Safety Assessment of Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients as Used in Cosmetics

Status: Final Report
Release Date: January 14, 2015
Panel Meeting Date: December 8-9, 2014

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ABSTRACT

This is a safety assessment of polyoxyalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients as used in cosmetics. The functions of these ingredients in cosmetics include hair conditioning agents, viscosity increasing agents, emulsion stabilizers, and film formers. The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) reviewed relevant animal and human data related to these ingredients. The Panel concluded that these polyoxyalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients were safe in cosmetics in the practices of use and concentration of this safety assessment.

INTRODUCTION

This is a safety assessment of polyoxyalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients as used in cosmetics. This group, in general, is referred to as alkoxy polysiloxanes in this report. The functions of the 111 ingredients in this report include hair conditioning agents, viscosity increasing agents, emulsion stabilizers, and film formers (Table 1).

In 1982, the Panel published a safety assessment of dimethicone copolyol with a safe as used conclusion.[1] At the time, the term dimethicone copolyol referred to polymers of dimethylsiloxane with polyoxyethylene and/or polyoxypropylene side chains. These polymers included straight-chain dimethicone polymers (up to 10 000 repeating units of dimethyl polysiloxanes) and silica-activated dimethicones forms. The dimethicone copolyols were divided into 2 categories: copolyol A and copolyol B. Copolyol A compounds were defined as copolymers of dimethicone with pendent side chains of polyethylene glycol (PEG), polypropylene glycol (PPG), or block polymers of polyoxyethylene/polyoxypropylene which are added through silicon-carbon bonds. Copolyol B ingredients are differentiated from type A by alkyl group side chains. The type B copolyols are differentiated from each other according to the length and nature of these side chains. The summary of the 1982 safety assessment is provided below.

Since the 1982 report, the International Nomenclature Cosmetic Ingredient (INCI) naming conventions for dimethicone copolyols have changed and each of these ingredients now has an individually assigned name and is no longer covered under the umbrella term dimethicone copolyol.[2] In a re-review of dimethicone copolyol, which was published in 2005, the Panel identified several of these ingredients under the new naming convention and included them under the safe as used conclusion reaffirmation.[1]

Behenoxy dimethicone and stearoxy dimethicone have been reviewed by CIR with a conclusion of safe as used.[3] Several structurally-related ingredients and ingredients with component moieties similar to the ingredients in this report have been reviewed by the Panel. The conclusions for all of these ingredients were safe as used or safe with qualifications (Table 2). This safety assessment does not include cyclic dimethicones, only acyclic copolymers.

It appears that cetyl PEG-8 dimethicone and PEG-8 cetyl dimethicone may be 2 names for the same ingredient. They have the same definition and structure in the *International Cosmetic Ingredient Dictionary and Handbook*,[2] but have different functions listed, surfactant – emulsifying agent and skin-conditioning agent – miscellaneous, respectively. These ingredients are treated as separate ingredients in this safety assessment.

Dimethicone Copolyol Summary, 1982

Dimethicones are polymers of methylsiloxane. Dimethicone Copolyols are Dimethicones copolymerized with polyalkoxy chains.[1] The Copolyols are chemically and physically inert ingredients used in cosmetics in a concentration range of less than or equal to 0.l% -10% as surface tension depressants, wetting agents, emulsifiers, foam builders, plasticizers, and lubricants. Copolyol containing products may be applied to all surfaces of the body on an occasional or daily basis over a period of years.

Silicone compounds do not easily cross membrane barriers and are not absorbed through the skin. Silicones are not metabolized by the body or by microorganisms. Silicone fluids are relatively innocuous when administered orally and parenterally.

Dimethicone Copolyols were at most slightly toxic to the rat when administered orally in a single dose. Single dermal application of Copolyols to rats and rabbits were practically nontoxic. Copolyols were not primary skin or ocular irritants in the rabbit. Inhalation studies at ambient temperatures in the rat indicated that little hazard exists. An 89-day feeding study in the rat using two concentrations of a Copolyol B gave no evidence of subchronic oral toxicity. Subchronic dermal tests in the rabbit using two undiluted Copolyol A ingredients showed little effect other than slight to moderate skin irritation at the application sites.

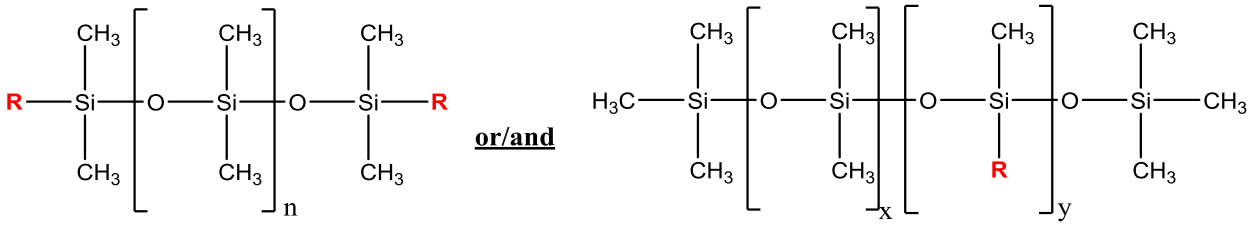
Clinical studies on a total of 39 subjects indicated that both 40% Dimethicone Copolyol in aqueous solution and undiluted Dimethicone Copolyol are not primary skin irritants.

Fifty subjects showed no indication of skin irritation or sensitization when tested with undiluted Dimethicone Copolyol A ingredients. An unspecified concentration of Dimethicone Copolyol was found to be nonirritating and nonsensitizing when tested on 201 volunteers.

CHEMISTRY

Definition and Structure

All of the ingredients in this report are alkoxylated derivatives of polysiloxanes (eg dimethicones). Within this grouping, there are 3 primary configurations: 1) end-capped polysiloxanes, wherein a siloxane polymer is terminated on either end with an alkoxy group (eg cetyloxy); 2) alkoxy-polysiloxane/polysiloxane co-polymers; and 3) some combination of 1 and 2 (Figure 1). Each of these ingredients may vary greatly in size depending on the size of the silicone portion of the polymer. These ingredients are derived from dimethicone, methicone, or silsequioxane. As will any polymeric ingredient, the number of monomeric repeat units (and thus polymeric size) has the potential to greatly impact the physical characteristics (eg matter phase, hardness, etc.) imbued on the moiety. Accordingly, size and distribution of variations, as used in cosmetic ingredients, are important considerations for understanding the nature of these materials. In general:



-wherein **R** is an alkoxy or polyalkoxy group

For example, Bis-Stearoxyethyl Dimethicone is the ingredient wherein R is stearoxyethyl:

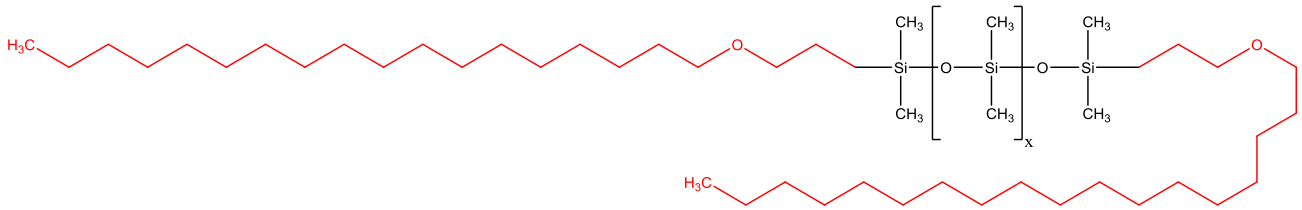


Figure 1. Alkoxy Polysiloxanes

Physical and Chemical Properties

The physical and chemical properties of the ingredients in this safety assessment are presented in Table 3. Physical and chemical properties of an ingredient will vary depending on the size of the silicone portion of the polymer; the PEG or PPG component only provides information on the size of that part of the compound and not any information on the size or the rest of the ingredient molecule.

Under the generic CAS No. 68937-54-2 (dimethylsiloxane, ethylene oxide block copolymer), the following were reported: melting point -14°C, boiling point >250°C, and density 1.035 g/mL at 25°C.[4]

Alkoxy polysiloxanes with a PEG moiety tend to be hydrophilic and soluble in water and alcohols.[5] In general, the longer the PEG chain length, the greater the foaming potential and the higher the cloud point (ie, the temperature at which a solution of the ingredients begins to separate into 2 phases). Compounds with >16 carbon atoms in the fatty acid group are the most hydrophobic..[6]

Alkoxy polysiloxanes with <12 carbon atoms in the fatty acid group are liquid at room temperature; those with >14 carbon atoms are solids.[7] Compounds with an unsaturated or branched fatty acid group are liquid at room temperature.

Molecular weight affects the orientation/configuration of the alkoxy polysiloxanes on the surface of the skin and, in general, low molecular weight polymers are very good wetting agents.[6] Cetyl PEG/PPG-10/1 dimethicone was reported to have an average molecular weight >1000 Da; less than 5.5% of this ingredient had a molecular weight <500 g/mol and 9.0% <1000 g/mol.[8] Less than 10% of PEG-9 polydimethylsiloxyethyl dimethicone was reported to be <1000 g/mol.[8]

Method of Manufacture

Alkoxy polysiloxanes are produced by hydrosilylation. In most cases, a hydrogen dimethicone polymer block is reacted with an allyl alkoxylate and alpha-olefin delta-alkene.[6,9] The product can be further modified polymerically with ethylene oxide or propylene oxide to produce PEG or PPG chains, respectively.

Newer catalyst systems allow for the manufacture of dimethicone copolyol compounds that contain simple hydroxypropyl groups.[6]

Polyoxyalkylene siloxane copolymers and alkyl-polyoxyalkylene siloxane copolymers (copolymers) are formed by reacting allyloxy terminated alkoxylates (polyethers) with dimethicone.[10-12] The typical molecular weight range for the

polyethers consumed in this reaction is 500 to 4000 g/mol. Commercial copolymer materials have a variety of ethylene oxide to propylene oxide ratios, polyether molecular weights, and end-cappings. The siloxane to polyether ratio also varies, depending on the hydrophilic-lipophilic balance needs for the copolymer applications as non-ionic surfactants. Typically the molecular weight of these copolymers is greater than 1000 g/mol.

The reaction requires an excess amount of polyethers to ensure the formation of the resulting copolymer.[13] Consequently, the resulting copolymer contains an excess of unreacted polyethers, typically between 10% and 30% by weight, and therefore these ingredients are actually considered mixtures. Removal of the excess polyether is not feasible due to the adverse effects on the copolymer performance and function. All siloxane polymers produced commercially using allyl polyether polymers will have these unreacted polyethers. In this report, the toxicity studies submitted by the Silicones Environmental, Health and Safety Center (SEHSC) that were conducted on the specified cosmetic ingredients all contain the excess-unreacted polyethers.

Impurities

Bis-PEG-15 methyl ethyl dimethicone was reported to contain 0.1% cyclotetrasiloxane.[14] Analysis of 3 batches of bis-PEG-15 methyl ethyl dimethicone found that there was <1% of each of the following: Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cu, Fe, Hg, Mn, Mo, Ni, Pb, Sb, Sn, Sr, Tl, V, W, Zn, and Zr. A maximum concentration of 0.1% cyclotetrasiloxane and cyclopentasiloxane was reported.

A supplier reported that an analysis of PEG-3 dimethicone did not detect chlorosilane (residual monomer; detection limit 100 ppm), but detected platinum (residual catalyst; <10 ppm), ethanol (residual solvent; <0.1%), polyethylene glycol (by-product; approximately 5%), cyclotetrasiloxane (D4; <0.1%), and decamethylcyclopentasiloxane (D5; <0.1%).[15]

A supplier reported that an analysis of PEG-12 dimethicone found that it contains 30%-40% poly(oxy-1,2-ethanediyl),-α-2-propen-1-yl-ω-hydroxy, therefore, the impurities will be related to both silicone and poly(oxy-1,2-ethanediyl,α-2-propen-1-yl-ω-hydroxy.[16] Cyclotetrasiloxane and decamethylcyclopentasiloxane were reported to be present at <0.1%.

PEG/PPG-25/25 dimethicone is reported to contain <1% cyclotetrasiloxane.[17] Pt-catalyst residues were reported to be <5 ppm. Cyclotetrasiloxane was reported to be present at a maximum concentration of 1.0%, and cyclopentasiloxane at no greater than 0.5%. Volatile organic compounds (VOC) were reported at <2%.

A product brochure reported that forms of PEG-12 dimethicone (ie, PEG-17 dimethicone, PEG-10 dimethicone, and PEG-20/PPG-23 dimethicone) are each "100% pure".[18]

USE

Cosmetic

The Food and Drug Administration (FDA) collects information from manufacturers on the use of individual ingredients in cosmetics as a function of cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP).[19] Use data are summarized in Table 4. The highest numbers of uses were reported for PEG-12 dimethicone (538 uses), PEG/PPG-18/18 dimethicone (461 uses), cetyl PEG/PPG-10/1 dimethicone (404 uses), and PEG-10 dimethicone (240 uses).

A survey was conducted of industry by the Personal Care Products Council (Council) of the maximum use concentrations for ingredients in this group.[20] These ingredients were reported to be used in almost all of the FDA VCRP product categories; the highest numbers were reported in makeup, including lipsticks and products used around the eyes. The highest maximum concentrations of use were reported for stearoxy dimethicone (22% for hair conditioners), cetyl PEG/PPG-10/1 dimethicone (15% for eyebrow pencils and 13.6% for eye shadow), PEG/PPG-17/18 dimethicone (14% for perfumes and 13% for hair products), and bis-hydroxyethyoxypropyl dimethicone (12% for blushers).

The VCRP reported data under the previous umbrella name of these ingredients (Table 4).[19] There are 28 uses reported for cetyl dimethicone copolyol, 322 uses for dimethicone copolyol, 5 uses for dimethicone copolyol crosspolymer, and 1 use for dimethicone copolyol methyl ether.

Table 5 lists the ingredients for which there were no uses reported by either the VCRP or the Council.

Alkoxy polysiloxanes were reported to be used in aerosol spray moisturizers, suntan products, perfumes, deodorants, body and hand products, and hair sprays, including pump hair sprays. The highest maximum reported concentration in these products was 2.8% PEG-14 dimethicone in a pump hair spray. Lauryl PEG-9 polydimethylsiloxyethyl dimethicone is used in deodorant aerosol sprays up to 0.29%. PEG-3 dimethicone is used in face powders up to 3%. 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 below 10 μm compared with pump sprays.[21-24] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (ie, they would not enter the lungs) to any appreciable amount.[21,24] There is some evidence indicating that deodorant spray products can release substantially larger fractions of particulates having aerodynamic equivalent diameters in the range considered to be respirable.[21] 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.

Non-Cosmetic

Polydimethylsiloxanes are used for the siliconization of needles and syringes, lubrication of medical devices, and as topical formulation excipients in skin-protecting compositions, and drug carriers.[25]

Dimethicone copolyol is listed in the FDA's Inactive Ingredient Database as pending for use in a topical gel at 1% and in a transdermal film for controlled release.[26]

TOXICOKINETICS

Absorption, Distribution, Metabolism, and Excretion

Low molecular weight alkoxy polysiloxanes penetrate and irritate the skin, as the result of the proclivity of these substances to wet surfaces.[6]

BIS-PEG-15 METHYL ETHYL DIMETHICONE

In a permeability test using pig skin and diffusion chambers (n=6), bis-PEG-15 methyl ethyl dimethicone was not detected in the receptor chamber (detection limit 0.5%) at 0, 16, 24, 40, 64, and 72 h.[27] In a second run of the experiment (n=3), the test substance was not detected (detection limit 1.25%) in pooled samples at 72 h. In both experiments, the test substance (16 mg/4 cm^2) was administered and left on the skin surface for 24 h and then washed off with a neutral shampoo.

TOXICOLOGICAL STUDIES

Acute Toxicity

Oral – Non-human

BIS-PEG-15 METHYL ETHYL DIMETHICONE

The oral LD_{50} of bis-PEG-15 methyl ethyl dimethicone was > 4640 mg/kg for rats. No further information was provided.[14,28]

CETYL PEG/PPG-10/1 DIMETHICONE

The oral LD_{50} of cetyl PEG/PPG-10/1 dimethicone was > 5000 mg/kg for Wistar rats (n=5).[16] The rats were observed for 14 days. There were no mortalities; 1 rat exhibited anogenital staining on day 1.

LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

The oral LD_{50} of lauryl PEG-9 polydimethylsiloxyethyl dimethicone was reported to be 5000 mg/kg for rats.[29] There were no adverse effects observed.

PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

The oral LD_{50} of PEG-9 polydimethylsiloxyethyl dimethicone in rats was reported to be >5000 mg/kg.[8] No mortalities or clinical signs were observed.

PEG/PPG-19/19 DIMETHICONE

The oral LD_{50} of PEG/PPG-19/19 dimethicone (100%) was >16 mL/kg in CFE rats (n=5/sex).[30] Controls were administered with tragacanth mucilage (0.5%). Clinical signs included piloerection and diuresis. All rats appeared healthy 4 days after dosing and gained weight normally. Necropsies were unremarkable.

PEG/PPG-25/25 DIMETHICONE

There were no mortalities or clinical signs in Sprague-Dawley rats (n=5/sex) orally administered a single dose of PEG/PPG-25/25 dimethicone (2007 mg/kg).[31] The authors concluded that the oral LD_0 was ≥ 2007 mg/kg. There were no behavioral abnormalities or physiological findings. Body weights were similar to controls. The test substance was administered neat. The rats were observed for 14 days and then necropsied.

Dermal – Non-human

BIS-PEG/PPG-14/14 DIMETHICONE

The dermal LD_{50} of bis-PEG/PPG-14/14 dimethicone, under occlusion, in Wistar rats (n=10) was >2000 mg/kg. The time of exposure was not provided. No mortalities or clinical signs were observed.[32] Slight erythema was observed in 4 of the rats.

PEG/PPG-19/19 DIMETHICONE

When PEG/PPG-19/19 dimethicone (2000 mg/kg) was administered to the dorso-lumbar region of New Zealand White rabbits (n=5/sex) for 24 h, none of the rabbits died during the course of the study.[30] There were no observed signs of systemic effects, except that 1 male rabbit had few feces on Day 3 of the study. There was slight to well-defined irritation in most of the rabbits, which resolved by the end of the study. There were no treatment-related effects on body-weight gain, nor were there macroscopic effects observed upon necropsy of the animals. The rabbits were observed for 15 days.

PEG-12 DIMETHICONE

The estimated acute dermal LD_{50} was >5 g/kg PEG-12 dimethicone in male albino rabbits (n=5).[30] One rabbit in the high-dose group was euthanized in a moribund condition. In the remaining animals, only slight exfoliation at the application site was observed. No test material-related lesions were observed microscopically in any of the rabbits. The test material (2 or 5 mg/kg) was administered to the clipped skin for 24 h on a cotton bandage under plastic wrap.

Inhalation – Non-Human

PEG-12 DIMETHICONE

In an acute inhalation study of PEG-12 dimethicone (0.68 mg/L) using Sprague-Dawley rats (n=5/sex), there were no deaths in the control or test groups, and no abnormalities were observed during the 4-h exposure or the observation.[30] Necropsies revealed no abnormalities in any major organs or tissues. Post-exposure observation period not provided.

Repeated Dose Toxicity

Oral – Non-human

BIS-PEG-15 METHYL ETHYL DIMETHICONE

There were no clinical signs observed when CD Sprague Dawley rats (n=5/sex) were administered bis-PEG-15 methyl ethyl dimethicone (0, 50, 200, 1000 mg/kg/d in corn oil) by gavage for 4 weeks.[33] There were no deaths during the study. Body weights and feed consumption were not affected by treatment. Clinical pathology, microscopic examination of the tissues, and necropsies were unremarkable. There was an increase in liver weights in the male rats of the high-dose group.

CETYL PEG/PPG-10/1 DIMETHICONE

There were no mortalities when cetyl PEG/PPG-10/1 dimethicone (5000 mg/kg/d) was administered by gavage to Wistar rats (n=5/sex) for 14 days.[8] One rat exhibited anogenital staining on day 1.

PEG-12 DIMETHICONE

The oral no observed adverse effect level (NOAEL) of PEG-12 dimethicone was 1000 mg/kg/d for Sprague-Dawley rats (n=5/sex) when administered by gavage for 29 days.[30] There were no test substance-related microscopic pathological findings. There were no signs of toxicity and no deaths occurred. Functional observation battery (FOB) assessments, manipulation, and motor-activity tests did not reveal any test-substance-related effects. The only treatment-related clinical chemistry and organ weight findings were decreased albumin/globulin ratio and increased liver weight in the 1000 mg/kg/d females. However, there were no microscopic changes in the livers.

