Safety Assessment of Dimethicone Crosspolymers as Used in Cosmetics

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ABSTRACT

The Cosmetic Ingredient Review Expert Panel reviewed the safety of 62 dimethicone crosspolymer ingredients as used in cosmetics. These ingredients function mostly as absorbents, bulking agents, film formers, hair-conditioning agents, emollient skin-conditioning agents, slip modifiers, surface modifiers, and nonaqueous viscosity increasing agents. The Panel reviewed available animal and human data related to these polymers and addressed the issue of residual monomers. The Panel concluded that these dimethicone crosspolymer ingredients are safe in the practices of use and concentration as given in this safety assessment.

INTRODUCTION

As given in the *International Cosmetic Ingredient Dictionary and Handbook*,[1] these 62 dimethicone crosspolymers mostly function as absorbents, bulking agents, film formers, hair-conditioning agents, emollient skin-conditioning agents, slip modifiers, surface modifiers, and nonaqueous viscosity increasing agents (Table 1). The ingredients included in this report are:

- 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/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

Several of the components of these ingredients have been previously reviewed by the Panel including dimethicone, which was found to be safe as a cosmetic ingredient (Table 2).[2]

CHEMISTRY

Overview and Method of Manufacture

Definitions, functions and CAS nos. are provided in Table 1. Idealized structures are shown in Figure 1.

These cosmetic ingredients are silicone elastomers comprised of dimethicone copolymers crosslinked with a bi-functional agent. For use in cosmetics, these crosspolymers are typically supplied to finishing houses as swollen gels (i.e., trade name mixtures) that contain various oils (e.g., silicone oils such as dimethicone).[3] The addition of hydrophilic components (e.g., addition of polyethylene glycol [PEG] chains to produce dimethicone/PEG-10 crosspolymer) or hydrophobic components (e.g., addition of long alkyl chains to produce behenyl dimethicone/bis-vinyldimethicone crosspolymer) affects both the chemical and rheological properties of the resultant ingredient. Accordingly, dimethicone crosspolymers represent a wide variety of materials ranging from liquids to elastomeric solids.

The majority of the ingredients in this review are produced by crosslinking dimethicone polymeric chains via a hydrosilation reaction.[3] This reaction consists of the addition of silicon hydride bonds (SiH) within the dimethicone polymer backbones across vinyl bonds within the selected crosslinking agents (Figure 2). These reactions usually require a catalyst, such as platinum. The reactions are rapid and produce chemically stable products. Since these reactions are net additions across a double bond, the only expected by-products are the starting materials, particularly the catalysts.

In some silicone polymers such as dimethicone, that has no silicon-hydrogen bonds, some amount of silicon hydride may exist. However, a silicone precursor polymer is made in order to add the silicon hydride groups that are utilized for the crosslinking process.[3] For example, a dimethicone precursor polymer is made by the copolymerization of dimethyl siloxane units with methylhydrogen siloxane units. Accordingly, even though we define dimethicone crosspolymer as "a polymer of dimethicone crosslinked with a C3 to C20 alkyl group," it is more likely that dimethicone crosspolymer is a methicone/ dimethicone copolymer (methicone has one methyl and one hydrogen on each silicon in the polymer backbone, whereas dimethicone has two methyl groups on each silicon in the polymer backbone) that is crosslinked with an α,ω-diene (i.e., the double bonds are at the ends of the chain), that is three to twenty carbons long.

Physical and Chemical Properties

Available information on the physical and chemical properties is provided in Table 3. Notable among these data is that these crosspolymers are not water soluble. Other data are provided below.

CROTONIC ACID/VINYL C8-12 ISOALKYL ESTERS/VA/BIS-VINYLDIMETHICONE CROSSPOLYMER

Crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer is stable at < 20°C in a sealed container protected from light for at least 12 months.[4]

DIMETHICONE CROSSPOLYMER

In a product mixture containing dimethicone crosspolymer (12% in cyclomethicone), the crosspolymer has a molecular weight of > 15,500 – 1,000,000.[5] The product is a clear/slightly translucent paste.

DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER

Dimethicone/divinyldimethicone/silsesquioxane crosspolymer is stable at room temperature for 36 months.[6]

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

Dimethicone/vinyltrimethylsiloxysilicate crosspolymer is provided by a manufacturer as a mixture with cyclopentasiloxane that creates a semitransparent gel with thixotropic properties.[7]

PEG-12 DIMETHICONE CROSSPOLYMER

PEG-12 Dimethicone is an amphiphilic molecule; the PEG-12 moieties are hydrophilic, whereas the dimethicone backbone is lipophilic.[8]

VINYL DIMETHICONE/METHICONE SILSEQUIOXANE CROSSPOLYMER

Vinyl dimethicone/methicone silsequioxane crosspolymer products were reported to have specific gravity ranging from 0.98 to 1.11.[9] These products were reported to be white, spherical powders.

VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer (20% in isododecane) is stable for at least 1 year with no special storage requirements.[10] This ingredient is provided by a manufacturer as a mixture with isododecane that creates a semitransparent gel with thixotropic properties.

Particle Size

Dimethicone/divinyldimethicone/silsesquioxane crosspolymer was reported in a patent to be spherical shaped particles with diameters ranging from 2 – 10 μm.[11] In finished products, even in those that are powders, these particles generally aggregate stably to produce much larger particles.

A manufacturer's product information sheet reported that vinyl dimethicone/methicone silsesquioxane crosspolymer had an average particle size range of 2 – 30 μm, depending on the product.[9] Diphenyl dimethicone/vinyl diephenyl dimethicone/silsequioxane crosspolymer has and average particle size of 5μm.

Impurities

CROTONIC ACID/VINYL C8-12 ISOALKYL ESTERS/VA/BIS-VINYLDIMETHICONE CROSSPOLYMER

Crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer is reported to not contain any heavy metals, polycyclic aromatic hydrocarbons, organohalogens, or nitrosamines.[4] Residuals from manufacturing include *tert*-butanol (<100 ppm), isododecane (< 1000 ppm), vinyl acetate (≤ 100 ppm), vinyl tert-decanoate (≤ 2000 ppm), crotonic acid (≤ 200 ppm), and trace amounts of isopropanol and ethyl acetate.

DIMETHICONE CROSSPOLYMER

A manufacturer's product containing dimethicone crosspolymer was reported to have no hazardous impurities.[5]

DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER

Dimethicone/divinyldimethicone/silsesquioxane crosspolymer was reported to be 100% pure by a manufacturer.[6] The same manufacture reported the content of heavy metals to be <20 ppm, arsenic < 2 ppm.[12]

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

Dimethicone/vinyltrimethylsiloxysilicate dimethicone crosspolymer (20% in cyclopentasiloxane) is reported to not contain any heavy metals, polycyclic aromatic hydrocarbons, organohalogen compounds, or nitrosamines.[7] Residuals from manufacturing include platinum (catalyst, < 25 ppm) and cyclotetrasiloxane (maximum 0.1%).

VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer (20% in isododecane) is reported to not contain any heavy metals, polycyclic aromatic hydrocarbons, organohalogen compounds, or nitrosamines.[10] Residuals from manufacturing include platinum (catalyst, < 25 ppm) and cyclotetrasiloxane (maximum < 1%).

PRODUCT MIXTURES

A manufacturer's product sheet reported that product mixtures containing dimethicone/vinyl dimethicone crosspolymer (4% - 30%), dimethicone/phenyl vinyl dimethicone crosspolymer (10% - 20%), vinyl dimethicone/lauryl dimethicone crosspolymer (20% - 35%), dimethicone/PEG-10/15 crosspolymer (15% - 30%), PEG-15/lauryl dimethicone crosspolymer (15% - 35%), or dimethicone/polyglycerin-3 crosspolymer (20% - 35%) had < 20 ppm heavy metal and < 2 ppm arsenic.[9]

USE

Cosmetic

Data on ingredients usage are provided by manufacturers to the Food and Drug Administration's (FDA) Voluntary Cosmetic Registration Program (VCRP) and a survey conducted by the Personal Care Products Council (Council) collected use concentrations for ingredients in this group (Table 4).[13,14] Dimethicone/vinyl dimethicone crosspolymer and dimethicone crosspolymer have the greatest number of uses at 457 and 442, respectively.

The VCRP and Council data were available for:

- Behenyl dimethicone/bis-vinyldimethicone crosspolymer was used in 6 leave-on products at concentrations up to 10% (eye liners at 2-10%, lipstick 0005 – 2%, foundation 0.001%).
- C30-45 alkyl cetearyl dimethicone crosspolymer was reported to be used in 25 leave-on products (up to 4%; including 5 eye products) and 2 rinse-off products.
- C4-24 alkyl dimethicone/divinyldimethicone crosspolymer was reported to be used in 1 leave-on product (a moisturizer) and in foundations up to 2%.
- Cetearyl dimethicone crosspolymer was reported to be used in 20 leave-on products (0.002%-23%) in 1 rinse-off product (0.2%), and in products diluted for bath use (0.002%).
- Dimethicone/bis-isobutyl PPG-20 crosspolymer was reported to be used in 12 leave-on products (0.1%-2%; 1 lipstick).
- Dimethicone crosspolymer was reported to be used in 430 leave-on products (0.02%-25%; including 40 eye products, 9 lipsticks, 11 deodorants; body paint sprays up to 0.3%) and in 12 rinse-off products (0.007%-5%).
- Dimethicone crosspolymer-3 was reported to be used in 52 leave-on products (0.02%-2%; including 13 eye products) and in rinse-off products (0.2%).
- Dimethicone/divinyldimethicone/silsesquioxane crosspolymer was reported to be used in 14 leave-on products (0.5%-5%).
- Dimethicone/PEG-10/15 crosspolymer was reported to be used in 51 leave-on products (0.03%-3%) and in a hair

conditioner (0.8%).

- Dimethicone/phenyl vinyl dimethicone crosspolymer was reported to be used in 10 leave-on products (0.8%-2%).
- Dimethicone/vinyl dimethicone crosspolymer was reported to be used in 444 leave-on products (0.003%-46%; including 1 baby product, 59 eye products, 9 lipsticks, and 47 products that may be inhaled) and 13 rinse-off products (0.06%-37%).
- Dimethicone/vinyltrimethylsiloxysilicate crosspolymer was reported to be used in 14 leave-on products (0.04%-6%; including eye products).
- Diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer was reported to be used in 13 leave-on products (0.1%-7%; up to 7% in face powders).
- Divinyldimethicone/dimethicone crosspolymer was reported to be used in 4 leave-on products (0.007%) and up to 0.7% in rinse-off products.
- Lauryl dimethicone/ polyglycerin-3 crosspolymer was reported to be used in 3 rinse-off products (2%).
- PEG-10 dimethicone crosspolymer was reported to be used in 15 leave-on products (0.6%-2%).
- PEG-12 dimethicone crosspolymer was reported to be used in 28 leave-on products (0.3%-2%; 17 deodorants) and 3 rinse-off products (0.3%).
- PEG-15/lauryl dimethicone crosspolymer was reported to be used in 4 leave-on products (up to 2%) and 3 rinse-off products.
- Silicone quaternium-16/glycidoxy dimethicone crosspolymer was reported to be used in 2 leave-on products (0.003%) and 4 rinse-off products (1%-3%).
- Vinyl dimethicone/lauryl dimethicone crosspolymer was reported to be used in 3 leave-on products (0.3%-2% including lipstick) and in rinse-off products up to 0.09%.
- Vinyl dimethicone/methicone silsesquioxane crosspolymer was reported to be used in 104 leave-on products (0.1%-20%; mostly in make-up products) and 1 rinse off product (0.5%-0.6%).

VCRP[15] data only were available for:

- C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer was reported to be used in 2 dermal products.
- Dimethicone/polyglycerin-3 crosspolymer was reported to be used in 7 leave-on products.
- Isopropyl titanium triisostearate/ triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer was reported to be used in 5 leave-on products.
- PEG-10 dimethicone/vinyl dimethicone crosspolymer was reported to be used in 7 leave-on products.
- Styrene/acrylates/dimethicone acrylate crosspolymer was reported to be used in 1 nail product.

Council[16] data only were available for:

- Cetyl dimethicone/vinyldimethicone crosspolymer was reported to be used in leave-on and rinse-off products up to 0.005% including eye shadow, bath soap and detergents, and shaving cream.
- Dimethicone/PEG-10 crosspolymer was reported to be used in leave-on products (0.5%; foundations).
- Dimethicone/PPG-20 crosspolymer was reported to be used in skin fresheners (0.2%).
- PEG-10/lauryl dimethicone crosspolymer was reported to be used in leave-on products (0.5%-0.7%) and rinse-off products (0.6%).
- Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer was reported to be used in lipstick (0.7%).

There were no reported uses in either the VCRP or in the Council survey for:

- acrylates/bis-hydroxypropyl dimethicone 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/methyl methacrylate crosspolymer
- cetearyl dimethicone/vinyl dimethicone crosspolymer
- cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer
- crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer
- dimethicone/bis-vinyldimethicone/ silsesquioxane crosspolymer
- dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer
- dimethicone/PEG-15 crosspolymer
- dimethicone/titanate crosspolymer

- diphenyl dimethicone crosspolymer
- hydroxypropyl dimethicone/polysorbate 20 crosspolymer
- lauryl dimethicone PEG-15 crosspolymer
- lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer
- PEG-8 dimethicone/polysorbate 20 crosspolymer
- PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer
- PEG-12 dimethicone/PPG-20 crosspolymer
- polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer
- PEG-15/lauryl polydimethylsiloxyethyl dimethicone
- polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone 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
- vinyldimethyl/trimethylsiloxysilicate/ dimethicone crosspolymer
- vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer

Dimethicone crosspolymer and dimethicone/vinyl dimethicone crosspolymer are used in cosmetic products that may be sprays, including hair and body paint products, and could possibly be inhaled. In practice, 95% - 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.[17,18] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal region and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[19,20] 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. None of the deodorants containing these ingredients were reported to be sprays.

TOXICOKINETICS

Absorption, Distribution, Metabolism, and Excretion

No published toxicokinetics data were discovered and no unpublished data were submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity

Dermal – Non-Human

DIMETHICONE CROSSPOLYMER

Dimethicone crosspolymer (12% in cyclomethicone) is reported to have a dermal LD_{50} of > 2000 mg/kg in rabbits (n = 5/sex).[5] There were no deaths or clinical signs.

Oral – Non-Human

DIMETHICONE CROSSPOLYMER

The oral LD_{50} of dimethicone crosspolymer (12% in cyclomethicone) was reported to be > 2000 mg/kg for rats (n = 5/sex).[5] There were no deaths or clinical signs of toxicity.

Inhalation – Non-Human

CROTONIC ACID/VINYL C8-12 ISOALKYL ESTERS/VA/BIS-VINYLDIMETHICONE CROSSPOLYMER

The acute inhalation LC_{50} of crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer (10% in ethanol/water, 4 h) for rats was > 5.29 mg/L.[4]

In Vitro

DIMETHICONE/BIS-VINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER

In an agar diffusion cytotoxicity test, dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer (concentration not provided, 100% assumed) was not cytotoxic to mammalian cell cultures (type of cell not provided).[22]

Repeated Dose Toxicity

No published repeated dose dermal or inhalation toxicity studies were discovered and no unpublished data were submitted.

Oral – Non-Human

DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER

Dimethicone/bis-isobutyl PPG-20 crosspolymer (0, 100, 300, and 1000 mg/kg/d) was orally administered to Crl:CD(SD) rats (n = 5/sex) for 14 consecutive days. All rats survived. There were no effects to body weight or food consumption. Macroscopic findings at necropsy were unremarkable. The mean absolute liver and relative liver weights in all test article-treated female groups was increased in a dose-dependent manner. However, only the high dose group values were statistically significant. The authors concluded that oral administration of dimethicone/bis-isobutyl PPG-20 crosspolymer to rats for 14 consecutive days was well tolerated at all doses.[23]

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

No published reproductive or developmental toxicity studies were discovered and no unpublished data were submitted.

GENOTOXICITY

In Vitro

DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER

Dimethicone/bis-isobutyl PPG-20 crosspolymer (0-5000 μg/plate) was not mutagenic to *Salmonella typhimurium* (strains TA98, TA100, TA1535 and TA1537) and *Escherichia coli* (WP2uvrA (pKM101) and WP2 (pKM101) with or without metabolic activation.[23]

DIMETHICONE CROSSPOLYMER

Dimethicone crosspolymer (0 – 1000 μg/plate; dissolved in tetrahydofuran) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535 and TA1537) and *E. coli* (WP2uvrA (pKM101) and WP2 (pKM101) with or without metabolic activation.[5]

DIMETHICONE/PEG-10/15 CROSSPOLYMER

A product mixture containing dimethicone/PEG-10/15 crosspolymer (~24%) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[24]

In a chromosomal aberration assay using cultured mammalian cells (CHL/IU), a product mixture containing dimethicone/PEG-10/15 crosspolymer (~24%; 1250, 2500, and 5000 μg/ml) did not produce and chromosomal abberations.[24]

DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER

Dimethicone/phenyl vinyl dimethicone crosspolymer (~16%) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[25]

DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

A product containing dimethicone/polyglycerin-3 crosspolymer (~40% in dimethicone; 5000 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[26]

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER

A product containing dimethicone/vinyl dimethicone crosspolymer (~24% in dimethicone; 5000 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[27]

DIPHENYL DIMETHICONE/VINYL DIPHENYL DIMETHICONE SILSESQUIOXANE CROSSPOLYMER

Dipheynyl dimethicone/vinyl diphenyl dimethicone silsesquioxane crosspolymer (100%; 5000 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[28]

LAURYL DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

Lauryl dimethicone/polyglycerin-3 crosspolymer (40% in mineral oil; 5000 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[29]

LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER

Lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer (100%; 312.5 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[30]

PEG-15 LAURYL DIMETHICONE CROSSPOLYMER

PEG-15 lauryl dimethicone crosspolymer (100%; 5000 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[31]

PEG-15/LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE CROSSPOLYMER

PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer (100%; 5000 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.[32]

POLYGLYCERYL-3/LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE CROSSPOLYMER

Polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer (100%; 2500 μg/plate) was not mutagenic to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic

activation.[33]

CARCINOGENICITY

No published carcinogenicity studies were discovered and no unpublished data were submitted.

IRRITATION AND SENSITIZATION

Irritation

Dermal – Non-Human

DIMETHICONE CROSSPOLYMER

Dimethicone crosspolymer (100%; 0.5 ml) was not dermally irritating when administered to female New Zealand White rabbits (n = 3) under semi-occlusion for 4 h.[5]

DIMETHICONE/PEG-10/15 CROSSPOLYMER

A product mixture containing dimethicone/PEG-10/15 crosspolymer (~24%; 0.5 ml) had a PPI of 1.20 when administered under occlusion to the intact and abraded skin of New Zealand White rabbits (n = 3).[24] The authors concluded that the test substance was non-irritating.

DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER

A product mixture containing dimethicone/vinyl dimethicone crosspolymer (~16% in diphenylsiloxy phenyl trimethicone; 0.5 ml) had a PPI of 2.38 when administered under occlusion to the intact and abraded skin of New Zealand White rabbits (n = 3).[25] The authors concluded that the test substance was a moderate irritant.

DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

A product containing dimethicone/polyglycerin-3 crosspolymer (~40% in dimethicone; 0.5 ml) had a PPI of 1.30 when administered under occlusion to the intact and abraded skin of New Zealand White rabbits (n = 6).[26] The authors concluded that the test substance was non-irritating.

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER

A product containing dimethicone/vinyl dimethicone crosspolymer (~24% in dimethicone) had a PPI of 1.42 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[27] The authors concluded that the test article was a mild irritant.

DIPHENYL DIMETHICONE/VINYL DIPHENYL DIMETHICONE SILSESQUIOXANE CROSSPOLYMER

Diphenyl dimethicone/vinyl diphenyl dimethicone silsesquioxane crosspolymer (100%) had a PPI of 0.10 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[28] The authors concluded that the test article was non-irritating.

LAURYL DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

Lauryl dimethicone/polyglycerini-3 crosspolymer (40% in triethylhexanoin; 0.5 ml) had a PPI of 1.50 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[28] The authors concluded that the test article was not a primary irritant.

LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER

Lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer (100%; 0.5 g) had a PPI of 0.98 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[30] The authors concluded that the test article was not a primary irritant.

PEG-10/LAURYL DIEMTHICONE CROSSPOLYMER AND PEG-15 LAURYL DIMETHICONE CROSSPOLYMER

A mixture of PEG-10/lauryl dimethicone crosspolymer and PEG-15 lauryl dimethicone crosspolymer (100%; 50/50 mix assumed) had a PPI of 0.25 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[34] The authors concluded that the test article was not a primary irritant.

PEG-15 LAURYL DIMETHICONE CROSSPOLYMER

PEG-15 lauryl dimethicone crosspolymer (100%) had a PPI of 0.10 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[31] The authors concluded that the test article was not a primary irritant.

PEG-15/LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE

PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer (100%; 0.5 g) had a PPI of 1.05 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[32] The authors concluded that the test article was not a primary irritant.

POLYGLYCERYL-3/LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE CROSSPOLYMER

Polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer (100%; 0.5 g) had a PPI of 0.33 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[33] The authors concluded that the test article was not a primary irritant.

VINYL DIMETHICONE/LAURYL DIMETHICONE CROSSPOLYMER

Vinyl dimethicone/lauryl dimethicone crosspolymer (100%; 0.5 g) had a PPI of 0.33 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[35] The authors concluded that the test article was not a primary irritant.

VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER

Vinyl dimethicone/lauryl dimethicone crosspolymer (100%; 0.5 ML) had a PPI of 0.25 when administered under

occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[36] The authors concluded that the test article was not a primary irritant.

Dermal – Human

DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER

Dimethicone/bis-isobutyl PPG-20 crosspolymer (10%, 40%, 70%, and 100% in isodecyl neopentanoate (IDNP)) was not irritating in an irritation test (n = 28). Erythema was observed in 0 – 6 subjects at evaluation on days 1, 3, and 5.[23]

DIMETHICONE CROSSPOLYMER

In a cumulative irritation test (n = 27), dimethicone crosspolymer (100%; 0.2 ml) was applied 10 times (with the patches remaining over the weekend) over 2 weeks. The authors concluded that dimethicone crosspolymer was dermally non-irritating to humans.[23]

Ocular

DIMETHICONE CROSSPOLYMER

Dimethicone crosspolymer (12% in cyclomethicone; 0.1 ml) was not an ocular irritant to male New Zealand White rabbits (n = 3).[5] There were no effects to the iris or corneal observed.

