

Tentative Report

On The Safety Assessment of Dimethicone Crosspolymer Ingredients as Used in Cosmetics

June 12, 2012

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ABSTRACT

The Cosmetic Ingredient Review Expert Panel (the 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 ingredients. The Panel concluded that these dimethicone crosspolymer ingredients are safe in the practices of use and concentration as given in this safety assessment.

INTRODUCTION

This is a tentative report of the available published and unpublished data relevant to assessing the safety of 62 dimethicone crosspolymers as used in cosmetics. As given in the *International Cosmetic Ingredient Dictionary and Handbook*,¹ these ingredients 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 polydimethylsiloxylethyl dimethicone crosspolymer
- lauryl dimethicone PEG-15 crosspolymer
- lauryl dimethicone/polyglycerin-3 crosspolymer
- lauryl polydimethylsiloxylethyl 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 polydimethylsiloxylethyl dimethicone crosspolymer
- perfluorononyl dimethicone/methicone/amodimethicone crosspolymer
- polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer
- polyglyceryl-3/lauryl polydimethylsiloxylethyl dimethicone crosspolymer
- silicone quaternium-16/glycidoxy dimethicone crosspolymer
- styrene/acrylates/dimethicone acrylate crosspolymer
- trifluoropropyl dimethicone/PEG-10 crosspolymer
- trifluoropropyl dimethicone/trifluoropropyl

- divinyl dimethicone 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
- vinyl dimethyl/trimethylsiloxysilicate/dimethicone crosspolymer
- vinyl dimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer

Several of the components of these ingredients have been previously reviewed by the Cosmetic Ingredient Review Expert Panel (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-vinyl dimethicone 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. Other data are provided below.

Additional physical and chemical properties have been submitted to CIR just prior to the review of this report. However, the data have not yet been processed and incorporated into this safety assessment. The data will be included in the next version of this document for the September Panel meeting.

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

Crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyl dimethicone 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/SILSESQUOXANE CROSSPOLYMER

Dimethicone/divinyl dimethicone/silsesquioxane crosspolymer is stable at room temperature for 36 months.⁶

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

Dimethicone/vinyl trimethylsiloxysilicate 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

VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

Vinyl dimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer (20% in isododecane) is stable for at least 1 year with no special storage requirements.⁹ 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 .¹⁰ In finished products, even in those that are powders, these particles generally aggregate stably to produce much larger particles.

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 (\leq 100 ppm), vinyl *tert*-decanoate (\leq 2000 ppm), crotonic acid (\leq 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.¹¹

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.⁹ Residuals from manufacturing include platinum (catalyst, < 25 ppm) and cyclotetrasiloxane (maximum < 1%).

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).^{12,13} 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 57 products that may be inhaled) and 12 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 25 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%).

VCRP¹⁴ 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.

Council¹⁵ data only were available for:

- Cetyl dimethicone/bis-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 | • dimethicone/PEG-15 crosspolymer |
| • bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer | • dimethicone/titanate crosspolymer |
| • bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer | • diphenyl dimethicone crosspolymer |
| • bis-vinyldimethicone crosspolymer | • hydroxypropyl dimethicone/polysorbate 20 crosspolymer |
| • bis-vinyldimethicone/ PEG-10 dimethicone crosspolymer | • lauryl dimethicone PEG-15 crosspolymer |
| • bis-vinyldimethicone/PPG-20 crosspolymer | • lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer |
| • butyldimethicone methacrylate/methyl methacrylate crosspolymer | • PEG-8 dimethicone/polysorbate 20 crosspolymer |
| • cetearyl dimethicone/vinyl dimethicone crosspolymer | • PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer |
| • cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer | • PEG-12 dimethicone/PPG-20 crosspolymer |
| • crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer | • polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer |
| • dimethicone/bis-vinyldimethicone/ silsesquioxane crosspolymer | • polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer |
| • dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer | • styrene/acrylates/ dimethicone acrylate crosspolymer |
| | • trifluoropropyl dimethicone/PEG-10 crosspolymer |

- trifluoropropyl dimethicone/trifluoropropyl divinyl dimethicone crosspolymer
- trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer
- trimethylsiloxysilicate/dimethicone crosspolymer
- vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer
- vinyl dimethyl/trimethylsiloxysilicate/dimethicone crosspolymer
- vinyl dimethyl/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.^{16,17} 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.^{18,19} 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.²⁰ 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

Dermal/Percutaneous

No data were discovered on the dermal or percutaneous toxicokinetics of these ingredients. However, manufacturer information was submitted.

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyl dimethicone crosspolymer, dimethicone/vinyl trimethylsiloxysilicate crosspolymer, and vinyl dimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer are unlikely to have any skin absorption due to the polymeric nature of the chemical. No further data on the “similar polymers” were provided.^{4,7,9}

Oral and Inhalation

No data were discovered on the oral or inhalation toxicokinetics of these ingredients.

TOXICOLOGICAL STUDIES

Acute Toxicity

Dermal – Non-Human

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

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, the acute dermal LD₅₀ for crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyl dimethicone crosspolymer for rats was estimated to be > 2000 mg/kg.⁴ No further data on the “similar polymers” were provided.

DIMETHICONE CROSSPOLYMER

Dimethicone crosspolymer (12% in cyclomethicone) is reported to have a dermal LD₅₀ of > 2000 mg/kg in rabbits (n = 5/sex).⁵ There were no deaths or clinical signs.

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, the acute dermal LD₅₀ for dimethicone/vinyl trimethylsiloxysilicate crosspolymer for rats was estimated to be > 2000 mg/kg.⁹ No further data on the “similar polymers” were provided.

VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, the acute dermal LD₅₀ of vinyl dimethyl/ trimethylsiloxysilicate stearyl dimethicone crosspolymer for rats was expected to be > 2000 mg/kg.⁹ No further data on the “similar polymers” were provided.

Oral – Non-Human

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

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, the acute oral LD₅₀ of crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyl dimethicone crosspolymer for rats is estimated to be > 2000 mg/kg.⁴ No further data on the “similar polymers” were provided.

DIMETHICONE CROSSPOLYMER

The oral LD₅₀ 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.

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, the acute oral LD₅₀ for dimethicone/ vinyltrimethylsiloxysilicate crosspolymer for rats is estimated to be > 5000 mg/kg.⁷ No further data on the “similar polymers” were provided.

VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, the acute oral LD₅₀ of vinyltrimethylsiloxysilicate stearyl dimethicone crosspolymer for rats is expected to be > 2000 mg/kg.⁹ No further data on the “similar polymers” were provided.

Inhalation – Non-Human

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

The acute inhalation LC₅₀ 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).²¹

Repeated Dose Toxicity

Dermal

No repeated dose dermal toxicity studies were discovered for these ingredients.

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.²²

Inhalation – Non-Human

No repeated dose inhalation studies were discovered for these ingredients.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

No primary reproductive or developmental toxicity studies were discovered.

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

According to a supplier of a trade name mixture, based on the structural analogy to a similar polymer, dimethicone/vinyltrimethylsiloxysilicate crosspolymer is not expected to be a reproductive toxicant.⁷ No further data on the “similar polymers” were provided.

GENOTOXICITY

In Vitro

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

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer is not expected to be mutagenic.⁴ No further data on the “similar polymers” were provided.

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.²²

DIMETHICONE CROSSPOLYMER

Dimethicone crosspolymer (0 – 1000 µg/plate; dissolved in tetrahydrofuran) 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. tryphimurium*

(strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.²³

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 aberrations.²³
DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER

Dimethicone/phenyl vinyl dimethicone crosspolymer (~16%) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.²⁴
DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

A product containing dimethicone/polyglycerin-3 crosspolymer (~40% in dimethicone; 5000 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.²⁵
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER

A product containing dimethicone/vinyl dimethicone crosspolymer (~24% in dimethicone; 5000 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.²⁶
DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, dimethicone/vinyltrimethylsiloxysilicate crosspolymer is not expected to be mutagenic.⁷ No further data on the “similar polymers” were provided.
DIPHENYL DIMETHICONE/VINYL DIPHENYL DIMETHICONE SILSESQUIOXANE CROSSPOLYMER

Dipheynyl dimethicone/vinyl diphenyl dimethicone silsesquioxane crosspolymer (100%; 5000 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.²⁷
LAURYL DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER

Lauryl dimethicone/polyglycerin-3 crosspolymer (40% in mineral oil; 5000 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.²⁸
LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER

Lauryl polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer (100%; 312.5 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.²⁹
PEG-15 LAURYL DIMETHICONE CROSSPOLYMER

PEG-15 lauryl dimethicone crosspolymer (100%; 5000 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.³⁰
PEG-15/LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE CROSSPOLYMER

PEG-15/lauryl polydimethylsiloxylethyl dimethicone crosspolymer (100%; 5000 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.³¹
POLYGLYCERYL-3/LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE CROSSPOLYMER

Polyglyceryl-3/lauryl polydimethylsiloxylethyl dimethicone crosspolymer (100%; 2500 µg/plate) was not mutagenic to *S. tryphimurium* (strains TA98, TA100, TA1535, TA1537) and *E. coli* (strain WP3uvrA) with or without metabolic activation.³²
VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer is not expected to be mutagenic.⁹ No further data on the “similar polymers” were provided.

CARCINOGENICITY

No carcinogenicity studies were discovered on these ingredients.

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

According to a supplier of a trade name mixture, based on the chemical structure of similar polymers, dimethicone/vinyltrimethylsiloxysilicate crosspolymer is not expected to be carcinogenic.⁷ No further data on the “similar polymers” were provided.

IRRITATION AND SENSITIZATION

Irritation

Dermal – Non-Human

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

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer is not expected to be dermally irritating.⁴ No further data on the “similar polymers” were provided.

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).²³ 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).²⁴ 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).²⁵ 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).²⁶ The authors concluded that the test article was a mild irritant.

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

Dimethicone/vinyltrimethylsiloxysilicate crosspolymer was not dermally irritating to rabbits.⁷ No further information was provided.

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).²⁷ 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).²⁷ 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).²⁹ 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).³³ 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).³⁰ 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).³¹ 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).³² 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).³⁴ 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).³⁵ 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 5.²²

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.²²

Mucosal

No mucosal irritation data were discovered for these ingredients.

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 cornea observed.

Dimethicone crosspolymer (100%; 0.1 ml) produced a mild, transient ocular irritant to male New Zealand White rabbits (n = 3).²²

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.³⁶

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

Dimethicone/vinyltrimethylsiloxysilicate crosspolymer was not an ocular irritant to rabbits.⁷ No further information was provided.