Dermal – Non-human

PEG/PPG-19/19 DIMETHICONE

When PEG/PPG-19/19 dimethicone (0, 100, 300, 1000 mg/kg/d) was dermally applied to female New Zealand White rabbits (n=10/sex) for 29 days, the authors reported a no observed effect level (NOEL) for systemic toxicity of 1000 mg/kg/d.[30] Each treatment was in place for 6 h. There were no deaths or clinical signs. Local irritation was observed at the application site of the majority of rabbits of all treatment groups. These signs were generally limited to erythema, edema, exfoliation, and scabs. Body weight and feed consumption were not affected by treatment. There were no ocular findings attributable to treatment and hematological and blood chemistry investigations were unremarkable. Absolute and relative organ weights were unaffected by treatment. There were no treatment-related macroscopic findings at necropsy, except those associated with the local signs of irritation at the application sites. Diffuse subcutaneous inflammation, acanthosis and follicular abscess were revealed upon microscopic examination of the application sites.

PEG-12 DIMETHICONE

PEG-12 dimethicone (100, 300, or 1000 mg/kg) did not produce any signs of systemic toxicity when dermally administered to New Zealand White rabbits (n=10/sex) 6 h/d under semi-occlusion for 29 days.[30] There were no deaths. Very slight erythema was observed in all treated groups, and the incidence of erythema increased in a dose-dependent manner; it was highest in females. One female in the highest dose group showed severe erythema, which resolved by the end of the study. Dermal administration of PEG-12 dimethicone produced no ophthalmologic findings attributable to treatment. Hematological and blood chemistry testing did not reveal any toxicological effects. Organ weights were unaffected by treatment. There were no treatment-related macroscopic findings at necropsy, other than those associated with the local signs of irritation at the dermal application sites. Microscopic examination yielded a number of findings at the application site, including diffuse subcutaneous inflammation, acanthosis, and a single case of follicular abscess. Ulcers were found on the application sites of females in the low- and mid-dose groups.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

PEG-12 DIMETHICONE

Dermally administered PEG-12 dimethicone (100%; 0, 50, 100 or 200 mg/kg) was not embryotoxic or teratogenic to New Zealand White rabbits treated on days 6 through 18 of gestation.[30] No adverse effects were observed in mean maternal body weights, feed consumption, or liver weights of the treated rabbits. No differences were observed in the number of implantation sites, number of live fetuses per litter, mean litter size, fetal body weights or crown-rump length between the control and treated groups. The incidence of resorption among the total fetal population of rabbits treated with test material was similar to that of the control group. No single alteration was observed in any of the treated litters which was different from the control group. No treatment related signs of toxicity or behavioral changes were observed in any of the pregnant rabbits. Three rabbits in the 50-mg/kg/d group, 1 in the 100-mg/kg/d group, and 3 in the 200-mg/kg/d group died during the study. Some pregnancies were terminated because of *Pasteurella multocida* infection, a known abortifacient in rabbits. Water served as the control. Litters were collected by Cesarean section on day 29 and the fetuses examined for external, visceral or skeletal defects

GENERIC SILOXANES AND SILICONES, DI-METHYL, 3-HYDROXYPROPYL METHYL ETHOXYLATED

New Zealand albino rabbit does (n=30) exhibited increased numbers of resorption sites when siloxanes and silicones, 3-hydroxypropyl methyl, di-methyl ethoxylated (generic compounds that fall within the description of the ingredients in this safety assessment; CAS No. 68937-54-2; 200 mg/kg in corn oil) were dermally administered to shaved backs of the does (approximately 10% body surface) on gestation days 6 to 18.[34] There were no deaths attributed to the test material. One pup in the treatment group displayed clubbing of the extremities, partial acranius, and an umbilical hernia. The 24-h survival of fetuses, abnormalities in the fetuses, and number of abnormal fetuses were similar across both control groups (administered the vehicle or nothing). No dermal effects were reported for the dams. Subsequent testing of the test substance demonstrated that it was neither embryotoxic nor teratogenic when dermally administered to New Zealand white rabbits at doses of 50, 100, or 200 mg/kg (data not provided). Does were killed and necropsied on gestation day 29.

GENOTOXICITY

BIS-PEG-15 METHYL ETHYL DIMETHICONE

In a reverse mutation assay using *Salmonella typhimurium* (strains TA98, TA100, TA1535, and TA1537) including a plate incorporation test and a pre-incubation test, bis-PEG-15 methyl ethyl dimethicone (0, 33, 100, 333, 1000, 2500, and 5000 µg/plate) was not genotoxic with or without metabolic activation.[35]

CETYL PEG/PPG-10/1 DIMETHICONE

Cetyl PEG/PPG-10/1 dimethicone (250, 500, 1000, 5000 µg/plate) was not mutagenic in *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *Escherichia coli* (strain WP2), with or without metabolic activation.[8]

LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

Lauryl PEG-9 polydimethylsiloxyethyl dimethicone was reported to be non-mutagenic in an Ames test.[29] No details were provided.

LAURYL PEG/PPG-18/18 METHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA98, TA100, TA1535, and TA1537) and *E. coli* (strains WP2 *ur*A pKM101 and WP2 pKM101), lauryl PEG/PPG-18/18 methicone (0, 15, 50, 150, 500, and 1500 µg/plate in ethanol) was not genotoxic with or without metabolic activation.[30] Precipitate was observed at 1500 µg/plate, but no appreciable toxicity was observed.

PEG/PPG-19/19 DIMETHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA98, TA100, TA1535, TA1537, and TA1538), PEG/PPG-19/19 dimethicone (0, 0.5, 5, 100, and 500 µg/plate) was not genotoxic with or without metabolic activation.[30]

PEG/PPG-25/25 DIMETHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) including a plate incorporation test and a pre-incubation test, PEG/PPG-25/25 dimethicone (33, 100, 333, 1000, 2500, 5000 µg/plate) was not genotoxic with or without metabolic activation.[36]

PEG-12 DIMETHICONE

In a reverse mutation assay using *S. typhimurium* strains (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP2uvrA), PEG-12 dimethicone was not mutagenic up to 5000 µg/plate, with or without metabolic activation.

PPG-2 DIMETHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA97, TA98, TA100, TA1535) and *E. coli* (strain WP2), PPG-2 dimethicone (0, 312.5, 625, 1250, 2500, and 5000 µg/plate in dimethylsulfoxide [DMSO]) was not genotoxic with or without metabolic activation.[30] When repeated with another strain of *S. typhimurium* (strains TA1535), PPG-2 dimethicone (0, 15 625, 31 250, 62 500, 125 000 and 250 000 µg/plate in ethanol) was not genotoxic with or without metabolic activation.

CARCINOGENICITY

Data on carcinogenicity of polyoxyalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients were not identified in the published literature nor were unpublished data provided.

IRRITATION AND SENSITIZATION

Irritation

Dermal – Non-human

BIS-CETYL/PEG-8 CETYL PEG-8 DIMETHICONE

Bis-cetyl/PEG-8 cetyl PEG-8 dimethicone (100%; 0.5 mL; MW > 10 000) was a dermal irritant when administered to the intact or abraded skin of New Zealand White rabbits (n=6) under occlusion for 24 h.[30] The Draize scores were 2, 1.995, and 1.915 for all test sites, intact skin, and abraded skin, respectively. Well-defined erythema was observed on 5/6 abraded sites and 5/6 intact sites at 24 h. Barely perceptible erythema was observed at 1 intact site and 1 abraded site. Barely perceptible edema was observed at all sites at 24 h. By 72 h, both incidence and severity of erythema and edema had subsided, but were not totally resolved.

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was not an acute skin irritant to rabbits. No further information was provided.[14,28]

CETYL PEG/PPG-10/1 DIMETHICONE

When administered to the intact or abraded skin of New Zealand White rabbits (n=6) for 24 h, cetyl PEG/PPG-10/1 dimethicone (MW <1000; 0.5 mL) caused very slight redness (grade 1) in 5 of 6 abraded sites and 5 of 6 intact sites.[30] The Draize scores were 0.4 for both intact and abraded skin. There was no edema observed for any rabbit for any time point. All test sites were normal at 72 h.

When administered to the intact or abraded skin of New Zealand White rabbits (n=6) for 24 h, cetyl PEG/PPG-10/1 dimethicone (MW >10 000; 0.5 mL) caused slight irritation in all tested rabbits.[30] The Draize scores were 1.17, 0.75, and 1.58 for all test sites, intact skin, and abraded skin, respectively. At 24 h, all abraded sites and most intact sites exhibited erythema, most of these with edema. Irritation was more severe on the abraded sites. At 72 h, only 2 abraded sites had very slight erythema; all other irritations had cleared.

In another study, it was concluded that cetyl PEG/PPG-10/1 dimethicone (assumed 100%; 0.5 mL) had some potential for dermal irritation, but well below the threshold to be classified as hazardous, when administered to the clipped skin of New Zealand White rabbits (n=6) for 24 h under occlusion.[8] Erythema was observed in all rabbits at 24 h after removal of the patches and in 4 rabbits at 72 h. At 24 h, the Draize scores for erythema for 5 of 6 of the rabbits were scores of 2 and 1 for the sixth rabbit. At 24 h after patch removal, the Draize score for edema was 1, which reduced to 0 in 4 of 6 rabbits.

Cetyl PEG/PPG-10/1 dimethicone (100%; 0.5 mL) was reported to be a potential dermal irritant in New Zealand White rabbits (n=6), but was not classified as an irritant using the National Occupational Health and Safety Commission's (NOHSC of Australia; now called Safe Work Australia) criteria for classifying hazardous substances.[16] The test substance was administered to 2.5 cm^2 clipped, intact skin. Low-level erythema and edema were observed on day 1, which were reduced or resolved by day 3.

LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

Lauryl PEG-9 polydimethylsiloxyethyl dimethicone (assumed 100%; 0.5 mL) was reported to be slightly irritating to rabbit skin (n=6).[29] Slight-to-moderate erythema was observed in all rabbits tested, at both the intact and abraded sites at 24 h, which was resolved in 5 of 6 guinea pigs at 72 h. The remaining guinea pig exhibited moderate erythema and slight edema at both the intact and abraded sites at 72 h. The testing protocol was reported to be similar to the protocol detailed in the Organization for Economic Co-operation and Development (OECD) Test Guidelines (TG) 404. The test substance was administered to the intact and abraded skin of the rabbits under an occlusive patch for 24 h, then observed at 24 and 72 h after the patch was removed.

PEG/PPG-25/25 DIMETHICONE

PEG/PPG-25/25 dimethicone (100%; 0.5 mL) was not a dermal irritant when administered to the skin of male New Zealand hybrid albino rabbits (n=6) for 4 h under semi-occlusion.[37] All scores for erythema and edema were 0 at all observation times. The test sites were examined at 1, 24, 48, and 72 h after removal.

PEG-12 DIMETHICONE

In a patch test of PEG-12 dimethicone (100%; 0.5 mL) using female New Zealand White rabbits (n=3), a single semi-occlusive application of the test material to intact clipped skin for 4 h elicited very slight erythema, which resolved within 72 h, and no edema.[30] The Primary Irritation Index (PII) was calculated to be 0.44. The sites were scored for irritation at 60 min and 24, 48 and 72 h.

PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

PEG-9 polydimethylsiloxyethyl dimethicone (20% and 100%) was a slight dermal irritant to the intact and abraded skin of rabbits.[8]

Slight to well-defined erythema, with some scaling, was observed when PEG-9 polydimethylsiloxyethyl dimethicone (5% in corn oil; 0.5 mL) was administered to the skin of rabbits 5 days per week for 2 weeks.[8]

GENERIC SILOXANES AND SILICONES, DI-METHYL, 3-HYDROXYPROPYL METHYL ETHOXYLATED

Siloxanes and silicones, di-methyl, 3-hydroxypropyl methyl ethoxylated (10% in distilled water; 0.5 mL; MW 1000-5000) was not an irritant when administered to the clipped intact or abraded skin of New Zealand White rabbits (n=6) for 24 h under occlusion.[30] The remaining test material was wiped from the skin when the patch was removed. The skin was evaluated for irritation 24 and 72 h after patch removal.

Dermal – Human

CETYL PEG/PPG-10/1 DIMETHICONE

In a human patch test (n=20), a brow pencil containing cetyl PEG/PPG-10/1 dimethicone (15%) was found to be non-irritating.[38] The test substance was administered for 24 h under occlusion.

PEG-12 DIMETHICONE

When PEG-12 dimethicone (0.5%, 2%, and 5%) was administered simultaneously with sodium lauryl sulfate (SLS) (1% aqueous) to the backs of subjects (n=48 female, 5 male) under occlusion for 24 h, the test material provided protection against the primary dermal irritation produced by the SLS compared to the SLS-only control.[30] The high dose provided the greatest protection. The sites were evaluated for erythema and edema 24 and 48 h after patch removal.

PEG-3 DIMETHICONE

A lip makeup base that contained PEG-3 dimethicone (5%) was found to be non-irritating in a human patch test (n=11).[39] The test substance was administered to the scapular part of the back and left in place under occlusion for 48 h.

Dermal - In Vitro

PEG-12 DIMETHICONE

In an in vitro human reconstructed epidermis cytotoxicity test (SkinEthic™), PEG-12 dimethicone was rated as a non-irritant.[16] The negative control (water) yielded 100% viability and the test substance was associated with 66.4% viability. The positive control produced the expected results. The cells were exposed to the test substance for 42 min and the cells were evaluated 42 h after exposure.

PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

PEG-9 polydimethylsiloxyethyl dimethicone was predicted to be a non-irritant in an EpiSkin™ assay.[40]

Ocular – Non-Human

As the molecular weight of PEG-8 dimethicone (632-2594) increased, ocular irritation scores decrease, as measured using the Draize Irritation Rating Scale (Table 6).[6] PEG-8 dimethicone was not an ocular irritant at MW 2594.

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was not an acute eye irritant in rabbits. No further information was provided.[14,28]

BIS-PEG/PPG-14/14 DIMETHICONE

Bis-PEG/PPG-14/14 dimethicone (assumed 100%) was a slight ocular irritant when administered to the eyes of New Zealand White rabbits (n=3).[32] Slight swelling of the conjunctiva, with slight ocular secretion, was observed in 1 rabbit at 1h. The rabbits were examined at 1, 24, 48, and 72 h.

CETYL PEG/PPG-10/1 DIMETHICONE

Cetyl PEG/PPG-10/1 dimethicone (100%; 0.1 mL) caused no opacity or iritis of the eyes of New Zealand White rabbits (n=6).[8] Redness and conjunctival effects were observed on days 1 and 2. The conjunctival effects were resolved by day 3; redness was reduced by day 3.

Cetyl PEG/PPG-10/1dimethicone (100%; 0.1 mL) was reported to be a potential ocular irritant in New Zealand White rabbits (n=6) but was not classified as an irritant using the NOHSC's criteria for classifying hazardous substances.[16] Conjunctival effects were observed on day 1, which were resolved, except for redness, at 72 h.

LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

Lauryl PEG-9 polydimethylsiloxyethyl dimethicone was reported to be slightly irritating to the eyes of rabbits (n=3).[29] The test substance was administered to the eyes, which were either washed or not washed in accordance with a similar procedure described in OECD TG 404. In all rabbits of both the non-washed and washed eye groups, slight conjunctival irritation was observed at 1 and 24 h, which was completely resolved by 48 h.

PEG-12 DIMETHICONE

In a repeated eye irritation test of PEG-12 dimethicone (0.1 mL) using male rabbits (n=6), there were no signs of irritation of the cornea or iris observed in any of the rabbits, but slight, transient conjunctival redness was noted 24 h following each instillation.[30] The test substance was administered daily for 5 days and observations continued for 7 more days.

In a second study, the average mean eye irritation scores after exposures to PEG-12 dimethicone and SLS together versus those after exposures to SLS alone, decreased from 10.4 (out of 38) to 1 and from 19.0 to 5.8, respectively, over the course of 7 days after administration.[30] The treated eyes of the rabbits in both groups showed signs of irritation consisting of moderate conjunctival redness, swelling, and discharge. Rabbits treated with SLS alone also showed transient corneal opacity and iridal congestion. The test material in SLS solution yielded evidence of rapid reduction in ocular irritation over a period of 48 h, compared to SLS alone. These results indicated that the test material effectively reduced eye irritation in rabbits exposed to SLS. A 1:1 ratio of PEG-12 dimethicone (100%) and SLS (3%) or a solution of SLS alone were administered into the right eye of male rabbits (n=6) per group. Observations were made by slit lamp at 1, 6, 24, 48, and 72 h, and at 7 days after exposure.

PEG/PPG-25/25 DIMETHICONE

In a Draize test, PEG/PPG-25/25 dimethicone (100%; 0.1 mL) was a slight ocular irritant when administered to the eyes of male New Zealand hybrid albino rabbits (n=6).[37] All irritation signs, except for mild congestion, were resolved by 72 h.

PPG-2 DIMETHICONE

Male rabbit (n=3) eyes treated with PPG-2 dimethicone (100%)/SLS (3%) in a 1:1 mixture (0.1 mL) showed reduced irritation during the first 48 h, compared with SLS alone.[30] The mean irritation scores for the treatment group decreased from a peak of 4.7 (out of 13.0) to 0.3 at 48 h. The rabbits were examined for indications of pain and discomfort, and ocular observations were made using a hand-held slit-lamp at 1, 24, 48, 72 h and 7 days, with sodium fluorescein (except for the 1-hour reading). All treated eyes exhibited signs of irritation including moderate-to-marked redness, slight swelling and discharge. One rabbit had moderate corneal irritation at 24 h only. All eyes appeared normal with no signs of irritation in any of the rabbits when examined at 72 h and at 7 days post-instillation.

Ocular - In Vitro

PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

PEG-9 polydimethylsiloxyethyl dimethicone was predicted to be slightly irritating in the Hen's Egg Test Chorioallantoic Membrane (HET-CAM) assay and the isolated Calf Cornea (BCOP) assay.[8]

GENERIC POLYSILOXANE POLYMERS

In an BCOP assay, silicone polyether (polydimethylsiloxane/ polyethoxy copolymer; generic term that could represent any of the alkoxy polysiloxanes with the name PEG-x dimethicone; 100%), was classified as yielding none-to-mild ocular irritation.[41] There was minimal-to-no effect on corneal opacity and permeability, compared to the controls.

Sensitization

Non-Human

BIS-CETYL/PEG-8 CETYL PEG-8 DIMETHICONE

In a guinea pig maximization test, bis-cetyl/PEG-8 cetyl PEG-8 dimethicone (100%; 0.5 mL; MW >10 000) was not sensitizing in guinea pigs (n=20).[30] Very faint to faint erythema (0.5-1) was noted at several test sites at 24 and 48 h. Very faint erythema (0.5) was observed at 2 test sites 24 h after challenge; very faint erythema persisted at 1 site at 48 h. No erythema was noted at any test site following rechallenge. In the induction phase, the test or control substance was

administered via intradermal induction followed by topical application 6 days later. The intradermal injections were made in combination with Freund's Complete Adjuvant (FCA). A challenge dose of the test or positive control substance (at the highest non-irritating concentration) was administered to a naive site of each animal 12 days later. The sites were scored 24-48 h later. The positive control was 2-mercaptobenzothiazole.

BIS-ISOBUTYL PEG-24/PPG-7/DIMETHICONE COPOLYMER

Bis-isobutyl PEG-24/PPG-7/dimethicone copolymer was not sensitizing in Hartley albino guinea pigs (n=10/sex).[30] The challenge concentration was 25% (in petrolatum). The guinea pigs were administered 3 pairs of intradermal injections (dose not specified), with and without the test material. During the second week of the induction phase, topical applications of the test material (dose not specified) were made to the induction site. Two weeks after the topical induction, the challenge applications were made to naïve sites for 24 h. The challenge concentration was the highest non-irritating concentration of the test article (25% in petrolatum). The guinea pigs were examined at 48 and 72 h for erythema, edema and other effects.

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was not a sensitizer in a Magnusson and Kligman assay using guinea pigs (n=20; control=10).[42] One death unrelated to the test substance occurred. There were responses in 15 guinea pigs in the test group and 7 in the control group. There were no reactions when the guinea pigs were re-challenged at 5% in petrolatum. Induction was performed by injection at a concentration of 20% (in Alembicol D or FCA) followed a week later by dermal application to the injection site at a concentration of 75%. The challenge was 2 weeks later by topical application at 50%.

CETYL PEG/PPG-10/1 DIMETHICONE

Cetyl PEG/PPG-10/1 dimethicone (100%) was not a dermal sensitizer in guinea pigs (n=20) when challenged at 100%.[8] The test substance was administered with FCA (50%) during induction. The test sites were pretreated with sodium lauryl sulfate (10%) at the challenge.

Cetyl PEG/PPG-10/1 dimethicone (induction at 100% or 10% in FCA) was found not to be a dermal sensitizer in Dunkin Hartley guinea pigs (n=20).[16] Dermal challenge was at 100% 24 h after the test site was treated with SLS. The results of the controls were as expected.

LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

Lauryl PEG-9 polydimethylsiloxyethyl dimethicone was reported not to be a sensitizer in a Buehler guinea pig sensitization test.[29] Concentrations and number of guinea pigs tested were not provided.