Dimethicone crosspolymer (100%; 0.1 ml) produced a mild, transient ocular irritant to male New Zealand White rabbits (n = 3).[23]

DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER

In a Skin ZK-1200 (tissue equivalent) ocular assay, dimethicone/phenyl vinyl dimethicone crosspolymer (25 μL) was not predicted to be an ocular irritant after 30 min of exposure.[37]

Sensitization

Dermal – Non-Human

DIMETHICONE CROSSPOLYMER

Dimethicone crosspolymer (12% in cyclomethicone) was not sensitizing to the clipped backs of Hartley guinea pigs (n = 10/sex).[5] There was no difference between the treatment and control groups.

Dimethicone crosspolymer (100%; 0.3 ml) was not sensitizing to guinea pigs (n = 10/sex). There was no dermal responses in the treatment group.[23]

DIMETHICONE/PEG-10/15 CROSSPOLYMER

A product mixture containing dimethicone/PEG-10/15 crosspolymer (~24%) was not sensitizing when administered by intradermal injection to albino Hartley-strain guinea pigs (n = 5).[24]

DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

A product containing dimethicone/polyglycerin-3 crosspolymer (~40% in dimethicone; 0.4 g) was not sensitizing to guinea pigs (n = 6/sex).[26]

DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER

In a dermal sensitization assay using albino Hartley-derived guinea pigs (n = 5/sex), a product containing dimethicone/phenyl vinyl dimethicone crosspolymers (~16%) was not sensitizing.[25]

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER

In a dermal sensitization assay using albino Hartley-derived guinea pigs (n = 5/sex), a product containing dimethicone/ vinyl dimethicone crosspolymers (~24%) was not sensitizing.[27]

DIPHENYL DIMETHICONE/VINYL DIPHENYL DIMETHICONE SILSESQUIOXANE CROSSPOLYMER

In a dermal sensitization assay using albino Hartley-derived guinea pigs (n = 6/sex), diphenyl dimethicone/vinyl diphenyl dimethicone silsesquioxane crosspolymer (100%) was not sensitizing.[28]

LAURYL DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

In a dermal sensitization assay using albino Hartley-derived guinea pigs (n = 6/sex), lauryl dimethicone/polyglycerin-3 crosspolymer (40% in mineral oil) was not sensitizing.[29]

LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER

In a local lymph node assay, lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer (1.5%, 3%, and 7.5% w/v) was not a sensitizer.[30]

PEG-15/LAUREL POLYDIMETHYLSILOXYETHY DIMETHICONE CROSSPOLYMER

In a local lymph node assay using mice, PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer (1.5%, 3%, and 7.5% w/v) was not a sensitizer.[32]

POLYGLYCERYL-3/LAURYL POLYDIMETHYLSILOXYETHY DIMETHICONE CROSSPOLYMER

In a local lymph node assay using mice, polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer (1.5%, 3%, and 7.5% w/v) was not a sensitizer.[33]

VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER

In a dermal sensitization assay using albino Hartley-derived guinea pigs (n = 10), lauryl dimethicone/polyglycerin-3 crosspolymer (50% in vaseline; 0.1 g) was not sensitizing.[36]

VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer (20% in isododecane) was not sensitizing to guinea pigs.[10]

Dermal – Human

DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER

In a human repeated insult patch test (HRIPT; n = 100), dimethicone/bis-isobutyl PPG-20 crosspolymer (70% in IDNP) was not sensitizing. There were no reactions during the challenge phase.[23]

DIMETHICONE CROSSPOLYMER

In a HRIPT (n = 101) of dimethicone crosspolymer (100%; 0.2 g), there were no adverse reactions of any kind during the course of this study. Dimethicone crosspolymer was not sensitizing.[23]

DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER

In a HRIPT (n = 55) of dimethicone/divinyldimethicone/silsesquioxane crosspolymer (30% in corn oil), there were no adverse reactions of any kind during the course of this study.[38]

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER

In two modified human repeated insult patch tests (n = 107), a facial lotion containing dimethicone/vinyl dimethicone crosspolymer (1%) was not sensitizing.[39]

SUMMARY

Dimethicone crosspolymers function in cosmetics as absorbents, bulking agents, film formers, hair conditioning agents, skin-conditioning agents-emollient, slip modifiers, surface modifiers, and viscosity increasing agents-nonaqueous. The 62 dimethicone crosspolymer ingredients in this report are silicone elastomers comprised of dimethicone copolymers that are crosslinked with a bi-functional agent.

These crosspolymer ingredients are typically supplied as swollen gels that contain various oils (e.g., silicone oils such as dimethicone). They are not soluble in water. Dimethicone/divinyldimethicone/silsesquioxane crosspolymer has a spherical shape with a particle diameter ranging from 2 – 10 μm.

Heavy metals, polycyclic aromatic hydrocarbons, organohalogen compounds, or nitrosamines were not detected in several dimethicone crosspolymers. Residuals from manufacturing of crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone corsspolymer included low levels of platinum tert-butanol, iso-dodecane, vinyl acetate, vinyl tert-decanoate, crotonic acid, isopropanol, and ethyl acetate.

Dimethicone/vinyl dimethicone crosspolymer and dimethicone crosspolymer have the greatest number of uses at 457 and 442, respectively.

Reported use and use concentration data were available for:

- Behenyl dimethicone/bis-vinyldimethicone crosspolymer
- C30-45 alkyl cetearyl dimethicone crosspolymer
- C4-24 alkyl dimethicone/divinyldimethicone crosspolymer
- Cetearyl dimethicone crosspolymer
- Dimethicone/bis-isobutyl PPG-20 crosspolymer
- Dimethicone crosspolymer
- Dimethicone crosspolymer-3
- Dimethicone/divinyldimethicone/silsesquioxane crosspolymer
- Dimethicone/PEG-10/15 crosspolymer
- Dimethicone/phenyl vinyl dimethicone crosspolymer
- Dimethicone/vinyl dimethicone crosspolymer
- Dimethicone/vinyltrimethylsiloxysilicate crosspolymer
- Diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer
- Divinyldimethicone/dimethicone crosspolymer
- Lauryl dimethicone/ polyglycerin-3 crosspolymer
- PEG-10 dimethicone crosspolymer
- PEG-12 dimethicone crosspolymer
- PEG-15/lauryl dimethicone crosspolymer
- Silicone quaternium-16/glycidoxy dimethicone crosspolymer
- Vinyl dimethicone/lauryl dimethicone crosspolymer
- Vinyl dimethicone/methicone silsesquioxane crosspolymer.

Reported uses, but not use concentration data, were available for:

- C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer
- Dimethicone/polyglycerin-3 crosspolymer

- Isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer
- PEG-10 dimethicone/vinyl dimethicone crosspolymer was reported to be used in 7 leave-on products.
- Styrene/acrylates/dimethicone acrylate crosspolymer.

Use concentration data only were available for:

- Cetyl dimethicone/bis-vinyldimethicone crosspolymer
- Dimethicone/PEG-10 crosspolymer
- Dimethicone/PPG-20 crosspolymer
- PEG-10/lauryl dimethicone crosspolymer
- Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer.

There were no reported uses or use concentrations for:

- Acrylates/bis-hydroxypropyl dimethicone crosspolymer
- Bis-phenylisopropyl phenylisopropyl dimethicone/vinly 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/methyl methacrylate crosspolymer
- cetyl dimethicone/bis-vinyldimethicone crosspolymer
- cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer
- crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer
- dimethicone/divinyldimethicone/silsesquioxane crosspolymer
- dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer
- dimethicone/PEG-15 crosspolymer
- dimethicone/titanate crosspolymer
- diphenyl dimethicone crosspolymer
- hydroxypropyl dimethicone/polysorbate 20 crosspolymer
- lauryl dimethicone PEG-15 crosspolymer
- lauryl dimethicone/polyglycerin-3 crosspolymer
- lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer
- PEG-8 dimethicone/polysorbate 20 crosspolymer
- PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer
- PEG-12 dimethicone/PPG-20 crosspolymer
- PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer
- polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer
- polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone 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
- vinyldimethyl/trimethylsiloxysilicate/ dimethicone crosspolymer
- vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer.

Dimethicone crosspolymer had a dermal LD_{50} of > 2000 mg/kg in rabbits. The oral LD_{50} of dimethicone crosspolymer was > 2000 mg/kg for rats. The acute inhalation LC_{50} of crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer at 10% over 4 h for rats was > 5.29 mg/L.

Dimethicone/bis-isobutyl PPG-20 crosspolymer at 1000 mg/kg/d was not toxic when orally administered to rats for 14 days.

In an agar diffusion cytotoxicity test, dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer was not cytotoxic to mammal cell cultures.

Dimethicone crosspolymer and several other ingredients were not mutagenic to *S. typhimurium* and *E. coli* with or without metabolic activation up to 312.5 - 5000 μg/plate.

Several of the dimethicone crosspolymers were not dermally irritating when administered to rabbits up to 100%. However, dimethicone/vinyl dimethicone crosspolymer at ~16% and dimethicone/vinyl dimethicone crosspolymer at ~24%

were mild irritants to rabbits.

Dimethicone crosspolymer was not an ocular irritant to rabbits at 100%. In a Skin ZK-1200 ocular assay, dimethicone/phenyl vinyl dimethicone crosspolymer was not predicted to be an ocular irritant. Dimethicone/ vinyltrimethylsiloxysilicate crosspolymer was not an ocular irritant to rabbits.

Dimethicone crosspolymer was not sensitizing to guinea pigs at 100%.

Several dimethicone crosspolymer were not sensitizing to guinea pigs up to 12% - 100%.

A product containing dimethicone/vinyl dimethicone crosspolymer at 1% was not sensitizing in an HRIPT. In an HRIPT of dimethicone/divinyldimethicone/silsesquioxane crosspolymer at 30%, there were no adverse reactions of any kind during the course of this study.

No published studies regarding toxicokinetics, repeated dose toxicity, reproductive or developmental toxicity, or carcinogenicity were discovered and no unpublished data for these endpoints were provided.

DISCUSSION

The Panel determined that the available data on acute toxicity, genotoxicity, irritation, and sensitization were adequate for assessing the safety of these ingredients.

The Panel noted the lack of toxicokinetics, repeated dose toxicity, carcinogenicity, and reproductive/developmental toxicology data for the dimethicone crosspolymers in this safety assessment. The Panel was not concerned about these gaps in information because these ingredients are large polymers that will not penetrate the skin. Also, the silicone backbone is stable under anticipated conditions of use and these ingredients do not contain monomers above the levels of toxicological concern. There are multiple animal irritation and sensitization studies as well as two HRIPT studies that were negative for effects. Ames tests were negative for three of these ingredients.

The Panel did express concern over the absence of information on the levels of residual monomers and catylysts. The monomers of concern include:

- α-methylstyrene
- bis-vinyldimethicone
- methyl methacrylate
- butyldimethylsilylmethacrylate
- vinyl cyclohexene oxide
- vinyl acetate
- α,ω-divinyl alkenes (C4-20)
- bis-vinyl phenylmethyldimethicone
- allyl alcohol
- isobutanol
- titanium species used in crosslinking [(0-IPr)4 or (0-iPr)2Cl2]
- unidentified diamine crosslinking agent in silicone quaternium-16/glycidoxy dimethicone crosspolymer
- styrene
- divinyl benezene
- allyl polyglyceryl-3
- bisvinyl trifluoroproyl methicone (if $n \leq \sim 8$).

In those cases where data were available, the monomer levels were low (e.g., vinyl acetate < 100 ppm in crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer) or below the limis of detection. In those cases where data were not available, the Panel determined that monomer levels would be very low or undetectable because any residual monomers/catalys are likely entrapped in the silicone backbone of these crosspolymers. Any monomers not so trapped are likely to disappear quickly because of their high volatility. This would be true because in general, based on Panel members experience, these volatile monomers have a distinctive odor that would render crosspolymer ingredients problematic for use in cosmetics. For all of these reasons, the Panel determided that current methods of manufacture are adequate to assure monomer levels are as low a reasonably achievable, but urged ingredient suppliers to continue to take steps to ensure that residual monomers and catalysts remain below any level of toxicological concern and as low at reasonably achievable.

The Panel discussed the issue of incidental inhalation exposure from face powders, foot powders and sprays, perfumes, and hair sprays. The data available from one acute inhalation exposure study indicated that the LC_{50} for crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone is greater than 5.29 mg/L. The Panel concluded that the sizes of a substantial majority of the particles of these ingredients, as manufactured, are larger than the respirable range and/or aggregate and agglomerate to form much larger particles in formulation. These ingredients are reportedly used at concentrations up to 20% in spray and up to 46% in powder cosmetic products that may become airborne. The Panel noted that 95% – 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, these ingredients are not likely to casue direct toxic effect in the upper respiratory tract, based on the chemical and biological properties of the dimethicone crosspolymers. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. The Panel considered other data available to characterize the potential for dimethicone crosspolymers to cause genotoxicity, irritation, and sensitization. They noted the lack of systemic toxicity in acute oral exposure studies, little or no irritation or sensitization in multiple tests of dermal and ocular exposure, and the absence of genotoxicity in multiple Ames tests. In addition, these ingredients are large macromolecules, insoluble in water, and chemically inert under physiological conditions or conditions of use, which supports the view that they are unlikely to be absorbed or cause local effects in the respiratory tract. A detailed discussion 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 the present practices of use and concentration described in this safety assessment:

- 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/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*

*Not reported in use. Were ingredients in this group to be 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 AND FIGURES

Table 1. Definitions and functions of the ingredients in this safety assessment.[1]
(The *italicized text* below represents additions made by CIR staff.)

Ingredient CAS No.	Definition	Function
Acrylates/Bis-Hydroxypropyl Dimethicone Crosspolymer	Acrylates/Bis-Hydroxypropyl Dimethicone Crosspolymer is a crosslinked polymer of bis-hydroxypropyl dimethicone, and one or more monomers consisting of acrylic acid, methacrylic acid, or one of their simple esters. *Herein, simple esters means methyl, ethyl, propyl, or butyl esters.*	Absorbent, film former, skin protectant, viscosity increasing agent-nonaqueous
Behenyl Dimethicone/Bis-Vinyldimethicone Crosspolymer	Behenyl Dimethicone/Bis-Vinyldimethicone Crosspolymer is structurally defined. *It is a copolymer of behenyl dimethicone crosslinked with divinyl dimethicone.*	Skin-conditioning agent-emollient
Bis-Phenylisopropyl Phenylisopropyl Dimethicone/ Vinyl Dimethicone Crosspolymer	Bis-Phenylisopropyl Phenylisopropyl Dimethicone/Vinyl Dimethicone Crosspolymer is a copolymer of phenylisopropyl dimethicone crosslinked with vinyl dimethicone.	Humectant
Bis-Vinyldimethicone/Bis-Isobutyl PPG-20 Crosspolymer	Bis-Vinyldimethicone/Bis-Isobutyl PPG-20 Crosspolymer is a crosslinked polymer of Bis-Vinyldimethicone partially crosslinked with methylhydrogen cyclic siloxanes and then further crosslinked with bis-methallyl PPG-20.	
Bis-Vinyldimethicone Crosspolymer	Bis-Vinyldimethicone Crosspolymer is structurally defined. *It is a copolymer of Dimethicone crosslinked with divinyl dimethicone*.	None listed
Bis-Vinyldimethicone/PEG-10 Dimethicone Crosspolymer	Bis-Vinyldimethicone/PEG-10 Dimethicone Crosspolymer is a copolymer of PEG-10 Dimethicone crosslinked with Vinyl Dimethicone.	Emulsion stabilizer, film former, skin-conditioning agent-miscellaneous, slip modifier, viscosity increasing agent-nonaqueous
Bis-vinyldimethicone/PPG-20 crosspolymer	Bis-vinyldimethicone/PPG-20 crosspolymer is a crosslinked polymer of bis-vinyldimethicone partially crosslinked with methylhydrogen cyclic siloxanes and the further crosslinked with bis-ally PPG-20.	Skin-conditioning agent-emollient; viscosity increasing agent-nonaqueous
Butyldimethicone Methacrylate/Methyl Methacrylate Crosspolymer	Butyldimethicone Methacrylate/Methyl Methacrylate Crosspolymer is a copolymer of butyl dimethicone methacrylate and methyl methacrylate monomers crosslinked with ethylene glycol dimethacrylate.	Film former, hair conditioning agent, skin-conditioning agent-emollient
C30-45 Alkyl Cetearyl Dimethicone Crosspolymer 443892-05-5	C30-45 Alkyl Cetearyl Dimethicone Crosspolymer is a copolymer of C30-45 alkyl cetearyl dimethicone crosslinked with vinyl cyclohexene oxide.	Dispersing agent-nonsurfactant, film former, skin-conditioning agent-occlusive, slip modifier, viscosity increasing agent-nonaqueous
C4-24 Alkyl Dimethicone/ Divinyldimethicone Crosspolymer	C4-24 Alkyl Dimethicone/Divinyldimethicone Crosspolymer is a copolymer of C4-24 alkyl dimethicone crosslinked with divinyldimethicone.	Dispersing agent-nonsurfactant, film former, skin-conditioning agent-occlusive, slip modifier, viscosity increasing agent-nonaqueous
C30-45 Alkyl Dimethicone/ Polycyclohexene Oxide Crosspolymer 330809-27-3 389082-70-6	C30-45 Alkyl Dimethicone/Polycyclohexene Oxide Crosspolymer is C30-45 Alkyl Dimethicone cross-linked with a polyether made from vinyl cyclohexene oxide.	Dispersing agent-nonsurfactant, film former, skin-conditioning agent-occlusive, slip modifier, viscosity increasing agent-nonaqueous
Cetearyl Dimethicone Crosspolymer 756876-51-4	Cetearyl Dimethicone Crosspolymer is a copolymer of cetearyl dimethicone crosslinked with vinyl cyclohexene oxide.	Film former; hair fixative
Cetearyl Dimethicone/Vinyl Dimethicone Crosspolymer	Cetearyl Dimethicone/Vinyl Dimethicone Crosspolymer is a copolymer of cetearyl dimethicone crosslinked with vinyl dimethylpolysiloxane.	Film former; hair fixative
Cetyl Dimethicone/Bis-Vinyldimethicone Crosspolymer	Cetyl Dimethicone/Bis-Vinyldimethicone Crosspolymer is structurally defined. *It is a copolymer of cetyl dimethicone crosslinked with divinyl dimethicone.*	Skin-conditioning agent-emollient
Cetyl Hexacosyl Dimethicone/ Bis-Vinyldimethicone Crosspolymer	Cetyl Hexacosyl Dimethicone/Bis-Vinyldimethicone Crosspolymer is a crosslinked polymer of cetyl hexacosyl dimethicone and bis-vinyldimethicone.	Skin-conditioning agent-emollient
Crotonic Acid/Vinyl C8-12 Isoalkyl Esters/VA/Bis-Vinyldimethicone Crosspolymer	Crotonic Acid/Vinyl C8-12 Isoalkyl Esters/VA/Bis-Vinyldimethicone Crosspolymer is a copolymer of crotonic acid, vinyl C8-12 isoalkyl esters and vinyl acetate crosslinked with bis-vinyldimethicone.	Film former; hair conditioning agent; hair fixative
Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer	Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer is a crosslinked polymer of Hydrogen Dimethicone crosslinked with bis-methallyl PPG-20.	Skin-conditioning agents-emollient; viscosity increasing agent-nonaqueous

Table 1. Definitions and functions of the ingredients in this safety assessment.[1]
(The *italicized text* below represents additions made by CIR staff.)

