rats gained weight. Necropsy was unremarkable. LD_{50} = > 5000 mg/kg, Toxicity Category III	32
Methoxy PEG-10 Polysilsesquioxane (5000 mg/kg)	Female Sprague Dawley albino rats (3)	Single oral dose after fasting. Rats observed first 30 min and 1, 3, 6, and 24 h after dosing; then daily for 14 days	There were no mortalities. All rats gained weight. Clinical signs: slight depression and muscle tremors. Necropsy was unremarkable. LD_{50} = > 5000 mg/kg, Toxicity Category III	33
Trimethylpentyl Polysilsesquioxane (5000 mg/kg)	Female Sprague Dawley albino rats (3)	Single oral dose after fasting. Rats observed first 30 min and 1, 3, 6, and 24 h after dosing; then daily for 14 days	There were no mortalities. All rats gained weight. Necropsy was unremarkable. LD_{50} = > 5000 mg/kg, Toxicity Category III	34
Trimethylpentyl Polysilsesquioxane (5000 mg/kg)	Female Sprague Dawley albino rats (3)	Single oral dose after fasting. Rats observed first 30 min and 1, 3, 6, and 24 h after dosing; then daily for 14 days	There were no mortalities. All rats gained weight. Necropsy was unremarkable. LD_{50} = > 5000 mg/kg, Toxicity Category III	35

Table 7. Genotoxicity studies of polysilsesquioxanes.

Ingredient (concentration)	Assay	Results	Reference
Methacryloyloxypropyl Polysilsesquioxane (50, 100, 500, 1000, and 5000 µg/plate; in 2-propanol)	Bacterial reverse mutation assay using *S. typhimurium* (strains TA97a, TA98, TA100, TA102, and TA1535), with and without metabolic activation	Not cytotoxic or genotoxic, with or without metabolic activation	[37]
Methacryloyloxypropyl Polysilsesquioxane (50, 100, 500, 1000, and 5000 µg/plate; in 2-propanol)	Bacterial reverse mutation assay using *S. typhimurium* (strains TA97a, TA98, TA100, TA102, and TA1535), with and without metabolic activation	Not cytotoxic or genotoxic, with or without metabolic activation	[38]
Methoxy PEG-10 Polymethylsilsesquioxane (5000 µg/plate; in 2-propanol)	Bacterial reverse mutation assay using *S. typhimurium* (strains TA97a, TA98, TA100, TA102, and TA1535), with and without metabolic activation	Not cytotoxic or genotoxic, with or without metabolic activation	[39]
Polymethylsilsesquioxane (50, 100, 500, 1000, and 5000 µg/plate; in DMSO)	Bacterial reverse mutation assay using *S. typhimurium* (strains TA97a, TA98, TA100, TA102, and TA1535), with and without metabolic activation	Not cytotoxic or genotoxic, with or without metabolic activation	[13]
Trimethylpentyl Polymethylsilsesquioxane (5000 µg/plate; in 2-propanol)	Bacterial reverse mutation assay using *S. typhimurium* (strains TA97a, TA98, TA100, TA102, and TA1535), with and without metabolic activation	Not cytotoxic and there were no detectable genotoxic activity	[39]

DMSO = dimethyl sulfoxide

Table 8. Dermal irritation studies of polysilsesquioxanes using New Zealand White rabbits.

Ingredient (concentration)	n	Procedure	Results	Reference
Isobutyl Polysilsesquioxane (100%; 0.5 g)	6	Test substance was moistened with distilled water then applied to clipped intact and abraded skin of for 24 h under occlusion. After 24 h, test substance was washed from rabbit's skin with water and paper towels. Test sites were observed at 24 and 72 h after application.	PII was 0.05 out of 8. All 6 rabbits had a score of 0 for erythema on intact skin at 24 h 1 rabbit had a score of 1 at 72 h. There was no edema observed.	[42]
Isobutyl/Methoxy PEG-10 Polysilsesquioxane (100%; 0.5 g)	3	OECD GL 404. Test substance was moistened with distilled water then applied to clipped intact skin for 4 h under occlusion. Test sites were observed at removal through 14 days.	Very slight to well defined, transient erythema was observed after dosing, which resolved by day 7. No corrosive effects were observed.	[45]
Methacryloyloxypropyl Polysilsesquioxane	6	Applied to the intact and abraded skin of for 24 h under occlusion. After 24 h, test substance was washed from rabbit's skin with water and paper towels. Test sites were observed at 24 and 72 h after application.	PII was 0.55 out of 8. All 6 rabbits had a score of 1 for erythema on intact skin at 24 h, which was resolved in all but 1 rabbit at 72 h. There was no edema observed.	[60]
Methoxy PEG-10 Polysilsesquioxane (100%; 0.5 mL)	6	Applied to the intact and abraded skin of for 24 h under occlusion. After 24 h, test substance was washed from rabbit's skin with water and paper towels. Test sites were observed at 24 and 72 h after application.	PII was 0.40 out of 8. Five of 6 rabbits had a score of 1 for erythema on intact and abraded skin at 24 h. One rabbit had a score of 0. All erythema were resolved at 72 h and all rabbits had scores of 0. There was no edema observed.	[43]
Polymethylsilsesquioxane (0 or 200 mg/kg/day; concentration of solids not specified)	10	Dermally administered to rabbits for 28 days[a]	Only adverse effect reported was slight local erythema and dryness following 7 to 14 dermal applications of the emulsion.	[36]
Trimethylpentyl Polysilsesquioxane (100%; 0.5 mL)[b]	6	Applied to the intact and abraded skin of for 24 h under occlusion. After 24 h, test substance was washed from rabbit's skin with water and paper towels. Test sites were observed at 24 and 72 h after application.	PII was 0.30 out of 8. Three of 6 rabbits had a score of 1 for erythema on intact and abraded skin at 24 h, 1 rabbit had a score of 1 for erythema on abraded skin, and 2 scored 0. All erythema was resolved at 72 h and all rabbits had scores of 0. At 24 and 72 h, all scored 0 for edema.	[44]