PEG/PPG-19/19 DIMETHICONE

In a sensitization test using albino Dunkin-Hartley guinea pigs (n=20; controls=5), PEG/PPG-19/19 dimethicone (5% in water; 0.1 mL) was not a sensitizer when administered to clipped and shaved skin.[30] No effects were noted by treatment with the test substance on clinical parameters or body weight gain. Severe irritation was noted at all sites injected with FCA, slight to moderate irritation at injection sites injected with the test substance, and slight irritation at the sites injected with hexyl cinnamic aldehyde, the positive control, but no irritation was seen at the negative control injection sites. Upon topical application, slight to well-defined redness was noted with the test substance and hexyl cinnamic aldehyde, but slight redness was seen in some control guinea pigs. After the second topical application, effects were the same for the test and control animals, although the hexyl cinnamic aldehyde-exposed animals exhibited more marked and longer lasting effects indicative of skin sensitization. On Day 1 of the study, 3 pairs of intradermal injections (0.1 mL/site) of 1 of the following were made in the shaved region: a 50:50 dilution of FCA in water; the test (5% solution of the test substance in water) or control materials (water or 10% hexyl cinnamic aldehyde in Alembicol D); or 50:50 dilution of FCA with either the test or control solutions. Dermal responses were evaluated 24 h later. Six days after the injection, the same site on each animal was again cleared of hair and sodium lauryl sulfate (10%; 0.5 mL in petrolatum) was gently rubbed on the site. The next day, a filter paper patch was soaked with neat test or control materials (size of patch and volume of test material not provided), placed on the hair-free area, and removed after 48 h. Skin reactions were evaluated upon removal of the dressing. After 2 weeks, the left flank of each guinea pig was clipped and shaved and a filter paper patch, soaked with the test material or the control materials, was administered to the hair-free sites for 24 h. The sites were evaluated upon removal of the patch, and 24 and 48 h later. All animals were observed daily for signs of ill health or toxicity, and body weights were taken prior to the first injection and at study termination.

PEG/PPG-25/25 DIMETHICONE

In a sensitization test using albino Dunkin-Hartley guinea pigs (n=40/sex), PEG/PPG-25/25 dimethicone (100%; 0.1 mL) was not a sensitizer when administered to the skin.[37] The induction phase included 3 series of 2 injections of FCA (50%), PEG/PPG-25/25 dimethicone (2.0% in 50/50 FCA /water) or PEG/PPG-25/25 dimethicone (2.0% w/v in water). This concentration (2%) was chosen because it provoked a weak to moderate irritation response during preliminary testing. Challenge was dermally administered (2.0%; 0.5 mL) on an occlusive patch left in place for 24 h.

PEG-12 DIMETHICONE

In a Magnusson and Kligman sensitization assay, PEG-12 dimethicone was not sensitizing when dermally administered to Dunkin-Hartley guinea pigs (test substance, n=20; negative control, n=10; positive control, n=5).[30] There were no signs of toxicity and there were no body-weight changes. Most of the guinea pigs of the positive-control group reacted to hexyl cinnamic aldehyde (10% v/v). The incidence and severity of reactions in the test group and negative control group were considered to represent skin irritation rather than sensitization. The intradermal induction consisted of 2 injections of 1:1 FCA: water (0.1 mL), 2 injections of the test substance (50% in water; 0.1 mL), and 2 injections of the test material (50% in FCA; 0.1 mL). The control animals were treated similarly to test animals except that the test material was omitted. Six days after injection, the application sites for the test group and negative control group were pre-treated with SLS (10% w/w in petrolatum; 0.5 mL) on the day prior to topical induction. During the topical induction phase, the test material (100%; 0.4 mL), hexyl cinnamic aldehyde (100%), or vehicle was administered under occlusion for 48 h. Challenge doses, administered 2 weeks after the topical induction, were administered to the anterior shaved sites on the flanks under occlusion. The treatment group and negative control group were treated on 3 sites per guinea pig with the test material at 100% and 50% water, and the vehicle under occlusion for 24 h. Dermal reactions to the challenge were evaluated using the Draize scale at 24 and 48 h after patch removal. Determination of sensitization potential was made by comparison of the challenge reactions in induced animals versus the respective control group.

PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE

PEG-9 polydimethylsiloxyethyl dimethicone was not a dermal sensitizer in guinea pigs when challenged at 50%.[40] Induction concentrations and number of guinea pigs tested were not provided.

Human

CETYL PEG/PPG-10/1 DIMETHICONE

In a maximization test (n=28), an eye brow pencil containing cetyl PEG/PPG-10/1 dimethicone (15%) was not sensitizing to human subjects and there were no signs of irritation during the induction period.[43] Aqueous SLS (0.25%; approximately 0.05 mL) was administered to the test site (eg, volar forearm, upper outer arm, or the back) for 24 h before the test substance (0.05 mL) was administered, under occlusion, for 48 h (72 h if applied on a Friday). The test site was examined at each patch removal. Because the test substance contained volatile ingredients, the test substance was allowed to air dry for 30 min before occlusion was applied. The induction was repeated 5 times. If there was irritation observed at the removal of an induction patch, the next step would be performed without the SLS. After a 10-day rest, the challenge was performed with the SLS (5.0%) pretreatment on a naïve site and the challenge patch was left in place for 48 h. The site was observed for irritation/sensitization 15-30 min and 24 h after patch removal.

LAURYL PEG/PPG-18/18 METHICONE

In a human repeat insult patch test (HRIPT; n=103), lauryl PEG/PPG-18/18 methicone (100%; 0.2 mL) was not sensitizing.[30] None of the subjects exhibited signs of irritation or sensitization during any part of the study. Nine patches were administered at 48- or 72-h intervals under semi-occlusion. Substances were not reapplied until Monday if the applications had been made on the previous Friday. Patches were administered to the infrascapular area of the back to 1 side of the midline. After a 12-14 day rest period, the same dose method was used on a previously unexposed site. The subjects removed the patches 24 h after they were administered. The sites were examined 24 and 48 h after the challenge patch was removed.

PEG-3 DIMETHICONE

A makeup base (0.2 mL) containing PEG-3 dimethicone (3%) was found to be non-sensitizing in an HRIPT (n=51).[44] No adverse effects were observed during induction or challenge phases. There were 9 sequential 24-h administrations of the test substance to the backs of each subject. The test substance was administered to a naïve site after a 2-week rest. Test sites were examined after each patch was removed during the induction phase and at 24 and 72 h after challenge.

In a modified HRIPT (n=102) of a face lotion containing PEG-3 dimethicone (1%) under occlusion, there were no signs of sensitization.[45] The standard cumulative irritation score was 0. The negative (clean patch) and positive control (0.5% SLS) responded as expected. The induction phase lasted 21 days; the rest period was 10-24 days; and the challenge phase was 4 days.

In a modified HRIPT (n=119) of a face lotion containing PEG-3 dimethicone (1%) under occlusion, there were no signs of sensitization.[46] The standard cumulative irritation score was 132. The negative (clean patch) and positive control (0.5% SLS) had scores of 294 and 3861, respectively. The induction phase lasted 21 days; the rest period was 10-24 days; and the challenge phase was 4 days.

Other Dermal Effects

Comedogenicity

Dimethicone, dimethicone copolyol, and silicone wax (10% in dimethicone) were reported to be non-comedogenic using the rabbit ear assay.[47]

SUMMARY

This is a safety assessment of polyoxyalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients (alkoxy polysiloxanes) as used in cosmetics. The functions of these ingredients include hair conditioning agents, viscosity increasing agents, emulsion stabilizers, and film formers.

Alkoxy polysiloxanes are alkoxylated derivatives of polysiloxanes.

Polyoxyalkylene siloxane copolymers and alkyl-polyoxyalkylene siloxane copolymers are formed by reacting allyloxy terminated alkoxylates, polyethers, with dimethicone. The reaction requires an excess amount of polyethers, which may remain in the final product as unreacted material.

These ingredients were reported to be used in almost all FDA product types. The most reported uses were in makeup, including lipsticks and products used around the eyes. The ingredients with the highest reported uses were PEG-12 dimethicone with 538 uses, cetyl PEG/PPG-10/1 dimethicone with 404 uses, PEG/PPG-18/18 dimethicone with 461 uses, and PEG-10 dimethicone with 240 uses. The highest concentrations of use were reported for stearoxy dimethicone in hair conditioners at 22%, cetyl PEG/PPG-10/1 dimethicone in eyebrow pencils at 15% and in eye shadow at 13.6%, PEG/PPG-17/18 dimethicone in perfumes at 14% and hair products at 13%, and bis-hydroxyethyoxypropyl dimethicone in blushes at 12%.

In vitro experiments showed that bis-PEG-15 methyl ethyl dimethicone did not penetrate pig ear skin.

The oral LD_{50} of bis-PEG-15 methyl ethyl dimethicone was >4640 mg/kg for rats. The oral LD_{50} of cetyl PEG/PPG-10/1 dimethicone was >5000 mg/kg in rats. The oral LD_{50} of lauryl PEG-9 polydimethylsiloxyethyl dimethicone was reported to be 5000 mg/kg in rats. The oral LD_{50} of PEG-9 polydimethylsiloxyethyl dimethicone in rats was reported to be >5000 mg/kg. The oral LD_{50} of PEG/PPG-19/19 dimethicone was >16 mL/kg in rats. There were no mortalities or clinical signs in rats orally administered 2007 mg/kg PEG/PPG-25/25 dimethicone.

The dermal LD_{50} was >5000 mg/kg PEG-12 dimethicone for rabbits. There were no observed signs of toxicity when 2000 mg/kg PEG/PPG-19/19 dimethicone was dermally administered to rabbits. The dermal LD_{50} of bis-PEG/PPG-14/14 dimethicone rats was >2000 mg/kg.

In an acute inhalation study of PEG-12 dimethicone at 0.68 mg/L in air, there were no deaths and no abnormalities observed among the rats during the 4-h exposure or the observation period.

There were no clinical signs observed when rats were orally administered up to 1000 mg/kg/d bis-PEG-15 methyl ethyl dimethicone for 4 weeks. There were no mortalities when 5000 mg/kg cetyl PEG/PPG-10/1 dimethicone was administered by gavage to rats for 14 days. The oral NOAEL of PEG-12 dimethicone was 1000 mg/kg for rats when administered for 29 days.

PEG-12 dimethicone up to 1000 mg/kg did not produce any signs of toxicity when dermally administered to rabbits 6 h/d for 29 days. The NOEL for dermally administered PEG/PPG-19/19 dimethicone was 1000 mg/kg/d for 29 days for rabbits.

Rabbit does exhibited increased numbers of resorption sites when 200 mg/kg siloxanes and silicones, 3-hydroxypropyl Me, di-Me, ethoxylated were dermally administered on gestation days 6 to 18. Dermally administered PEG-12 dimethicone up to 200 mg/kg administered on days 6 through 18 of gestation was not embryotoxic or teratogenic in rabbits. Dermally administered siloxanes and silicones, 3-hydroxypropyl methyl, di-methyl ethoxylated on gestation days 6-18 was not teratogenic to rabbits.

In a reverse mutation assay using *S. typhimurium*, including a plate incorporation test and a pre-incubation test, bis-PEG-15 methyl ethyl dimethicone was not genotoxic, with or without metabolic activation, up to 5000 µg/plate. Cetyl PEG/PPG-10/1 dimethicone was not mutagenic to *S. typhimurium* and *E. coli* up to 5000 µg/plate, with or without metabolic activation. Lauryl PEG-9 polydimethylsiloxyethyl dimethicone was reported to be non-mutagenic in an Ames test. Lauryl PEG/PPG-18/18 methicone was not genotoxic to *S. typhimurium* and *E. coli* up to 1500 µg/plate. PPG-2 dimethicone was not genotoxic to *S. typhimurium* and *E. coli* up to 5000 µg/plate and up to 250 000 µg/plate for the TA1535 strain of *S. typhimurium*. PEG-12 dimethicone was not mutagenic up to 5000 µg/plate, with or without metabolic activation, in a reverse mutation assay using *S. typhimurium* and *E. coli*. PEG/PPG-19/19 dimethicone was not genotoxic to *S. typhimurium* up to 500 µg/plate. In a reverse mutation assay using *S. typhimurium*, including a plate incorporation test and a pre-incubation test, PEG/PPG-25/25 dimethicone was not genotoxic, with or without metabolic activation, up to 5000 µg/plate.

In a patch test, bis-cetyl/PEG-8 cetyl PEG-8 dimethicone at 100% with a MW >10 000 was a dermal irritant when administered to the intact or abraded skin of rabbits for 24 h. The Draize scores were 2, 1.995, and 1.915 for all test sites, intact skin, and abraded skin, respectively.

Cetyl PEG/PPG-10/1 dimethicone with a MW <1000 caused very slight redness (grade 1) in 5 of 6 abraded sites and 5 of 6 intact sites at 24 h in rabbits; the Draize scores were 0.4 for both intact and abraded skin. Cetyl PEG/PPG-10/1 dimethicone with a MW >10 000 caused slight irritation in all tested rabbits when administered to the intact or abraded skin of rabbits. The Draize scores were 1.17, 0.75, and 1.58 for all test sites, intact skin, and abraded skin, respectively. Cetyl PEG/PPG-10/1 dimethicone at 100% had some potential for dermal irritation, but well below the threshold to be classified as hazardous, when administered to the skin of rabbits.

Lauryl PEG-9 polydimethylsiloxyethyl dimethicone at 100% was reported to be slightly irritating to rabbit skin. PEG-9 polydimethylsiloxyethyl dimethicone at 20% and 100% was a slight dermal irritant to the intact and abraded skin of

rabbits. Slight to well-defined erythema, with some scaling, was observed at 5%. PEG-12 dimethicone at 100% elicited very slight erythema, which resolved within 72 h, in rabbits. The PII was calculated to be 0.44. PEG/PPG-25/25 dimethicone at 100% was not a dermal irritant when administered to the skin of rabbits for 4 h.

A lip makeup base that contained 5% PEG-3 dimethicone and face lotions containing 1% PEG-3 dimethicone were found to be non-irritating in human patch tests.

PEG-9 polydimethylsiloxyethyl dimethicone was predicted to be a non-irritant in an in vitro EpiSkin™ assay.

A brow pencil containing 15% cetyl PEG/PPG-10/1 dimethicone was non-irritating in a patch test and a maximization test. A lip makeup base that contained 5% PEG-3 dimethicone was non-irritating in a patch test.

PEG-12 dimethicone at 0.5%, 2%, and 5% provided protection against the dermal irritation effect of 1% SLS in humans. In an in vitro human reconstructed epidermis cytotoxicity test (SkinEthic™) PEG-12 dimethicone was rated as a non-irritant.

Bis-PEG-15 methyl ethyl dimethicone was not an acute eye irritant in rabbits. Bis-PEG/PPG-14/14 dimethicone, cetyl PEG/PPG-10/1 dimethicone, lauryl PEG-9 polydimethylsiloxyethyl, PEG-9 polydimethylsiloxyethyl dimethicone, and PEG/PPG-25/25 dimethicone were mild ocular irritants to rabbits. In a repeated eye irritation test of PEG-12 dimethicone, rabbit eyes showed no signs of irritation of the cornea or iris, but slight, transient conjunctival redness was noted at 24 h following each of 5 instillations.

PEG-9 polydimethylsiloxyethyl dimethicone was predicted to be slightly irritating in the HET-CAM and the BCOP assays. Increased molecular weight was reported to decrease the potential of ocular irritation.

The eyes of rabbits treated with PPG-2 dimethicone or PEG-12 dimethicone mixed with SLS showed reduced irritation compared with treatment with SLS alone.

The following were not sensitizing to guinea pigs:
bis-cetyl/PEG-8 cetyl PEG-8 dimethicone at 100% and MW >10 000
bis-isobutyl PEG-24/PPG7/dimethicone copolymer at 100%
bis-PEG-15 methyl ethyl dimethicone at 20%
cetyl PEG/PPG-10/1 dimethicone at 100%
lauryl PEG-9 polydimethylsiloxyethyl dimethicone
PEG-12 dimethicone at 100%
PEG/PPG-19/19 dimethicone at 5%
PEG/PPG-25/25 dimethicone at 100%
PEG-9 polydimethylsiloxyethyl dimethicone

An eye brow pencil containing cetyl PEG/PPG-10/1 dimethicone at 15% was not sensitizing and there were no signs of irritation during the induction period in a human maximization test. Lauryl PEG/PPG-18/18 methicone at 100% was not sensitizing in an HRIPT. None of the subjects exhibited signs of irritation or sensitization during any part of the study.

A makeup base containing 3% PEG-3 dimethicone was nonsensitizing in an HRIPT

Dimethicone-based compounds were not comedogenic when tested on the ears of rabbits.

DISCUSSION

The Panel noted that of these polyoxyalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients are large macromolecules and are not expected to penetrate the skin. Even with the size and distribution of structural variations of these ingredients, this would be the case for all of the ingredients in this safety assessment regardless of the size or structural variations. The Panel notes that the size of these ingredients is not driven by the size of the PEG and/or PPG moiety, but by size of the siloxy or silicone portion and the number of times these units are repeated in the molecule and that these sizes are also a range.

The Panel noted the low toxicity in oral and dermal studies, the lack of embryotoxicity and teratogenicity, and the lack of genotoxicity. Several irritation and sensitization studies were negative at, or at greater than expected use concentrations.

The Panel discussed its initial concern about the reported presence of up to 30% residual allyl alcohol ethoxylates as impurities. An industry representative clarified that the manufacturing process of these copolymers involves the silylation of preformed polyethers (ie, not all allyl alcohol ethers) with dimethicone, which yields products containing up to 30% of the polyether starting material. Additionally, the negative results of toxicity studies of ingredients that are known to have quantities of the residual material, assured the Panel that the residual polyethers are not a concern.

The Panel discussed the issue of incidental inhalation exposure from aerosol spray moisturizers, suntan products, perfumes, deodorants, body and hand products, and hair sprays, including pump hair sprays. The limited data available from acute inhalation studies suggest little potential for respiratory effects at relevant doses. However, no chronic inhalation studies were available. These ingredients are reportedly used at concentrations up to 2.8% in cosmetic products that may be aerosolized and up to 4% in other products that may become airborne. The Panel noted that 95%–99% of droplets/particles would not be respirable to any appreciable amount. Additional information that the Panel considered to evaluate inhalation exposure included data available to characterize the potential for alkoxy polysiloxanes to cause toxicity, irritation, sensitization, reproductive and developmental toxicity, and genotoxicity. There was no toxicity observed from oral and

dermal studies. There was no evidence of reproductive toxicity and little evidence of developmental toxicity, no genotoxicity in multiple assays, and no irritation and sensitization observed in studies of these ingredients. In addition, these ingredients are large macromolecules (MW >500) and some are insoluble in water. Coupled with the small actual exposure in the breathing zone and the concentrations at which these 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 http://www.cir-safety.org/cir-findings.