Ingredient CAS No.	Definition	Function
Dimethicone/Bis-Vinyldimethicone/ Silsesquioxane Crosspolymer	Dimethicone/Bis-Vinyldimethicone/Silsesquioxane Crosspolymer is a copolymer of dimethicone, bis-vinyldimethicone and silsesquioxane monomers.	Skin-conditioning agent-miscellaneous
Dimethicone Crosspolymer 213629-14-2 [*CAS No. is specific to C5*]	Dimethicone Crosspolymer is a polymer of dimethicone crosslinked with a C3 to C20 alkyl group.	Dispersing agent-nonsurfactant; emulsion stabilizer; hair fixative; viscosity increasing agent-nonaqueous
Dimethicone Crosspolymer-3	Dimethicone Crosspolymer-3 is structurally defined. *It is a polymer of dimethicone, crosslinked with ethylene linkages to form cyclized-like repeat units.*	Skin-conditioning agent-miscellaneous; slip modifier
Dimethicone/ Divinyldimethicone/ Silsesquioxane Crosspolymer	Dimethicone/Divinyldimethicone/Silsesquioxane Crosspolymer is a crosslinked copolymer of dimethicone, divinyldimethicone, and silsesquioxane monomers.	Anticaking agent; humectant; skin protectant; viscosity increasing agent-nonaqueous
Dimethicone/Lauryl Dimethicone/Bis-Vinyldimethicone Crosspolymer	Dimethicone/Lauryl Dimethicone/Bis-Vinyldimethicone Crosspolymer is a copolymer of dimethicone and lauryl dimethicone crosslinked with bis-vinyl dimethicone.	Emulsion stabilizer; skin-conditioning agent-miscellaneous; viscosity increasing agent-nonaqueous
Dimethicone/ PEG-10 Crosspolymer	Dimethicone/PEG-10 Crosspolymer is a copolymer of dimethylpolysiloxane crosslinked with diallyl PEG-10.	Skin-conditioning agent-emollient; surfactant-dispersing agent; surfactant-emulsifying agent; viscosity increasing agent-aqueous
Dimethicone/ PEG-10/15 Crosspolymer	Dimethicone/PEG-10/15 Crosspolymer is a copolymer of dimethicone crosslinked with a mixture of PEG-10 and PEG-15 diallyl ethers.	Emulsion stabilizer; viscosity increasing agent
Dimethicone/ PEG-15 Crosspolymer	Dimethicone/PEG-15 Crosspolymer is a polymer of dimethicone crosslinked with PEG-15 diallyl ether.	Deodorant agent; emulsion stabilizer; skin-conditioning agent-miscellaneous; sunscreen agent; surfactant-dispersing agent; surfactant-emulsifying agent; viscosity increasing agent-aqueous
Dimethicone/ Phenyl Vinyl Dimethicone Crosspolymer	Dimethicone/Phenyl Vinyl Dimethicone Crosspolymer is a copolymer of dimethylpolysiloxane crosslinked with phenyl vinyl dimethylpolysiloxane.	Viscosity increasing agent-nonaqueous
Dimethicone/Polyglycerin-3 Crosspolymer	Dimethicone/Polyglycerin-3 Crosspolymer is the polymer of dimethicone crosslinked with diallyl polyglycerin-3.	Skin-conditioning agent-miscellaneous; surfactant-cleansing agent; surfactant-emulsifying agent; surfactant-solubilizing agent; viscosity increasing agent-nonaqueous
Dimethicone/PPG-20 Crosspolymer	Dimethicone/PPG-20 Crosspolymer is a crosslinked polymer of hydrogen dimethicone crosslinked with bis-allyl PPG-20.	Skin-conditioning agent-emollient; viscosity increasing agent-nonaqueous
Dimethicone/Titanate Crosspolymer	Dimethicone/Titanate Crosspolymer is the crosslinked polymer formed by the reaction of titanium tetraisopropoxide and methoxy dimethicone.	Bulking agent
Dimethicone/Vinyl Dimethicone Crosspolymer	Dimethicone/Vinyl Dimethicone Crosspolymer is a copolymer of dimethylpolysiloxane crosslinked with vinyl dimethylpolysiloxane.	Viscosity increasing agent-nonaqueous
Dimethicone/ Vinyltrimethylsiloxysilicate Crosspolymer	Dimethicone/Vinyltrimethylsiloxysilicate Crosspolymer is a copolymer of dimethylpolysiloxane crosslinked with vinyltrimethylsiloxysilicate.	Film former; viscosity increasing agent-nonaqueous
Diphenyl Dimethicone Crosspolymer	Diphenyl Dimethicone Crosspolymer is crosslinked Diphenyl Dimethicone. *Wherein the crosslinking agent is not disclosed.*	Skin-conditioning agent-miscellaneous; slip modifier
Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/ Silsesquioxane Crosspolymer	Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer is a crosslinked copolymer of diphenyl dimethicone, vinyl diphenyl dimethicone and silsesquioxane monomers.	Viscosity increasing agent-nonaqueous
Divinyldimethicone/ Dimethicone Crosspolymer	Divinyldimethicone/Dimethicone Crosspolymer is dimethicone crosslinked with divinyldimethicone.	Film former; skin-conditioning agent-miscellaneous; viscosity increasing agent-nonaqueous
Hydroxypropyl Dimethicone/ Polysorbate 20 Crosspolymer	Hydroxypropyl Dimethicone/Polysorbate 20 Crosspolymer is a copolymer of hydroxypropyldimethicone and polysorbate 20 crosslinked with succinic acid.	Hair fixatives
Isopropyl Titanium Triisostearate/ Triethoxysilylethyl Polydimethylsiloxyethyl Dimethicone Crosspolymer	Isopropyl Titanium Triisostearate/Triethoxysilylethyl Polydimethylsiloxyethyl Dimethicone Crosspolymer is a complex polymer formed by the hydrolysis and condensation of isopropyl titanium triisostearate with triethoxysilylethyl polydimethylsiloxyethyl dimethicone.	Surface modifier

Table 1. Definitions and functions of the ingredients in this safety assessment.[1]
(The *italicized text* below represents additions made by CIR staff.)

Ingredient CAS No.	Definition	Function
Lauryl Dimethicone PEG-15 Crosspolymer	Lauryl Dimethicone PEG-15 Crosspolymer is a crosslinked copolymer formed from *diallyl* PEG-15 and lauryl dimethicone.	Surfactant-dispersing agent; surfactant-emulsifying agent; viscosity increasing agent-aqueous
Lauryl Dimethicone/ Polyglycerin-3 Crosspolymer	Lauryl Dimethicone/Polyglycerin-3 Crosspolymer is a polymer of lauryl dimethicone crosslinked with diallyl polyglycerin-3.	Skin-conditioning agent-miscellaneous; surfactant-cleansing agent; surfactant-emulsifying agent; surfactant-solubilizing agent; viscosity increasing agent-nonaqueous
Lauryl Polydimethylsiloxyethyl Dimethicone/Bis-Vinyldimethicone Crosspolymer	Lauryl Polydimethylsiloxyethyl Dimethicone/Bis-Vinyldimethicone Crosspolymer is a copolymer of lauryl polydimethylsiloxyethyl dimethicone crosslinked by bis-vinyldimethicone	Viscosity increasing agent-nonaqueous
PEG-10 Dimethicone Crosspolymer	PEG-10 Dimethicone Crosspolymer is a crosslinked copolymer formed from *diallyl* PEG-10 and dimethicone	Viscosity increasing agent-nonaqueous
PEG-12 Dimethicone Crosspolymer	PEG-12 Dimethicone Crosspolymer is a copolymer of PEG-12 dimethicone crosslinked with a C3-20 diene.	Dispersing agent-nonsurfactant; emulsion stabilizer; surfactant-emulsifying agent; viscosity increasing agent-nonaqueous
PEG-8 Dimethicone/ Polysorbate 20 Crosspolymer	PEG-8 Dimethicone/Polysorbate 20 Crosspolymer is a copolymer of a complex mixture of esters formed from the reaction of PEG-8 dimethicone and polysorbate 20 crosslinked with succinic acid.	Emulsion stabilizer
PEG-12 Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer	PEG-12 Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer is a polymer of PEG-12 dimethicone crosslinked with bis-methallyl PPG-20.	None reported
PEG-12 Dimethicone/ PPG-20 Crosspolymer	PEG-12 Dimethicone/PPG-20 Crosspolymer is a crosslinked polymer of hydrogen dimethicone crosslinked with bis-allyl PPG-20.	Skin-conditioning agent-emollient
PEG-10 Dimethicone/ Vinyl Dimethicone Crosspolymer	PEG-10 Dimethicone/Vinyl Dimethicone Crosspolymer is PEG-10 dimethicone crosslinked with vinyl dimethicone	Skin protectants; viscosity increasing agents-nonaqueous
PEG-10/Lauryl Dimethicone Crosspolymer	PEG-10/Lauryl Dimethicone Crosspolymer is a copolymer of Lauryl Dimethicone crosslinked with diallyl PEG-10.	Surfactant-dispersing agent; viscosity increasing agent-aqueous
PEG-15/Lauryl Dimethicone Crosspolymer	PEG-15/Lauryl Dimethicone Crosspolymer is a copolymer of lauryl dimethicone crosslinked with diallyl PEG-15.	Viscosity increasing agent-aqueous
PEG-15/Lauryl Polydimethylsiloxyethyl Dimethicone Crosspolymer	PEG-15/Lauryl Polydimethylsiloxyethyl Dimethicone Crosspolymer is a copolymer of lauryl polydimethylsiloxyethyl dimethicone crosslinked with diallyl PEG-15.	Viscosity increasing agent-nonaqueous
Perfluorononyl Dimethicone/ Methicone/Amodimethicone Crosspolymer	Perfluorononyl Dimethicone/Methicone/Amodimethicone Crosspolymer is a crosslinked silicone polymer that is formed by reacting a copolymer of perfluorononyl dimethicone and methicone with methicone and amodimethicone	Slip modifier; surface modifier
Polydimethylsiloxyethyl Dimethicone/Bis-Vinyldimethicone Crosspolymer	Polydimethylsiloxyethyl Dimethicone/Bis-Vinyldimethicone Crosspolymer is a copolymer of polydimethylsiloxyethyl dimethicone crosslinked with bis-vinyldimethicone	Viscosity increasing agent-nonaqueous
Polyglyceryl-3/Lauryl Polydimethylsiloxyethyl Dimethicone Crosspolymer	Polyglyceryl-3/Lauryl Polydimethylsiloxyethyl Dimethicone Crosspolymer is a copolymer of lauryl polydimethylsiloxyethyl dimethicone crosslinked with an *di*allyl polyglyceryl-3.	Viscosity increasing agent-nonaqueous
Silicone Quaternium-16/ Glycidoxy Dimethicone Crosspolymer	Silicone Quaternium-16/Glycidoxy Dimethicone Crosspolymer is silicone quaternium-16 that has been crosslinked with glycidoxy dimethicone.	Hair conditioning agent; hair fixative
Styrene/Acrylates/ Dimethicone Acrylate Crosspolymer	Styrene/Acrylates/Dimethicone Acrylate Crosspolymer is a copolymer of styrene, dimethicone acrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked with divinylbenzene. *Herein, simple esters means methyl, ethyl, propyl, or butyl esters*	Skin-conditioning agent-miscellaneous
Trifluoropropyl Dimethicone/ PEG-10 Crosspolymer	Trifluoropropyl Dimethicone/PEG-10 Crosspolymer is a polymer of trifluoropropyl dimethicone crosslinked with PEG-10 diallyl ether.	Skin-conditioning agent-miscellaneous; surfactant-dispersing agent; surfactant-emulsifying agent; viscosity increasing agent-nonaqueous

Table 1. Definitions and functions of the ingredients in this safety assessment.[1]
(The *italicized text* below represents additions made by CIR staff.)

Ingredient CAS No.	Definition	Function
Trifluoropropyl Dimethicone/ Trifluoropropyl Divinyldimethicone Crosspolymer	Trifluoropropyl Dimethicone/Trifluoropropyl Divinyldimethicone Crosspolymer is a copolymer of trifluoropropyl dimethicone crosslinked with trifluoropropyl divinyldimethicone.	Skin-conditioning agent-miscellaneous; surfactant-dispersing agent; viscosity increasing agent-nonaqueous
Trifluoropropyl Dimethicone/Vinyl Trifluoropropyl Dimethicone/ Silsesquioxane Crosspolymer	Trifluoropropyl Dimethicone/Vinyl Trifluoropropyl Dimethicone/Silsesquioxane Crosspolymer is a crosslinked copolymer of trifluoropropyl dimethicone, vinyl trifluoropropyl dimethicone and silsesquioxane monomers.	Viscosity increasing agent-nonaqueous
Trimethylsiloxysilicate/ Dimethicone Crosspolymer	Trimethylsiloxysilicate/Dimethicone Crosspolymer is the product of the reaction between dimethicone and trimethylsiloxysilicate under conditions that produce rearrangement, condensation, and crosslinking of the dimethicone polymer onto the trimethylsiloxysilicate resin.	Antifoaming agent
Vinyl Dimethicone/Lauryl/ Behenyl Dimethicone Crosspolymer	Vinyl Dimethicone/Lauryl/Behenyl Dimethicone Crosspolymer is lauryl/behenyl dimethicone crosslinked with divinyl dimethicone.	Skin-conditioning agent-miscellaneous
Vinyl Dimethicone/ Lauryl Dimethicone Crosspolymer	Vinyl Dimethicone/Lauryl Dimethicone Crosspolymer is lauryl dimethicone crosslinked with divinyl dimethicone.	Surfactant-dispersing agent; viscosity increasing agent-nonaqueous
Vinyl Dimethicone/ Methicone Silsesquioxane Crosspolymer	Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer is a copolymer of methicone silsesquioxane crosslinked with *bis*-vinyl dimethylpolysiloxane.	Viscosity increasing agent-nonaqueous
Vinyldimethyl/ Trimethylsiloxysilicate/ Dimethicone Crosspolymer	Monograph in development	None reported
Vinyldimethyl/ Trimethylsiloxysilicate Stearyl Dimethicone Crosspolymer	Vinyldimethyl/Trimethylsiloxysilicate Stearyl Dimethicone Crosspolymer is stearyl methicone crosslinked with *bis*-vinyldimethyl/trimethylsiloxysilicate.	Absorbent; bulking agent; film former; viscosity increasing agent-nonaqueous

Table 2. Component ingredients previously reviewed by CIR.

Component ingredient	Conclusion	Reference
Acrylates copolymer	Safe for use in cosmetic ingredients when formulated to avoid skin irritation	40
Dimethicone, methicone, vinyl dimethicone	Safe as a cosmetic ingredient	2
PEG-8, -10, -15, -12,	Safe in the present practices of use and concentration	41
Polysorbate 20	Safe as a cosmetic ingredient in the concentration of present use	42
PPG-20	Safe for use in cosmetic products at concentrations up to 50%	43,44
Trimethylsiloxysilicate	Safe as used when formulated and delivered in the final product to be not irritating or sensitizing to the respiratory tract	45

Table 3. Chemical and physical properties of dimethicone crosspolymers

Property	Value	Reference
Acrylates/bis-hydroxypropyl dimethicone crosspolymer		
No data were discovered or submitted.		
Behenyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted.		
Bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer		
No data were discovered or submitted.		
Bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer		
No data were discovered or submitted.		

Table 3. Chemical and physical properties of dimethicone crosspolymers

Property	Value	Reference
Bis-vinyldimethicone crosspolymer		
No data were discovered or submitted.		
Bis-vinyldimethicone/PEG-10 dimethicone crosspolymer		
No data were discovered or submitted.		
Bis-vinyldimethicone/PPG-20 crosspolymer		
No data were discovered or submitted.		
Butyldimethicone methacrylate/methyl methacrylate crosspolymer		
No data were discovered or submitted.		
C30-45 alkyl cetearyl dimethicone crosspolymer		
No data were discovered or submitted.		
C4-24 alkyl dimethicone/divinyldimethicone crosspolymer		
No data were discovered or submitted.		
C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer		
No data were discovered or submitted.		
Cetearyl dimethicone crosspolymer		
No data were discovered or submitted.		
Cetearyl dimethicone/vinyl dimethicone crosspolymer		
No data were discovered or submitted.		
Cetyl dimethicone/bis-vinyldimethicone crosspolymer		
Physical form	Liquid	46
Water solubility 1% & 10%	Insoluble	46
Other solubility isopropyl alcohol 1% & 10%	Insoluble	46
mineral spirits 1% & 10%	Soluble	
mineral oil 1% & 10%	Soluble	
aromatic solvents 1% & 10%	Soluble	
cyclomethicone 1% & 10%	Soluble	
Cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted.		
Crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer		
Physical form	Granules	4
Density g/cm^3	1122	4
Water solubility	Dispersible	4
Other solubility cyclopentasiloxane	Insoluble	4
dimethicone	Insoluble	
isopropanol	1-10% soluble	
ethanol	Soluble	
acetone	Soluble	
isopropyl myristate	Insoluble	
ethyl acetate	Soluble	
butyl acetate	1%-10% soluble	
Dimethicone/bis-isobutyl ppg-20 crosspolymer		
No data were discovered or submitted.		
Dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer		
No data were discovered or submitted.		
Dimethicone crosspolymer		
No data were discovered or submitted.		

Table 3. Chemical and physical properties of dimethicone crosspolymers

Property	Value	Reference
Dimethicone crosspolymer-3		
No data were discovered or submitted.		
Dimethicone/divinyldimethicone/silsesquioxane crosspolymer		
Physical Form	Powder	12
Color	Off white	12
Odor	Typical	12
Vapor pressure mmHg@ 25°C	<0.1	6
Boiling Point °C	>300° (decomposes)	6
Water Solubility g/L @ °C & pH	Insoluble	6
Dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted.		
Dimethicone/PEG-10 crosspolymer		
No data were discovered or submitted.		
Dimethicone/PEG-10/15 crosspolymer		
No data were discovered or submitted.		
Dimethicone/PEG-15 crosspolymer		
No data were discovered or submitted.		
Dimethicone/phenyl vinyl dimethicone crosspolymer		
No data were discovered or submitted.		
Dimethicone/polyglycerin-3 crosspolymer		
No data were discovered or submitted.		
Dimethicone/PPG-20 crosspolymer		
No data were discovered or submitted.		
Dimethicone/titanate crosspolymer		
No data were discovered or submitted.		
Dimethicone/vinyl dimethicone crosspolymer		
No data were discovered or submitted.		
Dimethicone/vinyltrimethylsiloxysilicate crosspolymer		
No data were discovered or submitted.		
Diphenyl dimethicone crosspolymer		
No data were discovered or submitted.		
Diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer		
No data were discovered or submitted.		
Divinyldimethicone/dimethicone crosspolymer		
No data were discovered or submitted.		
Hydroxypropyl dimethicone/polysorbate 20 crosspolymer		
No data were discovered or submitted.		
Isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer		
No data were discovered or submitted.		
Lauryl dimethicone PEG-15 crosspolymer		
No data were discovered or submitted.		

Table 3. Chemical and physical properties of dimethicone crosspolymers

Property	Value	Reference
Lauryl dimethicone/polyglycerin-3 crosspolymer		
No data were discovered or submitted.		
Lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted.		
PEG-10 dimethicone crosspolymer		
No data were discovered or submitted.		
PEG-12 dimethicone crosspolymer		
No data were discovered or submitted.		
PEG-8 dimethicone/polysorbate 20 crosspolymer		
No data were discovered or submitted.		
PEG-12 dimethicone/PPG-20 crosspolymer		
No data were discovered or submitted.		
PEG-12 dimethicone/PPG-20 crosspolymer		
No data were discovered or submitted.		
PEG-10/lauryl dimethicone crosspolymer		
No data were discovered or submitted.		
PEG-15/lauryl dimethicone crosspolymer		
No data were discovered or submitted.		
PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer		
No data were discovered or submitted.		
Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer		
No data were discovered or submitted.		
Polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted.		
Polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer		
No data were discovered or submitted.		
Silicone quaternium-16/glycidoxy dimethicone crosspolymer		
No data were discovered or submitted.		
Styrene/acrylates/dimethicone acrylate crosspolymer		
No data were discovered or submitted.		
Trifluoropropyl dimethicone/PEG-10 crosspolymer		
No data were discovered or submitted.		
Trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer		
No data were discovered or submitted.		
Trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer		
No data were discovered or submitted.		
Trimethylsiloxysilicate/dimethicone crosspolymer		
No data were discovered or submitted.		
Vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer		
No data were discovered or submitted.		

Table 3. Chemical and physical properties of dimethicone crosspolymers

Property	Value	Reference
Vinyl dimethicone/lauryl dimethicone crosspolymer		
No data were discovered.		
Vinyl dimethicone/methicone silsesquioxane crosspolymer		
No data were discovered.		
Vinyldimethyl/trimethylsiloxysilicate/dimethicone crosspolymer		
No data were discovered.		
Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer		
No data were discovered.		

Table 3. Frequency of use according to duration and exposure of dimethicone crosspolymers.[13,14]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Behenyl dimethicone/bis-vinyldimethicone crosspolymer		**C30-45 alkyl cetearyl dimethicone crosspolymer**		**C4-24 alkyl dimethicone/ divinyldimethicone crosspolymer**		**C30-45 alkyl dimethicone/ polycyclohexene oxide crosspolymer**	
Total/range	**6**	**0.005-10**	**27**	**0.2-4**	**1**	**2**	**2**	NR
Duration of use								
Leave-on	6	0.005-10	25	0.2-4	1	2	2	NR
Rinse-off	NR	NR	2	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	2-10	5	0.6-4	NR	NR	NR	NR
Incidental ingestion	NR	0.005-2	NR	0.6	NR	NR	NR	NR
Incidental Inhalation-sprays	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-powders	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	6	0.01-10	27	0.2-4	1	2	2	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	0.005-2	NR	0.6	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency of use according to duration and exposure of dimethicone crosspolymers.[13,14]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Cetearyl dimethicone crosspolymer		Cetearyl dimethicone/bis-vinyl dimethicone crosspolymer		Cetyl dimethicone/bis-vinyldimethicone crosspolymer		Dimethicone/bis-isobutyl PPG-20 crosspolymer	
Total/range	**21**	**0.002-23**	**NR**	**0.001-0.005**	**NR**	**0.001-0.005**	**12**	**0.1-2**
Duration of use								
Leave-on	20	0.002-23	NR	0.001-0.005	NR	0.001-0.005	12	0.01-2
Rinse-off	1	0.2	NR	0.005	NR	0.005		
Diluted for (bath) use	NR	0.002	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	0.005	NR	0.005	1	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	1	0.1-0.2
Incidental Inhalation-sprays	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-powders	NR	0.02-0.6	NR	NR	NR	NR	NR	NR
Dermal contact	21	0.002-23	NR	0.001-0.005	NR	0.001-0.005	11	0.4-2
Deodorant (underarm)	NR	0.002	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	0.002		0.005	NR	0.005	1	0.1-0.2
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	Dimethicone crosspolymer		Dimethicone crosspolymer-3		Dimethicone/ divinyldimethicone/ silsesquioxane crosspolymer		Dimethicone/PEG-10 crosspolymer	
Total/range	**442**	**0.007-25**	**52**	**0.2-2**	**14**	**0.5-5**	**NR**	**0.5**
Duration of use								
Leave-on	430	0.02-25	52	0.2-2	14	0.5-5	NR	0.5
Rinse-off	12	0.007-5	NR	0.2	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	40	0.3-4	13	0.2	NR	NR	NR	NR
Incidental ingestion	9	0.1-12	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	27	NR	6	0.2	NR	NR	NR	NR
Incidental inhalation-powders	NR	0.03	NR	NR	NR	0.9	NR	NR
Dermal contact	420	0.03-25	43	0.2-2	14	0.5-5	NR	0.5
Deodorant (underarm)	11	0.3-0.5	NR	NR	NR	NR	NR	NR
Hair-noncoloring	10	0.007-11	NR	NR	NR	NR	NR	NR
Hair-coloring			NR	NR	NR	NR	NR	NR
Nail	1	4	NR	NR	NR	NR	NR	NR
Mucous Membrane	9	0.1-12	NR	NR	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency of use according to duration and exposure of dimethicone crosspolymers.[13,14]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Dimethicone/PEG-10/15 crosspolymer		**Dimethicone/phenyl vinyl dimethicone crosspolymer**		**Dimethicone/ polyglycerin-3 crosspolymer**		**Dimethicone/PPG-20 crosspolymer**	
Total/range	**52**	**0.03-3**	**10**	**0.8-2**	**7**	NR	NR	**0.2**
Duration of use								
Leave-on	51	0.03-3	10	0.8-2	7	NR	NR	0.2
Rinse-off	1	0.8	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	3	0.03-3	NR	0.8-2	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	3	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-powders	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	50	0.03-3	10	0.8-2	7	NR	NR	0.2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	2	0.8-2	NR	NR	NR	NR	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