Sensitization

Dermal – Non-Human

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

According to a supplier of a trade name mixture, based on physico-chemical characteristics of data on similar polymers, crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer is not expected to be sensitizing.⁴ No further data on the “similar polymers” were provided.

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.²²

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).²³

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).²⁵

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.²⁴

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.²⁶

DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER

According to a supplier of a trade name mixture, based on physico-chemical characteristics and data on similar polymers, dimethicone/vinyltrimethylsiloxysilicate crosspolymer is not expected to be sensitizing.⁷ No further data on the “similar polymers” were provided.

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.²⁷

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.²⁸

LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER

In a local lymph node assay, lauryl polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer (1.5%, 3%, and 7.5% w/v) was not a sensitizer.²⁹

PEG-15/LAUREL POLYDIMETHYLSILOXYETHYL DIMETHICONE CROSSPOLYMER

In a local lymph node assay using mice, PEG-15/lauryl polydimethylsiloxylethyl dimethicone crosspolymer (1.5%, 3%, and 7.5% w/v) was not a sensitizer.³¹

POLYGLYCERYL-3/LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE CROSSPOLYMER

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

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.³⁵

VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER

Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer (20% in isododecane) was not sensitizing to guinea pigs.⁹

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.²²

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.²²

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.³⁷

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.³⁸

SUMMARY

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

Dimethicone/divinyldimethicone/silsesquioxane crosspolymer has a spherical shape with a particle diameter ranging from 2 – 10 µm.

These crosspolymer ingredients are typically supplied as swollen gels that contain various oils (e.g., silicone oils such as dimethicone).

Heavy metals, polycyclic aromatic hydrocarbons, organohalogen compounds, or nitrosamines were not detected in dimethicone crosspolymers. Residuals from manufacturing include 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.

Behenyl dimethicone/bis-vinyldimethicone crosspolymer was used in 5 leave-on products at concentrations up to 10%. C30-45 alkyl cetearyl dimethicone crosspolymer was reported to be used in 25 leave-on up to 4% and 2 rinse-off products. C4-24 alkyl dimethicone/divinyldimethicone crosspolymer was reported to be used in 1 leave-on product and in foundations up to 2%. Cetearyl dimethicone crosspolymer was reported to be used in 20 leave-on products up to 23%, in 1 rinse-off product up to 0.2%, and in products diluted for bath use up to 0.002%. Dimethicone/bis-isobutyl PPG-20 crosspolymer was reported to be used in 12 leave-on products up to 2%. Dimethicone crosspolymer was reported to be used in 430 leave-on products up to 25% and in 12 rinse-off products up to 5%. Dimethicone crosspolymer-3 was reported to be used in 52 leave-on products up to 2% and in rinse-off products up to 0.2%. Dimethicone/divinyldimethicone/silsesquioxane crosspolymer was reported to be used in 14 leave-on products up to 5%. Dimethicone/PEG-10/15 crosspolymer was reported to be used in 51 leave-on products up to 3% and in a hair conditioner up to 0.8%. Dimethicone/phenyl vinyl dimethicone crosspolymer was reported to be used in 10 leave-on products up to 2%. Dimethicone/vinyl dimethicone crosspolymer was reported to be used in 444 leave-on products up to 46% (including 1 baby product) and in 12 rinse-off products up to 37%. Dimethicone/vinyltrimethylsiloxysilicate crosspolymer was reported to be used in 14 leave-on products up to 6%. Diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer was reported to be used in 13 leave-on products up to 7%. Divinyldimethicone/dimethicone crosspolymer was reported to be used in 4 leave-on products up to 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 up to 2%. PEG-10 dimethicone crosspolymer was reported to be used in 15 leave-on products up to 2%. PEG-12 dimethicone crosspolymer was reported to be used in 25 leave-on products up to 2% and 3 rinse-off products up to 0.3%. PEG-15/lauryl dimethicone crosspolymer was reported to be used in 4 leave-on products up to 2% and in 3 rinse-off products. Silicone quaternium-16/glycidoxy dimethicone crosspolymer was reported to be used in 2 leave-on products up to 0.003% and 4 rinse-off products up to 3%. Vinyl dimethicone/lauryl dimethicone crosspolymer was reported to be used in 3 leave-on products up to 2% and in rinse-off products up to 0.09%. Vinyl dimethicone/methicone silsesquioxane

crosspolymer was reported to be used in 104 leave-on products up to 20% and 1 rinse off product up to 0.6%.

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.

Cetyl dimethicone/bis-vinyldimethicone crosspolymer was reported to be used in leave-on and rinse-off products up to 0.005%. Dimethicone/PEG-10 crosspolymer was reported to be used in leave-on products up to 0.5%. Dimethicone/PPG-20 crosspolymer was reported to be used in skin fresheners up to 0.2%. PEG-10/lauryl dimethicone crosspolymer was reported to be used in leave-on products up to 0.7% and rinse-off products up to 0.6%. Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer was reported to be used in lipstick up to 0.7%.

There were no reported uses for 31 ingredients in this report.

Dimethicone crosspolymer had a dermal LD₅₀ of > 2000 mg/kg in rabbits. The oral LD₅₀ of dimethicone crosspolymer was > 2000 mg/kg for rats. The acute inhalation LC₅₀ 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/vinyltrimethylsiloxy silicate 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.

DISCUSSION

The Panel noted the satisfactory amount of data on acute toxicity, genotoxicity, irritation, and sensitization.

The Panel also noted the lack of toxicokinetics, repeated dose, 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 and will not penetrate the skin. Also, the properties of the silica backbone show stability and should not leach nor break down. There are multiple animal irritation and sensitization studies as well as two HRIPT studies that were negative for effects.

The Panel noted that even though the ingredients are stable, there should be no residual monomers or catalysts in the final product, including:

- 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]
- unidentifiable diamine crosslinking agent in silicone quaternium-16/glycidoxy dimethicone crosspolymer
- styrene
- divinyl benzene
- allyl polyglyceryl-3
- bisvinyl trifluoropropyl methicone (if n ≤ ~8).

Because these ingredients were reported to be used in products that may be aerosolized, including face powders, foot powders and sprays, perfumes, and hair sprays, the Panel discussed the issue of incidental inhalation exposure. The limited data available include just one acute study that does suggest little potential for respiratory effects with an LD₅₀ for crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone of > 5.29 mg/L. The Panel believes that the sizes of a substantial majority of the particles of these ingredients, as manufactured, are larger than the respirable range and/or aggregate and agglomerate to form much larger particles in formulation. The Panel considered other data available to characterize the potential for dimethicone crosspolymers to cause genotoxicity, irritation, and sensitization or other effects. 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, 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. Further, these ingredients are reportedly used at concentrations up to 20% in spray and up to 46% in powder cosmetic products that may be aerosolized. The Panel noted that 95% – 99% of droplets/particles produced in cosmetic aerosols would not be respirable to any appreciable amount. However, the potential for inhalation toxicity is not limited to respirable droplets/particles deposited in the lungs. Inhaled droplets/particles deposited in the nasopharyngeal and thoracic regions of the respiratory tract may cause toxic effects depending on their chemical and other properties. 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.

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/ divinyl dimethicone 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
- divinyl dimethicone/dimethicone crosspolymer
- hydroxypropyl dimethicone/polysorbate 20 crosspolymer*
- isopropyl titanium triisostearate/ triethoxysilylethyl polydimethylsiloxylethyl dimethicone crosspolymer
- lauryl dimethicone PEG-15 crosspolymer*
- lauryl dimethicone/polyglycerin-3 crosspolymer*
- lauryl polydimethylsiloxylethyl 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 polydimethylsiloxylethyl dimethicone crosspolymer*
- perfluorononyl dimethicone/methicone/ amodimethicone crosspolymer
- polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer*
- polyglyceryl-3/lauryl polydimethylsiloxylethyl dimethicone crosspolymer*
- silicone quaternium-16/glycidoxy dimethicone crosspolymer
- styrene/acrylates/dimethicone acrylate

- crosspolymer
- trifluoropropyl dimethicone/PEG-10 crosspolymer*
 - trifluoropropyl dimethicone/trifluoropropyl divinyl dimethicone crosspolymer*
 - trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer*
 - trimethylsiloxysilicate/ dimethicone crosspolymer*
 - vinyl dimethicone/lauryl/behanyl dimethicone

- crosspolymer*
- vinyl dimethicone/lauryl dimethicone crosspolymer
 - vinyl dimethicone/methicone silsesquioxane crosspolymer
 - vinyl dimethyl/trimethylsiloxysilicate/dimethicone crosspolymer*
 - vinyl dimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer*

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

TABLES 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. <i>Herein, simple esters means methyl, ethyl, propyl, or butyl esters.</i>	Absorbent, film former, skin protectant, viscosity increasing agent-nonaqueous
Behenyl Dimethicone/Bis-Vinyldimethicone Crosspolymer	Behenyl Dimethicone/Bis-Vinyldimethicone Crosspolymer is structurally defined. <i>It is a copolymer of behenyl dimethicone crosslinked with divinyl dimethicone.</i>	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. <i>It is a copolymer of Dimethicone crosslinked with divinyl dimethicone.</i>	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-allyl 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 divinyl dimethicone.	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. <i>It is a copolymer of cetyl dimethicone crosslinked with divinyl dimethicone.</i>	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. <i>It is a polymer of dimethicone, crosslinked with ethylene linkages to form cyclized-like repeat units.</i>	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. <i>Wherein the crosslinking agent is not disclosed.</i>	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 <i>diallyl</i> 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 <i>diallyl</i> 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 <i>diallyl</i> 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. <i>Herein, simple esters means methyl, ethyl, propyl, or butyl esters</i>	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/ Silsequioxane Crosspolymer	Trifluoropropyl Dimethicone/Vinyl Trifluoropropyl Dimethicone/Silsequioxane Crosspolymer is a crosslinked copolymer of trifluoropropyl dimethicone, vinyl trifluoropropyl dimethicone and silsequioxane 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 Silsequioxane Crosspolymer	Vinyl Dimethicone/Methicone Silsequioxane Crosspolymer is a copolymer of methicone silsequioxane crosslinked with <i>bis</i> -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 <i>bis</i> -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	³⁹
Dimethicone, methicone, vinyl dimethicone	Safe as a cosmetic ingredient	2
PEG-8, -10, -15, -12,	Safe in the present practices of use and concentration	40
Polysorbate 20	Safe as a cosmetic ingredient in the concentration of present use	41
PPG-20	Safe for use in cosmetic products at concentrations up to 50%	42,43
Trimethylsiloxysilicate	Safe as used when formulated and delivered in the final product to be not irritating or sensitizing to the respiratory tract	44