CONCLUSION

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

behenoxy dimethicone
behenoxy PEG-10 dimethicone*
bis-cetyl/PEG-8 cetyl PEG-8 dimethicone*
bis-hydroxyethoxypropyl dimethicone
bis-isobutyl PEG/PPG-10/7/dimethicone copolymer*
bis-isobutyl PEG-13/dimethicone copolymer*
bis-isobutyl PEG-24/PPG-7/dimethicone copolymer*
bis-PEG-1 dimethicone*
bis-PEG-4 dimethicone
bis-PEG-8 dimethicone*
bis-PEG-10 dimethicone*
bis-PEG-12 dimethicone
bis-PEG-12 dimethicone beeswax
bis-PEG-12 dimethicone candelillate
bis-PEG-15 methyl ether dimethicone
bis-PEG-20 dimethicone*
bis-PEG-8 PEG-8 dimethicone*
bis-PEG/PPG-14/14 dimethicone
bis-PEG/PPG-15/5 dimethicone*
bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone
bis-PEG/PPG-18/6 dimethicone*
bis-PEG/PPG-20/20 dimethicone
bis-PEG/PPG-20/5 PEG/PPG-20/5 dimethicone*
bis-stearoxy dimethicone*
bis-stearoxyethyl dimethicone*
cetyl PEG/PPG-10/1 dimethicone
cetyl PEG/PPG-15/15 butyl ether dimethicone*
cetyl PEG/PPG-7/3 dimethicone*
cetyl PEG-8 dimethicone*
lauryl isopentyl-PEG/PPG-18/18 methicone*
lauryl PEG/PPG-18/18 methicone
lauryl PEG-10 methyl ether dimethicone*
lauryl PEG-10 tris(trimethylsiloxy)silylethyl dimethicone*
lauryl PEG-8 dimethicone
lauryl PEG-8 PPG-8 dimethicone*
lauryl PEG-9 polydimethylsiloxyethyl dimethicone
lauryl polyglyceryl-3 polydimethylsiloxyethyl dimethicone*
methoxy PEG-11 methoxy PPG-24 dimethicone*
methoxy PEG/PPG-25/4 dimethicone
methoxy PEG-13 ethyl polysilsesquioxane*
PEG/PPG-10/2 dimethicone*
PEG/PPG-10/3 oleyl ether dimethicone*
PEG/PPG-12/16 dimethicone*
PEG/PPG-12/18 dimethicone*
PEG/PPG-14/4 dimethicone
PEG/PPG-15/15 dimethicone
PEG/PPG-15/5 dimethicone*
PEG/PPG-16/2 dimethicone*
PEG/PPG-16/8 dimethicone*
PEG/PPG-17/18 dimethicone
PEG/PPG-18/12 dimethicone*
PEG/PPG-18/18 dimethicone
PEG/PPG-18/6 dimethicone*
PEG/PPG-19/19 dimethicone
PEG/PPG-20/15 dimethicone
PEG/PPG-20/20 dimethicone
PEG/PPG-20/22 butyl ether dimethicone*
PEG/PPG-20/22 methyl ether dimethicone*
PEG/PPG-20/23 dimethicone
PEG/PPG-20/29 dimethicone*
PEG/PPG-20/6 dimethicone
PEG/PPG-22/22 butyl ether dimethicone*
PEG/PPG-22/23 dimethicone
PEG/PPG-22/24 dimethicone
PEG/PPG-23/23 butyl ether dimethicone*
PEG/PPG-23/6 dimethicone*
PEG/PPG-24/18 butyl ether dimethicone*
PEG/PPG-25/25 dimethicone
PEG/PPG-27/27 dimethicone*
PEG/PPG-27/9 butyl ether dimethicone*
PEG/PPG-3/10 dimethicone*
PEG/PPG-30/10 dimethicone
PEG/PPG-4/12 dimethicone
PEG/PPG-6/4 dimethicone*
PEG/PPG-6/11 dimethicone*
PEG/PPG-8/14 dimethicone
PEG/PPG-8/26 dimethicone*
PEG-10 dimethicone
PEG-10 methyl ether dimethicone
PEG-10 polydimethylsiloxyethyl dimethicone/bis-vinyl dimethicone crosspolymer*
PEG-11 methyl ether dimethicone
PEG-12 dimethicone
PEG-14 dimethicone
PEG-17 dimethicone
PEG-3 dimethicone
PEG-32 methyl ether dimethicone
PEG-4 PEG-12 dimethicone*
PEG-6 dimethicone*
PEG-6 methyl ether dimethicone
PEG-7 dimethicone
PEG-7 methyl ether dimethicone*
PEG-8 cetyl dimethicone
PEG-8 dimethicone
PEG-8 dimethicone dimer dilinoleate*
PEG-8 dimethicone/dimer dilinoleic acid copolymer

PEG-8 methicone
PEG-8 methyl ether dimethicone*
PEG-8 PEG-4 dimethicone*
PEG-8 PPG-8 dimethicone*
PEG-9 dimethicone
PEG-9 methyl ether dimethicone*
PEG-9 polydimethylsiloxyethyl dimethicone
polysilicone-13
PPG-12 butyl ether dimethicone*
PPG-12 dimethicone
PPG-2 dimethicone
PPG-25 dimethicone*
PPG-27 dimethicone*
PPG-4 oleth-10 dimethicone*
stearoxy dimethicone
stearoxymethicone/dimethicone copolymer

*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, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

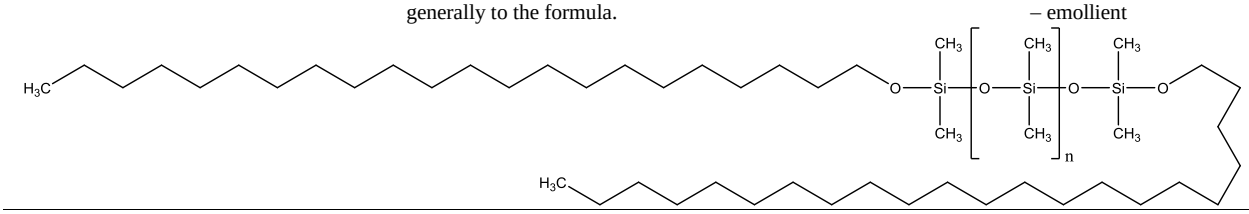
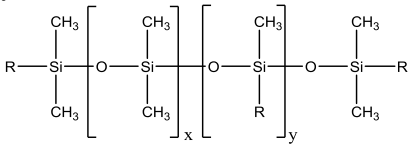
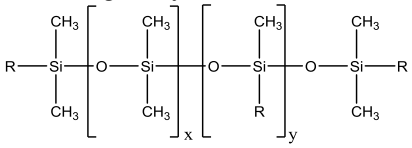
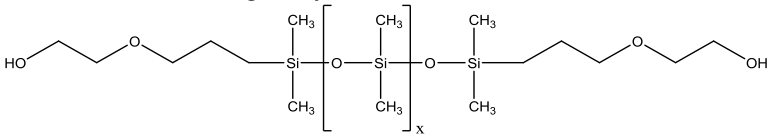
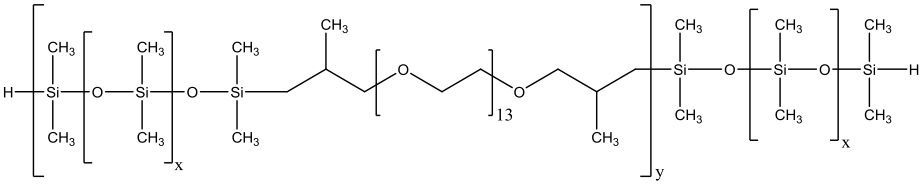
Ingredient CAS No.	Definition / Structure	Function
Behenoxy dimethicone	Behenoxy dimethicone is a dimethyl siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – emollient
Behenoxy PEG-10 dimethicone 1136947-78-8	Behenoxy PEG-10 dimethicone is the product obtained by the reaction of hydrogen dimethicone with behenyl alcohol and PEG-10 allyl ether.  where R may be a behenyl grouping or $-(CH_2)_3O(CH_2CH_2O)_8H$	Humectant; viscosity increasing agent – aqueous
Bis-cetyl/PEG-8 Cetyl PEG-8 dimethicone	Bis-cetyl/PEG-8 Cetyl PEG-8 dimethicone is the silicone compound that conforms generally to the formula,  where R may be a cetyl grouping or $-(CH_2)_3O(CH_2CH_2O)_8H$	Emulsion stabilizer
Bis-hydroxyethoxypropyl dimethicone 222416-17-3	Bis-hydroxyethoxypropyl dimethicone is the siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – emollient
Bis-isobutyl PEG/PPG-10/7/ dimethicone copolymer 158451-77-5 (generic)	Bis-isobutyl PEG/PPG-10/7/dimethicone copolymer is a block copolymer that is made by reacting bis-hydrogen dimethicone with a bis-methallyl ether of a random copolymer of polyethylene glycol and polypropylene glycol. The polyether copolymer contains an average of 10 moles of ethylene oxide and 7 moles of propylene oxide.	Surfactant – emulsifying agent
Bis-isobutyl PEG-13/dimethicone copolymer 197980-52-2	Bis-isobutyl PEG-13/dimethicone copolymer is a block copolymer made by reacting bis-hydrogen dimethicone with the bis-methallyl ether of PEG-13. 	Film former
Bis-isobutyl PEG-24/PPG-7/ dimethicone copolymer 158451-77-5 (generic)	Bis-isobutyl PEG-24/PPG-7/dimethicone copolymer is a block copolymer of polyethylene glycol, polypropylene glycol and dimethicone containing an average of 24 moles of ethylene oxide and 7 moles of propylene oxide.	Film former; humectant

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

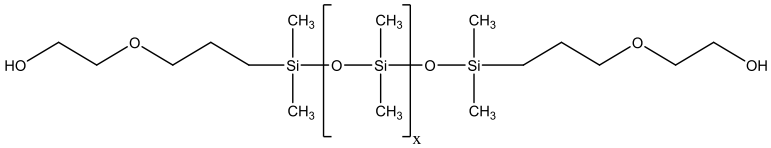
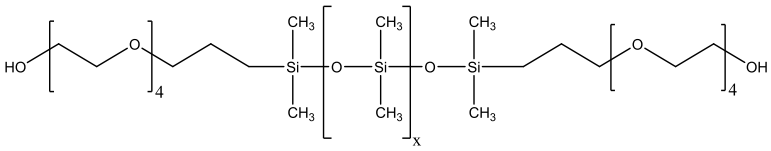
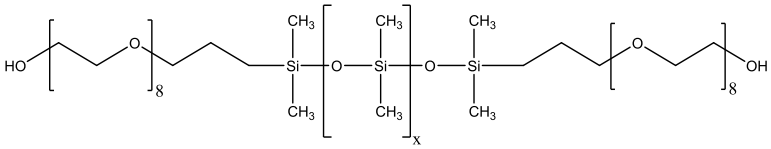
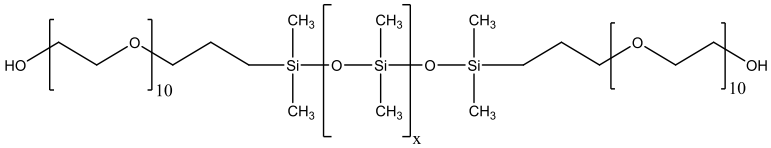
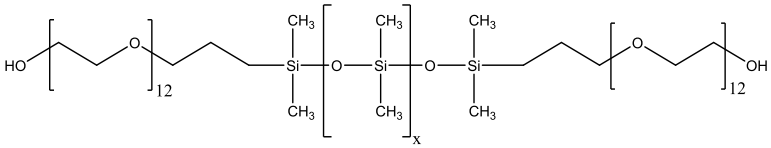
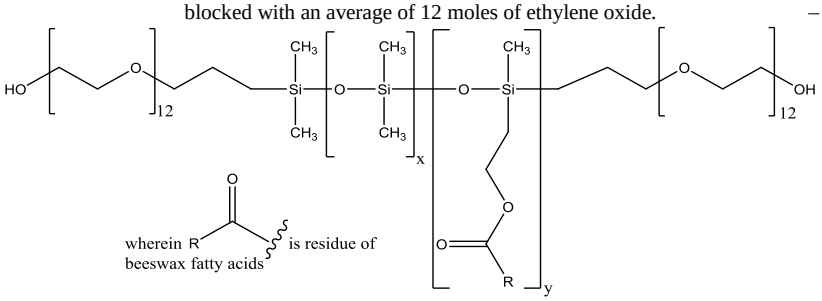
Ingredient CAS No.	Definition / Structure	Function
Bis-PEG-1 dimethicone	Bis-PEG-1 dimethicone is dimethicone end-blocked with an average of 1 mole of ethylene oxide. 	Hair conditioning agent; plasticizer; skin-conditioning agent – miscellaneous; surfactants – dispersing agent
Bis-PEG-4 dimethicone	Bis-PEG-4 dimethicone is the siloxane polymer that conforms generally to the formula: 	Hair conditioning agent; plasticizer; skin-conditioning agent – emollient
Bis-PEG-8 dimethicone	Bis-PEG-8 dimethicone is dimethicone end-blocked with an average of 8 moles of ethylene oxide. 	Hair conditioning agent; plasticizer; skin-conditioning agent – miscellaneous; surfactants – dispersing agent
Bis-PEG-10 dimethicone	Bis-PEG-10 dimethicone is dimethicone end-blocked with an average of 10 moles of ethylene oxide 	Dispersing agent – nonsurfactant; hair conditioning agent; plasticizer; skin-conditioning agent – miscellaneous
Bis-PEG-12 dimethicone	Bis-PEG-12 dimethicone is dimethicone end-blocked with an average of 12 moles of ethylene oxide. 	Hair conditioning agent; skin-conditioning agent – emollient
Bis-PEG-12 dimethicone beeswax [151661-97-1]	Bis-PEG-12 dimethicone beeswax is the partial ester of the fatty acids derived from beeswax and a derivative of dimethicone, end-blocked with an average of 12 moles of ethylene oxide. 	Hair conditioning agent; skin-conditioning agent – occlusive

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

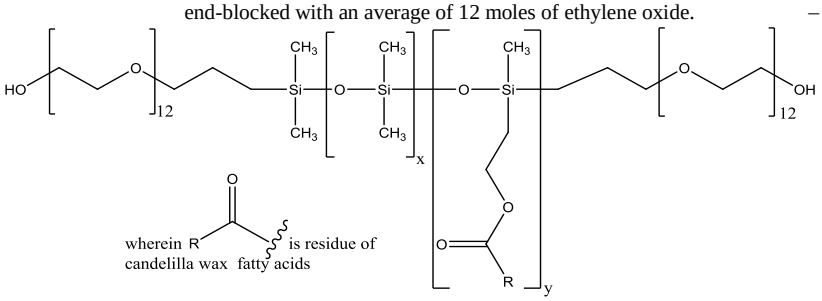
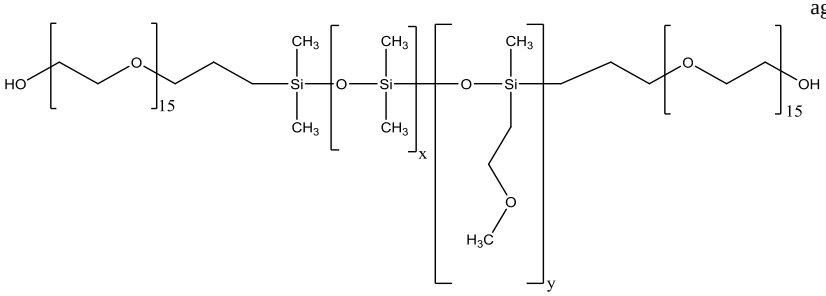
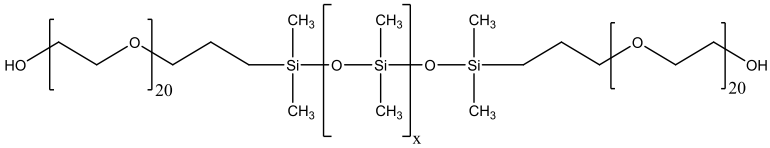
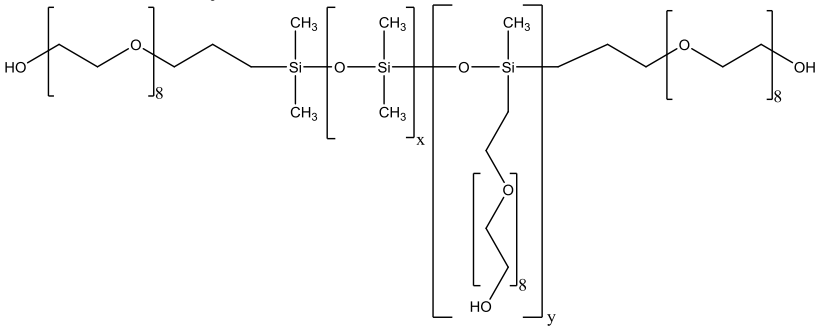
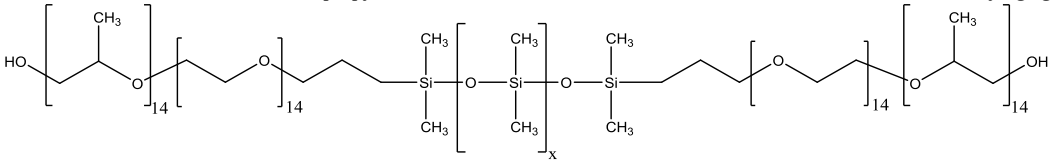
Ingredient CAS No.	Definition / Structure	Function
Bis-PEG-12 dimethicone candelillate	Bis-PEG-12 dimethicone candelillate is the partial ester of the fatty acids derived from candelilla wax and a derivative of dimethicone, end-blocked with an average of 12 moles of ethylene oxide. 	Hair conditioning agent; skin-conditioning agent – occlusive
Bis-PEG-15 methyl ether dimethicone	Bis-PEG-15 methyl ether dimethicone is the methyl ether of a derivative of dimethicone end-blocked with an average of 15 moles of ethylene oxide. 	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactants – emulsifying agent
Bis-PEG-20 dimethicone	Bis-PEG-20 dimethicone is the siloxane polymer that conforms generally to the formula, *and is a derivative of dimethicone end-blocked with an average of 20 moles of ethylene oxide.* 	Hair conditioning agent; skin-conditioning agent – miscellaneous
Bis-PEG-8 PEG-8 dimethicone	Bis-PEG-8 PEG-8 dimethicone is a derivative of dimethicone containing alkoxylated side chain with an average of 8 moles of ethylene oxide, and end-blocked with an average of 8 moles of ethylene oxide. 	Hair conditioning agent
Bis-PEG/PPG-14/14 dimethicone 151662-01-0	Bis-PEG/PPG-14/14 dimethicone is dimethicone end-blocked with an average of 14 moles of ethylene oxide and an average of 14 moles of propylene oxide. 	Skin-conditioning agents – emollients; surfactant – emulsifying agent

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

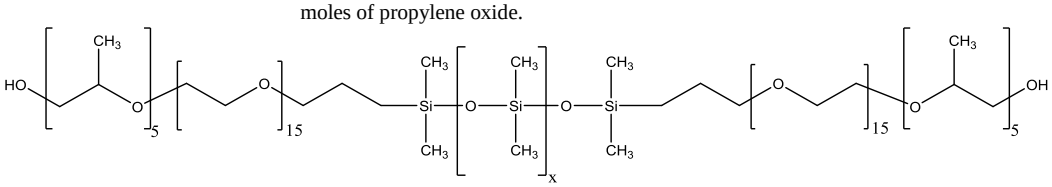
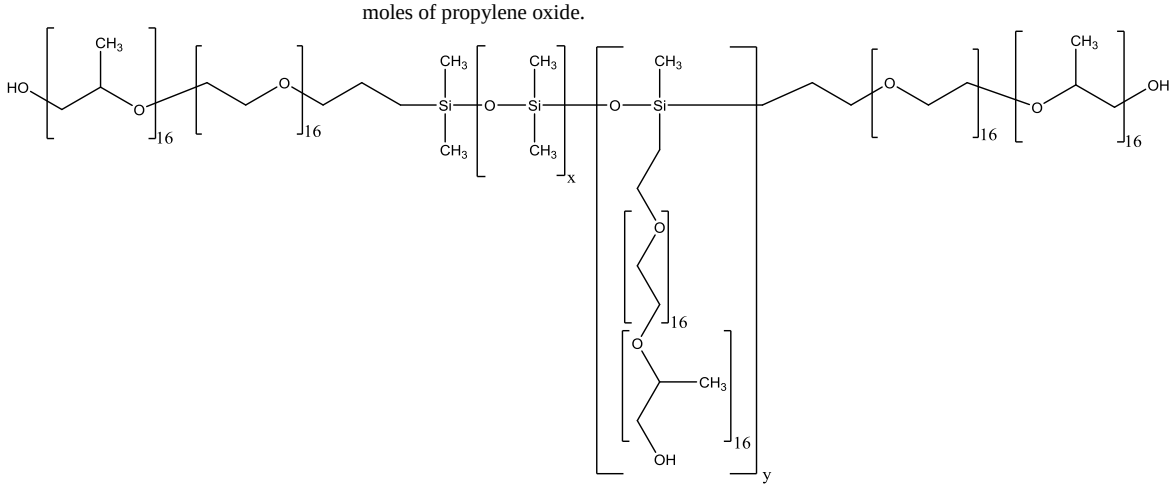
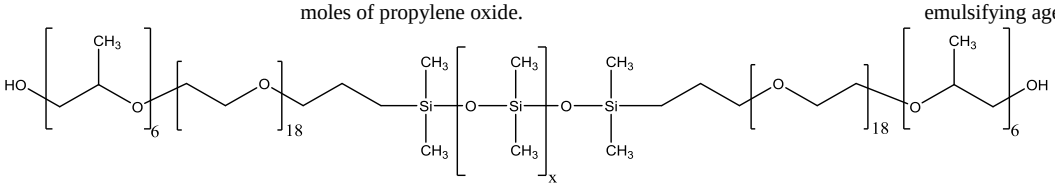
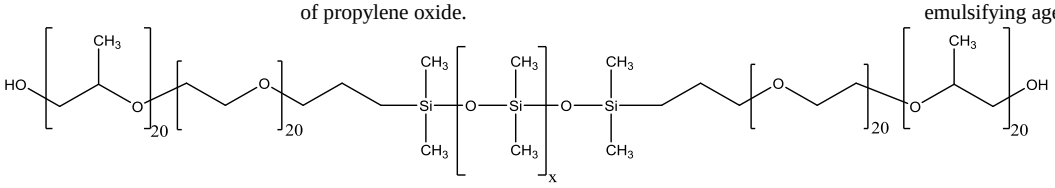
Ingredient CAS No.	Definition / Structure	Function
Bis-PEG/PPG-15/5 dimethicone	Bis-PEG/PPG-15/5 dimethicone is dimethicone end-blocked with the random addition of an average of 15 moles of ethylene oxide and 5 moles of propylene oxide. 	Emulsion stabilizer; humectant
Bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone	Bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone is a derivative of dimethicone containing an alkoxylated side chain with an average of 16 moles of ethylene oxide and 16 moles of propylene oxide, and end-blocked with an average of 16 moles of ethylene oxide and 16 moles of propylene oxide. 	Skin-conditioning agent – occlusive; surfactant – emulsifying agent
Bis-PEG/PPG-18/6 dimethicone	Bis-PEG/PPG-18/6 dimethicone is dimethicone end-blocked with the random addition of an average of 18 moles of ethylene oxide and 6 moles of propylene oxide. 	Skin-conditioning agent – emollient; surfactant – emulsifying agent
Bis-PEG/PPG-20/20 dimethicone	Bis-PEG/PPG-20/20 dimethicone is dimethicone end-blocked with an average of 20 moles of ethylene oxide and an average of 20 moles of propylene oxide. 	Skin-conditioning agent – emollient; surfactant – emulsifying agent