	Dimethicone/vinyl dimethicone crosspolymer		**Dimethicone/ vinyltrimethylsiloxy-silicate crosspolymer**		**Diphenyl dimethicone/vinyl diphenyl dimethicone/ silsesquioxane crosspolymer**		**Divinyldimethicone/ dimethicone crosspolymer**	
Total/range	**457**	**0.003-46**	**14**	**0.04-6**	**13**	**0.1-7**	**4**	**0.007-0.7**
Duration of use								
Leave-on	444	0.003-46	14	0.04-6	13	0.1-7	4	0.007
Rinse-off	13	0.06-37	NR	NR	NR	NR	NR	0.007-0.7
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	59	0.02-33	2	0.04-6	NR	0.2-5	3	NR
Incidental ingestion	9	0.02-3	NR	NR	NR	0.1	NR	NR
Incidental Inhalation-sprays	24	0.2-0.5	NR	NR	NR	0.1	NR	NR
Incidental inhalation-powders	23	0.2-46	NR	NR	2	0.2-7	NR	NR
Dermal contact	433	0.02-46	14	0.04-6	13	0.1-7	4	0.7
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	14	0.2-3	NR	NR	NR	0.1	NR	0.007
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	0.003	NR	NR	NR	NR	NR	NR
Mucous Membrane	10	0.02-3	NR	NR	NR	0.1	NR	NR
Baby	1	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency of use according to duration and exposure of dimethicone crosspolymers.[13,14]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Isopropyl titanium triisostearate/ triethoxysilylethylpoly-dimethylsiloxyethyl dimethicone crosspolymer		**Lauryl dimethicone/ polyglycerin-3 crosspolymer**		**PEG-10 dimethicone crosspolymer**		**PEG-12 dimethicone crosspolymer**	
Total/range	**5**	NR	**3**	**2**	**15**	**0.6-2**	**28**	**0.3-2**
Duration of use		NR						
Leave-on	5	NR	NR	NR	15	0.6-2	25	0.5-2
Rinse-off	NR	NR	3	2	NR	NR	3	0.3
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	4	NR	NR	NR	1	NR	3	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	NR	NR	NR	NR	NR	NR	19	NR
Incidental inhalation-powders	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	5	NR	3	2	15	0.6-2	21	0.3-2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	17	0.5
Hair-noncoloring	NR	NR	NR	NR	NR	NR	6	0.3
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	0.3
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	PEG-10 dimethicone/vinyl dimethicone crosspolymer		**PEG-10/lauryl dimethicone crosspolymer**		**PEG-15/lauryl dimethicone crosspolymer**		**Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer**	
Total/range	**7**	NR	NR	**0.5-0.7**	**7**	**0.7-2**	NR	**0.7**
Duration of use								
Leave-on	7	NR	NR	0.5-0.7	4	0.7-2	NR	0.7
Rinse-off	NR	NR	NR	0.6	3	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	1	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	0.7
Incidental Inhalation-sprays	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-powders	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	7	NR	NR	0.5-0.7	7	0.7-2	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	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	0.7
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency of use according to duration and exposure of dimethicone crosspolymers.[13,14]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Silicone quaternium-16/ glycidoxy dimethicone crosspolymer		**Styrene/acrylates/ dimethicone acrylate crosspolymer**		**Vinyl dimethicone/lauryl dimethicone crosspolymer**		**Vinyl dimethicone/methicone silsesquioxane crosspolymer**	
Total/range	**6**	**0.003-3**	**1**	**0.09-2**	**3**	**0.09-2**	**105**	**0.1-20**
Duration of use								
Leave-on	2	0.003	1	NR	3	0.3-2	104	0.1-20
Rinse-off	4	1-3	NR	NR	NR	0.09	1	0.5-0.6
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	21	0.3-17
Incidental ingestion	NR	NR	NR	NR	NR	2	2	0.5
Incidental Inhalation-sprays	NR	NR	NR	NR	NR	NR	2	20
Incidental inhalation-powders	NR	NR	NR	NR	NR	NR	9	0.1-20
Dermal contact	NR	NR	NR	NR	2	1	102	0.1-20
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	6	0.003-3	NR	NR	1	0.09-0.3	1	0.5-2
Hair-coloring	NR	1	NR	NR	NR	NR	NR	
Nail	NR	NR	1	NR	NR	NR	NR	0.5
Mucous Membrane	NR	NR	NR	NR	NR	2	2	0.5
Baby	NR	NR	NR	NR	NR	NR	NR	NR

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

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

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

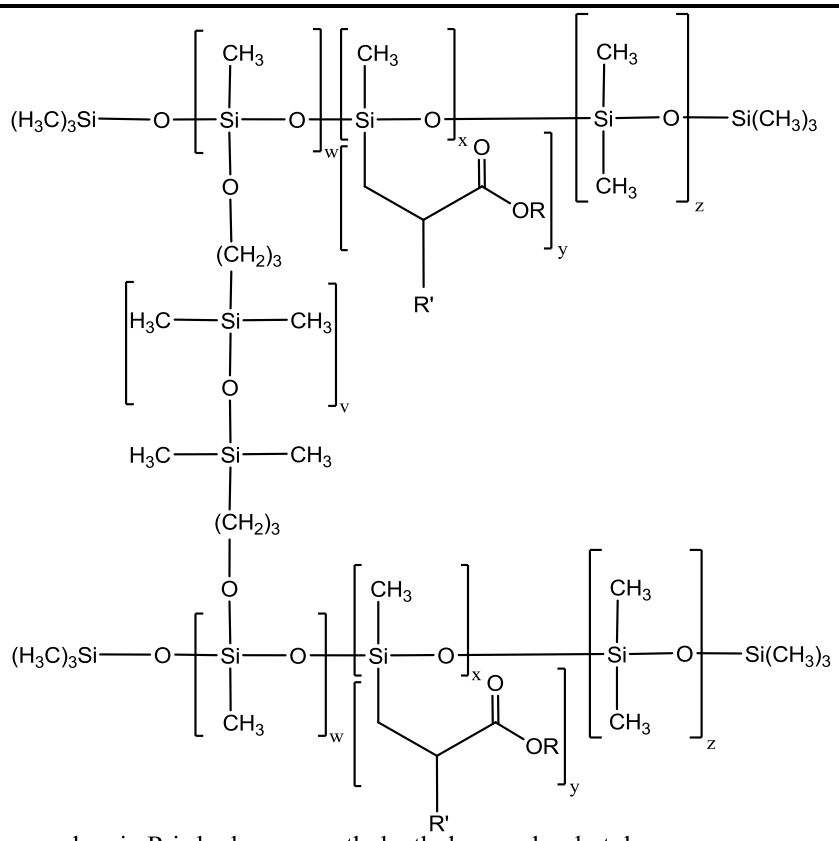
Ingredient	Idealized structure
Acrylates/bis-hydroxypropyl dimethicone crosspolymer	 wherein R is hydrogen, methyl, ethyl, propyl or butyl wherein R' is hydrogen or another dimethicone chain

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

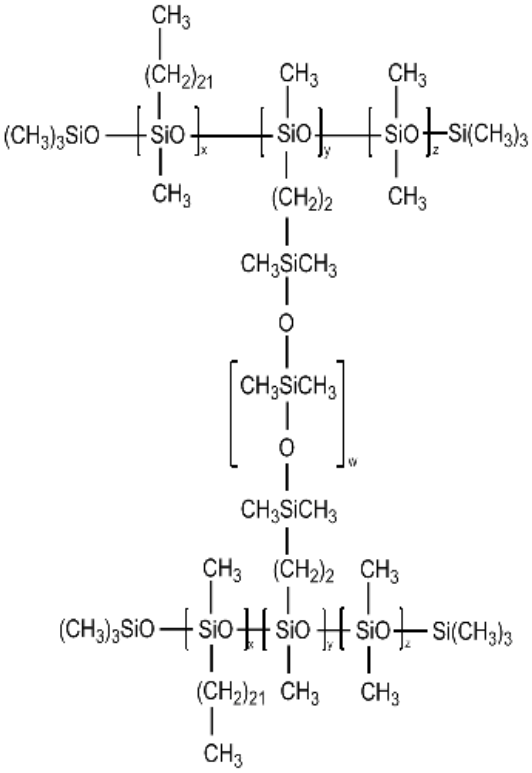
Ingredient	Idealized structure
Behenyl dimethicone/bis-vinyldimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

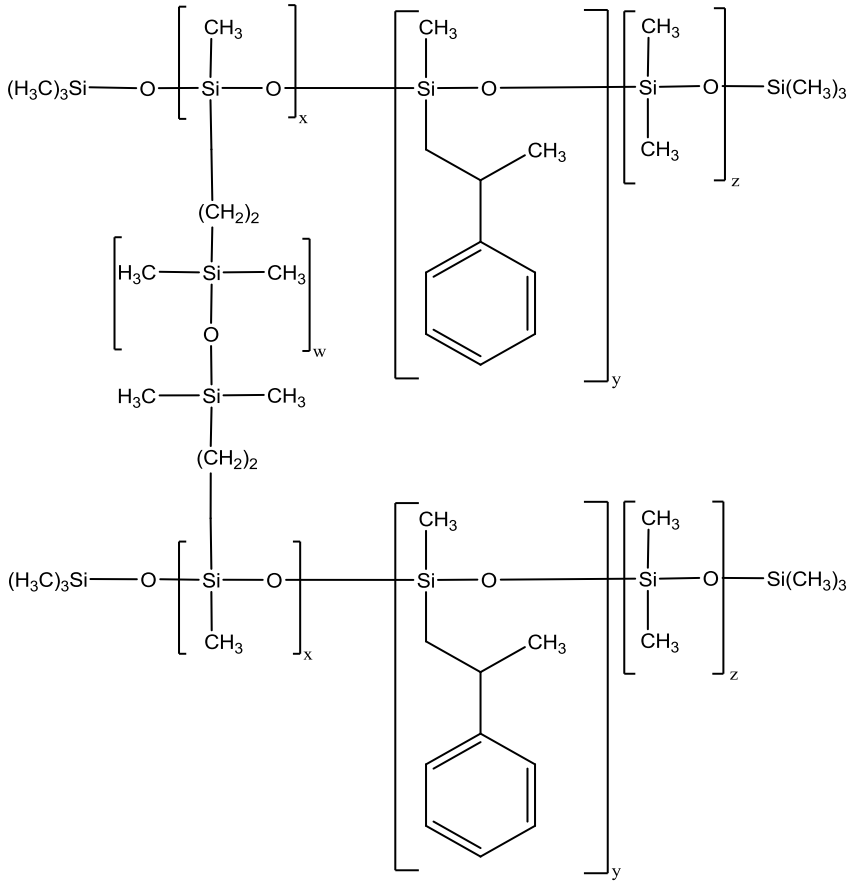
Ingredient	Idealized structure
Bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

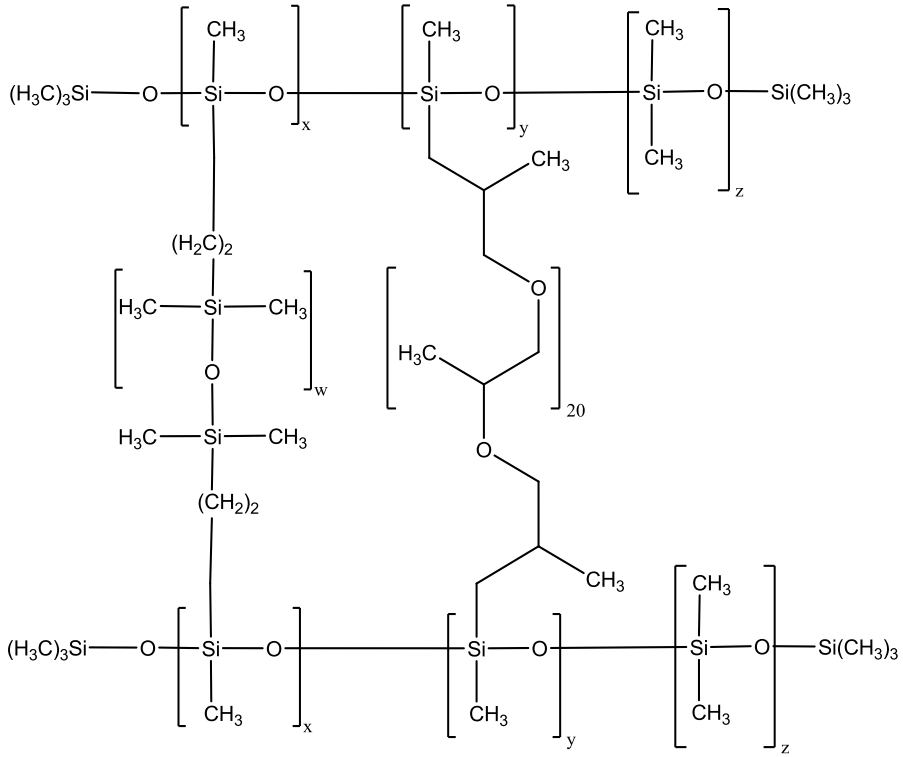
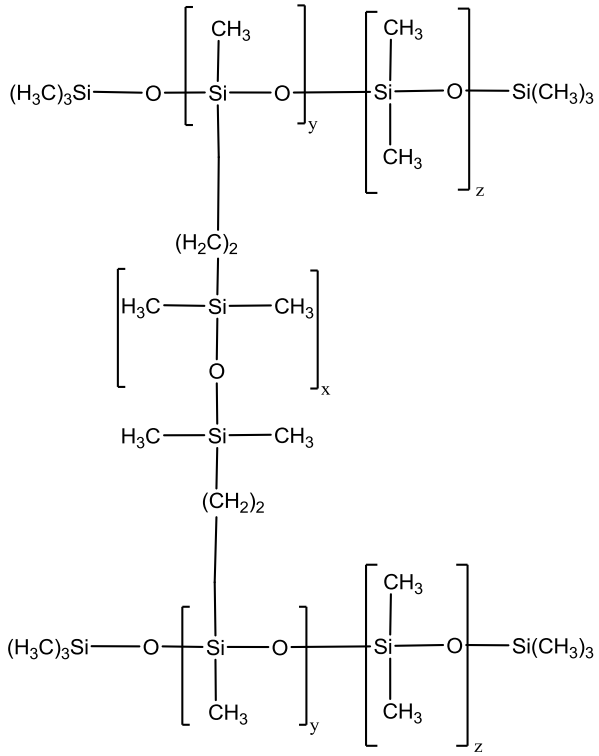
Ingredient	Idealized structure
Bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer	
Bis-vinyldimethicone crosspolymer	
Bis-Vinyldimethicone/ PPG-20 Crosspolymer	Bis-Vinyldimethicone/PPG-20 Crosspolymer is a crosslinked polymer of Bis-Vinyldimethicone partially crosslinked with methylhydrogen cyclic siloxanes and then further crosslinked with bis-allyl PPG-20. *The immense connectivity variability added by "methylhydrogen cyclic siloxanes" makes a structural representation of this ingredient quite challenging.*

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

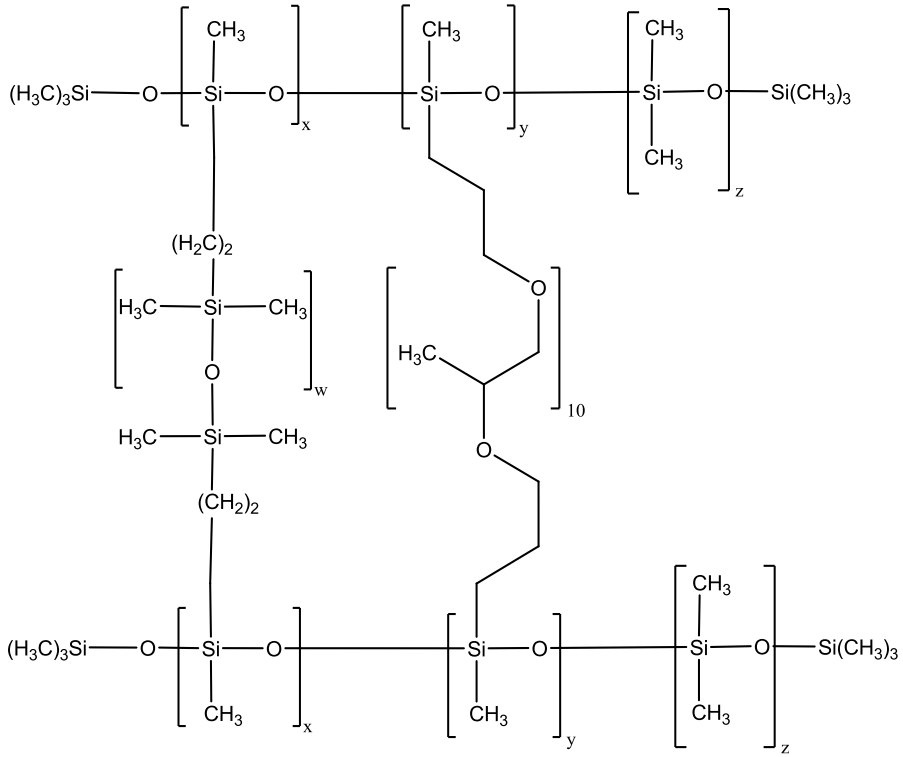
Ingredient	Idealized structure
Bis-vinyldimethicone/ PEG-10 dimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

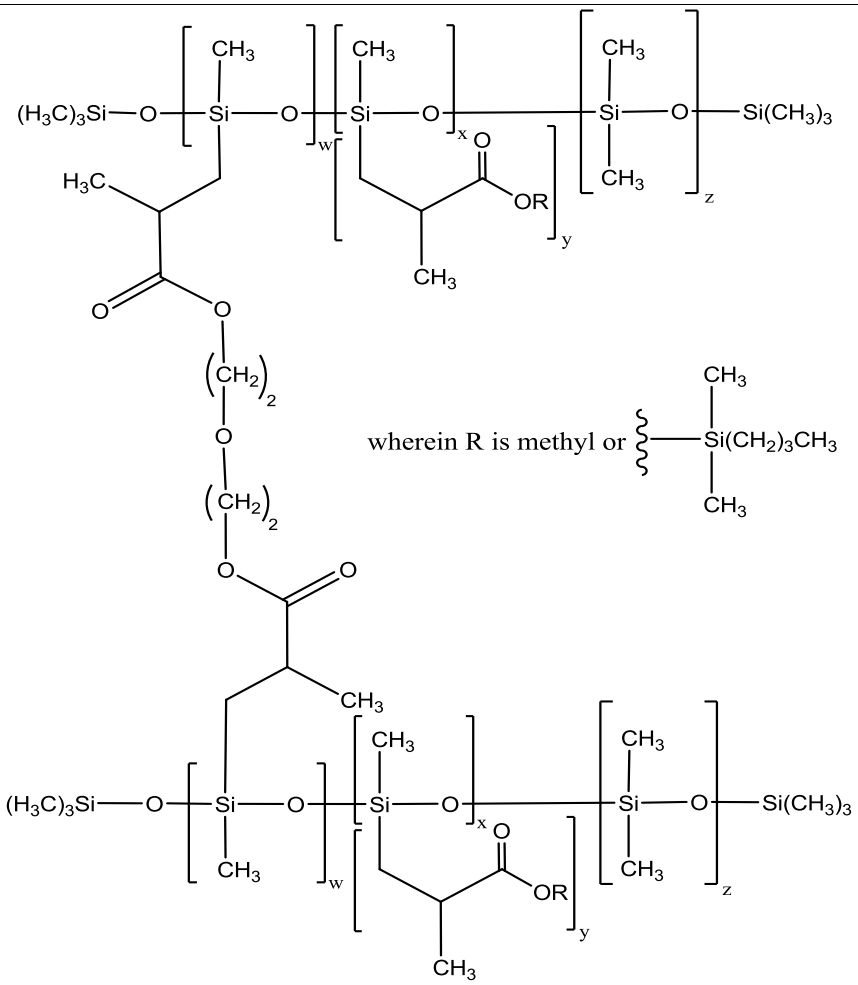
Ingredient	Idealized structure
Butyldimethicone methacrylate/methyl methacrylate crosspolymer	 wherein R is methyl or

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

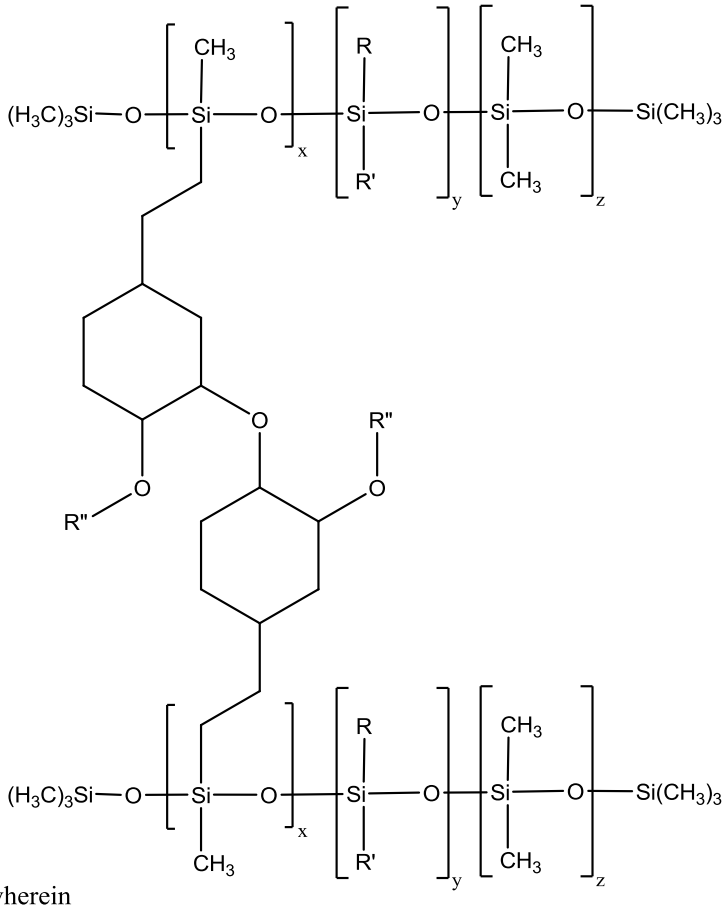
Ingredient	Idealized structure
C30-45 alkyl cetearyl dimethicone crosspolymer 443892-05-5	 wherein R represents an alkyl chain 30 to 45 carbons long R' repesents an alkyl chain 16 to 18 carbons long R" represents additional crosslinks through other vinyl cyclohexene oxide residues