Table 3. Chemical and physical properties of dimethicone crosspolymers

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

Table 3. Chemical and physical properties of dimethicone crosspolymers

Property	Value	Reference
Bis-vinyldimethicone crosspolymer		
No data were discovered.		
Bis-vinyldimethicone/PEG-10 dimethicone crosspolymer		
No data were discovered.		
Bis-vinyldimethicone/PPG-20 crosspolymer		
No data were discovered.		
Butyldimethicone methacrylate/methyl methacrylate crosspolymer		
No data were discovered.		
C30-45 alkyl cetearyl dimethicone crosspolymer		
No data were discovered.		
C4-24 alkyl dimethicone/divinyldimethicone crosspolymer		
No data were discovered.		
C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer		
No data were discovered.		
Cetearyl dimethicone crosspolymer		
No data were discovered.		
Cetearyl dimethicone/vinyl dimethicone crosspolymer		
No data were discovered.		
Cetyl dimethicone/bis-vinyldimethicone crosspolymer		
Physical form	Liquid	45
Water solubility 1% & 10%	Insoluble	45
Other solubility isopropyl alcohol 1% & 10%	Insoluble	45
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.		
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.		
Dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer		
No data were discovered.		
Dimethicone crosspolymer		
No data were discovered.		

Table 3. Chemical and physical properties of dimethicone crosspolymers

Property	Value	Reference
Dimethicone crosspolymer-3		
No data were discovered.		
Dimethicone/divinyldimethicone/silsesquioxane crosspolymer		
Physical Form	Powder	11
Color	Off white	11
Odor	Typical	11
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.		
Dimethicone/PEG-10 crosspolymer		
No data were discovered.		
Dimethicone/PEG-10/15 crosspolymer		
No data were discovered.		
Dimethicone/PEG-15 crosspolymer		
No data were discovered.		
Dimethicone/phenyl vinyl dimethicone crosspolymer		
No data were discovered.		
Dimethicone/polyglycerin-3 crosspolymer		
No data were discovered.		
Dimethicone/PPG-20 crosspolymer		
No data were discovered.		
Dimethicone/titanate crosspolymer		
No data were discovered.		
Dimethicone/vinyl dimethicone crosspolymer		
No data were discovered.		
Dimethicone/vinyltrimethylsiloxysilicate crosspolymer		
No data were discovered		
Diphenyl dimethicone crosspolymer		
No data were discovered.		
Diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer		
No data were discovered.		
Divinyldimethicone/dimethicone crosspolymer		
No data were discovered.		
Hydroxypropyl dimethicone/polysorbate 20 crosspolymer		
No data were discovered.		
Isopropyl titanium triisostearate/triethoxysilyl ethyl polydimethylsiloxyethyl dimethicone crosspolymer		
No data were discovered.		
Lauryl dimethicone PEG-15 crosspolymer		
No data were discovered.		

Table 3. Chemical and physical properties of dimethicone crosspolymers

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

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 4. Frequency of use according to duration and exposure of dimethicone crosspolymers. There were no uses reported 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 polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer, PEG-8 dimethicone/polysorbate 20 crosspolymer, PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer, PEG-12 dimethicone/PPG-20 crosspolymer, polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer, polyglyceryl-3/lauryl polydimethylsiloxylethyl dimethicone crosspolymer, styrene/acrylates/ dimethicone acrylate crosspolymer, trifluoropropyl dimethicone/PEG-10 crosspolymer, trifluoropropyl dimethicone/trifluoropropyl divinyl dimethicone crosspolymer, trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer, trimethylsiloxysilicate/ dimethicone crosspolymer, vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer, vinyldimethyl/ trimethylsiloxysilicate/ dimethicone crosspolymer, and vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer.^{12,13}

Use type	Maximum Concentration		Maximum Concentration		Maximum Concentration		Maximum Concentration	
	Uses	(%)	Uses	(%)	Uses	(%)	Uses	(%)
	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
<i>Duration of use</i>								
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
<i>Exposure type</i>								
Eye area	6	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

	Cetearyl dimethicone crosspolymer		Cetearyl dimethicone/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
<i>Duration of use</i>								
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
<i>Exposure type</i>								
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	0.002	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
<i>Duration of use</i>								
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
<i>Exposure type</i>								
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	0.3-0.5	6	0.2	NR	NR	NR	NR
Incidental inhalation-powders	NR	0.03	NR	NR	NR	NR	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

	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
<i>Duration of use</i>								
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
<i>Exposure type</i>								
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	0.5-0.6	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
<i>Duration of use</i>								
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
<i>Exposure type</i>								
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	0.2-2	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

	Isopropyl titanium triisostearate/triethoxysilylethylpolydimethylsiloxyethyl 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
<i>Duration of use</i>		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
<i>Exposure type</i>								
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	0.5
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/a modimethicone crosspolymer	
Total/range	7	NR	NR	0.5-0.7	7	0.7-2	NR	0.7
<i>Duration of use</i>								
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
<i>Exposure type</i>								
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

	Silicone quaternium-16/ glycidoxy dimethicone crosspolymer		Vinyl dimethicone/lauryl dimethicone crosspolymer		Vinyl dimethicone/methicone silsesquioxane crosspolymer		
Total/range	6	0.003-3	3	0.09-2	105	0.1-20	
<i>Duration of use</i>							
Leave-on	2	0.003	3	0.3-2	104	0.1-20	
Rinse-off	4	1-3	NR	0.09	1	0.5-0.6	
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	
<i>Exposure type</i>							
Eye area	NR	NR	NR	NR	21	0.3-17	
Incidental ingestion	NR	NR	NR	2	2	0.5	
Incidental Inhalation-sprays	NR	NR	NR	NR	2	5-20	
Incidental inhalation-powders	NR	NR	NR	NR	9	0.1-20	
Dermal contact	NR	NR	2	1	102	0.1-20	
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	
Hair-noncoloring	6	0.003-3	1	0.09-0.3	1	0.5-2	
Hair-coloring	NR	1	NR	NR	NR		
Nail	NR	NR	NR	NR	NR	0.5	
Mucous Membrane	NR	NR	NR	2	2	0.5	
Baby	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.

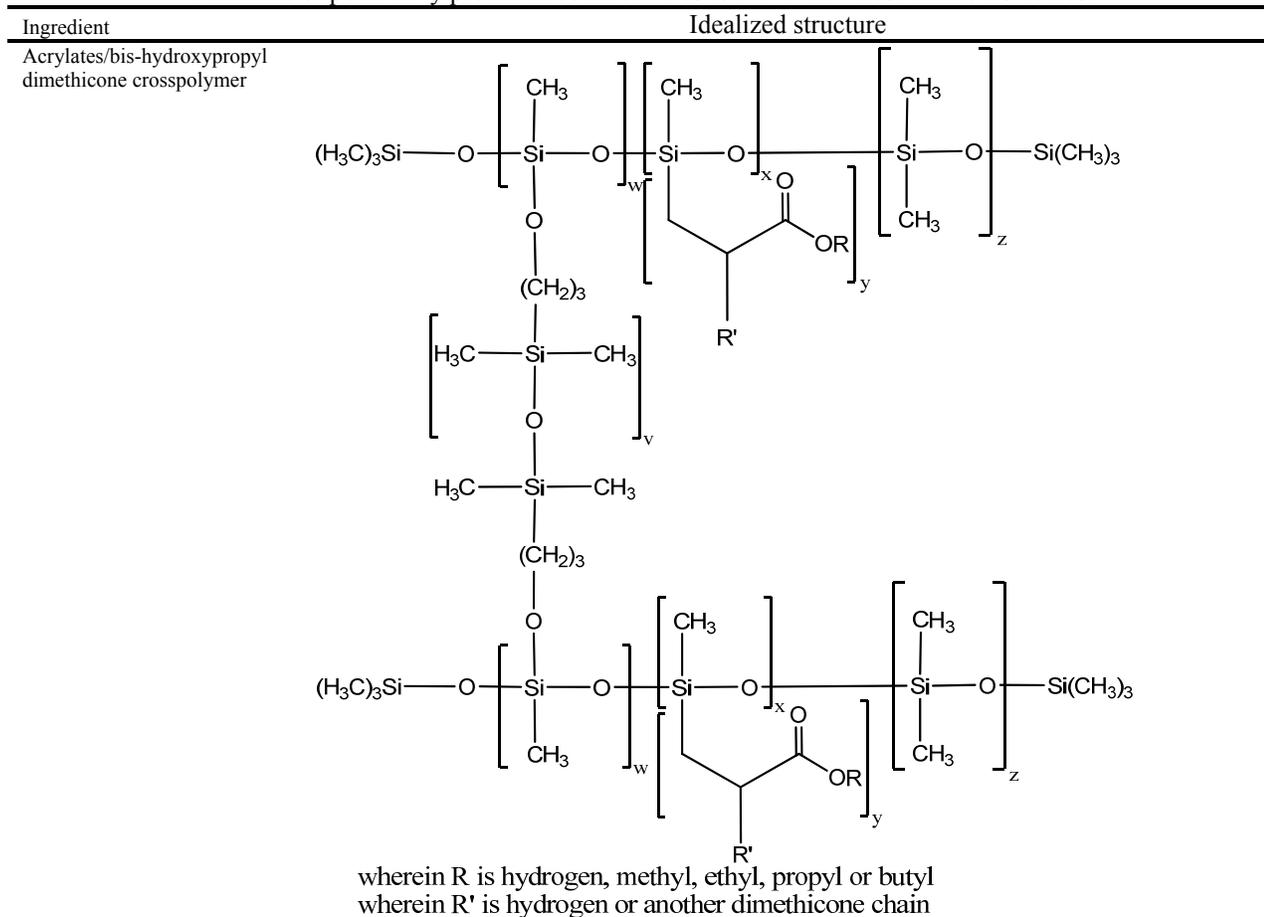


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Ingredient	Idealized structure
Behenyl dimethicone/bis-vinyldimethicone crosspolymer	