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

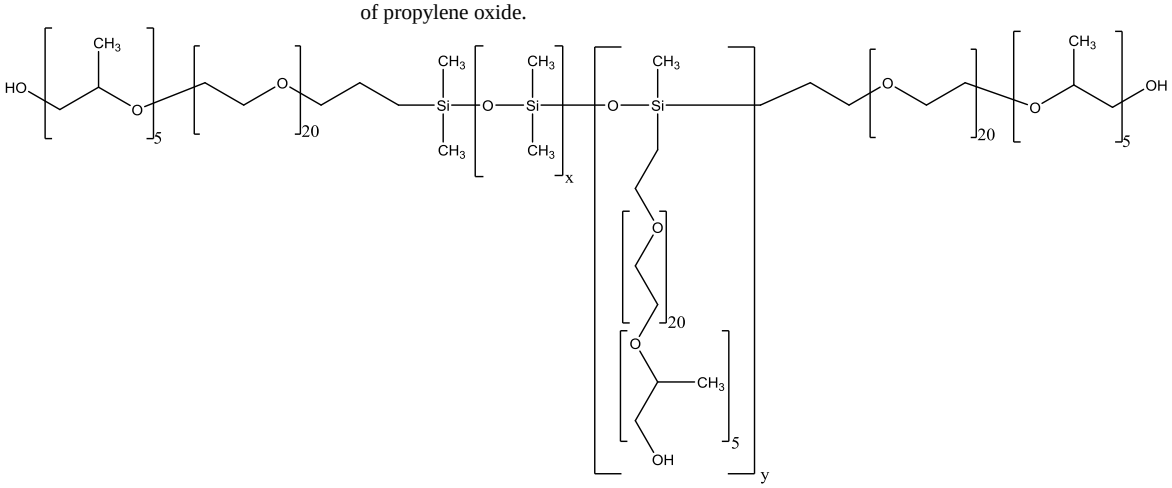
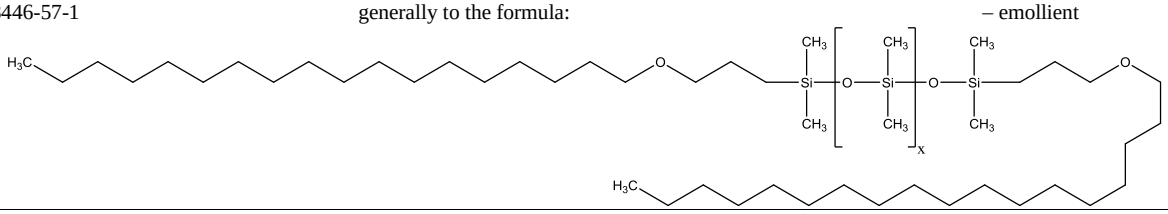
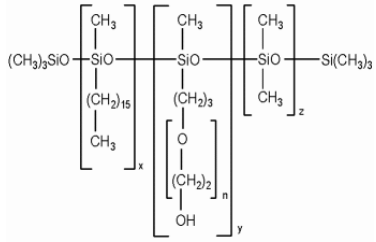
Ingredient CAS No.	Definition / Structure	Function
Bis-PEG/PPG-20/5 PEG/PPG-20/5 dimethicone	Bis-PEG/PPG-20/5 PEG/PPG-20/5 dimethicone is a derivative of dimethicone containing an alkoxylated side chain with an average of 20 moles of ethylene oxide and 5 moles of propylene oxide, and end-blocked with an average of 20 moles of ethylene oxide and 5 moles of propylene oxide. 	Emulsion stabilizer; surfactant – emulsifying agent
Bis-stearoxy dimethicone	Bis-stearoxy dimethicone is the polymer formed by the reaction between bis-hydrogen dimethicone and allyl stearyl ether.	Film former; skin-conditioning agent - emollient
Bis-stearoxyethyl dimethicone 128446-57-1	Bis-stearoxyethyl dimethicone is the silicone polymer that conforms generally to the formula: 	Skin-conditioning agent – emollient
Cetyl PEG/PPG-10/1 dimethicone	Cetyl PEG/PPG-10/1 dimethicone is a copolymer of cetyl dimethicone and an alkoxylated derivative of dimethicone containing an average of 10 moles of ethylene oxide and 1 mole of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Cetyl PEG/PPG-15/15 butyl ether dimethicone	Cetyl PEG/PPG-15/15 butyl ether dimethicone is the copolymer of cetyl dimethicone and a butyl ether of a derivative of dimethicone containing an average of 15 moles of ethylene oxide and 15 moles of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Cetyl PEG/PPG-7/3 dimethicone	Cetyl PEG/PPG-7/3 dimethicone is a copolymer of cetyl dimethicone and an alkoxylated derivative of dimethicone containing an average of 7 moles of ethylene oxide and 3 moles of propylene oxide.	Emulsion stabilizer; surfactant – emulsifying agent
Cetyl PEG-8 dimethicone[a]	Cetyl PEG-8 dimethicone is the polydimethylsiloxane that conforms to the formula  where n has an average value of 8.	Surfactant – emulsifying agent
Lauryl isopentyl-PEG/PPG-18/18 methicone 1112315-26-0	Lauryl isopentyl-PEG/PPG-18/18 methicone is the copolymer formed by the reaction of methicone with dodecene and a dimethyallyl-terminated polyethylene oxide/polypropylene oxide copolymer.	Surfactant – emulsifying agent
Lauryl PEG/PPG-18/18 methicone	Lauryl PEG/PPG-18/18 methicone is an alkoxylated derivative of lauryl methicone containing an average of 18 moles of ethylene oxide and 18 moles of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

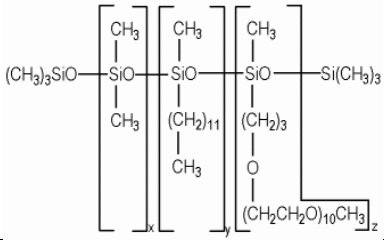
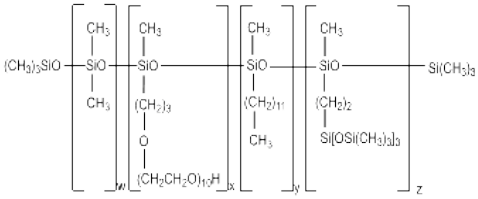
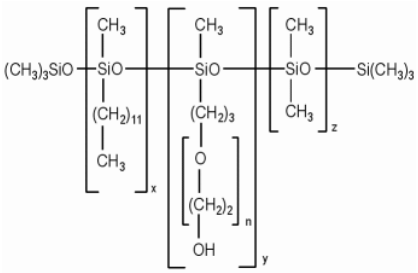
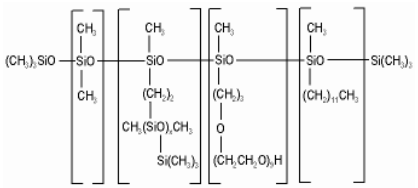
Ingredient CAS No.	Definition / Structure	Function
Lauryl PEG-10 methyl ether dimethicone	Lauryl PEG-10 methyl ether dimethicone is the silicone polymer that conforms generally to the formula. 	Surfactant – emulsifying agent
Lauryl PEG-10 tris(trimethylsiloxy)silylethyl dimethicone	Lauryl PEG-10 tris(trimethylsiloxy)silylethyl dimethicone is the silicone compound that conforms generally to the formula. 	Surfactant – emulsifying agent
Lauryl PEG-8 dimethicone	Lauryl PEG-8 dimethicone is the polydimethylsiloxane that conforms to the formula  where n has an average value of 8.	External analgesics; surfactant – emulsifying agent
Lauryl PEG-8 PPG-8 dimethicone	Lauryl PEG-8 PPG-8 dimethicone is a terpolymer obtained by reacting hydrogen dimethicone with dodecene, the allyl ether of PEG-8, and the allyl ether of PPG-8.	Surfactant – emulsifying agent
Lauryl PEG-9 polydimethylsiloxyethyl dimethicone	Lauryl PEG-9 polydimethylsiloxyethyl dimethicone is the silicone polymer that conforms generally to the formula 	Hair conditioning agent; hair fixative; skin-conditioning agent – miscellaneous; surface modifier; surfactant – emulsifying agent; surfactant – solubilizing agent; viscosity increasing agent – aqueous

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

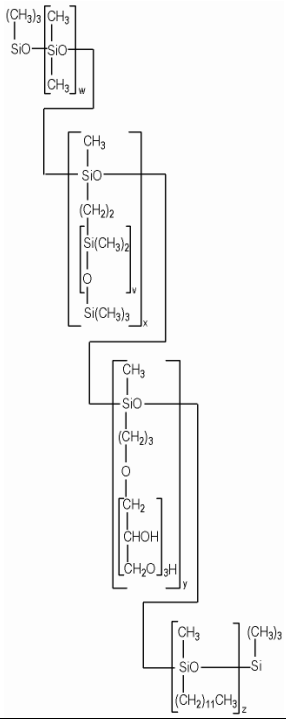
Ingredient CAS No.	Definition / Structure	Function
Lauryl polyglyceryl-3 polydimethylsiloxyethyl dimethicone	Lauryl polyglyceryl-3 polydimethylsiloxyethyl dimethicone is a derivative of dimethicone in which some of the methyl groups on the siloxane backbone have been replaced by lauryl, polyglyceryl-3, and polydimethylsiloxyethyl groups. It conforms generally to the formula. 	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – cleansing agent; surfactant – emulsifying agent; surfactant – solubilizing agent; viscosity increasing agent – aqueous
Methoxy PEG-11 methoxy PPG-24 dimethicone 472975-82-9	Methoxy PEG-11 methoxy PPG-24 dimethicone is the methyl ether of an alkoxylated derivative of dimethicone containing an average of 11 moles of ethylene oxide and 24 moles propylene oxide.	Antifoaming agent
Methoxy PEG/PPG-25/4 dimethicone	Methoxy PEG/PPG-25/4 dimethicone is the methyl ether of an alkyoxylated derivative of dimethicone containing an average of 25 moles of ethylene oxide and 4 moles of propylene oxide.	Emulsion stabilizer; surfactant – emulsifying agent
Methoxy PEG-13 ethyl polysilsesquioxane	Methoxy PEG-13 ethyl polysilsesquioxane is the polymerized resin of polysilsesquioxane containing ethyl methoxy PEG-13 groupings.	Humectant
PEG/PPG-10/2 dimethicone	PEG/PPG-10/2 dimethicone is the alkoxylated derivative of dimethicone containing an average of 10 moles of ethylene oxide and 2 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – emollient
PEG/PPG-10/3 oleyl ether dimethicone	PEG/PPG-10/3 oleyl ether dimethicone is the oleyl ether of a derivative of dimethicone containing an average of 10 moles of ethylene oxide and 3 moles of propylene oxide.	Emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent; surfactant – solubilizing agent
PEG/PPG-12/16 dimethicone	PEG/PPG-12/16 dimethicone is the alkoxylated derivative of dimethicone containing an average of 12 moles of ethylene oxide and 16 moles of propylene oxide.	Antifoaming agent; skin-conditioning agent – miscellaneous; slip modifier; surfactant – emulsifying agent
PEG/PPG-12/18 dimethicone	PEG/PPG-12/18 dimethicone is the alkoxylated derivative of dimethicone containing an average of 12 moles of ethylene oxide and 18 moles of propylene oxide.	Antifoaming agent; skin-conditioning agent – miscellaneous; slip modifier; surfactant – emulsifying agent
PEG/PPG-14/4 dimethicone	PEG/PPG-14/4 dimethicone is the alkoxylated derivative of dimethicone containing an average of 14 moles of ethylene oxide and 4 moles of propylene oxide.	Surfactant – emulsifying agent

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

Ingredient CAS No.	Definition / Structure	Function
PEG/PPG-15/15 dimethicone	PEG/PPG-15/15 dimethicone is the alkoxylated derivative of dimethicone containing an average of 15 moles of ethylene oxide and 15 moles of propylene oxide.	Anticaking agent; surfactant – emulsifying agent
PEG/PPG-15/5 dimethicone	PEG/PPG-15/5 dimethicone is the alkoxylated derivative of dimethicone containing an average of 15 moles of ethylene oxide and 5 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-16/2 dimethicone	PEG/PPG-16/2 dimethicone is the alkoxylated derivative of dimethicone containing an average of 16 moles of ethylene oxide and 2 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-16/8 dimethicone	PEG/PPG-16/8 dimethicone is the alkoxylated derivative of dimethicone containing an average of 16 moles of ethylene oxide and 8 moles of propylene oxide.	Antifoaming agent; skin-conditioning agent – miscellaneous; slip modifier; surfactant – emulsifying agent
PEG/PPG-17/18 dimethicone	PEG/PPG-17/18 dimethicone is the alkoxylated derivative of dimethicone containing an average of 17 moles of ethylene oxide and 18 moles of propylene oxide	Surfactant – emulsifying agent
PEG/PPG-18/12 dimethicone	PEG/PPG-18/12 dimethicone is the alkoxylated derivative of dimethicone containing an average of 18 moles of ethylene oxide and 12 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-18/18 dimethicone	PEG/PPG-18/18 dimethicone is the alkoxylated derivative of dimethicone containing an average of 18 moles of ethylene oxide and 18 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-18/6 dimethicone	PEG/PPG-18/6 dimethicone is alkoxylated derivative of dimethicone containing a random addition of an average of 18 moles of ethylene oxide and 6 moles of propylene oxide.	Skin-conditioning agent – emollient
PEG/PPG-19/19 dimethicone	PEG/PPG-19/19 dimethicone is the alkoxylated derivative of dimethicone containing an average of 19 moles of ethylene oxide and 19 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/15 dimethicone	PEG/PPG-20/15 dimethicone is the alkoxylated derivative of dimethicone containing an average of 20 moles of ethylene oxide and 15 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/20 dimethicone	PEG/PPG-20/20 dimethicone is the alkoxylated derivative of dimethicone containing an average of 20 moles of ethylene oxide and 20 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/22 butyl ether dimethicone 67762-87-2	PEG/PPG-20/22 butyl ether dimethicone is the butyl ether of a derivative of dimethicone containing an average of 20 moles of ethylene oxide and 22 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – miscellaneous
PEG/PPG-20/22 methyl ether dimethicone 125857-75-2	PEG/PPG-20/22 methyl ether dimethicone is the methyl ether of a derivative of dimethicone containing an average of 20 moles of ethylene oxide and 22 moles of propylene oxide.	Hair conditioning agent; surfactant – cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent
PEG/PPG-20/23 dimethicone	PEG/PPG-20/23 dimethicone is the alkoxylated derivative of dimethicone containing an average of 20 moles of ethylene oxide and 23 moles of propylene oxide.	Emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; slip modifier; surface modifier; surfactant – solubilizing agent
PEG/PPG-20/29 dimethicone	PEG/PPG-20/29 dimethicone is the alkoxylated derivative of dimethicone containing an average of 20 moles of ethylene oxide and 29 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/6 dimethicone	PEG/PPG-20/6 dimethicone is the alkoxylated derivative of dimethicone containing an average of 20 moles of ethylene oxide and 6 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-22/22 butyl ether dimethicone	PEG/PPG-22/22 butyl ether dimethicone is the butyl ether of a derivative of dimethicone containing an average of 22 moles of ethylene oxide and 22 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG/PPG-22/23 dimethicone	PEG/PPG-22/23 dimethicone is the alkoxylated derivative of dimethicone containing an average of 22 moles of ethylene oxide and 23 moles of propylene oxide.	Emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; slip modifier; surface modifier; surfactant – solubilizing agent

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

Ingredient CAS No.	Definition / Structure	Function
PEG/PPG-22/24 dimethicone	PEG/PPG-22/24 dimethicone is the alkoxylated derivative of dimethicone containing an average of 22 moles of ethylene oxide and 24 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-23/23 butyl ether dimethicone	PEG/PPG-23/23 butyl ether dimethicone is the butyl ether of a derivative of dimethicone containing an average of 23 moles of ethylene oxide and 23 moles of propylene oxide.	Hair conditioning agent; humectant; skin-conditioning agent – miscellaneous; surfactant – dispersing agent; surfactant – emulsifying agent
PEG/PPG-23/6 dimethicone	PEG/PPG-23/6 dimethicone is the alkoxylated derivative of dimethicone containing an average of 23 moles of ethylene oxide and 6 moles of propylene oxide.	Emulsion stabilizer; slip modifier; surface modifier; surfactant – solubilizing agent
PEG/PPG-24/18 butyl ether dimethicone 67762-87-2	PEG/PPG-24/18 butyl ether dimethicone is the butyl ether of a derivative of dimethicone containing an average of 24 moles of ethylene oxide and 18 moles of propylene oxide.	Hair conditioning agent; humectant; surfactant – cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent
PEG/PPG-25/25 dimethicone	PEG/PPG-25/25 dimethicone is the alkoxylated derivative of dimethicone containing an average of 25 moles of ethylene oxide and 25 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-27/27 dimethicone	PEG/PPG-27/27 dimethicone is the alkoxylated derivative of dimethicone containing an average of 27 moles of ethylene oxide and 27 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-27/9 butyl ether dimethicone	PEG/PPG-27/9 butyl ether dimethicone is the butyl ether of a derivative of dimethicone containing an average of 27 moles of ethylene oxide and 9 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent - miscellaneous; surfactant – emulsifying agent
PEG/PPG-3/10 dimethicone	PEG/PPG-3/10 dimethicone is the alkoxylated derivative of dimethicone containing an average of 3 moles of ethylene oxide and 10 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-30/10 dimethicone	PEG/PPG-30/10 dimethicone is the alkoxylated derivative of dimethicone containing an average of 30 moles of ethylene oxide and 10 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-4/12 dimethicone	PEG/PPG-4/12 dimethicone is the alkoxylated derivative of dimethicone containing an average of 4 moles of ethylene oxide and 12 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-6/4 dimethicone	PEG/PPG-6/4 dimethicone is the alkoxylated derivative of dimethicone containing an average of 6 moles of ethylene oxide and 4 moles of propylene oxide.	Emulsion stabilizer; humectant
PEG/PPG-6/11 dimethicone	PEG/PPG-6/11 dimethicone is the alkoxylated derivative of dimethicone containing an average of 6 moles of ethylene oxide and 11 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-8/14 dimethicone	PEG/PPG-8/14 dimethicone is the alkoxylated derivative of dimethicone containing an average of 8 moles of ethylene oxide and 14 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-8/26 dimethicone	PEG/PPG-8/26 dimethicone is the alkoxylated derivative of dimethicone containing an average of 8 moles of ethylene oxide and 26 moles of propylene oxide.	Antifoaming agent; plasticizer; skin-conditioning agent – miscellaneous; surfactant – dispersing agent
PEG-10 dimethicone 68937-54-2 (generic)	PEG-10 dimethicone is the polyethylene glycol derivative of dimethicone containing an average of 10 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-10 methyl ether dimethicone 68938-54-5 (generic)	PEG-10 methyl ether dimethicone is the methyl ether of a derivative of dimethicone containing an average of 10 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-10 polydimethylsiloxyethyl dimethicone/bis-vinyl dimethicone crosspolymer	PEG-10 polydimethylsiloxyethyl dimethicone/bis-vinyl dimethicone crosspolymer is a copolymer of PEG-10 polydimethylsiloxyethyl dimethicone crosslinked with bis-vinyldimethicone.	Film former; skin-conditioning agent – emollient; slip modifier; surfactant – emulsifying agent
PEG-11 methyl ether dimethicone 68938-54-5 (generic)	PEG-11 methyl ether dimethicone is the methyl ether of a derivative of dimethicone containing an average of 11 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