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

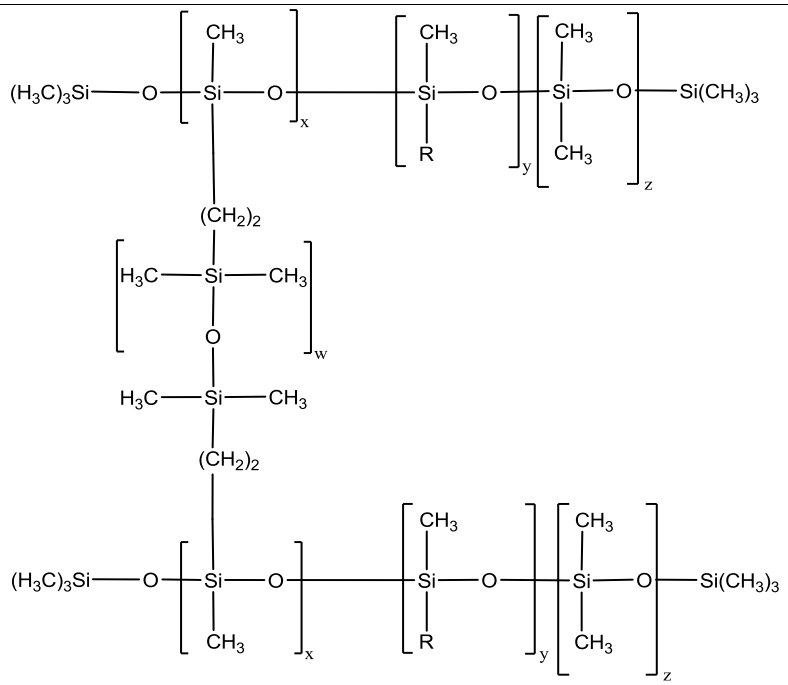
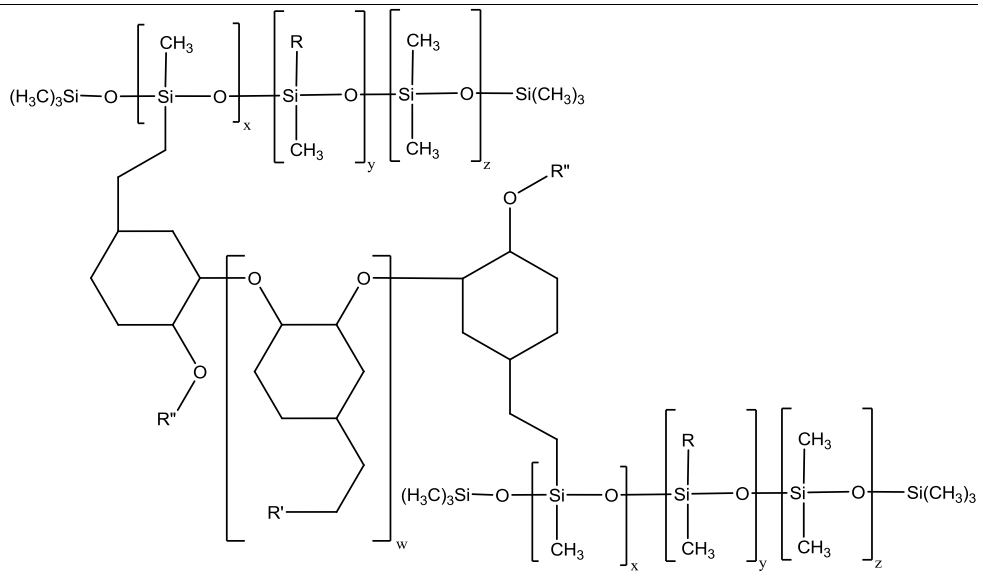
Ingredient	Idealized structure
C4-24 alkyl dimethicone/ divinyldimethicone crosspolymer	 wherein R represents an alkyl chain 4 to 24 carbons long
C30-45 alkyl dimethicone/ polycyclohexene oxide crosspolymer 330809-27-3 389082-70-6	 wherein R represents an alkyl chain 30 to 45 carbons long R' repesents additional dimethicone backbones R" represents additional crosslinks through other vinyl cyclohexene oxide residues

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

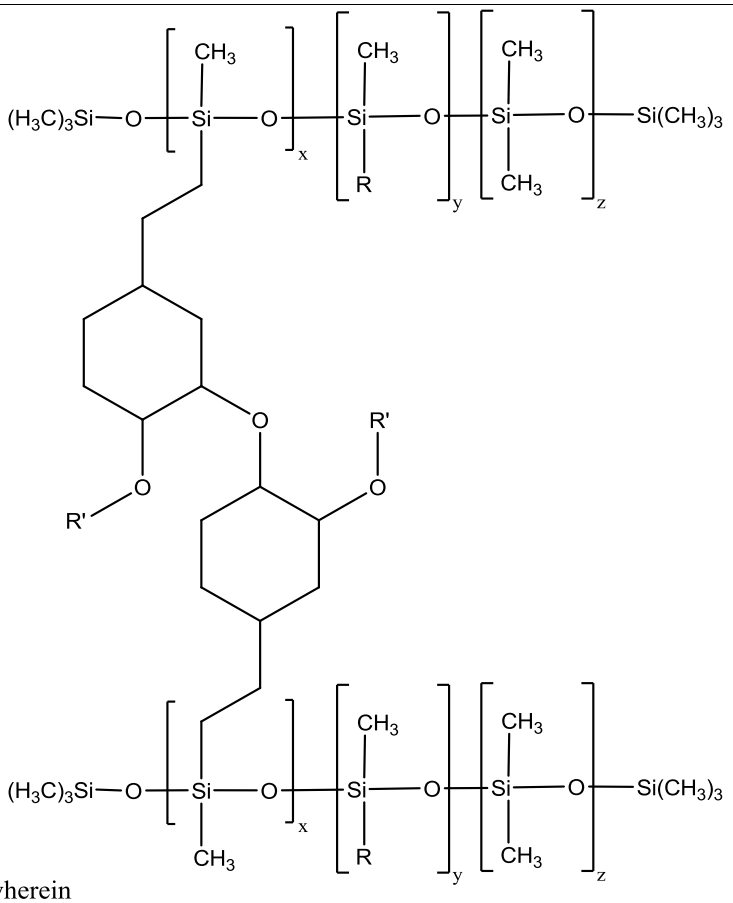
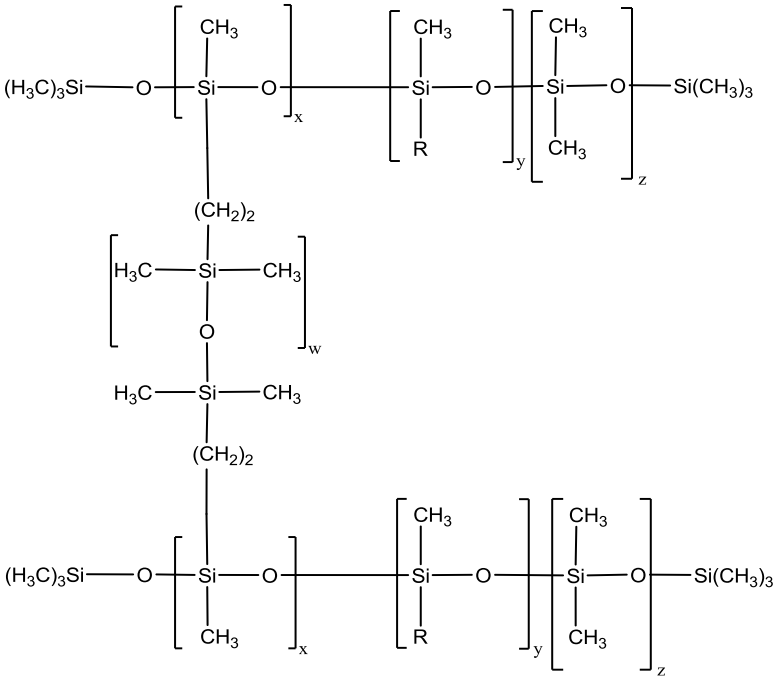
Ingredient	Idealized structure
Cetearyl dimethicone crosspolymer 756876-51-4	 wherein R repesents an alkyl chain 16 to 18 carbons long R' represents additional crosslinks through other vinyl cyclohexene oxide residues
Cetearyl dimethicone/ vinyl dimethicone crosspolymer	 wherein R represents an alkyl chain 16 to 18 carbons long

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

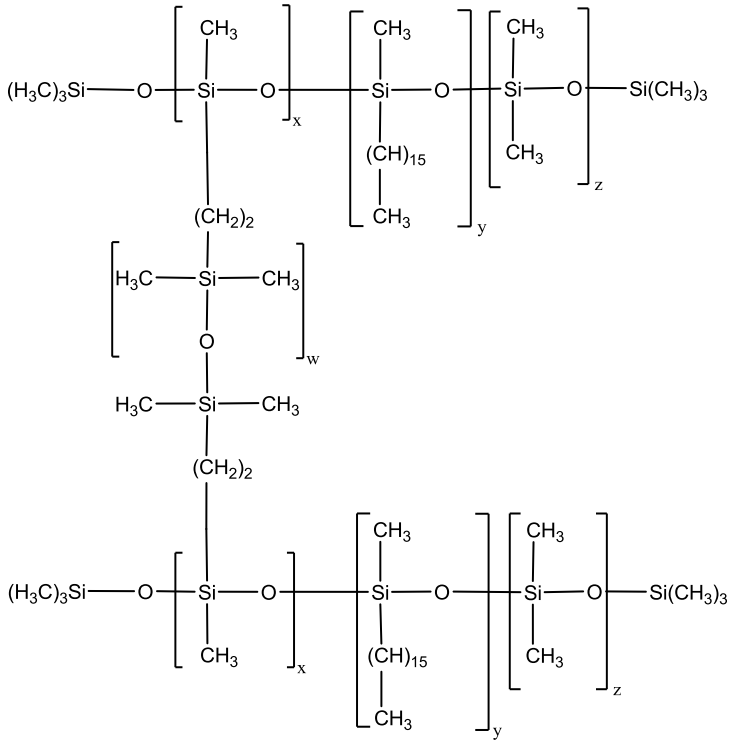
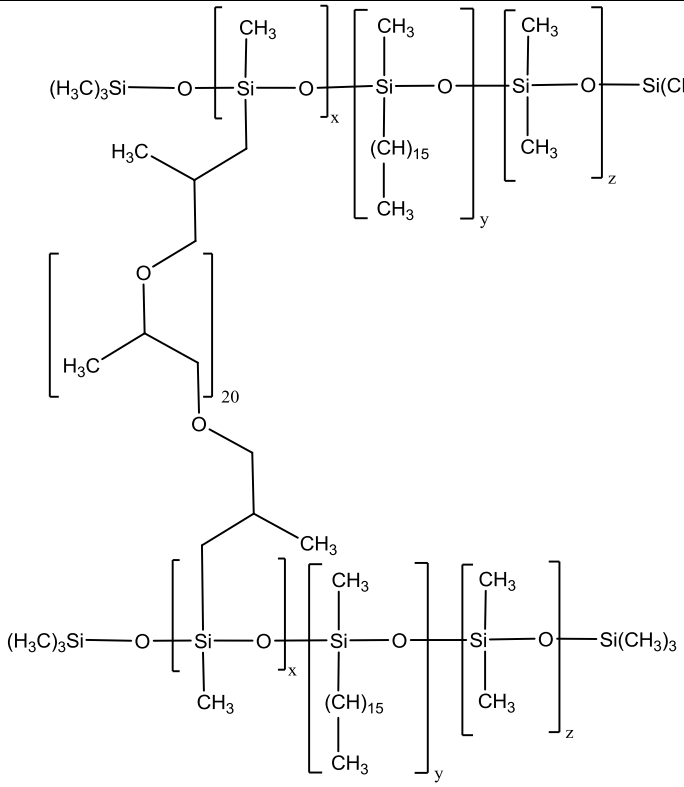
Ingredient	Idealized structure
Cetyl dimethicone/bis-vinyldimethicone crosspolymer	
Cetyl hexacosyl dimethicone/ bis-vinyldimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

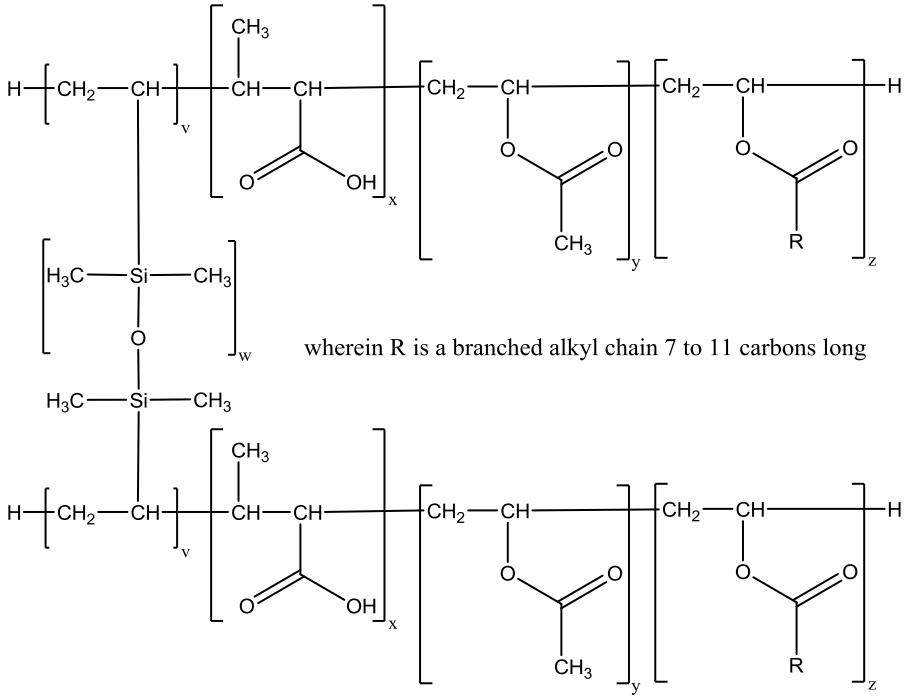
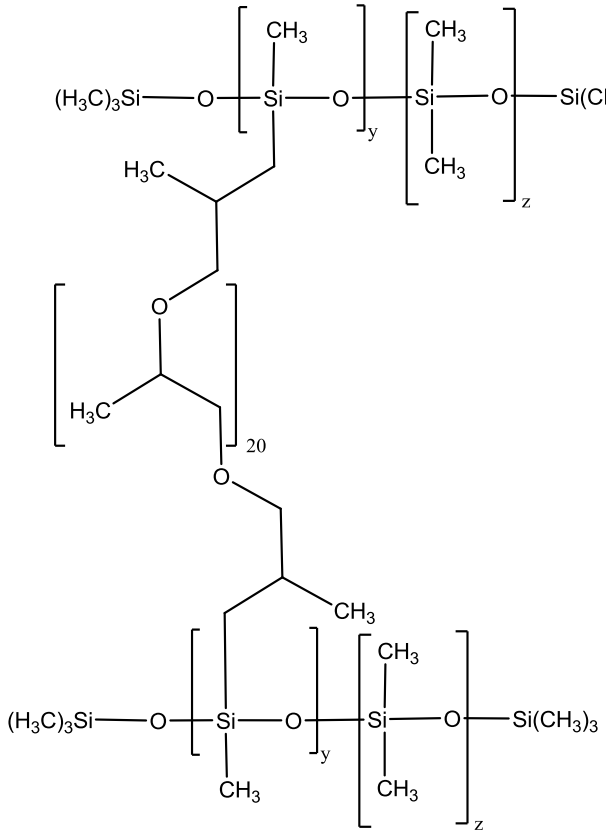
Ingredient	Idealized structure
Crotonic acid/vinyl C8-12 isoalkyl esters/ VA/bis-vinyldimethicone crosspolymer	 wherein R is a branched alkyl chain 7 to 11 carbons long
Dimethicone/bis-isobutyl PPG-20 crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

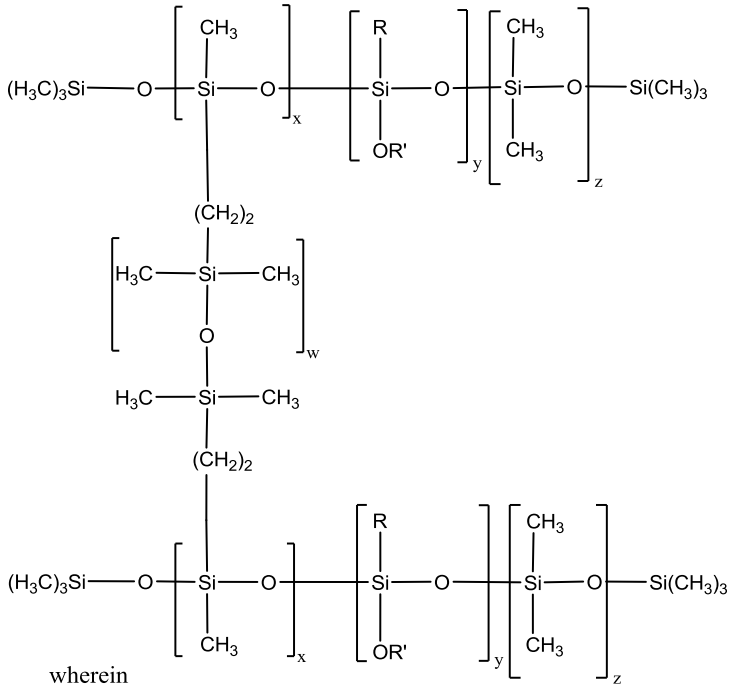
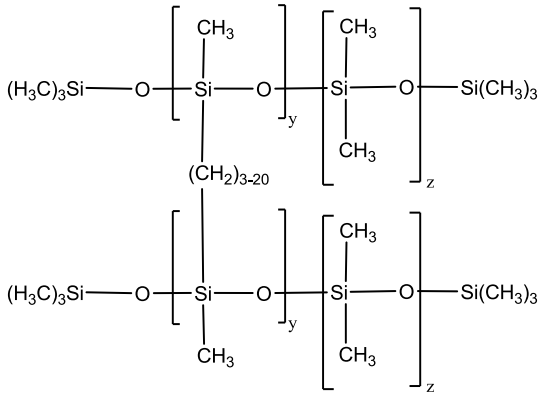
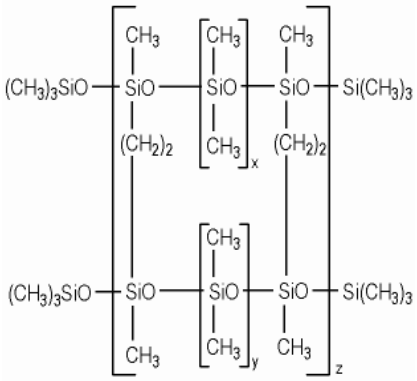
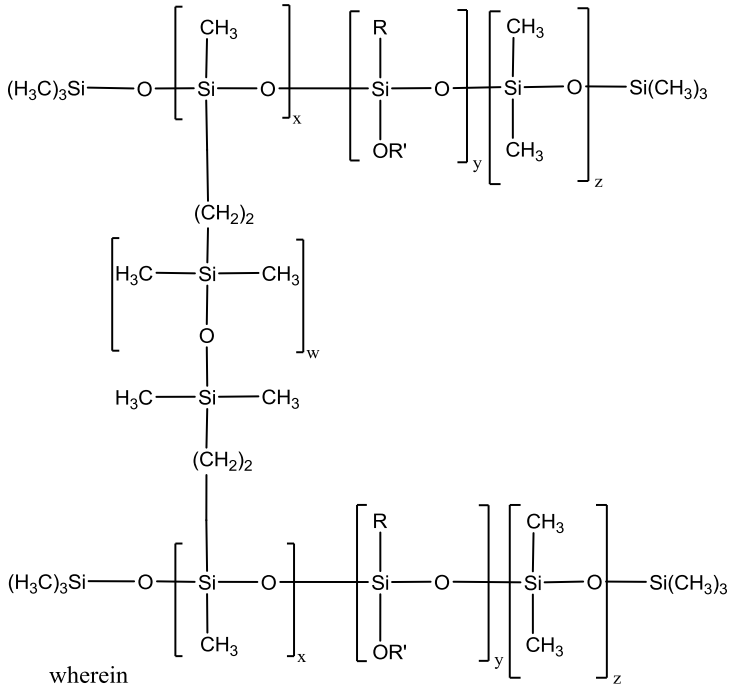
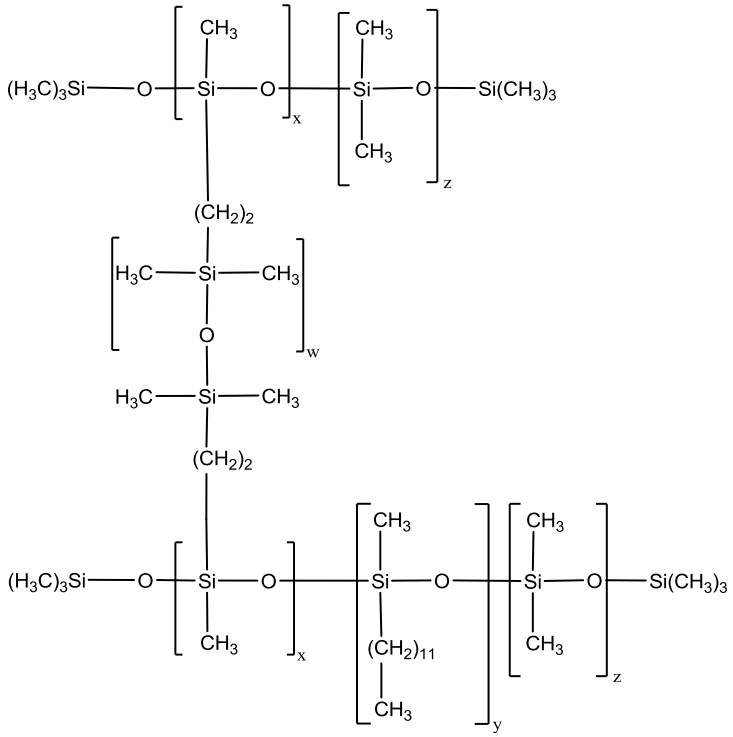
Ingredient	Idealized structure
Dimethicone/bis-vinyldimethicone/ silsesquioxane crosspolymer	 wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones
Dimethicone crosspolymer 213629-14-2	
Dimethicone crosspolymer-3	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