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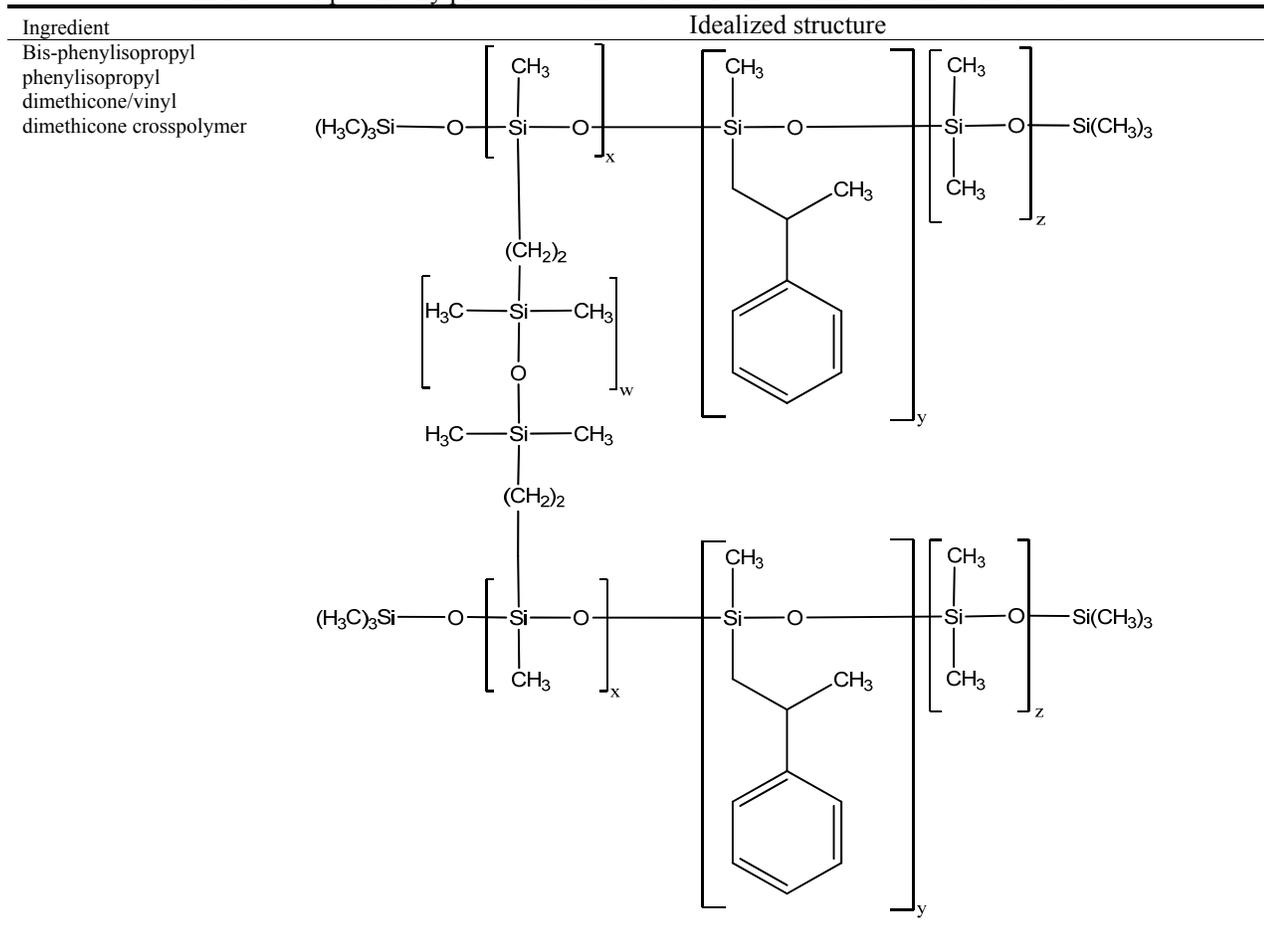


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Ingredient	Idealized structure
Bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer	
Bis-vinyldimethicone crosspolymer	
Bis-Vinyldimethicone/PPG-20 Crosspolymer	<p>Bis-Vinyldimethicone/PPG-20 Crosspolymer is a crosslinked polymer of Bis-Vinyldimethicone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

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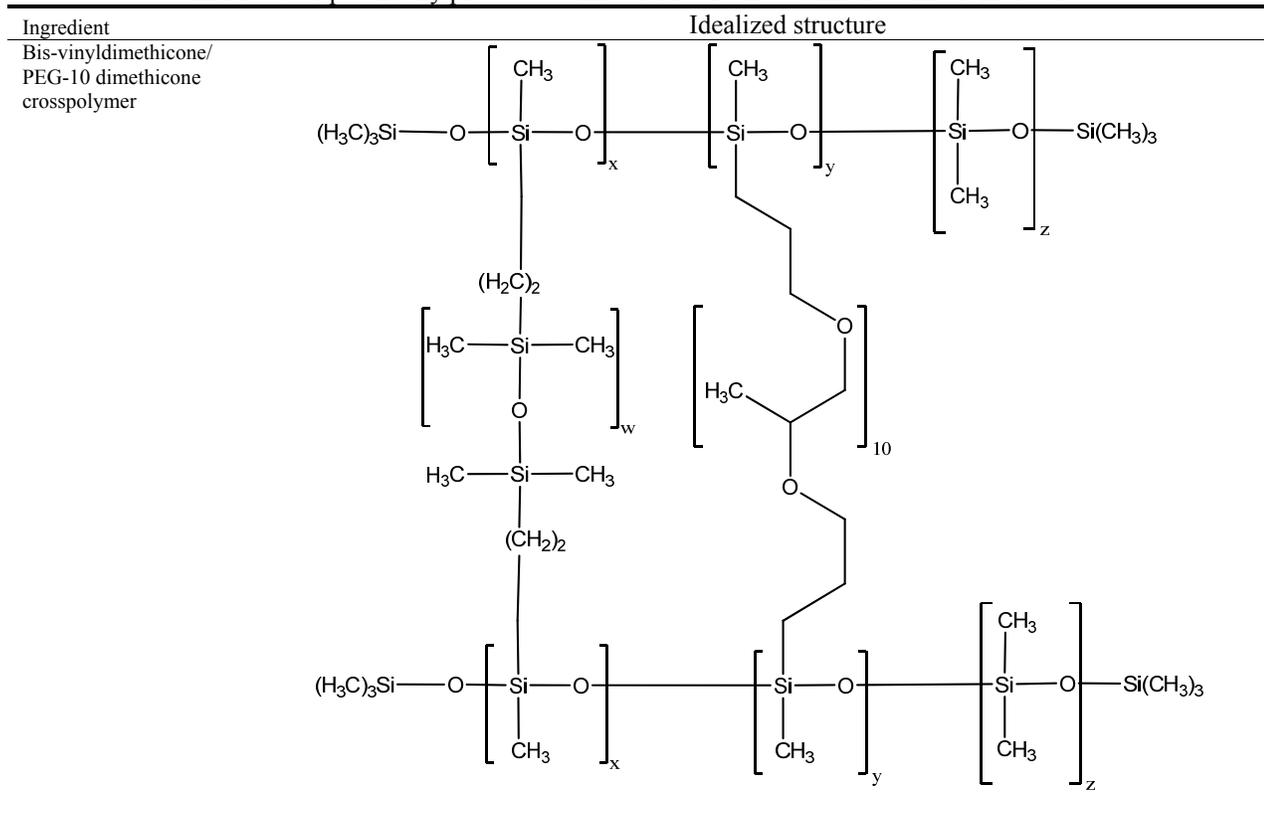


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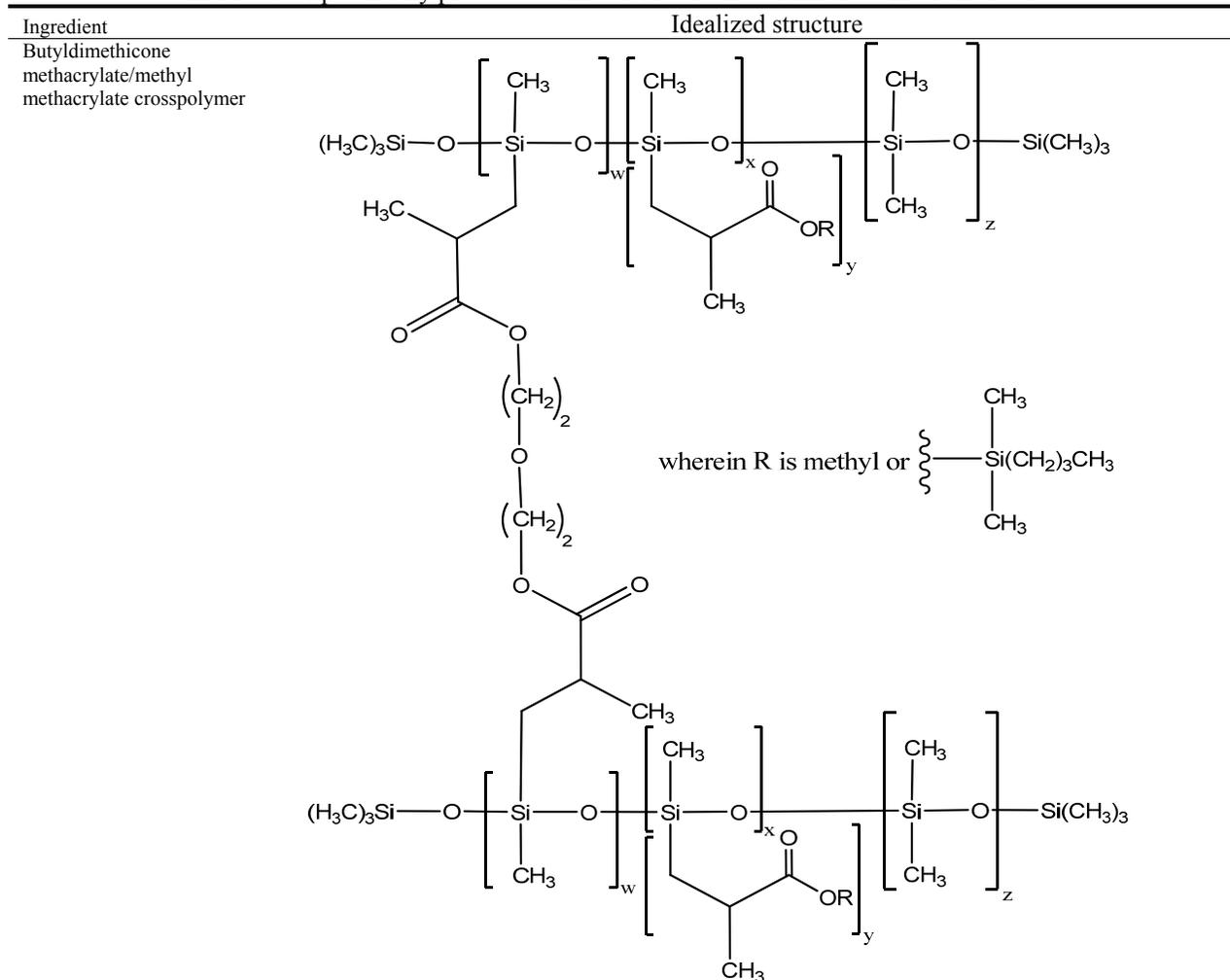