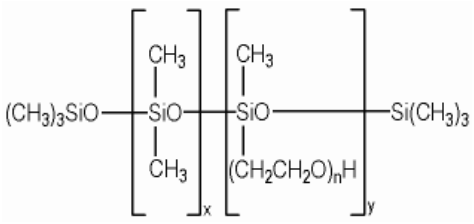
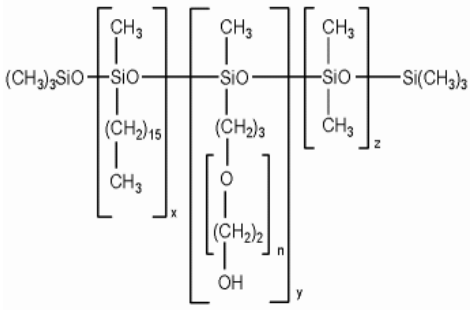
Ingredient CAS No.	Definition / Structure	Function
PEG-12 dimethicone 68937-54-2 (generic)	PEG-12 dimethicone is the polyethylene glycol derivative of dimethicone containing an average of 12 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-14 dimethicone 68937-54-2 (generic)	PEG-14 dimethicone is the polyethylene glycol derivative of dimethicone containing an average of 14 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-17 dimethicone 68937-54-2 (generic)	PEG-17 dimethicone is the polyethylene glycol derivative of dimethicone containing an average of 17 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-3 dimethicone 68937-54-2 (generic)	PEG-3 dimethicone is the siloxane polymer that conforms generally to the formula  where n has an average value of 3.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-32 methyl ether dimethicone 68938-54-5 (generic)	PEG-32 methyl ether dimethicone is the methyl ether of a derivative of dimethicone containing an average of 32 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-4 PEG-12 dimethicone	PEG-4 PEG-12 dimethicone is the reaction product of hydrogen dimethicone and allyl PEG-4 and allyl PEG-12.	Emulsion stabilizers
PEG-6 dimethicone 68937-54-2 (generic)	PEG-6 dimethicone is the polyethylene glycol derivative of dimethicone containing an average of 6 moles of ethylene oxide.	Humectant; plasticizer; slip modifier
PEG-6 methyl ether dimethicone 68938-54-5 (generic)	PEG-6 methyl ether dimethicone is the methyl ether of a polyethylene glycol derivative of dimethicone containing an average of 6 moles of ethylene oxide	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-7 dimethicone 68937-54-2 (generic)	PEG-7 dimethicone is the polyethylene glycol derivative of dimethicone containing an average of 7 moles of ethylene oxide.	Film former
PEG-7 methyl ether dimethicone 68938-54-5 (generic)	PEG-7 methyl ether dimethicone is the methyl ether of a derivative of dimethicone containing an average of 7 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – humectant; surfactant – emulsifying agent
PEG-8 cetyl dimethicone[a]	PEG-8 cetyl dimethicone is the polydimethylsiloxane that conforms to the formula  where n has an average value of 8.	Skin-conditioning agent – miscellaneous
PEG-8 dimethicone 68937-54-2 (generic)	PEG-8 dimethicone is the polyethylene glycol derivative of dimethicone containing an average of 8 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-8 dimethicone dimer dilinoleate	PEG-8 dimethicone dimer dilinoleate is the ester formed by the reaction of PEG-8 dimethicone and dilinoleic acid.	Film former
PEG-8 dimethicone/dimer dilinoleic acid copolymer	PEG-8 dimethicone/dimer dilinoleic acid copolymer is a copolymer of PEG-8 dimethicone and dilinoleic acid.	Skin-conditioning agent – emollient
PEG-8 methicone	PEG-8 methicone is the polyethylene glycol derivative of methicone containing an average of 8 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – emollient

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

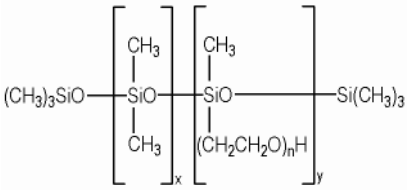
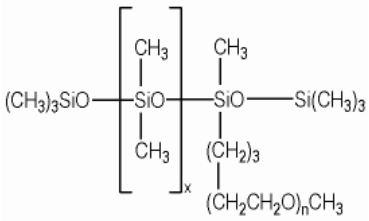
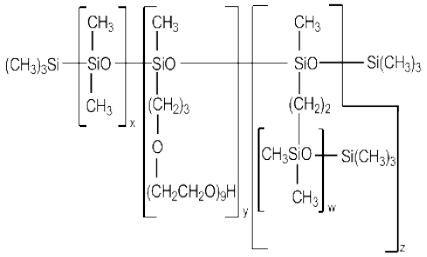
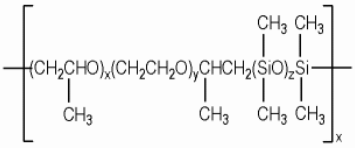
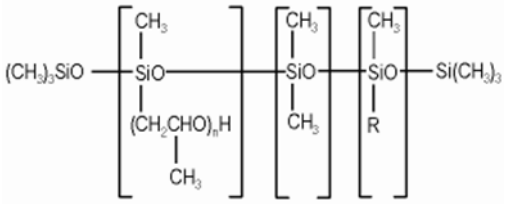
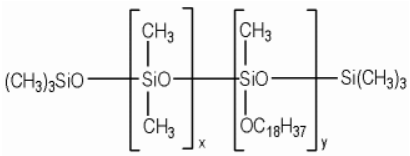
Ingredient CAS No.	Definition / Structure	Function
PEG-8 methyl ether dimethicone 68938-54-5 (generic)	PEG-8 methyl ether dimethicone is the methyl ether of a derivative of dimethicone containing an average of 8 moles of ethylene oxide.	Hair conditioning agent; humectant; surfactant – cleansing agent; surfactant – dispersing agent
PEG-8 PEG-4 dimethicone	PEG-8 PEG-4 dimethicone is the reaction product of hydrogen dimethicone and allyl PEG-8 and allyl PEG-4.	Hair conditioning agent; surfactant – emulsifying agent
PEG-8 PPG-8 dimethicone	PEG-8 PPG-8 dimethicone is the polyoxypropylene, polyoxyethylene ether of dimethicone with an average propoxylation value of 8 and an average ethoxylation value of 8.	Surfactant – emulsifying agent
PEG-9 dimethicone 68937-54-2 (generic)	PEG-9 dimethicone is the siloxane polymer that conforms generally to the formula  where n has an average value of 9.	Hair conditioning agent; skin-conditioning agent – miscellaneous
PEG-9 methyl ether dimethicone	PEG-9 methyl ether dimethicone is a siloxane polymer that conforms generally to the formula  where n has an average value of 9.	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-9 polydimethylsiloxyethyl dimethicone	PEG-9 polydimethylsiloxyethyl dimethicone is the siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Polysilicone-13 158451-77-5 197980-52-2	Polysilicone-13 is the siloxane polymer that conforms generally to the formula. 	Hair conditioning agent
PPG-12 butyl ether dimethicone	PPG-12 butyl ether dimethicone is a butyl ether of a derivative of dimethicone containing an average of 12 moles of propylene oxide.	Hair conditioning agent; humectant; surfactant – dispersing agent; surfactant – emulsifying agent
PPG-12 dimethicone 68440-66-4 68554-64-3	PPG-12 dimethicone is the polypropylene glycol derivative of dimethicone containing an average of 12 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – emollient

Table 1. Definitions, functions, and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

Ingredient CAS No.	Definition / Structure	Function
PPG-2 dimethicone	PPG-2 dimethicone is the polypropylene glycol derivative of dimethicone containing an average of 2 moles of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – dispersing agent
PPG-25 dimethicone 68957-00-6 (generic)	PPG-25 dimethicone is the polypropylene glycol derivative of dimethicone containing an average of 25 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent - miscellaneous; surfactant – emulsifying agent
PPG-27 dimethicone	PPG-27 dimethicone is the polypropylene glycol derivative of dimethicone containing an average of 27 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – miscellaneous
PPG-4 oleth-10 dimethicone	PPG-4 oleth-10 dimethicone is the silicone polymer that conforms generally to the formula  where R represents Oleth-10 and n has an average value of 4.	Film former
Stearoxy Dimethicone 68554-53-0	Stearoxy dimethicone is a polymer of dimethylpolysiloxane with some methyl groups replaced by stearoxy groups.	Skin-conditioning agent – emollient
Stearoxymethicone/dimethicone copolymer	Stearoxymethicone/dimethicone copolymer is the siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – occlusive; viscosity increasing agent – nonaqueous

n, x, y, z – representing the non-specific number of repeating units in the molecule.
[a] Cetyl PEG-8 dimethicone and PEG-8 cetyl dimethicone may be 2 names for the same ingredient.

Table 2. Safety assessments of cosmetic ingredients related to the alkoxy polysiloxanes in this safety assessment. These include previous safety assessments of ingredients in this report as well as ingredients related to or moieties of ingredients in this report.

Ingredients	Conclusion	Maximum use concentration (%)	Reference
Cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane	Safe in the present practices of use and concentration	94	48,49
Dimethicone copolyol Re-review also included: Dimethicone PEG-7 Phosphate, Dimethicone PEG-10 Phosphate, Dimethicone PEG/PPG-7 /4 Phosphate, Dimethicone PEG/PPG-12/4 Phosphate, Dimethicone PEG/PPG-20/23 Benzoate, Dimethicone PEG-8 Benzoate, Dimethicone PEG-6 Acetate, Dimethicone PEG-8 Adipate, PEG-3 Dimethicone, PEG-9 Dimethicone, PEG/PPG-20/29 Dimethicone, PEG/PPG-6111 Dimethicone, PEG-7 Dimethicone, PEG-8 Dimethicone, PEG-14 Dimethicone, PEG/PPG-14/4 Dimethicone, PEG/PPG-4/12 Dimethicone, PEG/PPG-20/20 Dimethicone, PEG/PPG-8114 Dimethicone, PEG/PPG-20/6 Dimethicone, PEG/PPG-20/15 Dimethicone, PEG-12 Dimethicone, PEG/PPG-18/ 18 Dimethicone, PEG/PPG-17 *I* 18 Dimethicone, PEG-10 Dimethicone, PEG/PPG-25/25 Dimethicone, PEG/PPG-19/19 Dimethicone, PEG/PPG-27 /27 Dimethicone, PEG/PPG-22/23 Dimethicone, PEG/PPG-3110 Dimethicone, PEG/PPG-16/2 Dimethicone, PEG/PPG-22/24 Dimethicone, PEG/PPG-15115 Dimethicone, PEG-17 Dimethicone, PEG/PPG-20/23 Dimethicone, and PEG/PPG-23/6 Dimethicone.	Safe as cosmetic ingredients in the present practices of use and concentration. Conclusion confirmed at re-review.	10	1,50
Dimethicone crosspolymers: acrylates/bis-hydroxypropyl dimethicone crosspolymer, behenyl dimethicone/bis-vinyldimethicone crosspolymer, bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer, bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer, bis-vinyldimethicone crosspolymer, bis-vinyldimethicone/PEG-10 dimethicone crosspolymer, bis-vinyldimethicone/PPG-20 crosspolymer, butyldimethicone methacrylate/	Safe in the present practices of use and concentration described in this safety assessment.	46	51

Table 2. Safety assessments of cosmetic ingredients related to the alkoxy polysiloxanes in this safety assessment. These include previous safety assessments of ingredients in this report as well as ingredients related to or moieties of ingredients in this report.

Ingredients	Conclusion	Maximum use concentration (%)	Reference
methyl methacrylate crosspolymer, C30-45 alkyl cetearyl dimethicone crosspolymer, C4-24 alkyl dimethicone/divinyldimethicone crosspolymer, C30-45 alkyl dimethicone/ polycyclohexene oxide crosspolymer, cetearyl dimethicone crosspolymer, cetearyl dimethicone/vinyl dimethicone crosspolymer, cetyl dimethicone/bis-vinyldimethicone crosspolymer, cetyl hexacosyl dimethicone /bis-vinyldimethicone crosspolymer, crotonic acid/vinyl C8-12 isoalkyl esters /VA/bis-vinyldimethicone crosspolymer, dimethicone/bis-isobutyl PPG-20 crosspolymer, dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer, dimethicone crosspolymer, dimethicone crosspolymer-3, dimethicone/ divinyldimethicone/ silsesquioxane crosspolymer, dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer, dimethicone/PEG-10 crosspolymer, dimethicone/PEG-10/15 crosspolymer, dimethicone/PEG-15 crosspolymer, dimethicone/phenyl vinyl dimethicone crosspolymer, dimethicone/polyglycerin-3 crosspolymer, dimethicone/PPG-20 crosspolymer, dimethicone/ titanate crosspolymer, dimethicone/vinyl dimethicone crosspolymer, dimethicone/ vinyltrimethylsiloxysilicate crosspolymer, diphenyl dimethicone crosspolymer, diphenyl dimethicone/vinyl diphenyl dimethicone/ silsesquioxane crosspolymer, divinyldimethicone/ dimethicone crosspolymer, hydroxypropyl dimethicone/polysorbate 20 crosspolymer, isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer, lauryl dimethicone PEG-15 crosspolymer, lauryl dimethicone/ polyglycerin-3 crosspolymer, lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer, PEG-10 dimethicone crosspolymer, PEG-12 dimethicone crosspolymer, PEG-8 dimethicone/polysorbate 20 crosspolymer, PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer, PEG-12 dimethicone/PPG-20 crosspolymer, PEG-10 dimethicone/vinyl dimethicone crosspolymer, PEG-10/lauryl dimethicone crosspolymer, PEG-15/lauryl dimethicone crosspolymer, PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer, perfluorononyl dimethicone/ methicone/amodimethicone crosspolymer, polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer, polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer, silicone quaternium-16/glycidoxy dimethicone crosspolymer, styrene/acrylates/ dimethicone acrylate crosspolymer, trifluoropropyl dimethicone/PEG-10 crosspolymer, trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer, trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer, trimethylsiloxysilicate/dimethicone crosspolymer, vinyl dimethicone/lauryl/ behenyl dimethicone crosspolymer, vinyl dimethicone/lauryl dimethicone crosspolymer, vinyl dimethicone/methicone silsesquioxane crosspolymer, vinyldimethyl/trimethylsiloxysilicate/ dimethicone crosspolymer, vinyldimethyl/ trimethylsiloxysilicate stearyl dimethicone crosspolymer			
Dimethicone: stearoxy dimethicone, dimethicone, methicone, amino bispropyl dimethicone, aminopropyl dimethicone, amodimethicone, amodimethicone hydroxystearate, behenoxy dimethicone, C24-28 alkyl methicone, C30-45 alkyl methicone, C30-45 alkyl dimethicone, cetearyl methicone, cetyl dimethicone, dimethoxysilyl ethylenediaminopropyl dimethicone, hexyl methicone, hydroxypropyldimethicone, stearamidopropyl dimethicone, stearyl dimethicone, stearyl methicone, and vinyldimethicone	Safe as a cosmetic ingredient	80	[3]
Polyethylene glycols: PEG-6, -8, -32, -75, -150, -14M, and -20M Amended report: Triethylene Glycol and Polyethylene Glycols (PEGs)-4, -6, -7, -8, -9, -10, -12, -14, -16, -18, -20, -32, -33, -40, -45, -55, -60, -75, -80, -90, -100, -135, -150, -180, -200, -220, -240, -350, -400, -450, -500, -800, -2M, -5M, -7M, -9M, -14M, -20M, -23M, -25M, -45M, -65M, -90M, -115M, -160M and -180M and any PEGs ≥ 4	Safe for use in cosmetics in the present practices of use and concentration.	50; 85	[52,53]
Polypropylene glycols: PG, tripropylene glycol, PPG-3, -7, -9, -12, -13, -15, -16, -17, 20, -26, -30, -33, -34, -51, -52, -69, and any PPG ≥3	Safe as cosmetic ingredients in when formulated to be nonirritating.	99	[54,55]
Siloxysilicates and silylates: trimethylsiloxysilicate, trifluoropropyldimethyl/trimethylsiloxy silicate, silica dimethyl silylate, silica silylate	Safe as used when formulated and delivered in the final product to be not irritating or sensitizing to the respiratory tract	30	[56]
Beeswax and euphorbia cerifera (candelilla) wax	Safe as used in cosmetics under present practices of concentration and use. Confirmed at re-review.	>25 – 50; 56	[50,57]

Table 3. Chemical and physical properties of alkoxyl polysiloxanes.

Property	Value	Reference
Bis-hydroxyethyoxypropyl dimethicone		
Physical Form	Liquid	58
Color	Colorless to pale yellow	58
Molecular Weight g/mol	>1000	58
Density/Specific Gravity @ 20°C	980	58
Water Solubility	<0.001	58
Bis-isobutyl PEG/PPG-10/7 dimethicone copolymer		
Molecular Weight g/mol	>1000	59
Bis-PEG-1 dimethicone		
Molecular Weight g/mol	>1000	59
Bis-PEG-4 dimethicone		
Molecular Weight g/mol	>500-1000	59
Bis-PEG-8 dimethicone		
Molecular Weight g/mol	>1000	59
Bis-PEG-15 methyl ether dimethicone		
Molecular Weight g/mol	>1000	59
Bis-PEG-12 dimethicone beeswax		
Color	White to light yellow	60
Melting Point °C	62-72	60
Bis-PEG-15 methyl ether dimethicone		
Physical Form	Solid	61
Color	White, opaque	61
Odor	Slight	28
Molecular Weight g/mol	~1600	14
Density/Specific Gravity	1.05	28
Viscosity kg/(s m) @ 25°C	52.5	28
Melting Point °C	~30	61
Water Solubility	Dispersable	14,28
Other Solubility		
Castor oil	>10% soluble	61
Oleyl alcohol	>10% soluble	61
Propylene glycol	>10% soluble	61
Isopropanol	>10% soluble	61
Ethanol	>10% soluble	61
Glycerol	>10% soluble	61
Mineral oils	Insoluble	61
Ester oils/waxes	Insoluble	61
Olive oil	Insoluble	61
Bis-PEG-20 dimethicone		
Molecular Weight g/mol	>1000	59
Bis-PEG/PPG-14/14 dimethicone		
Physical Form	Liquid	32
Color	Yellowish	32
Density/Specific Gravity @ 25°C	0.97	32
Water Solubility	145	32
Cetyl PEG/PPG-10/1 dimethicone		
Physical Form	Viscous liquid	8
Color	Colorless	8
Molecular Weight g/mol	>1000 500-1000	8,59 59
Density/Specific Gravity @ 25°C	0.941	8
Water Solubility mg/L @ 25°C	8	8
Lauryl PEG-9 polydimethylsiloxyethyl dimethicone		
Physical Form		
Color	Colorless to light brown, transparent to slightly hazy	29
Molecular Weight g/mol	>1000	59
Density/Specific Gravity @ 25°C	940-980	29
Water Solubility mg/L @ 25°C	Expected to have low solubility in water based on its predominantly hydrophobic structure	29

Table 3. Chemical and physical properties of alkoxyl polysiloxanes.

Property	Value	Reference
Lauryl PEG-10 tris(trimethylsiloxy)silylethyl dimethicone		
Physical Form	Liquid	[40]
Color	Light brown	[40]
Molecular Weight g/mol	>1000	[40]
Density/Specific Gravity	960.8	[40]
Lauryl PEG/PPG-18/18 methicone		
Molecular Weight g/mol	>1000	[59]
Lauryl polyglyceryl-3 polydimethylsiloxyethyl dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-14/4 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-15/15 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-18/18 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-19/19 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-20/15 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-20/20 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-20/22 butyl ether dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-20/23 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-23/6 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-25/25 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-4/12 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG/PPG-8/26 dimethicone		
Molecular Weight g/mol	>1000	[59]
PEG 20/PPG-23 dimethicone		
Physical Form	Liquid	[18]
Color	Clear, pale yellow	[18]
Density/Specific Gravity	1.023	[18]
PEG/PPG-20/15 dimethicone		
Physical Form	Liquid	[18]
Color	Clear, straw-colored	[18]
Density/Specific Gravity	1.04	[18]
PEG/PPG-25/25 dimethicone		
Physical Form	Liquid	[62,63]
Color	Yellowish	[62,63]
Odor	Slight	[62]
Molecular Weight g/mol	~17 000	[17]
Density/Specific Gravity @ 25°C	1.03	[62,63]
Water Solubility	> 10% soluble Completely miscible	[63] [62]
Other Solubility		
Octyl dodecanol	> 10% soluble	[63]
Oleyl alcohol	> 10% soluble	[63]
Isopropanol	> 10% soluble	[63]
Ethanol	> 10% soluble	[63]
Ethyl acetate	1%-10% soluble	[63]
Mineral oils	Insoluble	[63]
Olive oil	Insoluble	[63]
Propylene glycol	Insoluble	[63]
Glycerol	Insoluble	[63]

Table 3. Chemical and physical properties of alkoxyl polysiloxanes.

Property	Value	Reference
PEG-10 dimethicone		
Physical Form		
End-blocked	Liquid	5
Color		
End-blocked	Clear, straw	5
Molecular Weight g/mol	>1000	59
Density/Specific Gravity	1.002	18
Water Solubility		
Linear	Soluble	5
Other Solubility		
End-blocked		
Ethanol	Soluble	5
PEG-12 dimethicone		
Physical Form	Liquid	16
Pendent	Liquid	5
End-blocked	Liquid	5
Pendent	Liquid	5
Pendent	Liquid	5
Color	Colorless to yellow	16
Pendent	Colorless	5
End-blocked	Clear, straw	5
Pendent	Amber	5
Pendent	Pale yellow	5
Odor	Characteristic	16
Molecular Weight g/mol	500-1000	59
	~3000	16
Density/Specific Gravity	1.09	18
	1.07	18
	0.989	18
	1.065-1.095	16
Water Solubility	Fully soluble	16
Pendent	Soluble	5
End-blocked	Soluble	5
Pendent	Soluble	5
Other Solubility		
Ethanol	Soluble	16
Pendent	Soluble	5
Ethanol	Insoluble	5
Mineral oil		
End-blocked	Soluble	5
Ethanol		
Pendent	Soluble	5
Ethanol	Insoluble	5
Mineral oil		
Pendent	Soluble	5
Ethanol		
PEG-14 dimethicone		
Molecular Weight g/mol	>1000	59
PEG-17 dimethicone		
Physical Form		
Pendent	Liquid	
Color		
Pendent	Straw	
Molecular Weight g/mol	>1000	59
Density/Specific Gravity	1.078	18
Water Solubility		
Pendent	Soluble	5
Other Solubility		
Pendent		
Ethanol	Soluble	5
Mineral oil	Insoluble	5
PEG-3 dimethicone		
Molecular Weight g/mol	>1000	59,64
PEG-32 dimethicone		
Molecular Weight g/mol	>1000	59
PEG-8 dimethicone		
Molecular Weight g/mol	~4238	65
PEG-8 dimethicone		

Table 3. Chemical and physical properties of alkoxyl polysiloxanes.