Ingredient	Idealized structure
Dimethicone/divinyldimethicone/silsesquioxane crosspolymer	
Dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer	

47

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

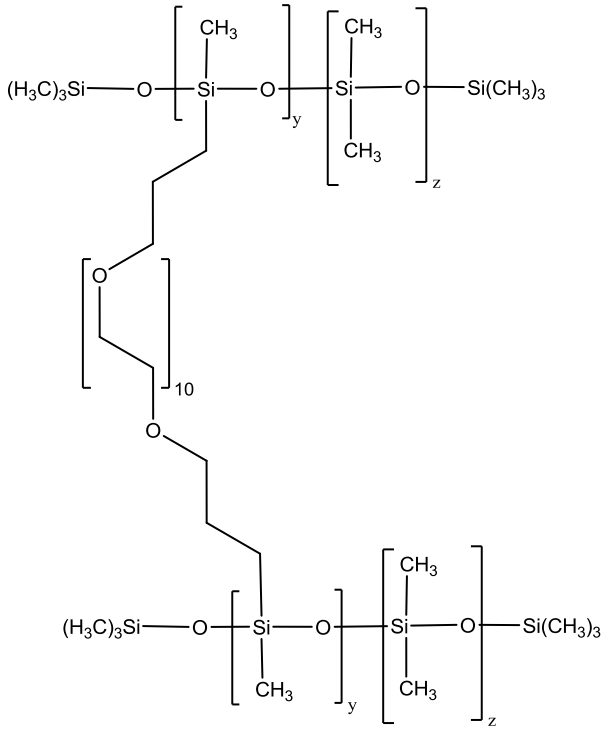
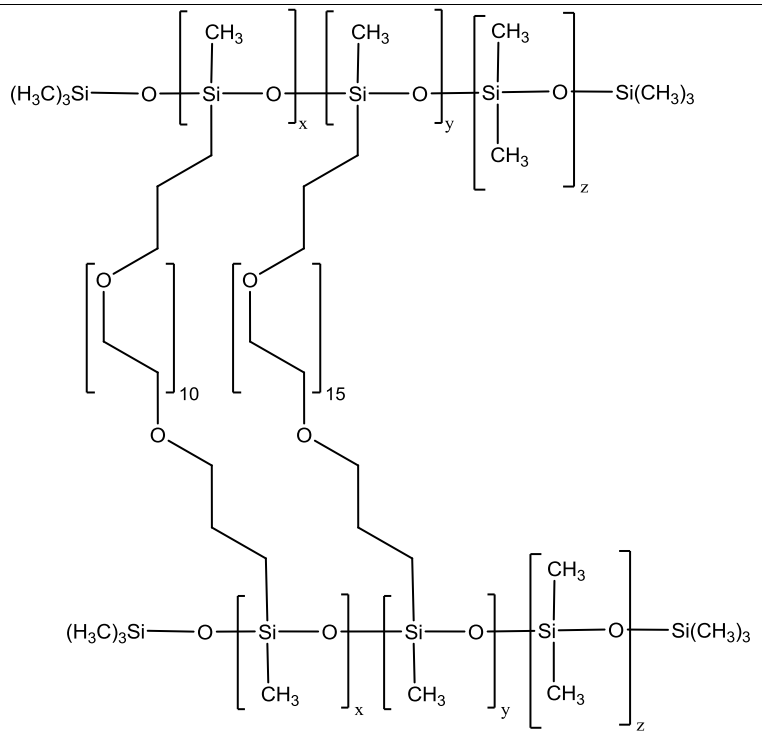
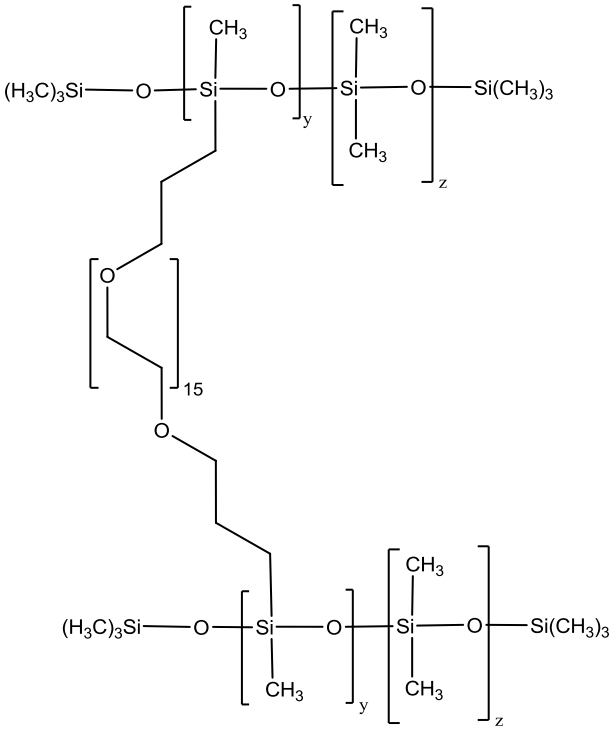
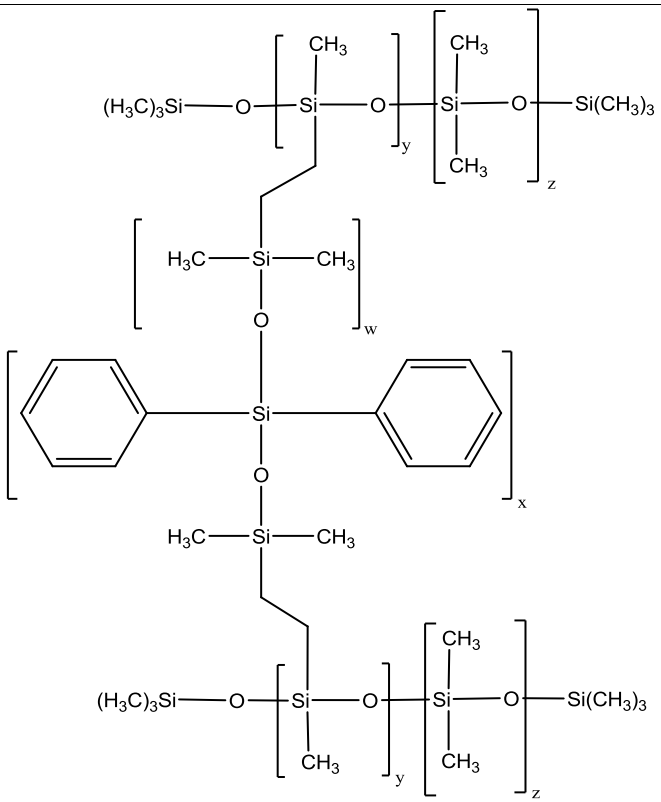
Ingredient	Idealized structure
Dimethicone/ PEG-10 crosspolymer	
Dimethicone/ PEG-10/15 crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

Ingredient	Idealized structure
Dimethicone/ PEG-15 crosspolymer	
Dimethicone/ phenyl vinyl dimethicone crosspolymer	

47

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

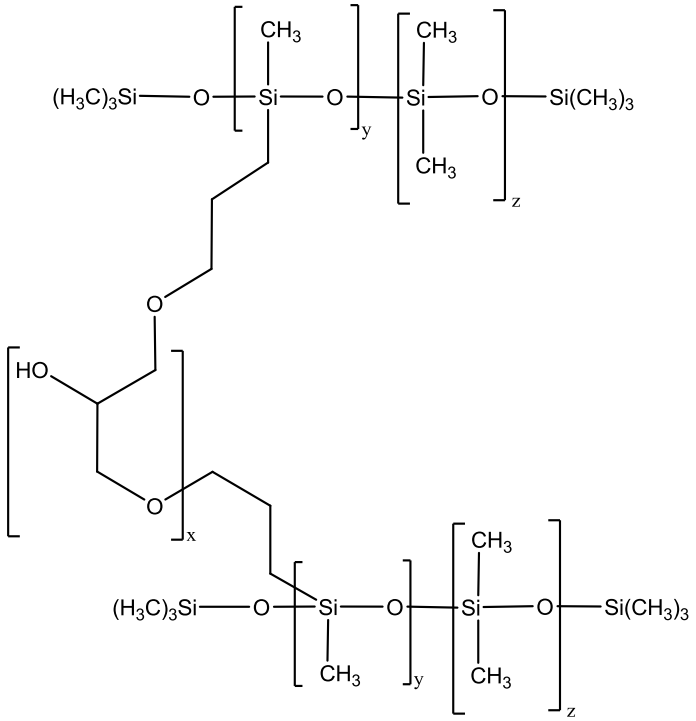
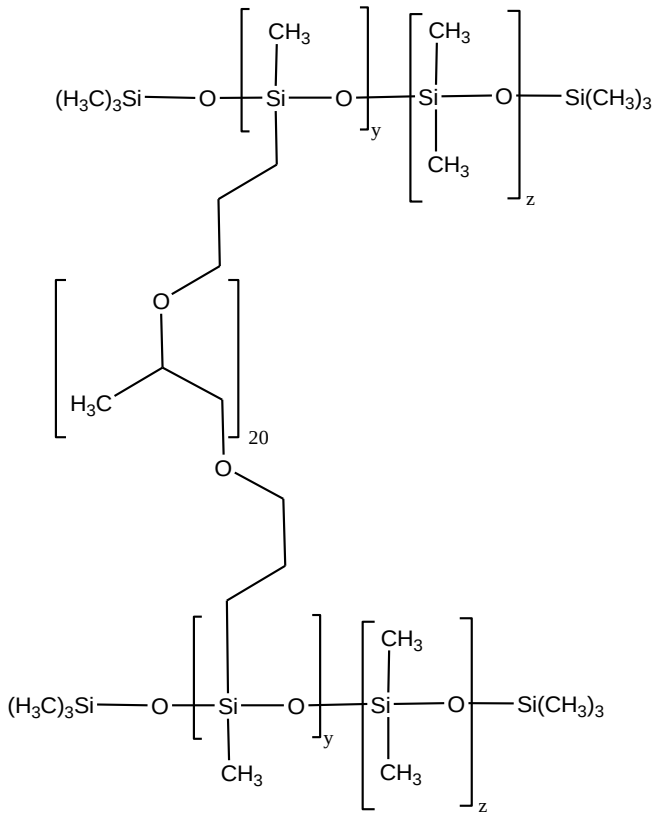
Ingredient	Idealized structure
Dimethicone/polyglycerin-3 crosspolymer	 47
Dimethicone/PPG-20 crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

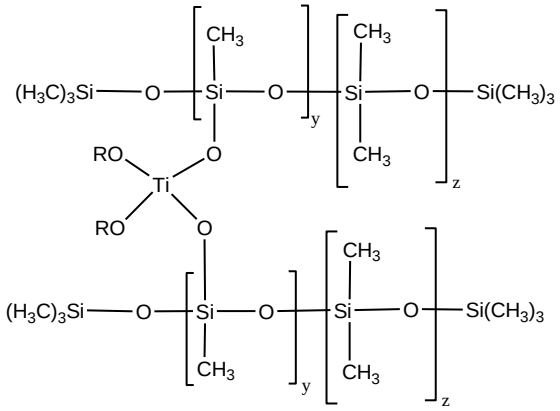
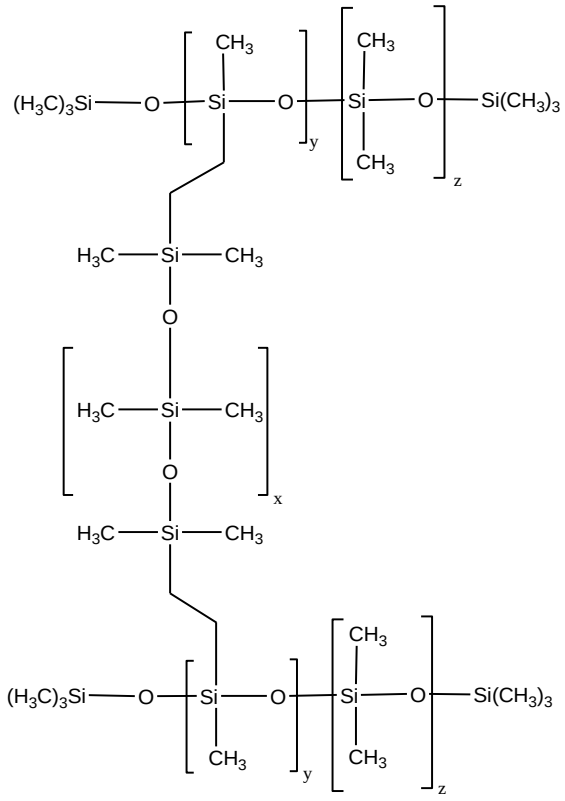
Ingredient	Idealized structure
Dimethicone/titanate crosspolymer	
	wherein R is isopropyl or an additional dimethicone crosslink
Dimethicone/vinyl dimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

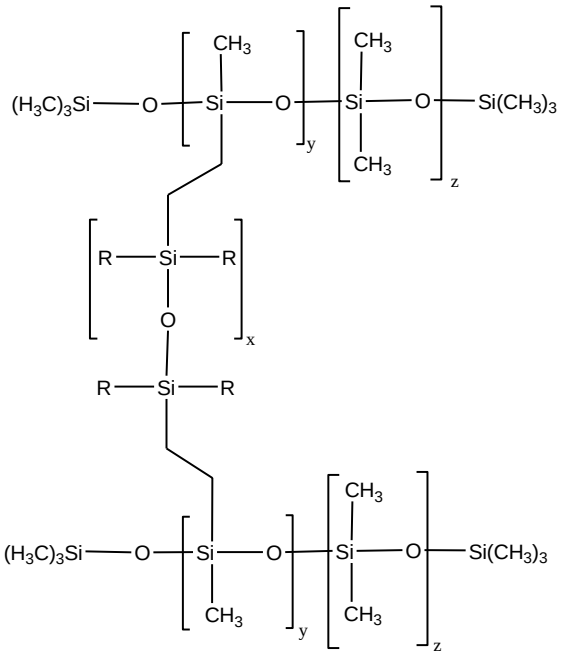
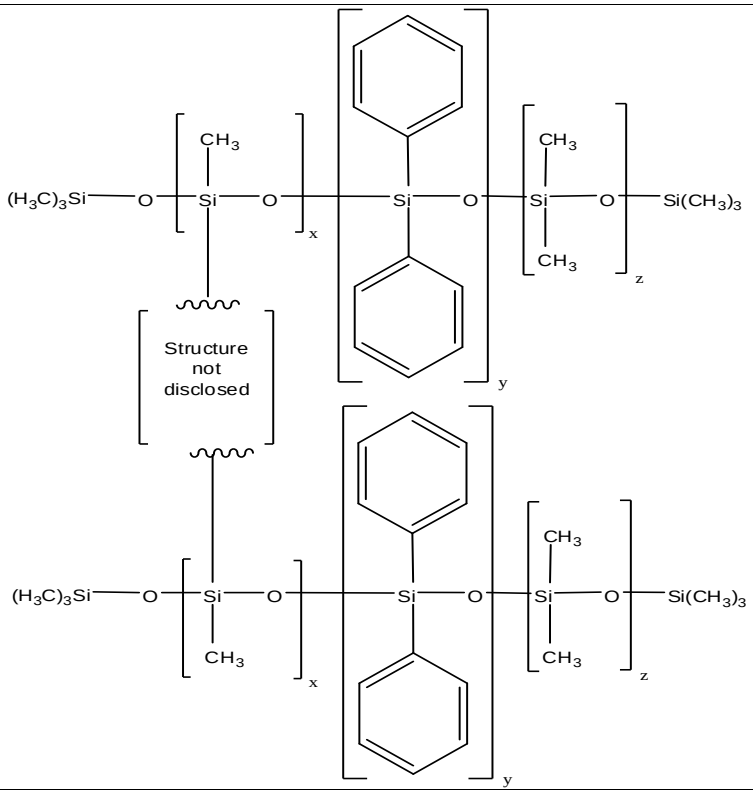
Ingredient	Idealized structure
Dimethicone/ vinyltrimethylsiloxysilicate crosspolymer	 wherein R represents a variable network of polysilicic acid units, which are endblocked with trimethylsilyl groups
Diphenyl dimethicone crosspolymer	
Diphenyl dimethicone/vinyl diphenyl dimethicone/ silsesquioxane crosspolymer	Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer is a crosslinked copolymer of diphenyl dimethicone, vinyl diphenyl dimethicone and silsesquioxane monomers. *The crosslinking connectivity here is unclear.*

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

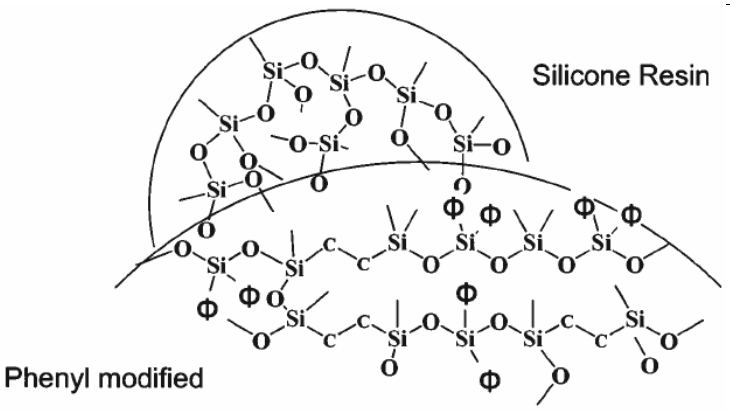
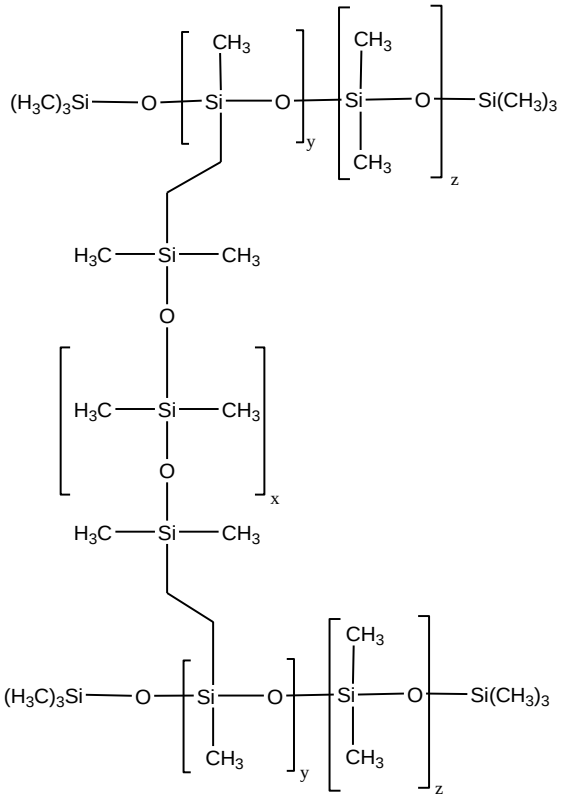
Ingredient	Idealized structure
	 47
Divinyldimethicone/ dimethicone crosspolymer	
Hydroxypropyl dimethicone/ polysorbate 20 crosspolymer	Hydroxypropyl Dimethicone/Polysorbate 20 Crosspolymer is a copolymer of Hydroxypropyldimethicone and Polysorbate 20 crosslinked with Succinic Acid. *The immense connectivity variability added by Polysorbate 20 makes a structural representation of this ingredient quite challenging.*
Isopropyl titanium triisostearate/triethoxysilyl-ethyl polydimethylsiloxyethyl dimethicone crosspolymer	Isopropyl Titanium Triisostearate/Triethoxysilylethyl Polydimethylsiloxyethyl Dimethicone Crosspolymer is a complex polymer formed by the hydrolysis and condensation of Isopropyl Titanium Triisostearate with Triethoxysilylethyl Polydimethylsiloxyethyl Dimethicone. *The immense connectivity variability in this polymer makes a structural representation of this ingredient quite challenging.*