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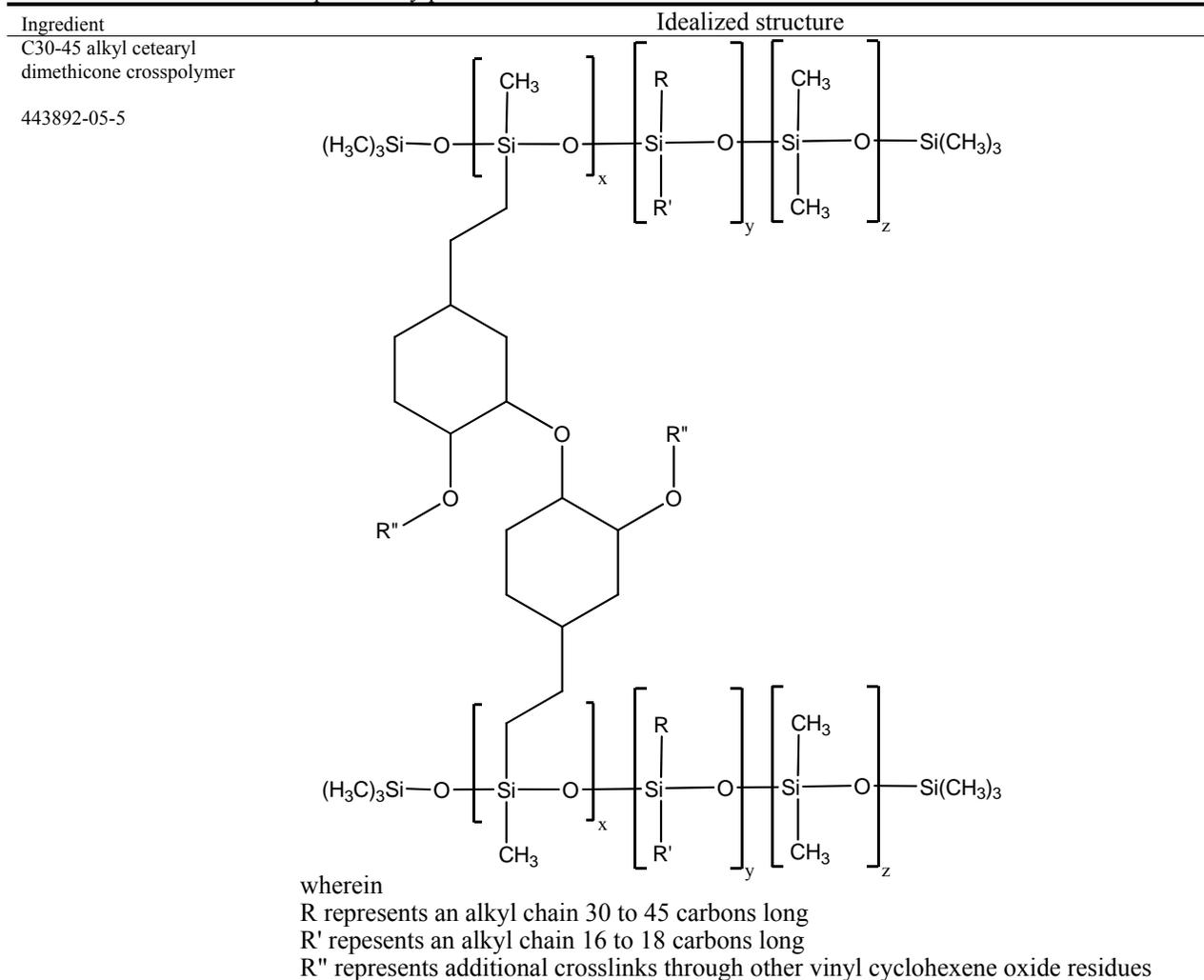


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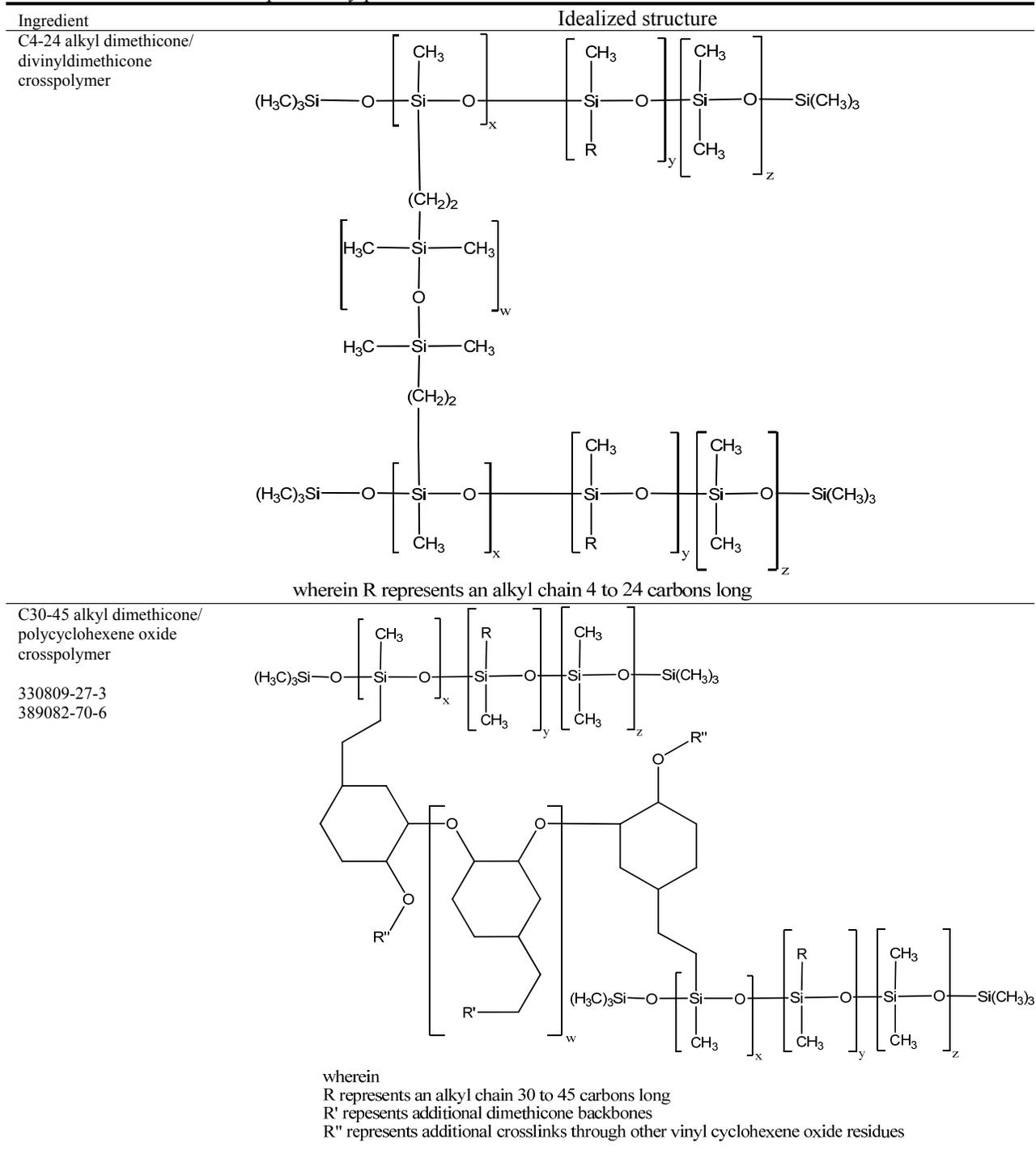


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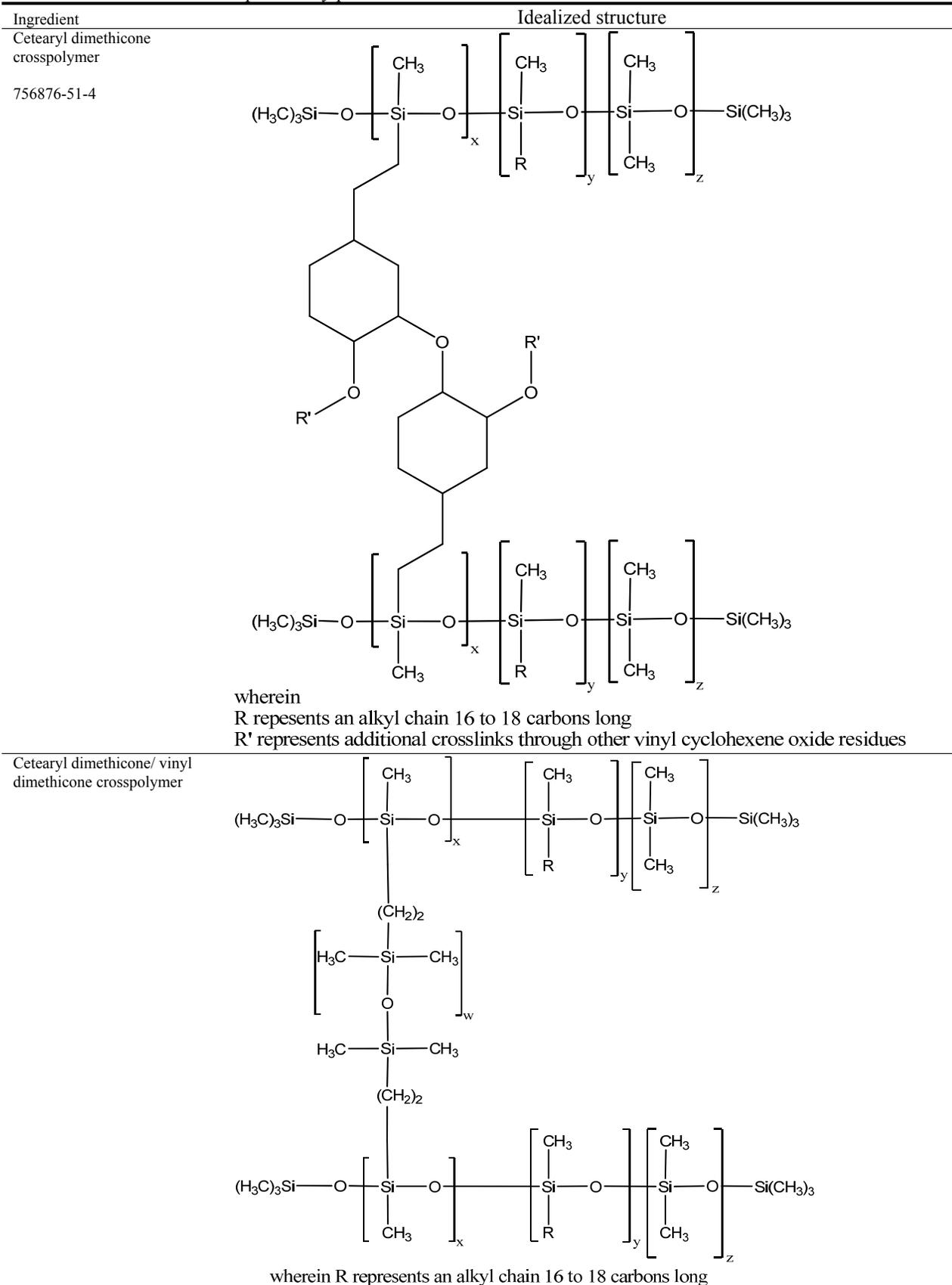