Table 8. Dermal irritation studies of polysilsesquioxanes using New Zealand White rabbits.

Ingredient (concentration)	n	Procedure	Results	Reference
Trimethylpentyl Polysilsesquioxane (100%; 0.5 mL)[b]	6	Applied to the intact and abraded skin of for 24 h under occlusion. After 24 h, test substance was washed from rabbit's skin with water and paper towels. Test sites were observed at 24 and 72 h after application.	PII was 0.78 out of 8. Four of 6 rabbits had a score of 1 for erythema on intact and abraded skin at 24 h, 1 rabbit had a score of 1 for erythema on abraded skin, and 1 scored 2 on intact and 1 on abraded skin. All erythema was resolved at 72 h and all rabbits had scores of 0. At 24 and 72 h, all scored 0 for edema.	[35]

PII = Primary Irritation Index
[a] Breed/strain of rabbit not known.
[b] Two different forms of Trimethylpentyl Polysilsesquioxane

Table 9. HRIPT studies of polysilsesquioxanes.

Ingredient (concentration)	n	Proceedure	Results	Reference
C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane (4.337%)	218	A product (0.2 g; neat) that is used near the eyes, containing ingredient at 4.337%, was applied to the infrascapular area of the back or the upper arm under occlusion three times per week for 3 weeks. Patches were left in place for 24 h. Challenge application was made (neat) after a one-week rest period to naïve sites. Test sites were examined before next application.	There were no adverse events reported at any time during the test. There was no evidence of sensitization during test period. It was concluded that that test substance was non-sensitizing.	[48]
Polymethylsilsesquioxane (100%; 0.2 g)	50	Induction applications were made three times per week for 3 weeks. After a rest period of 10 to 14 days, challenge patch, also containing 0.2 g Polymethyl-silsesquioxane, was administered.	There were no adverse reactions of any type observed during the course of this study.	[13]
Polymethylsilsesquioxane (50%)	100	A makeup product, containing the ingredient at 50%, was applied to upper backs under occlusion three times per week for 3 weeks. After at least a two-week rest, challenge application was made (neat) to a naïve site on the back. Test sites were examined before next application.	There were no signs of erythema or other signs of irritation or sensitization at any time during test. It was concluded that test substance was non-sensitizing.	[49]
Polymethylsilsesquioxane (22.0%)	108	A makeup product, containing the ingredient at 22.0%, was applied to backs under occlusion three times per week for 3 weeks. Patches remained in place for at least 24 h. After a 12 to 14-day rest, the challenge application was applied (neat) to a naïve site on backs and to the upper arm. Test sites were examined before the next application during induction and at 24 and 72 h after the removal of the challenge patch.	There were two instances of barely perceptible erythema (±) after the removal of an induction patch; there were no other signs of erythema, or signs of irritation or sensitization, at any time during the test. It was concluded that the test substance was non-sensitizing.	[50]
Polymethylsilsesquioxane/ Trimethylsiloxysilicate (50% in cyclopentasiloxane)	50	Induction applications were made with test substance (0.2 g) three times per week for 3 weeks to infrascapular region of backs. Subjects removed occlusive hypoallergenic patches after 24 h. After a rest period of 10 to 14 days, the challenge patch, also containing 0.2 g test substance (50%) was administered.	There were no adverse reactions of any type observed during course of this study, and test substance was considered a non-primary irritant and a non-primary sensitizer to the skin.	[18]

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