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

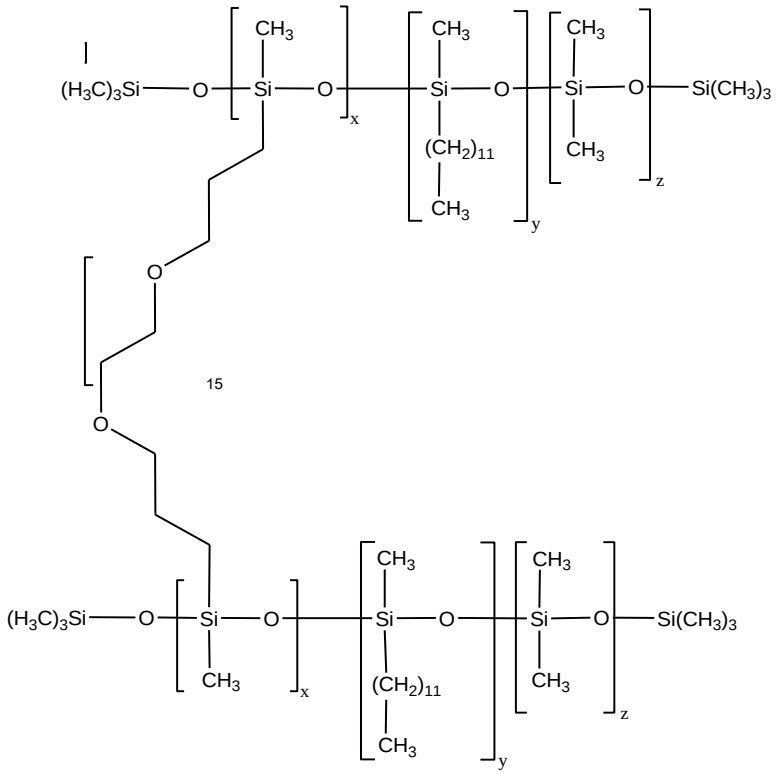
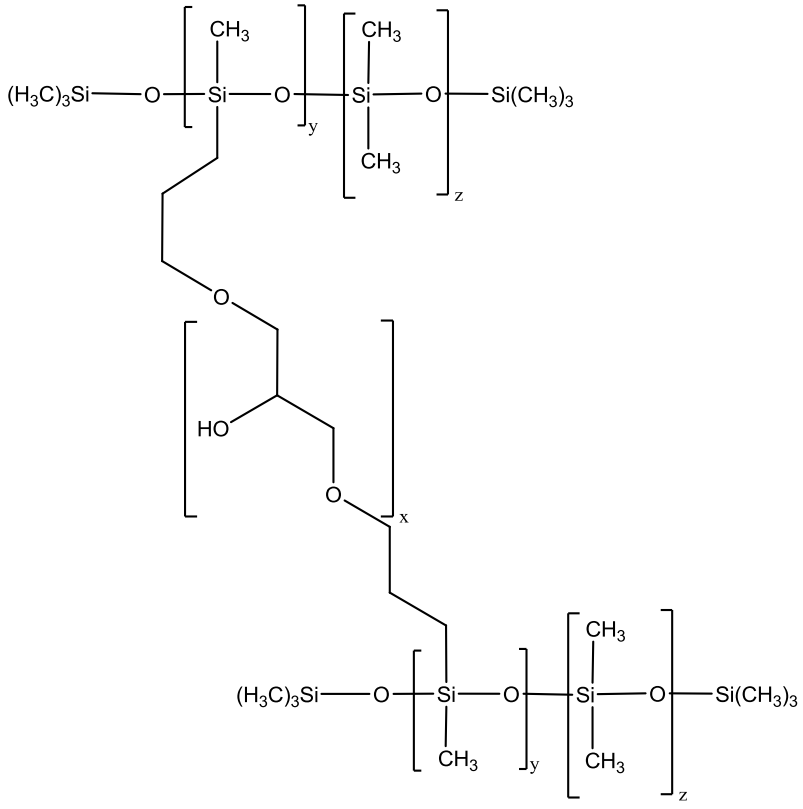
Ingredient	Idealized structure
Lauryl dimethicone PEG-15 crosspolymer	
Lauryl dimethicone/ polyglycerin-3 crosspolymer	 Wherein v + w = 3

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

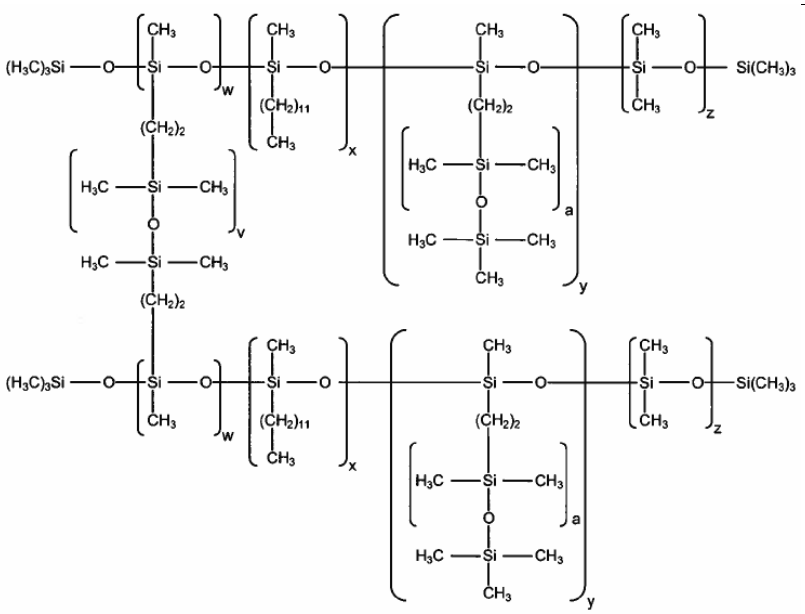
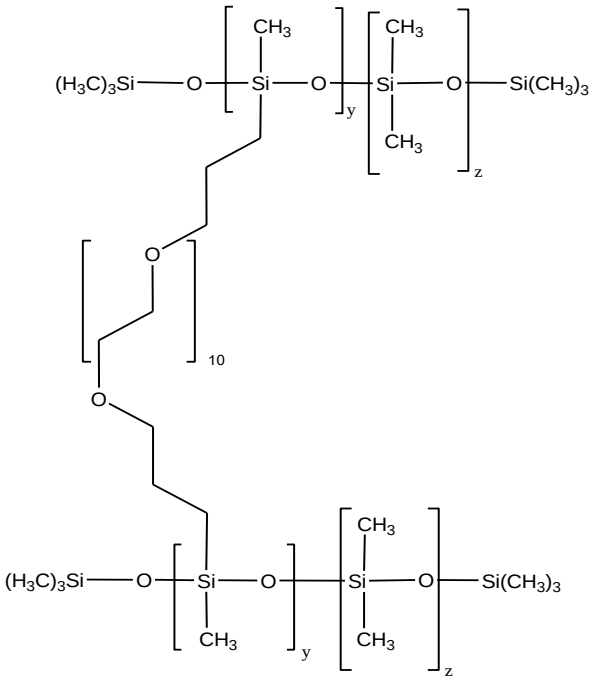
Ingredient	Idealized structure	
Lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer		47
PEG-10 dimethicone crosspolymer		

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

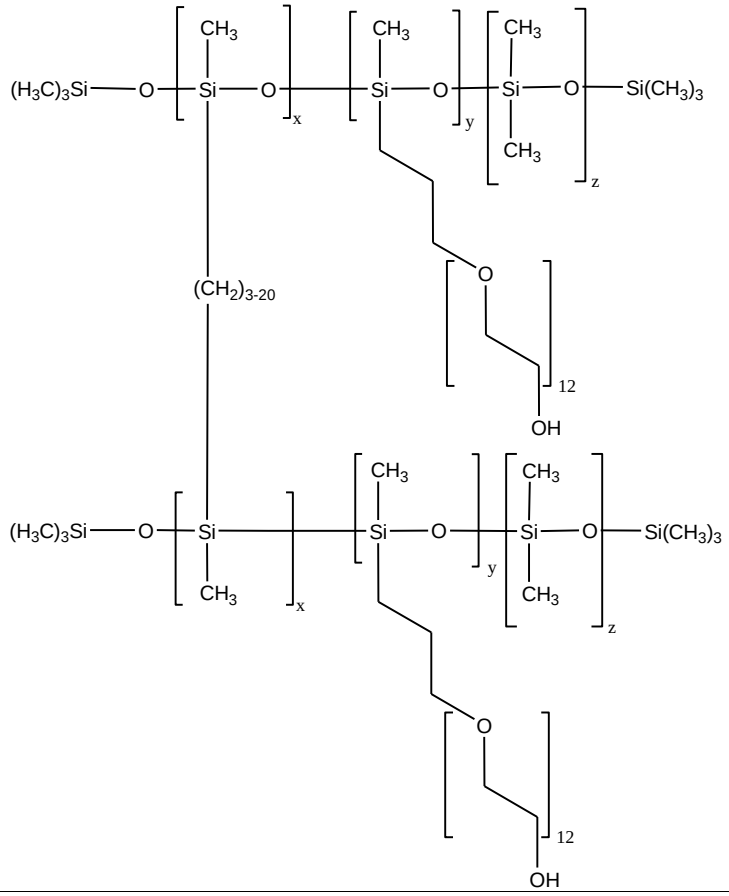
Ingredient	Idealized structure
PEG-12 dimethicone crosspolymer	
PEG-8 dimethicone/ polysorbate 20 crosspolymer	PEG-8 dimethicone/polysorbate 20 crosspolymer is a copolymer of a complex mixture of esters formed from the reaction of PEG-8 dimethicone and polysorbate 20 crosslinked with Succinic Acid. *The immense connectivity variability added by Polysorbate 20 makes a structural representation of this ingredient quite challenging.*

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

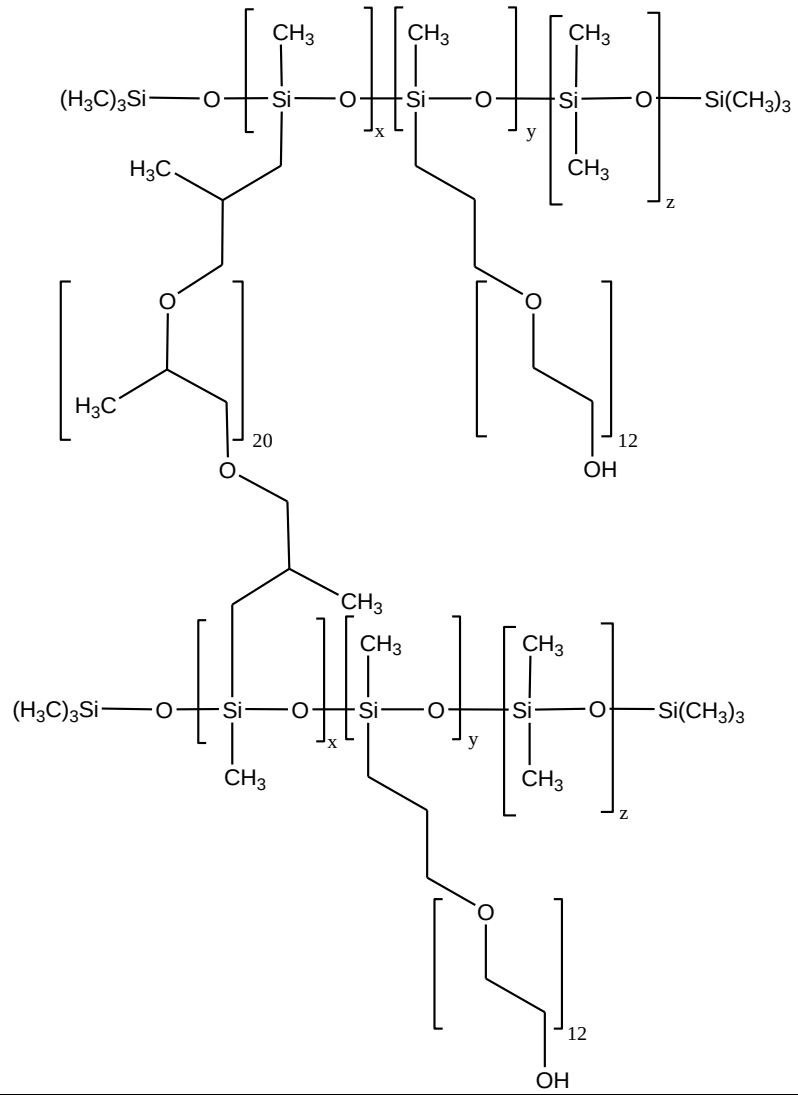
Ingredient	Idealized structure
PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

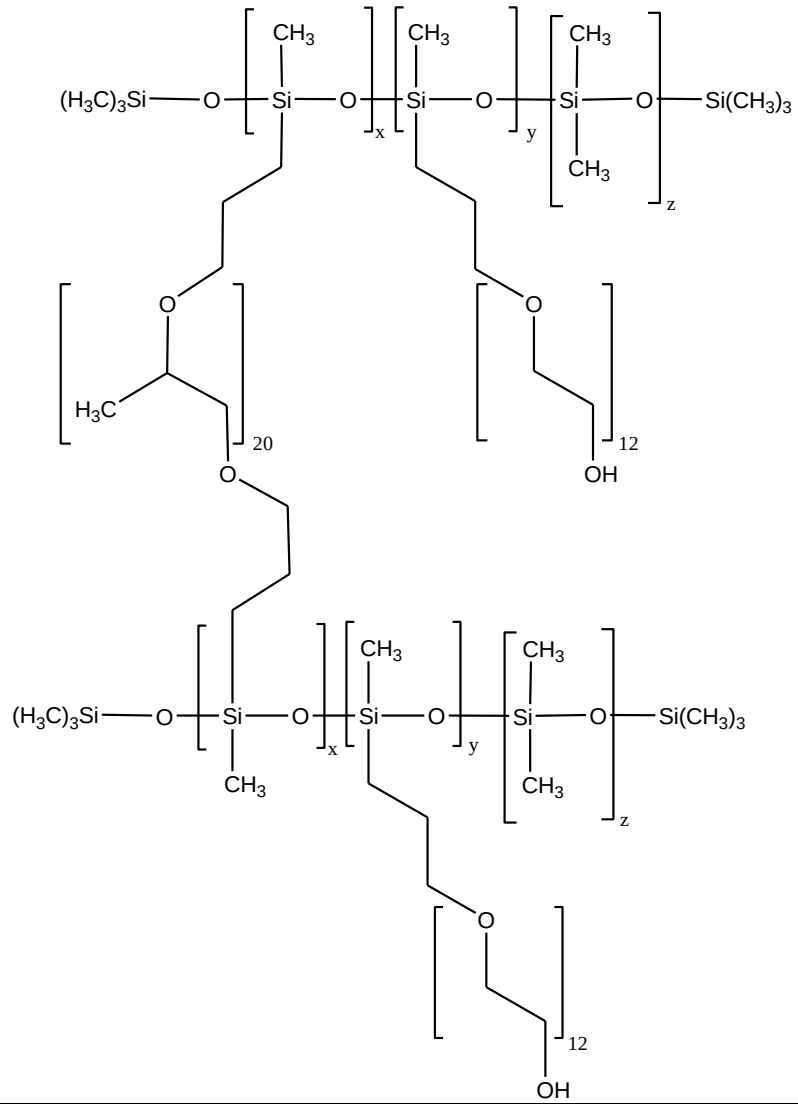
Ingredient	Idealized structure
PEG-12 dimethicone/PPG-20 crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

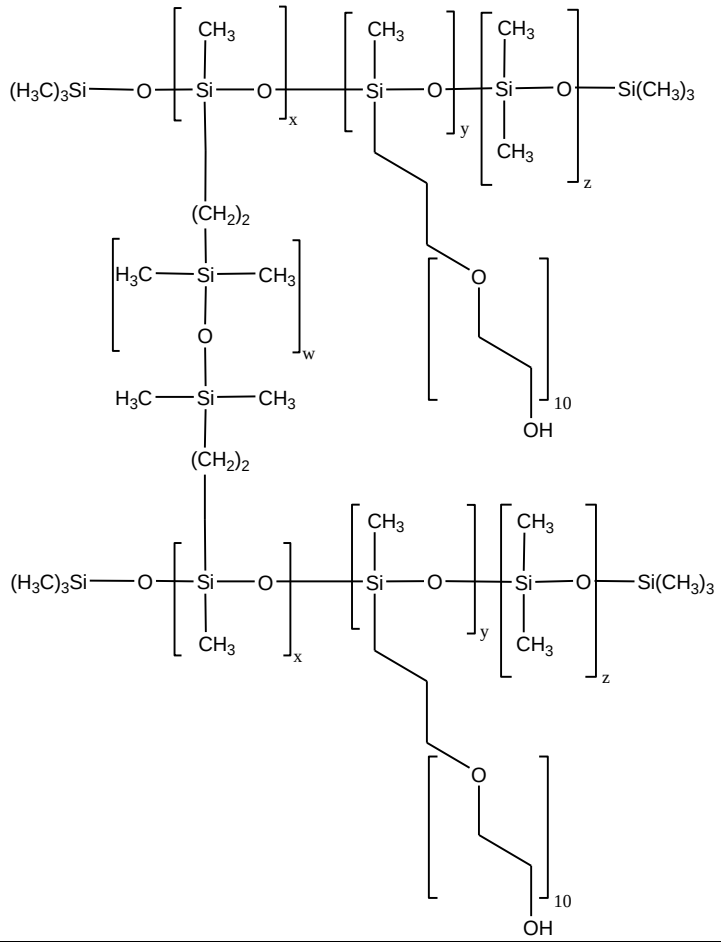
Ingredient	Idealized structure
PEG-10 dimethicone/vinyl dimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

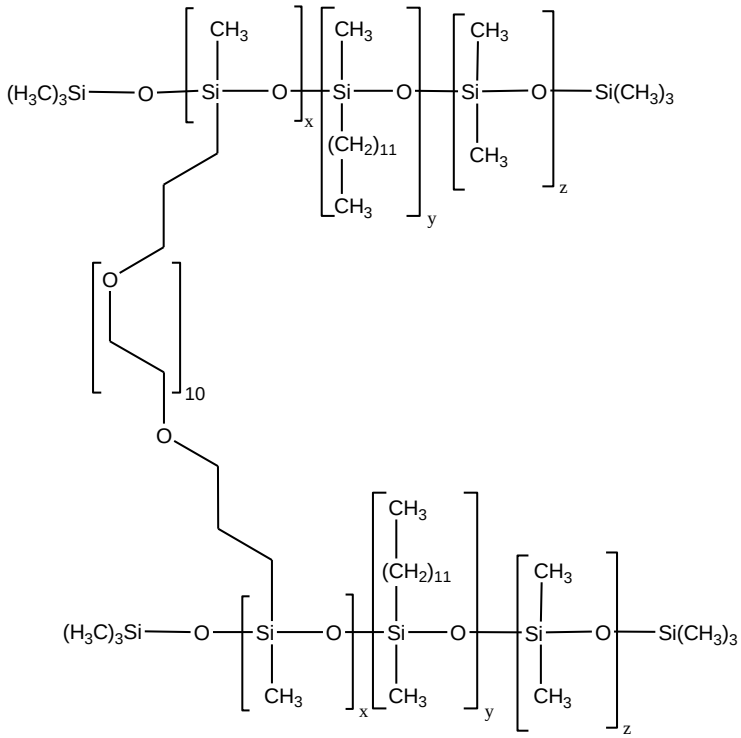
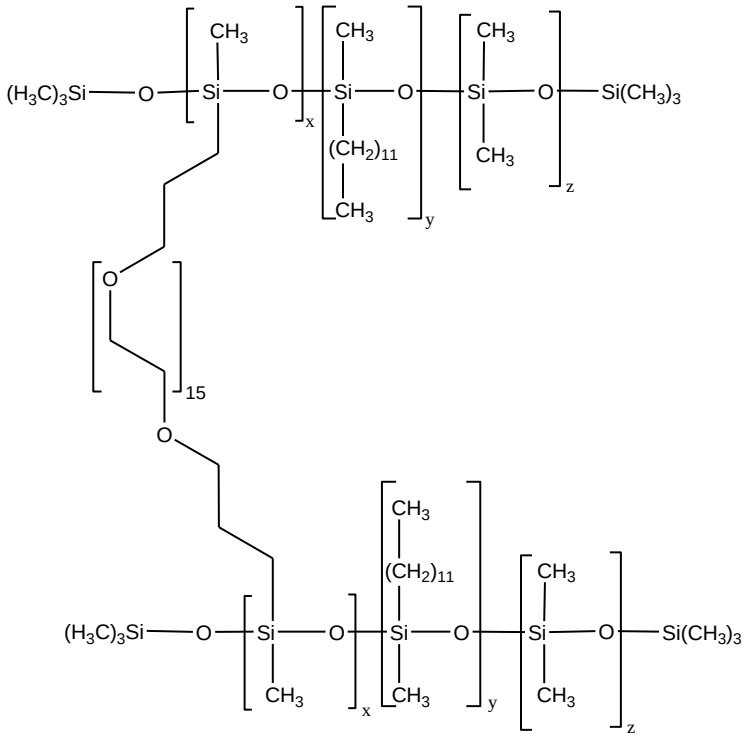
Ingredient	Idealized structure
PEG-10/lauryl dimethicone crosspolymer	
PEG-15/lauryl dimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