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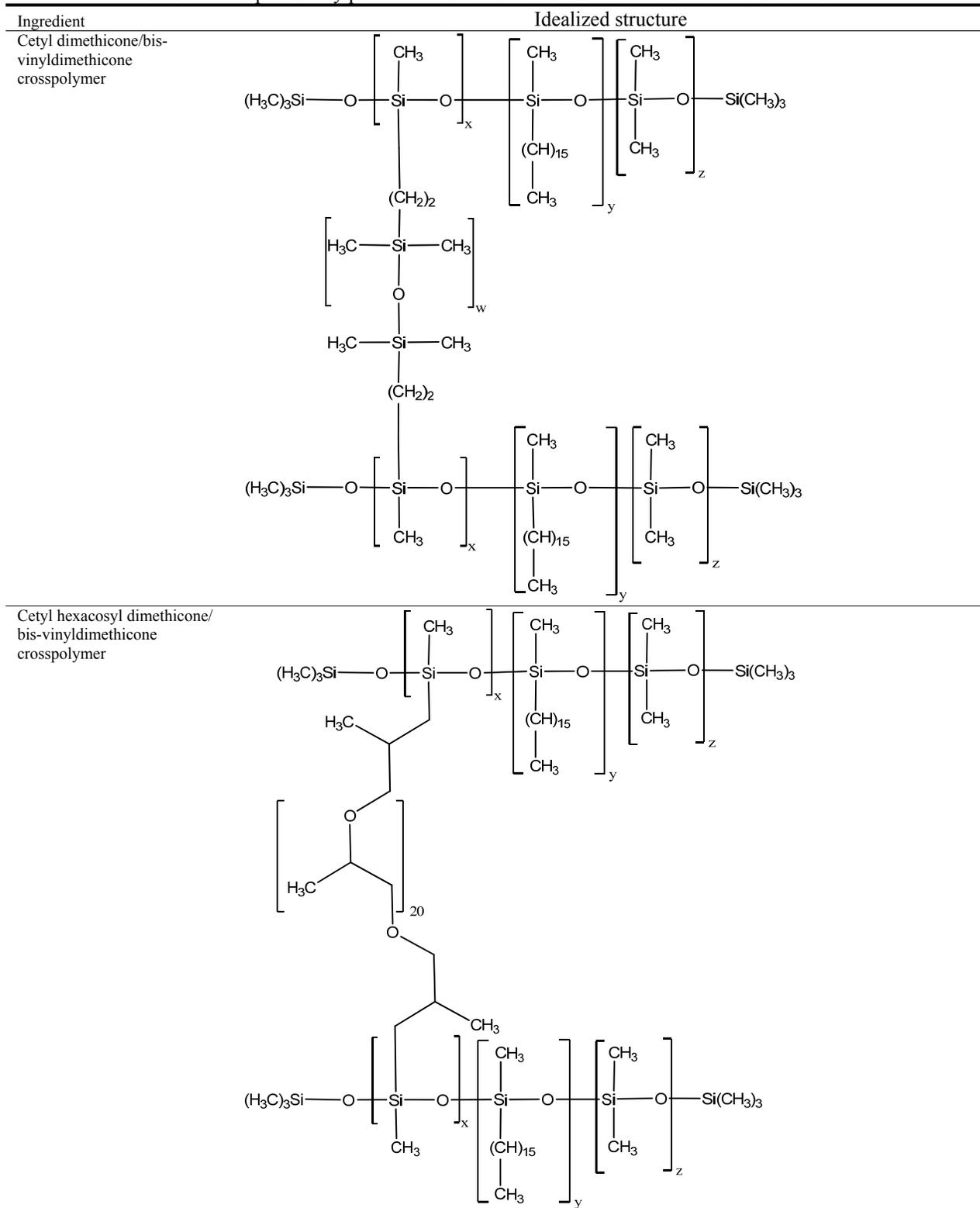


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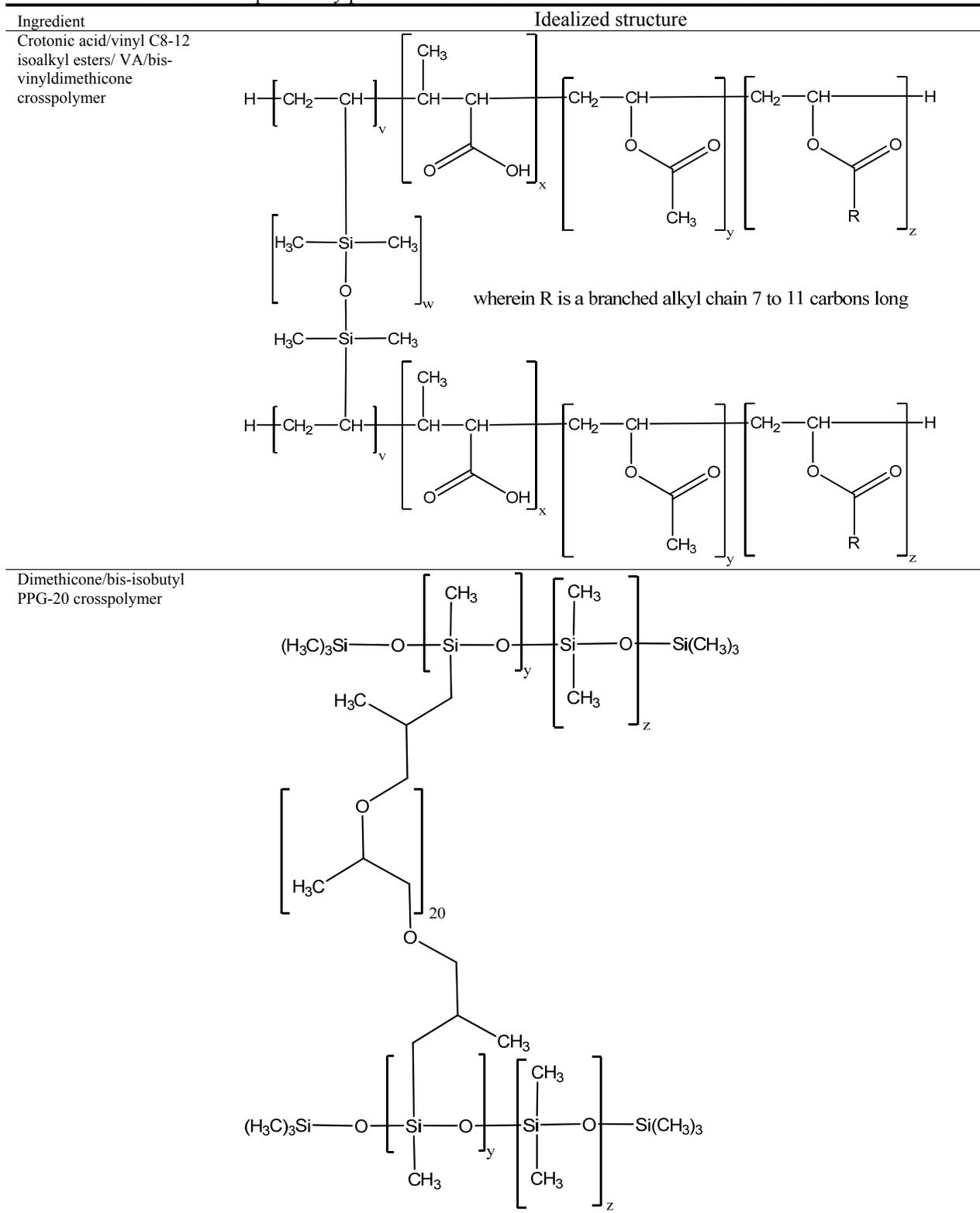