Property	Value	Reference
Physical Form		
Pendent	Liquid	5
End-blocked	Liquid	5
Color		
Pendent	Clear, pale yellow	5
End-blocked	Clear, straw	5
Molecular Weight g/mol	>1000	59
Water Solubility		
Pendent	Insoluble	5
Other Solubility		
End-blocked		
Ethanol	Soluble	5
Mineral oil	Insoluble	5
Pendent		
Ethanol	Soluble	5
Mineral oil	Soluble	5
PEG-9 dimethicone		
Molecular Weight g/mol	>1000	59
PEG-9 methyl ether dimethicone		
Molecular Weight g/mol	>1000	59
PEG-9 polydimethylsiloxyethyl dimethicone		
Physical Form	Liquid	8
Color	Colorless to light brown	8
Molecular Weight g/mol	>1000	8,59
Density/Specific Gravity @ 25ºC	990-1010	8
Water Solubility @ 20ºC	<1000	8
Polysilicone-13		
Molecular Weight g/mol	>1000	59
PPG-12 dimethicone		
Molecular Weight g/mol	>1000	59
PPG-2 dimethicone		
Color	Clear	66
Density/Specific Gravity	0.99	66
Water Solubility		
Pendent	Insoluble	66
Other Solubility		
Pendent		
Acetone	Soluble	66
PPG-25 dimethicone		
Molecular Weight g/mol	>1000	59
Stearoxymethicone/dimethicone copolymer		
Molecular Weight g/mol	>1000	59
Vinyl dimethicone crosspolymer		
Molecular Weight g/mol	>1000	59

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Behenoxy dimethicone		Bis-hydroxyethoxypropyl dimethicone		Bis-PEG-4 dimethicone		Bis-PEG-12 dimethicone	
Total/range	**20**	**0.5-3**	**19**	**0.7-12**	**9**	**0.4**	**NR**	**0.28**
Duration of use								
Leave-on	17	0.5-3	19	0.7-12	3	NR	NR	0.28
Rinse-off	3	0.5	NR	NR	6	0.4	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type[a]								
Eye area	6	NR	14	1.3-3.4	NR	NR	NR	0.28
Incidental ingestion	2	NR	2	0.7-1	NR	NR	NR	NR
Incidental Inhalation-sprays	7[b];2[d]	NR	NR	NR	3[b]	NR	NR	NR
Incidental inhalation-powders	6[c]; 2[d]	0.5-3[c]	NR	NR	NR	NR	NR	NR
Dermal contact	18	0.5-3	17	1.3-12	NR	NR	NR	0.28
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	9	0.4	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	NR	2	0.7-1	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	Bis-PEG-12 dimethicone beeswax		Bis-PEG-12 dimethicone candelillate		Bis-PEG-15 methyl ether dimethicone		Bis-PEG/PPG-14/14 dimethicone	
Total/range	**23**	**0.01-5.7**	**19**	**0.5-5.1**	**2**	**1-1.5**	**77**	**0.2-5**
Duration of use								
Leave-on	23	0.01-5.7	19	0.5-5.1	2	1-1.5	77	0.2-5
Rinse-off	NR	NR	NR	NR	NR	NR	NR	0.9
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	10	1-4.5	2	1	1	1	5	0.42-1.1
Incidental ingestion	NR	NR	14	5.1	NR	NR	2	NR
Incidental Inhalation-sprays	2[b]; 4[d]	0.01[b]	1[b]	NR	NR	1.5[e]	7;10[b]; 7[d]	NR
Incidental inhalation-powders	4[d]	NR	NR	NR	NR	NR	2; 7[d]	0.2-1.2[c]
Dermal contact	16	0.2-5.7	1	0.5	1	1.5	65	0.2-5
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	3[f]
Hair-noncoloring	2	0.01	3	NR	NR	NR	10	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	14	5.1	NR	NR	2	NR
Baby	NR	NR	NR	NR	NR	NR	NR	1.1

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone		**Bis-PEG/PPG-20/20 dimethicone**		**Cetyl PEG/PPG-10/1 dimethicone**		**Lauryl PEG/PPG-18/18 methicone**	
Total/range	**30**	**0.4-1.7**	**4**	**0.2-0.5**	**404**	**0.02-15**	**78**	**0.33-5**
Duration of use								
Leave-on	26	0.4-1.7	2	0.2-0.5	399	0.02-15	46	0.5-5
Rinse-off	4	0.65	2	0.5	5	0.5-3.5	32	0.33-2
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	15	0.99	NR	NR	59	0.53-15	11	0.5-2.2
Incidental ingestion	NR	NR	NR	NR	46	0.098-3.8	2	3.8
Incidental Inhalation-sprays	4[b]; 4[d]	NR	1[b]	0.35[b]	1; 51[b]; 26[d]	1-3[b]	9[b]; 2[d]	1.4[b]
Incidental inhalation-powders	4[d]	1.7[c]	1[c]	0.35-0.5[c]	1[c]; 26[d]	0.4; 1-4[c]	2[c]; 2[d]	0.54-2[c]
Dermal contact	28	0.4-1.7	4	0.2-0.5	334	0.034-15	37	0.5-5
Deodorant (underarm)	NR	NR	NR	NR	NR	0.7-2[f]	NR	NR
Hair-noncoloring	NR	NR	NR	NR	11	0.5-3.5	39	0.33-1.4
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	8	0.02	NR	NR
Mucous Membrane	3	NR	2	NR	46	0.098-3.8	2	3.8
Baby	NR	NR	NR	NR	1	4.1[g]	NR	NR

	Lauryl PEG-8 dimethicone		**Lauryl PEG-9 polydimethylsiloxyethyl dimethicone**		**Methoxy PEG/PPG-25/4 dimethicone**		**PEG/PPG-14/4 dimethicone**	
Total/range	**2**	**1-5**	**27**	**0.2-6**	**NR**	**0.8-1.1**	**49**	**0.092-2**
Duration of use								
Leave-on	2	1-5	27	0.2-6	NR	0.8-1.1	43	0.092-2
Rinse-off	NR	NR	NR	NR	NR	NR	2	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	4	NR
Exposure type								
Eye area	NR	NR	2	1-2	NR	NR	17	0.95-2
Incidental ingestion	1	NR	NR	NR	NR	NR	4	0.95-1
Incidental Inhalation-sprays	NR	1[h]	10[b]; 5[d]	NR	NR	NR	14[b]; 4[d]	0.092-0.14[j]
Incidental inhalation-powders	NR	NR	5[d]	0.2-2.8[c]	NR	0.8-1.1[c]	4[d]	1[c]
Dermal contact	1	1-5	27	0.2-6	NR	0.8-1.1	36	0.95-2
Deodorant (underarm)	NR	NR	NR	0.8[f]; 0.29[i]	NR	NR	1[b]	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	9	0.092-0.25
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR	NR	NR	8	0.95-1
Baby	NR	5[g]	NR	NR	NR	NR	NR	NR

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG/PPG-15/15 dimethicone		**PEG/PPG-17/18 dimethicone**		**PEG/PPG-18/18 dimethicone**		**PEG/PPG-19/19 dimethicone**	
Total/range	**12**	1.5	**112**	**0.019-14**	**461**	**0.0001-10**	**40**	**0.32-10.7**
Duration of use								
Leave-on	8	NR	108	0.019-14	373	0.0001-10	40	0.32-10.7
Rinse-off	4	1.5	4	0.5-1.5	87	0.0001-3	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	1	NR	NR	NR
Exposure type								
Eye area	NR	NR	44	0.6	29	0.015-9.8	9	1-10.7
Incidental ingestion	NR	NR	NR	NR	1	1.6	NR	2
Incidental Inhalation-sprays	3; 3[b]	NR	23; 17[b]; 1[d]	0.027-14[k]; 0.019-13[b]	18; 95[b]; 89[d]	0.0001-1[l]; 0.02-3[b];	1[b]; 4[d]	2[m]; 7[b]
Incidental inhalation-powders	NR	NR	1[d]	NR	89[d]	0.068-2.4[c]	4[d]	2-5[c]
Dermal contact	1	NR	6	1.5-14	335	0.0001-10	40	0.32-10.7
Deodorant (underarm)	NR	NR	NR	NR	21[b]	0.24-5[f]	17[b]	NR
Hair-noncoloring	8	1.5	62	0.019-13	106	0.0001-3	NR	2-7
Hair-coloring	3	NR	NR	NR	19	NR	NR	NR
Nail	NR	NR	NR	NR	NR	0.1	NR	NR
Mucous Membrane	NR	NR	NR	NR	24	0.0001-1.6	NR	2
Baby	NR	NR	NR	NR	1	NR	NR	NR

	PEG/PPG-20/15 dimethicone		**PEG/PPG-20/20 dimethicone**		**PEG/PPG-20/23 dimethicone**		**PEG/PPG-20/6 dimethicone**	
Total/range	**68**	**0.00045-2.3**	**21**	**0.11-0.33**	**29**	**0.006-1.3**	**46**	**0.19-0.51**
Duration of use								
Leave-on	64	0.00045-2	20	0.11-0.33	21	0.0006-1.3	13	0.19-0.51
Rinse-off	4	NR	1	NR	8	0.1-1.3	33	0.28-0.38
Diluted for (bath) use	NR	2.3	NR	NR	NR	0.0006	NR	NR
Exposure type								
Eye area	6	1.1	4	0.27	NR	NR	2	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	12; 16[b]; 10[d]	0.35-0.9[n]; 0.046-1.4[b];	2; 12[b]	0.21[n]; 0.33[b]	7[b]; 4[d]	NR	6[b]; 2[d]	0.43[n]; 0.2[b]
Incidental inhalation-powders	10[d]	0.54; 0.00045-1.6[c]	NR	0.16-0.21[c]	2; 4[d]	0.0038; 0.0028-0.83[c]	2[d]	0.5[c]
Dermal contact	39	0.00045-2.3	13	0.11-0.3	19	0.0006-1.3	38	0.19-0.51
Deodorant (underarm)	NR	0.75[f]	NR	NR	1[b]	0.0006[f]	NR	0.51[f]
Hair-noncoloring	25	0.046-1.4	8	0.21-0.33	10	0.1-1.3	8	0.2-0.43
Hair-coloring		NR	NR	NR	NR	0.25	NR	NR
Nail	2	0.18-0.75	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	2.3	NR	NR	4	0.0006	26	0.28
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG/PPG-22/23 dimethicone		**PEG/PPG-22/24 dimethicone**		**PEG/PPG-25/25 dimethicone**		**PEG/PPG-30/10 dimethicone**	
Total/range	**4**	**0.00025-0.0025**	**22**	**0.1-1**	**2**	**0.7**	**1**	**0.00005-0.3**
Duration of use								
Leave-on	4	0.00025-0.0025	21	0.1-1	2	0.7	1	0.00005-0.3
Rinse-off	NR	NR	1	0.1	NR	0.7	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	1	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	3[b]	0.00025; 0.0025[b]	5; 3[b]; 1[d]	0.11-1[o]	1[b]	0.7[b]	1[b]	NR
Incidental inhalation-powders	NR	0.0025[c]	1[d]	NR	NR	NR	NR	0.3[c]
Dermal contact	4	NR	3	NR	1	NR	1	0.00005-0.3
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	19	0.1-1	1	0.7	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	PEG/PPG-4/12 dimethicone		**PEG/PPG-8/14 dimethicone**		**PEG-10 dimethicone**		**PEG-10 methyl ether dimethicone**	
Total/range	**34**	**0.6-2.9**	NR	**0.5-0.88**	**240**	**0.013-6**	**4**	**0.01-5**
Duration of use								
Leave-on	20	0.6-2.9	NR	0.05-0.75	238	0.013-6	3	0.1-3
Rinse-off	14	1.4	NR	0.12-0.88	2	0.1-6	1	0.01-5
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	46	0.38-4.2	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	4	NR	NR
Incidental Inhalation-sprays	3[o]; 1[b]	0.6-1.7[p]; 2.9[b]	NR	0.05-0.12[q]; 0.4[b]	39[b]; 44[d]	1[m]; 0.013-6[b];	3[d]	0.16[m]; 3[b]
Incidental inhalation-powders	2	NR	NR	NR	2; 44[d]	0.5; 0.013-4	3[d]	0.3-1[c]
Dermal contact	3	1	NR	0.1-0.88	229	0.013-5.3	4	0.3-5
Deodorant (underarm)	NR	NR	NR	NR	NR	0.3[f]	NR	NR
Hair-noncoloring	28	0.6-2.9	NR	0.05-0.55	2	0.3-6	NR	0.1-3
Hair-coloring	3	1.4	NR	NR	NR	0.35-0.4	NR	0.01
Nail	NR	0.95	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	4	NR	NR
Baby	NR	NR	NR	NR	NR	2[g]	NR	NR

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG-11 methyl ether dimethicone		PEG-12 dimethicone		PEG-14 dimethicone		PEG-17 dimethicone	
Total/range	**26**	**0.1-7**	**538**	**0.0016-6.5**	**41**	**0.006-2.8**	**NR**	**0.48-0.79**
Duration of use								
Leave-on	22	0.1-7	315	0.0016-6.5	35	0.006-2.8	NR	0.48
Rinse-off	4	0.45-6	220	0.1-5	6	0.6-1.8	NR	0.79
Diluted for (bath) use	NR	NR	3	0.5-1	NR	NR	NR	NR
Exposure type								
Eye area	8	0.75-7	10	0.0016-2	4	0.95-1	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	8[b]; 5[d]	0.16[m]; 2[b]	54; 147[b]; 18[d]	0.1-2[r] 0.03-5[b]; 2[d];	3; 3[b]	0.006-2.8[s]; 1.6[b]	NR	NR
Incidental inhalation-powders	5[d]	0.1-1[c]	4[c]; 18[d]	0.6; 0.3-6.5[c]; 2[d];	NR	NR	NR	NR
Dermal contact	25	0.1-7	230	0.0016-6.5	4	0.95-1	NR	0.48-0.79
Deodorant (underarm)	NR	0.5[f]	10[b]	0.5-2.5[f]; 0.1[i]	NR	NR	NR	NR
Hair-noncoloring	1	0.16-2	288	0.01-5	37	0.006-2.8	NR	NR
Hair-coloring	NR	NR	9	0.1-1	NR	NR	NR	NR
Nail	NR	NR	5	0.24	NR	NR	NR	NR
Mucous Membrane	NR	NR	79	0.5-3	NR	NR	NR	NR
Baby	NR	NR	6	4	NR	NR	NR	NR

	PEG-3 dimethicone		PEG-32 methyl ether dimethicone		PEG-6 methyl ether dimethicone		PEG-7 dimethicone	
Total/range	**NR**	**0.5-5**	**1**	**NR**	**8**	**NR**	**2**	**4.3-5**
Duration of use								
Leave-on	NR	0.5-5	1	NR	5	NR	2	4.3-5
Rinse-off	NR	NR	NR	NR	3	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	0.5	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	NR	NR	NR	NR	NR	NR	1[b]	NR
Incidental inhalation-powders	NR	3; 1-3[c]	NR	NR	NR	NR	NR	NR
Dermal contact	NR	1-5	1	NR	NR	NR	1	4.3-5
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	1	NR
Hair-coloring	NR	NR	NR	NR	8	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	0.5	NR	NR	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG-8 cetyl dimethicone[t]		PEG-8 dimethicone		PEG-8 dimethicone/dimer dilinoleic acid copolymer		PEG-8 methicone	
Total/range	**5**	**0.0005**	**175**	**0.024-5.6**	**1**	NR	**10**	**0.5**
Duration of use								
Leave-on	5	0.0005	108	0.024-5.6	1	NR	10	0.5
Rinse-off	NR	NR	67	0.38-2	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	1	NR	9	0.024-1.2	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	2[d]	NR	29; 46[b]; 17[d]	0.1-1.7[u]; 0.059-1[b]	1[b]	NR	10[b]	0.5[b]
Incidental inhalation-powders	2[d]	0.0005[c]	17[d]	0.38-5.6[c]	NR	NR	NR	NR
Dermal contact	5	0.0005	142	0.38-5.6	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	30	0.059-0.8	1	NR	10	0.5
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	55	1	NR	NR	NR	NR
Baby	NR	NR	NR	0.38	NR	NR	NR	NR

	PEG-9 dimethicone		PEG-9 polydimethylsiloxyethyl dimethicone		Polysilicone-13		PPG-12 dimethicone	
Total/range	**25**	**0.0016-5.6**	**46**	**0.3-4**	**11**	**0.003-4**	**17**	**0.0001-3.2**
Duration of use								
Leave-on	23	0.0016-5.6	46	0.3-4	4	0.003-1	17	0.0001-3.2
Rinse-off	2	0.5-1.5	NR	NR	7	0.072-4	NR	1-2
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	16	0.0056-0.4	3	0.3	NR	NR	NR	0.0006
Incidental ingestion	NR	NR	NR	2	NR	NR	NR	NR
Incidental Inhalation-sprays	3[b]; 2[d]	0.05; 0.059-0.26[b]	4[b]; 5[d]	NR	2[b]	0.003[m]	16	0.0001-0.05[v]
Incidental inhalation-powders	2[d]	0.0016-5.6[c]	5[d]	1.8-4[c]	NR	NR	NR	0.4-0.9[c]
Dermal contact	9	0.0016-5.6	46	0.3-4	11	NR	2	0.0001-3.2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	0.059-0.5	NR	NR	NR	0.003-0.1	15	0.0008-2
Hair-coloring	NR	0.05-1.5	NR	NR	NR	4	NR	NR
Nail	NR	NR	NR	NR	NR	1	NR	NR
Mucous Membrane	1	NR	NR	2	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	2-3.2

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PPG-2 dimethicone		**Stearoxy dimethicone**		**Stearoxymethicone/ dimethicone copolymer**		**Cetyl dimethicone copolyol[w]**	
Total/range	**14**	**0.001-1**	**50**	**0.45-22**	**9**	**0.2-2**	**32**	**NS**
Duration of use								
Leave-on	14	0.001-1	49	0.45-8	9	0.2-2	26	NS
Rinse-off	NR	NR	1	22	NR	NR	6	NS
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NS
Exposure type								
Eye area	NR	NR	13	0.9-6	NR	NR	4	NS
Incidental ingestion	NR	NR	11	0.99-8	2	2	NR	NS
Incidental Inhalation-sprays	NR	NR	9[b]; 8[d]	NR	1[b]; 1[d]	NR	1[b]; 3[d]	NS
Incidental inhalation-powders	NR	NR	9[c]; 8[d]	2[c]	1[d]	0.2[c]	1; 3[d]	NS
Dermal contact	NR	NR	38	0.45-6	7	0.2-2	24	NS
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NS
Hair-noncoloring	NR	NR	1	22	NR	NR	6	NS
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NS
Nail	14	0.001-1	NR	NR	NR	NR	1	NS
Mucous Membrane	NR	NR	11	0.99-8	2	2	NR	NS
Baby	NR	NR	NR	NR	NR	NR	NR	NS

Table 4. Frequency of use and concentration of use according to duration and exposure of alkoxy polysiloxane ingredients in cosmetics.[19,20]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Dimethicone copolyol[w]		Dimethicone copolyol crosspolymer[w]		Dimethicone coployol methyl ether[w]			
Total/range	**322**	**NS**	**5**	**NS**	**1**	**NS**		
Duration of use								
Leave-on	249	NS	5	NS	1	NS		
Rinse-off	73	NS	NR	NS	NR	NS		
Diluted for (bath) use	NR	NS	NR	NS	NR	NS		
Exposure type								
Eye area	11	NS	NR	NS	NR	NS		
Incidental ingestion	8	NS	NR	NS	NR	NS		
Incidental Inhalation-sprays	28; 75[b]; 40[d]	NS	3[b]; 2[d]	NS	NR	NS		
Incidental inhalation-powders	40[d]	NS	2[d]	NS	NR	NS		
Dermal contact	190	NS	5	NS	1	NS		
Deodorant (underarm)	3[b]	NS	NR	NS	NR	NS		
Hair-noncoloring	121	NS	NR	NS	NR	NS		
Hair-coloring		NS	NR	NS	NR	NS		
Nail	1	NS	NR	NS	NR	NS		
Mucous Membrane	22	NS	NR	NS	NR	NS		
Baby	NR	NS	NR	NS	NR	NS		

NR=Not Reported; NS=Not Surveyed; Totals=Rinse-off + Leave-on 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] It is possible these products may be powders, but it is not specified whether the reported uses are powders.