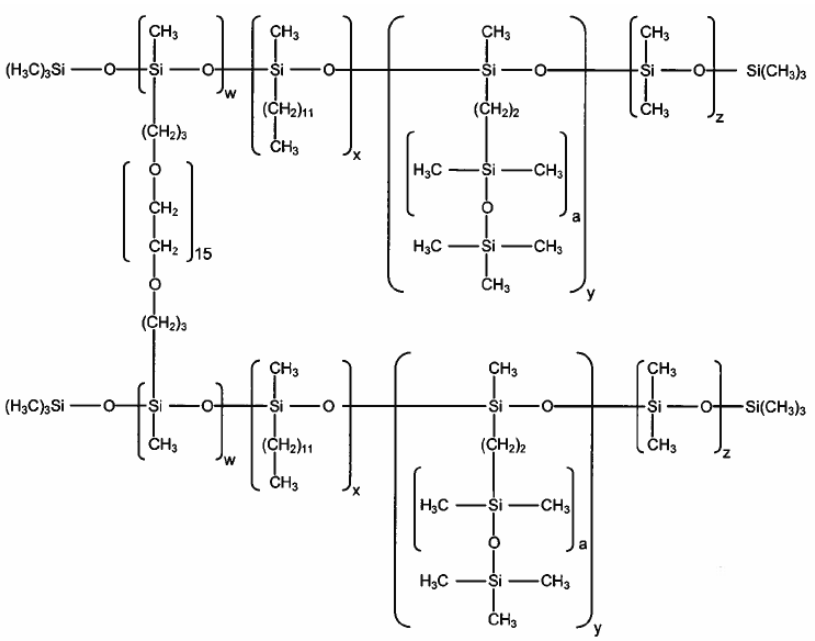
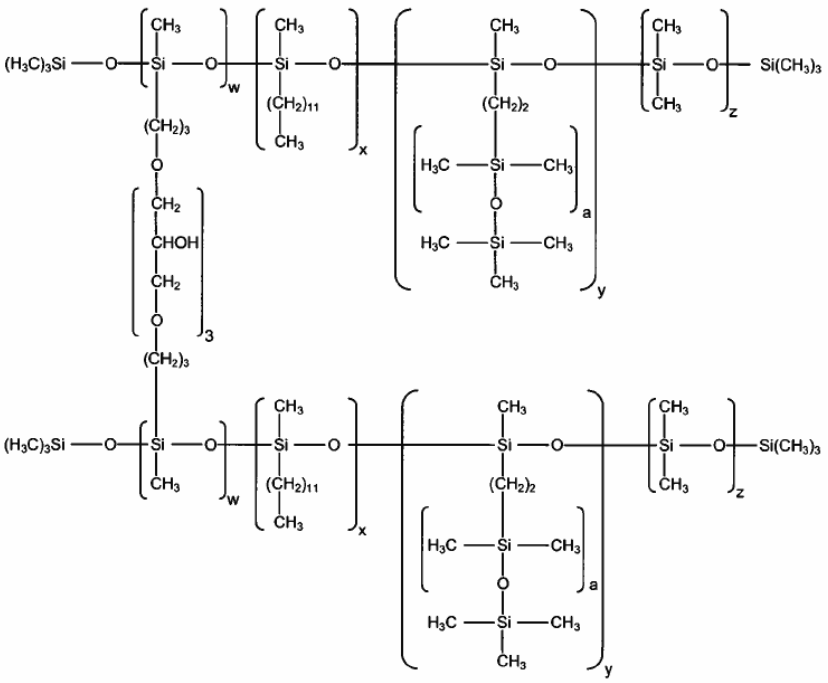
Ingredient	Idealized structure
PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer	 47
Perfluorononyl dimethicone/ methicone/amodimethicone crosspolymer	Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer is a crosslinked silicone polymer that is formed by reacting a copolymer of perfluorononyl dimethicone and methicone with methicone and amodimethicone.
Polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer	Polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer is a copolymer of polydimethylsiloxyethyl dimethicone crosslinked with bis-vinyldimethicone. *The immense connectivity variability in this polymer makes a structural representation of this ingredient quite challenging.*
Polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer	 47

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

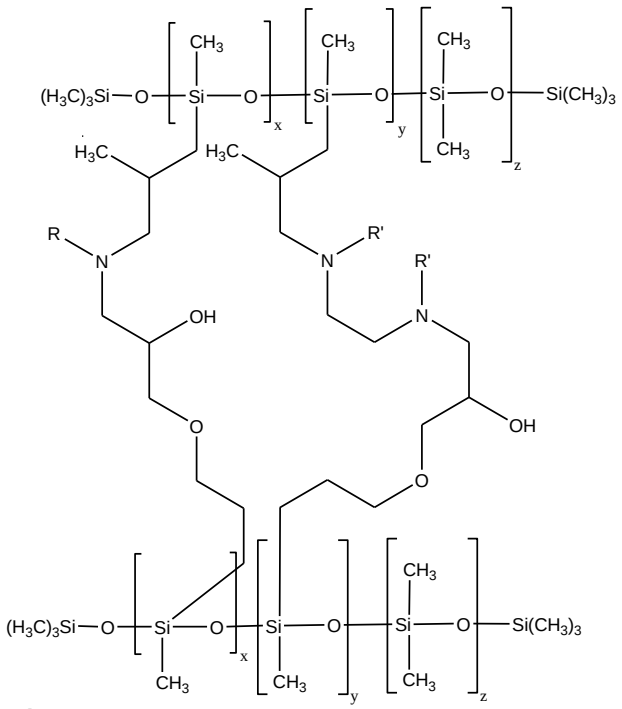
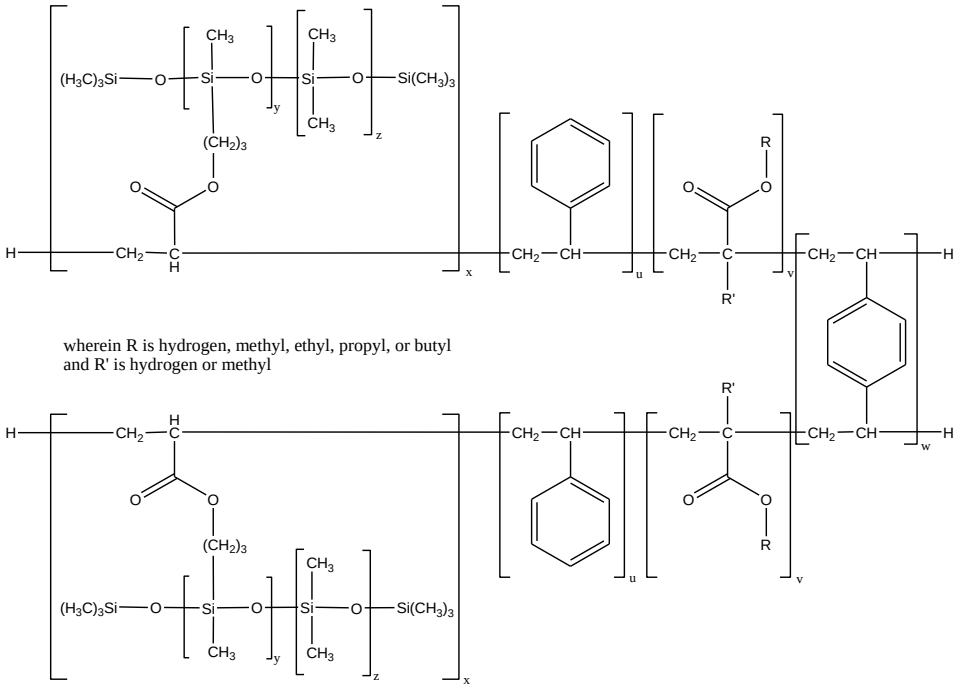
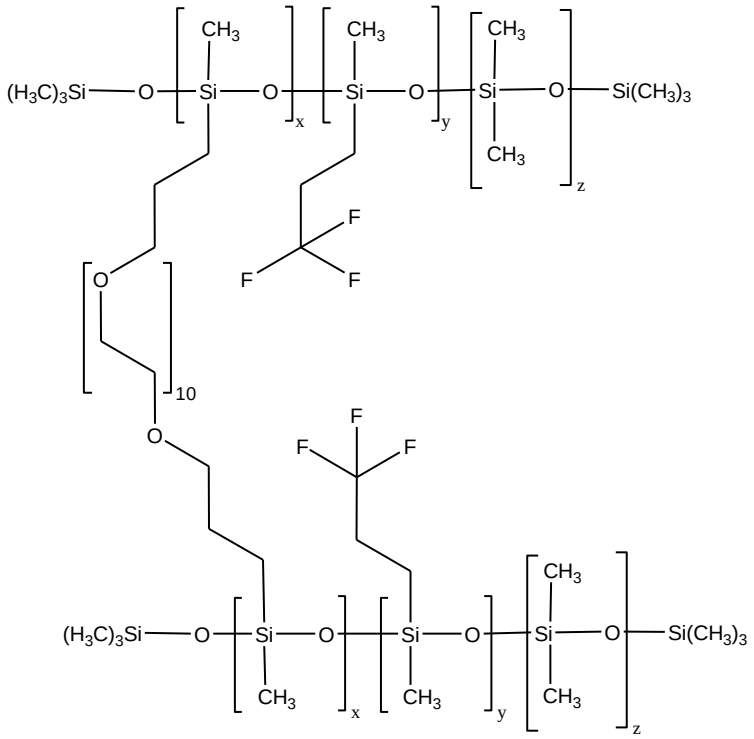
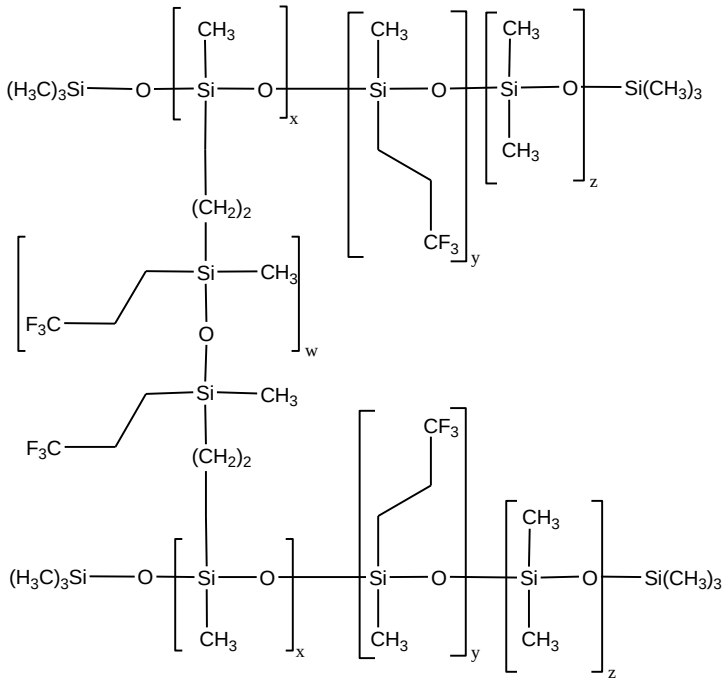
Ingredient	Idealized structure
Silicone quaternium-16/ glycidoxy dimethicone crosspolymer	 wherein R represents $\sim CH_2CH_2NR'$ R' repesents $\sim CH_2CH(OH)CH_2\overset{\oplus}{N}((CH_2)_{0\text{-}17}CH_3)_3\ Cl^{\ominus}$
Styrene/acrylates/ dimethicone acrylate crosspolymer	 wherein R is hydrogen, methyl, ethyl, propyl, or butyl and R' is hydrogen or methyl

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

Ingredient	Idealized structure
Trifluoropropyl dimethicone/ PEG-10 crosspolymer	
Trifluoropropyl dimethicone/ trifluoropropyl divinyldimethicone crosspolymer	

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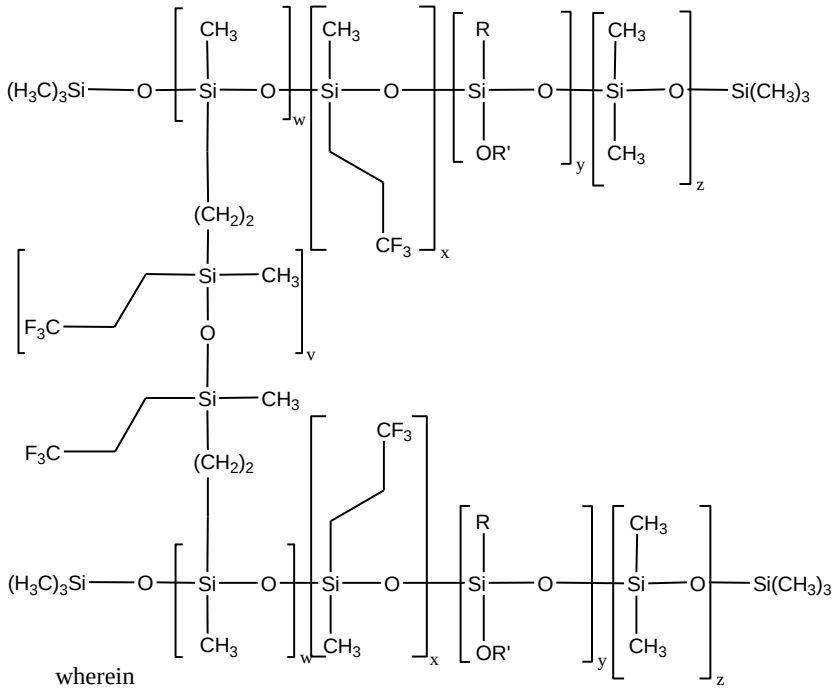
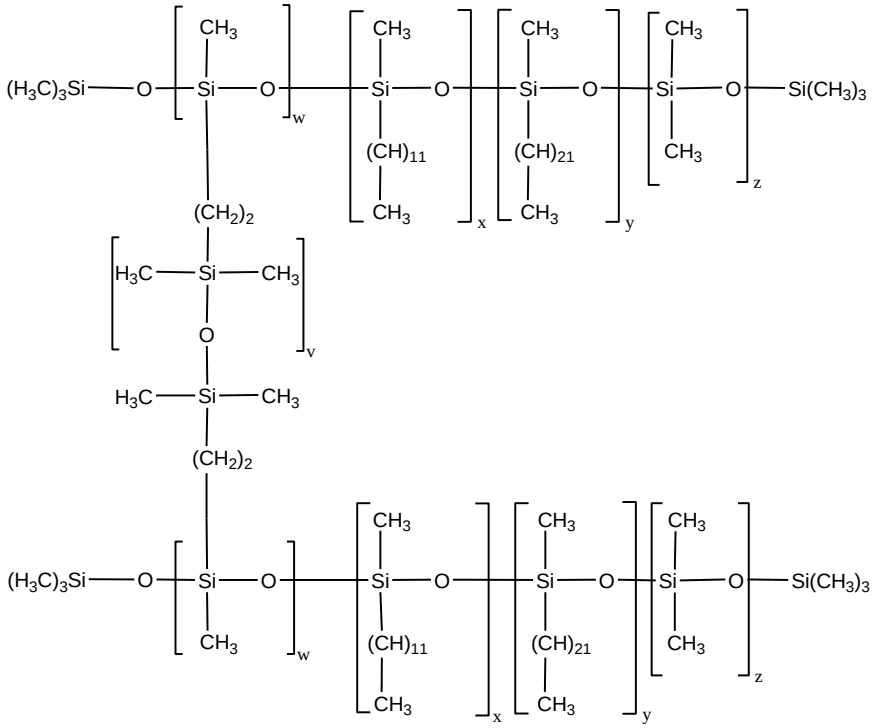
Ingredient	Idealized structure
Trifluoropropyl dimethicone/ vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer	 wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones
Trimethylsiloxysilicate/ dimethicone crosspolymer	Trimethylsiloxysilicate/dimethicone crosspolymer is the product of the reaction between dimethicone and trimethylsiloxysilicate under conditions that produce rearrangement, condensation, and crosslinking of the dimethicone polymer onto the trimethylsiloxysilicate resin. *The immense connectivity variability in this polymer makes a structural representation of this ingredient quite challenging.*
Vinyl dimethicone/ lauryl/ behenyl dimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

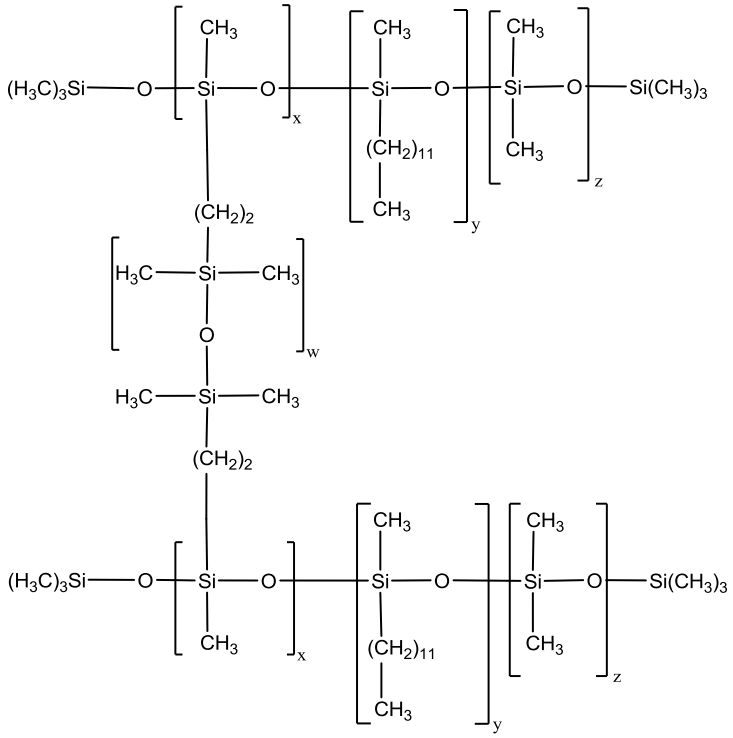
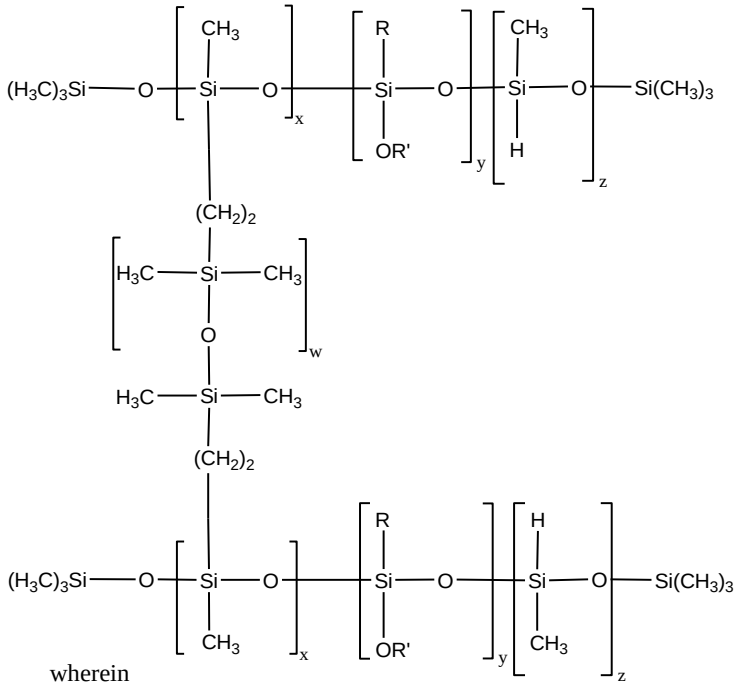
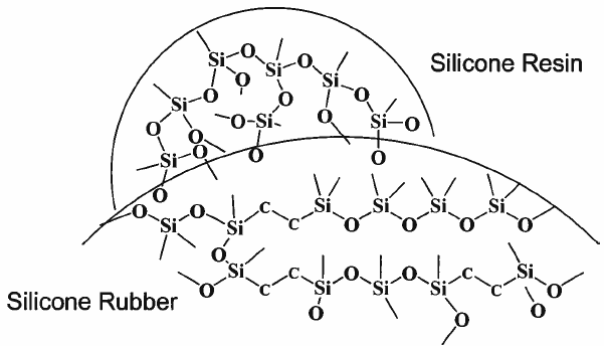
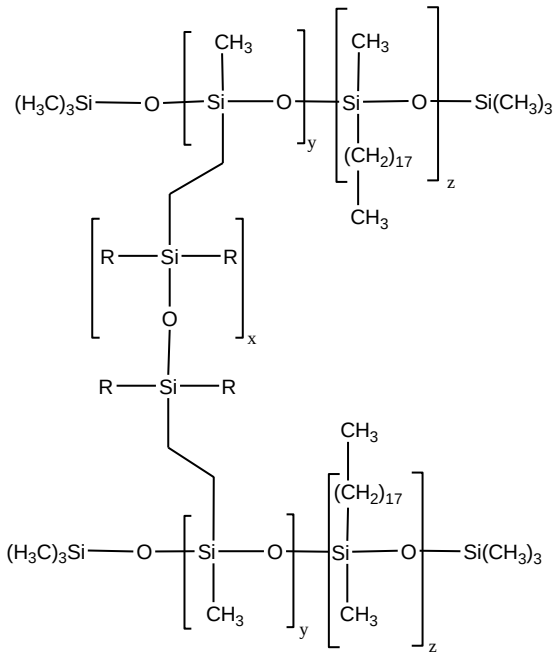
Ingredient	Idealized structure
Vinyl dimethicone/lauryl dimethicone crosspolymer	
Vinyl dimethicone/methicone silsesquioxane crosspolymer	 wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones may also be visualized as:

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, two-dimensional depictions of the true three-dimensional frameworks that comprise these polymers. Though monomer units are drawn sequentially, by necessity, this by no means implies that these are block-type polymers. Instead, these structures are meant to represent only one example of the multitude of potentially produced connectivities found within these macromolecules.

Ingredient	Idealized structure
	 47
Vinyldimethyl/ trimethylsiloxysilicate/ dimethicone crosspolymer	Monograph in development
Vinyldimethyl/ trimethylsiloxysilicate stearyl dimethicone crosspolymer	 wherein R represents methyl or a variable network of polysilicic acid units, which are endblocked with trimethylsilyl groups

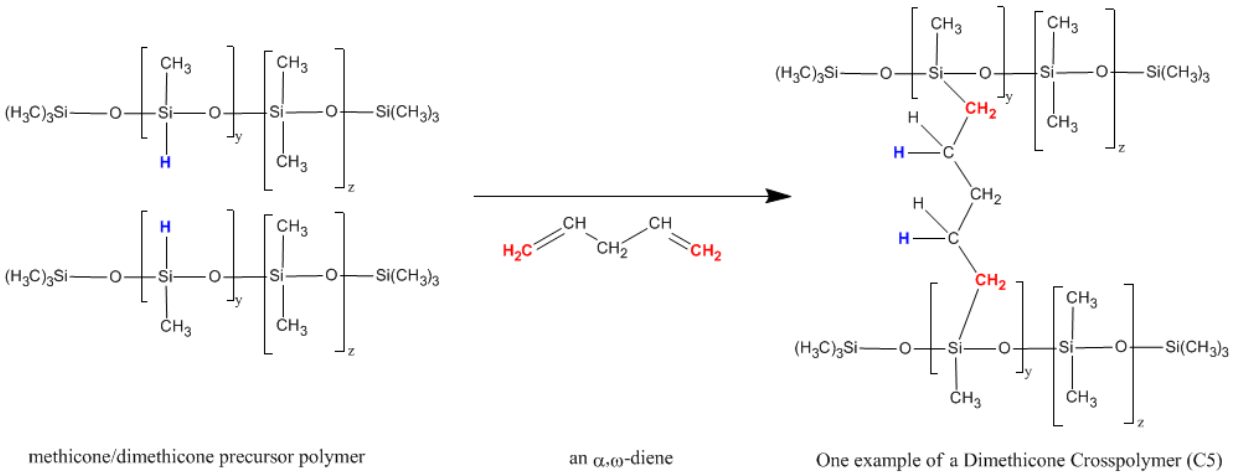


Figure 2. Example of the hydrosilation-crosslinking of a dimethicone precursor polymer.

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