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Ingredient	Idealized structure
Dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer	$ \begin{array}{c} \text{(H}_3\text{C)}_3\text{Si}-\text{O}-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \end{array} \right]_x-\left[\begin{array}{c} \text{R} \\ \\ \text{Si} \\ \\ \text{OR}' \end{array} \right]_y-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \\ \\ \text{CH}_3 \end{array} \right]_z-\text{Si}(\text{CH}_3)_3 \\ \\ \text{(CH}_2\text{)}_2 \\ \left[\begin{array}{c} \text{H}_3\text{C}-\text{Si}-\text{CH}_3 \\ \\ \text{O} \end{array} \right]_w \\ \\ \text{H}_3\text{C}-\text{Si}-\text{CH}_3 \\ \\ \text{(CH}_2\text{)}_2 \\ \text{(H}_3\text{C)}_3\text{Si}-\text{O}-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \end{array} \right]_x-\left[\begin{array}{c} \text{R} \\ \\ \text{Si} \\ \\ \text{OR}' \end{array} \right]_y-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \\ \\ \text{CH}_3 \end{array} \right]_z-\text{Si}(\text{CH}_3)_3 \end{array} $ <p>wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones</p>
Dimethicone crosspolymer 213629-14-2	$ \begin{array}{c} \text{(H}_3\text{C)}_3\text{Si}-\text{O}-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \end{array} \right]_y-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \\ \\ \text{CH}_3 \end{array} \right]_z-\text{Si}(\text{CH}_3)_3 \\ \\ \text{(CH}_2\text{)}_{3-20} \\ \left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \\ \\ \text{CH}_3 \end{array} \right]_z \\ \\ \text{(H}_3\text{C)}_3\text{Si}-\text{O}-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \end{array} \right]_y-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{Si} \\ \\ \text{O} \\ \\ \text{CH}_3 \end{array} \right]_z-\text{Si}(\text{CH}_3)_3 \end{array} $
Dimethicone crosspolymer-3	$ \begin{array}{c} \left[\begin{array}{c} \text{CH}_3 \\ \\ \text{SiO} \\ \\ \text{(CH}_2\text{)}_2 \\ \\ \text{CH}_3 \end{array} \right]_x-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{SiO} \\ \\ \text{CH}_3 \end{array} \right]_y-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{SiO} \\ \\ \text{(CH}_2\text{)}_2 \\ \\ \text{CH}_3 \end{array} \right]_z-\text{Si}(\text{CH}_3)_3 \\ \\ \text{(CH}_3\text{)}_3\text{SiO}-\text{SiO}-\left[\begin{array}{c} \text{CH}_3 \\ \\ \text{SiO} \\ \\ \text{CH}_3 \end{array} \right]_y-\text{SiO}-\text{Si}(\text{CH}_3)_3 \end{array} $

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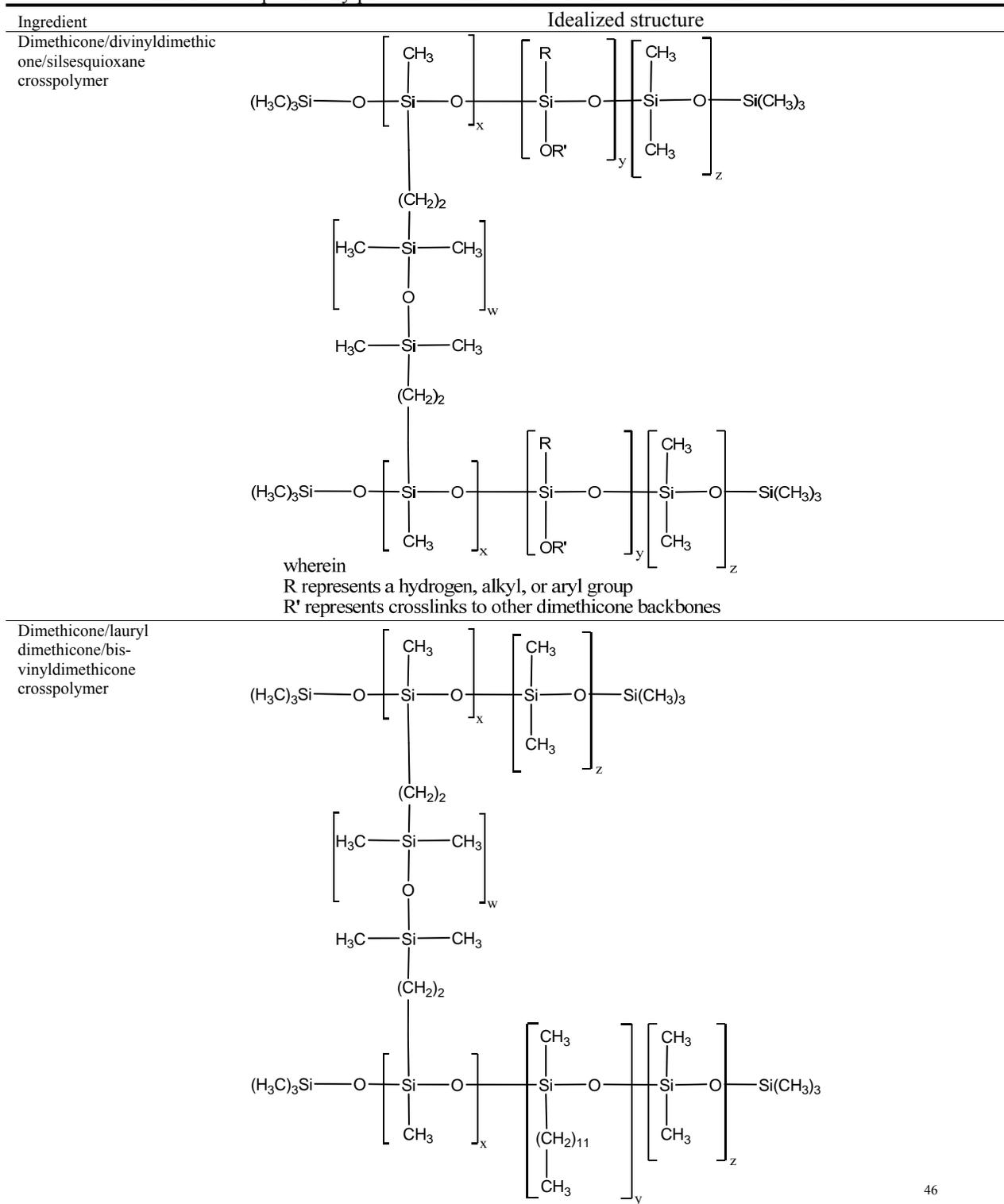


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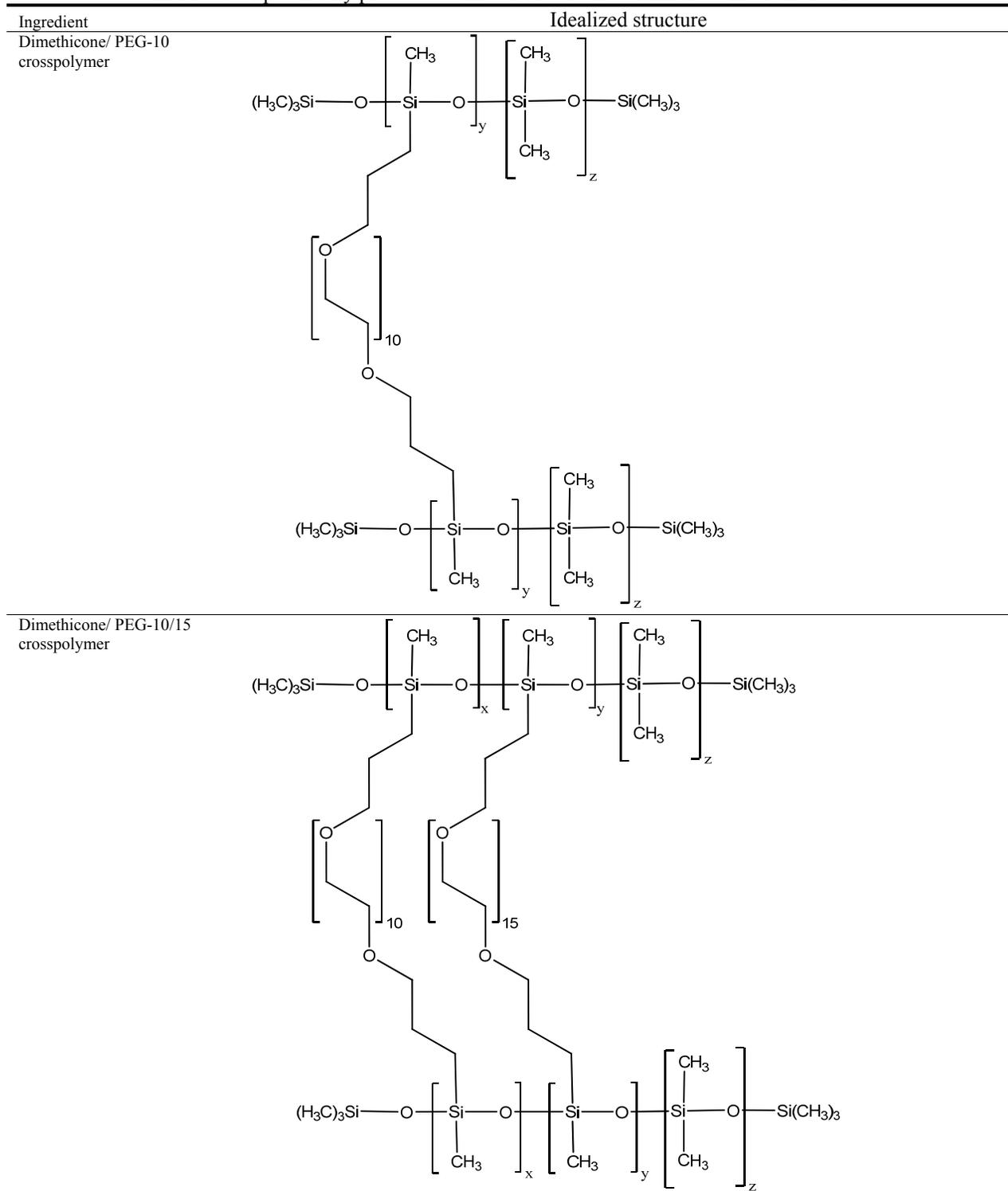