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

[e] Moisturizing product.

[f] Not sprays.

[g] Baby product is not a powder.

[h] Suntan product.

[i] Aerosol spray.

[j] Aerosol hair spray 0.092%; pump hair spray 0.14%.

[k] Aerosol hair spray 0.027%-0.5%; pump hair spray 1%.

[l] Aerosol hair spray 0.0001%-0.35%; pump hair spray 0.1%-1%.

[m] Pump hair spray.

[n] Aerosol hair spray.

[o] Aerosol hair spray 0.11%; pump hair spray 1%.

[p] Aerosol hair spray 1.7%; pump hair spray 0.6%.

[q] Aerosol hair spray 0.12%; pump hair spray 0.05%.

[r] Aerosol hair spray 0.1%-2%; pump hair spray 0.15%-0.5%; body and hand products 0.4%.

[s] Aerosol hair spray 0.006%; pump hair spray 2.8%.

[t] PEG-8 cetyl dimethicone and Cetyl PEG-8 dimethicone may be 2 names for the same ingredient.

[u] Aerosol hair spray 0.24%; pump hair spray 0.1%.

[v] Aerosol spray 0.0008%-0.05%; pump spray 0.037%.

[w] Old umbrella term for this class of ingredients still used in the VCRP.

Table 5. Ingredients that do not have any reported uses in the VCRP or concentrations of use reported to the Council.[19,20]

Behenoxy PEG-10 dimethicone	PEG/PPG-16/2 dimethicone
Bis-cetyl/PEG-8 cetyl PEG-8 dimethicone	PEG/PPG-16/8 dimethicone
Bis-isobutyl PEG/PPG-10/7/dimethicone copolymer	PEG/PPG-18/12 dimethicone
Bis-isobutyl PEG-13/dimethicone copolymer	PEG/PPG-18/6 dimethicone
Bis-isobutyl PEG-24/PPG-7/dimethicone copolymer	PEG/PPG-20/22 butyl ether dimethicone
Bis-PEG-1 dimethicone	PEG/PPG-20/22 methyl ether dimethicone
Bis-PEG-8 dimethicone	PEG/PPG-20/29 dimethicone
Bis-PEG-10 dimethicone	PEG/PPG-22/22 butyl ether dimethicone
Bis-PEG-20 dimethicone	PEG/PPG-23/23 butyl ether dimethicone
Bis-PEG-8 PEG-8 dimethicone	PEG/PPG-23/6 dimethicone
Bis-PEG/PPG-15/5 dimethicone	PEG/PPG-24/18 butyl ether dimethicone
Bis-PEG/PPG-18/6 dimethicone	PEG/PPG-27/27 dimethicone
Bis-PEG/PPG-20/5 PEG/PPG-20/5 dimethicone	PEG/PPG-27/9 butyl ether dimethicone
Bis-stearoxy dimethicone	PEG/PPG-3/10 dimethicone
Bis-stearoxyethyl dimethicone	PEG/PPG-6/4 dimethicone
Cetyl PEG/PPG-15/15 butyl ether dimethicone	PEG/PPG-6/11 dimethicone
Cetyl PEG/PPG-7/3 dimethicone	PEG/PPG-8/26 dimethicone
Cetyl PEG-8 dimethicone	PEG-10 polydimethylsiloxyethyl dimethicone/bis-vinyl dimethicone crosspolymer
Lauryl isopentyl-PEG/PPG-18/18 methicone	PEG-4 PEG-12 dimethicone
Lauryl PEG-10 methyl ether dimethicone	PEG-6 dimethicone
Lauryl PEG-10 tris(trimethylsiloxy)silylethyl dimethicone	PEG-7 methyl ether dimethicone
Lauryl PEG-8 PPG-8 dimethicone	PEG-8 dimethicone dimer dilinoleate
Lauryl polyglyceryl-3 polydimethylsiloxyethyl dimethicone	PEG-8 methyl ether dimethicone
Methoxy PEG-11 methoxy PPG-24 dimethicone	PEG-8 PEG-4 dimethicone
Methoxy PEG-13 ethyl polysilsesquioxane	PEG-8 PPG-8 dimethicone
PEG/PPG-10/2 dimethicone	PEG-9 methyl ether dimethicone
PEG/PPG-10/3 oleyl ether dimethicone	PPG-12 butyl ether dimethicone
PEG/PPG-12/16 dimethicone	PPG-25 dimethicone
PEG/PPG-12/18 dimethicone	PPG-27 dimethicone
PEG/PPG-15/5 dimethicone	PPG-4 oleth-10 dimethicone

Table 6. Eye irritation rating of PEG-8 dimethicone according to molecular weight.[6]

Molecular weight	Draize score[1]		
	Day 1	Day 3	Day 7
632	28.3	17.0	4.3
701	13.0	9.0	2.0
1240	4.7	9.3	2.0
1917	4.0	2.0	0.0
2525	2.0	0.7	0.0
2594	0.0	0.0	0.0

[1] Moderately irritating – 25.1-50; mildly irritating – 15.1-25.0; minimally irritating – 2.6 – 15.0; practically non-irritating – 0.6-2.5; non-irritating – 0-0.5.

REFERENCES

1. Elder RE. Final report on the safety assessment of dimethicone copolyol. *Journal of the American College of Toxicology*. 1982;1(4):33-54.

2. Nikitakis, J and Breslawec HP. International Cosmetic Ingredient Dictionary and Handbook. 15 *ed*. Washington, DC: Personal Care Products Council, 2014.

3. Nair B, Elmore AR, Bergfeld WF, Belsito DV, Klaassen CD, Marks, Jr JG, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final Report on the Safety Assessment of Stearoxy Dimethicone, Dimethicone, Methicone, Amino Bispropyl Dimethicone, Aminopropyl Dimethicone, Amodimethicone, Amodimethicone Hydroxystearate, Behenoxy Dimethicone, C24-28 Alkyl Methicone, C30-45 Alkyl Methicone, C30-45 Alkyl Dimethicone, Cetearyl Methicone, Cetyl Dimethicone, Dimethoxysilyl Ethylenediaminopropyl Dimethicone, Hexyl Methicone, Hydroxypropyldimethicone, Stearamidopropyl Dimethicone, Stearyl Dimethicone, Stearyl Methicone, and Vinyldimethicone. *International Journal of Toxicology*. 2003;22(Suppl. 2):11-35.

4. Chemical Book. Dimethylsiloxane, ethylene oxide block copolymer. http://www.chemicalbook.com/ChemicalProductProperty_EN_CB8143073.htm. Date Accessed 11-20-2013.

5. Momentive Performance Materials, Inc. Momentive marketing bulletin: Silsoft dimethicone copopyol conditioning agents [pamphlet]. Albany, NY: Momentive; 2011.

6. O'Lenick Jr, AJ. Dimethicone copolyol chemistry. Chapter: 6. In: *Silicones for Personal Care*. 2 ed. Carol Stream, IL: Allured Publishing Corporation; 2008:93-122.

7. O'Lenick Jr, AJ. Silicone esters. Chapter: 7. In: *Silicones for Personal Care*. 2 ed. Carol Stream, IL: Allured Publishing Corporation; 2008:123-142.

8. National Industrial Chemicals Notificaton and Assessment Scheme (NICNAS). Full Public Report: Abil EM90. Sidney, Australia, Australian Government Department of Health and Ageing. 1997. http://www.nicnas.gov.au/__data/assets/pdf_file/0004/9229/NA460FR.PDF. Report No. PLC/1119. pp. 1-16.

9. O'Lenick Jr, AJ. Alkyl dimethicone copolyol compounds. Chapter: 8. In: *Silicones for Personal Care*. 2 ed. Carol Stream, IL: Allured Publishing Corporation; 2008:143-162.

10. Grüning, B. Chemistry and technology of silicone surfactants. Bayer, AG. In: *Silicones*. Essen, Germany: Vulkan-Verlag, Essen.; 1991:111-117.

11. Allen, RB, Kochs, P, and Chandra, G. Industrial organosilicon materials, their environmental entry and predicted fate. Chapter: 1. Chandra, A. In: *Antropogenic Compounds*. Vol. 3. Berlin, Germany: Springer-Verlag; 1997:9

12. Legrow, GE and Petroff, LJ. Silicone polyether copolymers: Synthetic methods and chemical compositions. Chapter: 2. Hill, RM. In: *Silicone Surfactants*. Vol. 86. New York, NY: Marcel Dekker, Inc.; 1999:50-64.

13. Silicone Environmental, Health, and Safety Center. 9-12-2014. CIR review: Assessment of polyoxyalkylene siloxane copolymers and alkyl-polyoxyakylene siloxane copolymers. Synthesis of polyoxyalkylene siloxane copolymers and alkyl-polyoxyalkylene siloxane copolymers (copolymers).

14. Wacker Silicones. 2012. Product dossier Belsil® DMC 6038 (Bis-PEG-15 Methyl Ether Dimethicone). Unpublished data submitted by Personal Care Products Council.

15. Personal Care Products Council. 7-24-2014. HRIPT on a product containing PEG-3 Dimethicone. Unpublished data submitted by Personal Care Products Council.

16. Anonymous. 2014. Safety assessment of PEG-12 Dimethicone. Unpublished data submitted by Personal Care Products Council.

17. Wacker Silicones. 2012. Product dossier Belsil® DMC 6031 (PEG/PPG-25/25 Dimethicone). Unpublished data submitted by Personal Care Products Council.

18. Momentive Performance Materials, Inc. Silicone specialties for personal care [pamphlet]. Albany, NY: Momentive Performance Materials, Inc.; 2012.

19. Food and Drug Administration (FDA). Frequency of use of cosmetic ingredients. *FDA Database.* Washington, DC: FDA.

20. Personal Care Products Council. 10-24-2014. Updated Concentration of Use by FDA Product Category: Polysiloxanes. Unpublished data submitted by Personal Care Products Council.

21. Bremmer HJ, Prud'homme de Lodder LCH, and van Engelen JGM. Cosmetics Fact Sheet: To assess the risks for the consumer; Updated version for ConsExpo 4. 2006. http://www.rivm.nl/bibliotheek/rapporten/320104001.pdf. Date Accessed 8-24-2011. Report No. RIVM 320104001/2006. pp. 1-77.

22. Johnsen MA. The Influence of Particle Size. *Spray Technology and Marketing*. 2004;14(11):24-27.

23. Rothe H. Special aspects of cosmetic spray safety evaluation. 2011. Unpublished information presented to the 26 September CIR Expert Panel. Washington D.C.

24. Rothe H, Fautz R, Gerber E, Neumann L, Rettinger K, Schuh W, and Gronewold C. Special aspects of cosmetic spray safety evaluations: Principles on inhalation risk assessment. *Toxicol Lett*. 8-28-2011;205(2):97-104.

25. Thomas X. Silicones in industrial applications. Chapter: 17. DeJaeger R and Gleria M. In: *Inorganic Polymers*. Nova Science Publishers; 2007:

26. Food and Drug Administration (FDA). Inactive ingredient search for approved drug products. *U.S.Department of Health & Human Services*. 10-24-2013. http://www.accessdata.fda.gov/scripts/cder/iig/index.CfmDate Accessed 10-17-2014

27. Labor L&S AG. 1997. Summary: Cutaneous permeation of Belsil DMC 6038 (Bis-PEG-15 Methyl Ether Dimethicone) through pig skin in vitro. Unpublished data submitted by Personal Care Products Council.

28. Wacker Silicones. 2013. Material Safety Data Sheet Belsil® DMC 6038 (Bis-PEG-15 Methyl Ether Dimethicone). Unpublished data submitted by Personal Care Products Council.

29. National Industrial Chemicals Notificaton and Assessment Scheme (NICNAS). National Industrial Chemicals Notification and Assessment Scheme (NICNAS): Polymer of low concern public report, KF-6038. Sydney, Austrailia, Austrailian Government Department of Health and Ageing. 2012. http://www.nicnas.gov.au/chemical-information. Report No. PLC/1018. pp. 1-6.

30. Silicone Environmental, Health, and Safety Center. 2014. [Unpublished data submitted to CIR by SEHSC on April 30, 2014, including PEG/PPG-19/19 dimethicone, PEG-12 dimethicone, and lauryl PEG/PPG-18/18 methicone data points.]. SEHSC submission received by email and is available upon request from CIR.

31. Hazelton France. 1988. Summary: Test to evaluate the acute toxicity following a single oral administration (limit test), in the rat (VP 1661 (PEG/PPG-25/25 Dimethicone)). Unpublished data submitted by Personal Care Products Council.

32. National Industrial Chemicals Notificaton and Assessment Scheme (NICNAS). Full Public Report: E-1275. Sidney, Australia, National Industrial Chemicals Notification and Assessment Scheme. 2001. http://www.nicnas.gov.au/chemical-information. Report No. PLC/245. pp. 1-14.

33. Research Toxicology Centre S.p.A. 1996. Summary: Belsil DMC 6038 (Bis-PEG-15 Methyl EtherDimethicone) 4 week oral toxicity study in rats followed by a 2 week recovery period. Unpublished data submitted by Personal Care Products Council.

34. Dow Corning Corporation. Initial submission: Rabbit teratology study (final report) on siloxanes and silicones, 3-hydroxypropyl Me, di-Me, ethoxylated with attachment and cover letter dated 021792. 1966. Report No. OTS0535681. pp. 1-26.

35. RCC. 1996. Summary: Salmonella typhimurium reverse mutation assay with Wacker Belsil DMC 6038 (Bis-PEG-15 Methyl Ether Dimethicone). Unpublished data submitted by Personal Care Products Council.

36. RCC. 1996. Summary: Salmonella typhimurium reverse mutation assay with Wacker silicone fluid L051 (PEG/PPG-25/25 Dimethicone). Unpublished data submitted by Personal Care Products Council.

37. Hazelton France. 1988. Summary: Test to evaluate the acute cutaneous primary irritation and corrosivity, in the rabbit; test to evaluate the acute ocular irritation and reversibility, in the rabbit; test to evaluate sensitizing potential in the guinea pig (Magnusson & Kligman) (PEG/PPG-25/25 Dimethicone). Unpublished data submitted by Personal Care Products Council.

38. Anonymous. 2006. Clinical evaluation report: Human patch test of a brow pencil containing 15% Cetyl PEG/PPG-1 011 Dimethicone. Unpublished data submitted by Personal Care Products Council.

39. Personal Care Products Council. 6-24-2014. Summary of a Patch Test on a Product Containing PEG-3 Dimethicone. Unpublished data submitted by Personal Care Products Council. 1 pages.

40. National Industrial Chemicals Notificaton and Assessment Scheme (NICNAS). National Industrial Chemicals Notification and Assessment Scheme (NICNAS): Polymer of low concern public report; PEG-9 polydimethylsiloxyethyl dimethicone. Sidney, Australia, NICNAS. 2014. http://www.nicnas.gov.au/chemical-information. Report No. PLC/1199. pp. 1-5.

41. Cassidy SL and Stanton E. In vitro eye irritation studies on organosilicon compounds. *Journal of Toxicology - Cutaneous & Ocular Toxicology*. 1997;16(1):45-60.

42. Research Toxicology Centre S.p.A. 2014. Belsil DMC 6038 (Bis-PEG-15 Methyl Ether Dimethicone). Summary: Delayed dermal sensitization study in the guinea pig. Unpublished data submitted by Personal Care Products Council.

43. KGL Inc. 2006. An evaluation of the contact-sensitization potential of a topical coded product (brow pencil containing 15% Cetyl PEG/PPG-10/1 Dimethicone) by means ofthe maximization assay. Unpublished data submitted by Personal Care Products Council.

44. Essex Testing Clinic Inc. 2003. Clinical safety evaluation repeated insult patch test of a product (makeup base) containing 3% PEG-3 Dimethicone. Unpublished data submitted by Personal Care Products Council.

45. Clinical Research Services Inc. 2008. Summary of a human repeat insult patch test of a face lotion containing 1% PEG-3 Dimethicone. Unpublished data submitted by Personal Care Products Council.

46. RTCS Inc. 2008. Summary of a human repeat insult patch test of a face lotion containing 1% PEG-3 Dimethicone. Unpublished data submitted by Personal Care Products Council.

47. Lanzet M. Comedogenic effects of cosmetic raw materials. *Cosmetics & Toiletries*. 1986;101(Feb):63-72.

48. Andersen FA. Final report on the safety assessment of cyclomethicone. *Journal of the American College of Toxicology*. 1991;10(1):9-19.

49. Johnson Jr, W, Bergfeld, WF, Belsito, DV, Hill, RA, Klaassen, CD, Liebler, DC, Marks Jr, JG, Shank, RC, Slaga, TJ, Snyder, PW, and Andersen, FA. Safety assessment of cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane. *International Journal of Toxicology*. 2011;30(Suppl 3):149S-227S.

50. Andersen FA. Annual review of cosmetic ingredient safety assessments -- 2002/2003. *International Journal of Toxicology*. 2005;24(Suppl. 1):1-102.

51. Becker LC, Bergfeld WF, Belsito DV, Klaassen CD, Liebler DC, Hill RA, Marks Jr JG, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Safety assessment of dimethicone crosspolymers as used in cosmetics. Washington, DC, Cosmetic Ingredient Review. 2012. pp. 1-62.

52. Andersen FA. Final report on the safety assessment of polyethylene glycols (PEGs) -6, -8, -32, -75, -150, -14M, -20M. *Journal of the American College of Toxicology*. 1993;12(5):429-457.

53. Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks, Jr JG, Shank RC, Slaga TJ, and Snyder PW. Final Report of the Cosmetic Ingredient Review Expert Panel: Amended Safety Assessment of Triethylene Glycol and Polyethylene Glycols (PEGs)-4, -6, -7, -8, -9, -10, -12, -14, -16, -18, -20, -32, -33, -40, -45, -55, -60, -75, -80, -90, -100, -135, -150, -180, -200, -220, -240, -350, -400, -450, -500, -800, -2M, -5M, -7M, -9M, -14M, -20M, -23M, -25M, -45M, -65M, -90M, -115M, -160M and -180M and any PEGs >= 4 as used in Cosmetics . Washington, DC, Cosmetic Ingredient Review. 2010. pp. 1-49.

54. Berfeld WF, Belsito DV, Klaassen CD, Marks, Jr JG, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final report on the safety assessment of propylene glycol and polypropylene glycols. *Journal of the American College of Toxicology*. 1994;13(6):437-491.

55. Fiume MZ, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks, Jr JG, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final amended report of the Cosmetic Ingredient Review Expert Panel: Safety assessment of Propylene glycol, tripropylene glycol, and PPGs as used in cosmetics. Washington, DC, Cosmetic Ingredient Review. 2010. pp. 1-31.

56. Becker LC, Bergfeld WF, Belsito DV, Klaassen CD, Marks, Jr JG, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final safety assessment: Silylates and surface modifiedsiloxysilicates as used in cosmetics. Washington, DC, Cosmetic Ingredient Review. 2011. pp. 1-25.

57. Elder RE. Final report on the safety assessment of candelilla wax, carnauba wax, Japan wax, and beeswax. *Journal of the American College of Toxicology*. 1984;3(3):1-41.

58. National Industrial Chemicals Notificaton and Assessment Scheme (NICNAS). Full public report: Polymer in 5562 Carbinol Fluid. Sidney, Austrailia, National Occupational Health and Safety Commission. 2004. http://www.nicnas.gov.au/chemical-information. Report No. PLC/503. pp. 1-8.

59. Silicone Environmental, Health, and Safety Center (SEHSC). 7-17-2014. CIR alkoxy polysiloxanes data call in molecular weight results 14 July 2014. Unpublished data submitted by Silicone Envirronmental, Health, and Safety Center.

60. Koster Keunen. Siliconyl beeswax [pamphlet]. Watertown, TC: Koster Keunen; 2013.

61. Wacker Silicones. 2013. Technical data sheet Belsil® DMC 6038 (Bis-PEG-15 Methyl Ether Dimethicone). Unpublished data submitted by Personal Care Products Council.

62. Wacker Silicones. 2013. Material Safety Data Sheet Belsil® DMC 6031 (PEG/PPG-25/25 Dimethicone). Unpublished data submitted by Personal Care Products Council.

63. Wacker Silicones. 2013. Technical data sheet Belsil® DMC 6031 (PEG/PPG-25/25 Dimethicone). Unpublished data submitted by Personal Care Products Council.

64. Personal Care Products Council. 8-19-2014. Information on PEG-3 Dimethicone. Unpublished data submitted by Personal Care Products Council.

65. Personal Care Products Council. 8-19-2014. Information on PEG-7 Dimethicone. Unpublished data submitted by Personal Care Products Council.

66. Dow Corning. New choices. More Opportinities. Dow Corning® FZ-series surfactants [pamphlet]. 2007.