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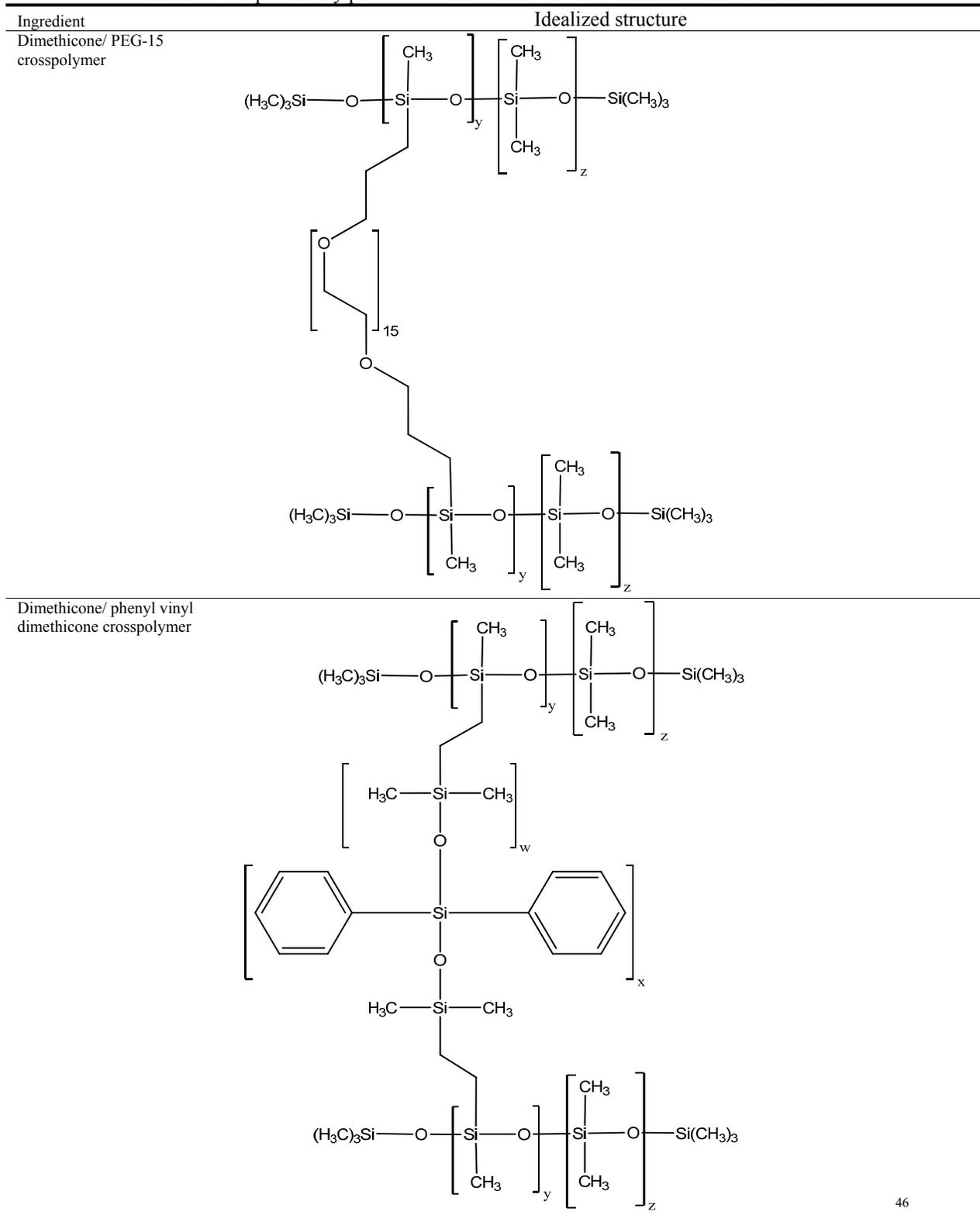


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Ingredient	Idealized structure
Dimethicone/polyglycerin-3 crosspolymer	
Dimethicone/PPG-20 crosspolymer	

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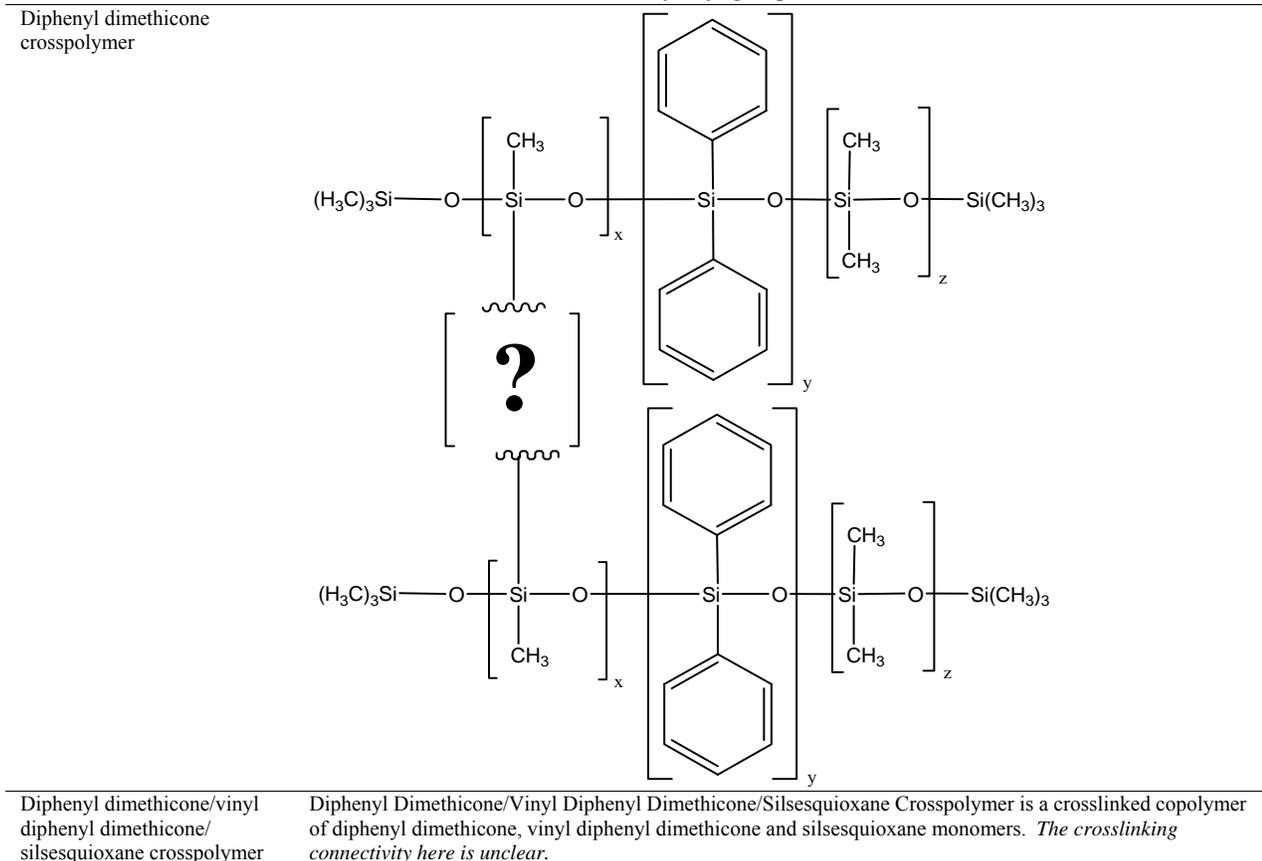
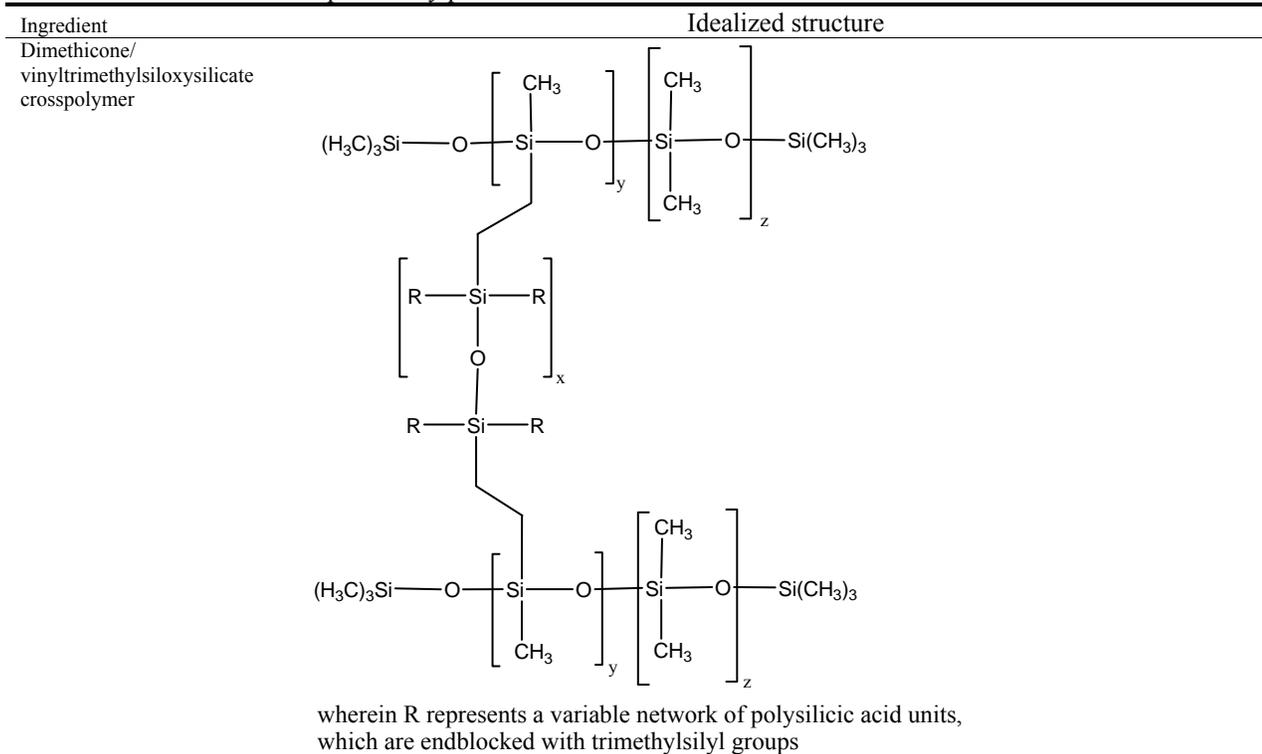


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Ingredient	Idealized structure
Phenyl modified Silicone Rubber	
Divinyldimethicone/ dimethicone crosspolymer	
Hydroxypropyl dimethicone/ polysorbate 20 crosspolymer	<p>Hydroxypropyl Dimethicone/Polysorbate 20 Crosspolymer is a copolymer of Hydroxypropyldimethicone and Polysorbate 20 crosslinked with Succinic Acid. <i>The immense connectivity variability added by Polysorbate 20 makes a structural representation of this ingredient quite challenging.</i></p>
Isopropyl titanium triisostearate/triethoxysilyl- ethyl polydimethylsiloxylethyl dimethicone crosspolymer	<p>Isopropyl Titanium Triisostearate/Triethoxysilylethyl Polydimethylsiloxylethyl Dimethicone Crosspolymer is a complex polymer formed by the hydrolysis and condensation of Isopropyl Titanium Triisostearate with Triethoxysilylethyl Polydimethylsiloxylethyl Dimethicone. <i>The immense connectivity variability in this polymer makes a structural representation of this ingredient quite challenging.</i></p>

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.

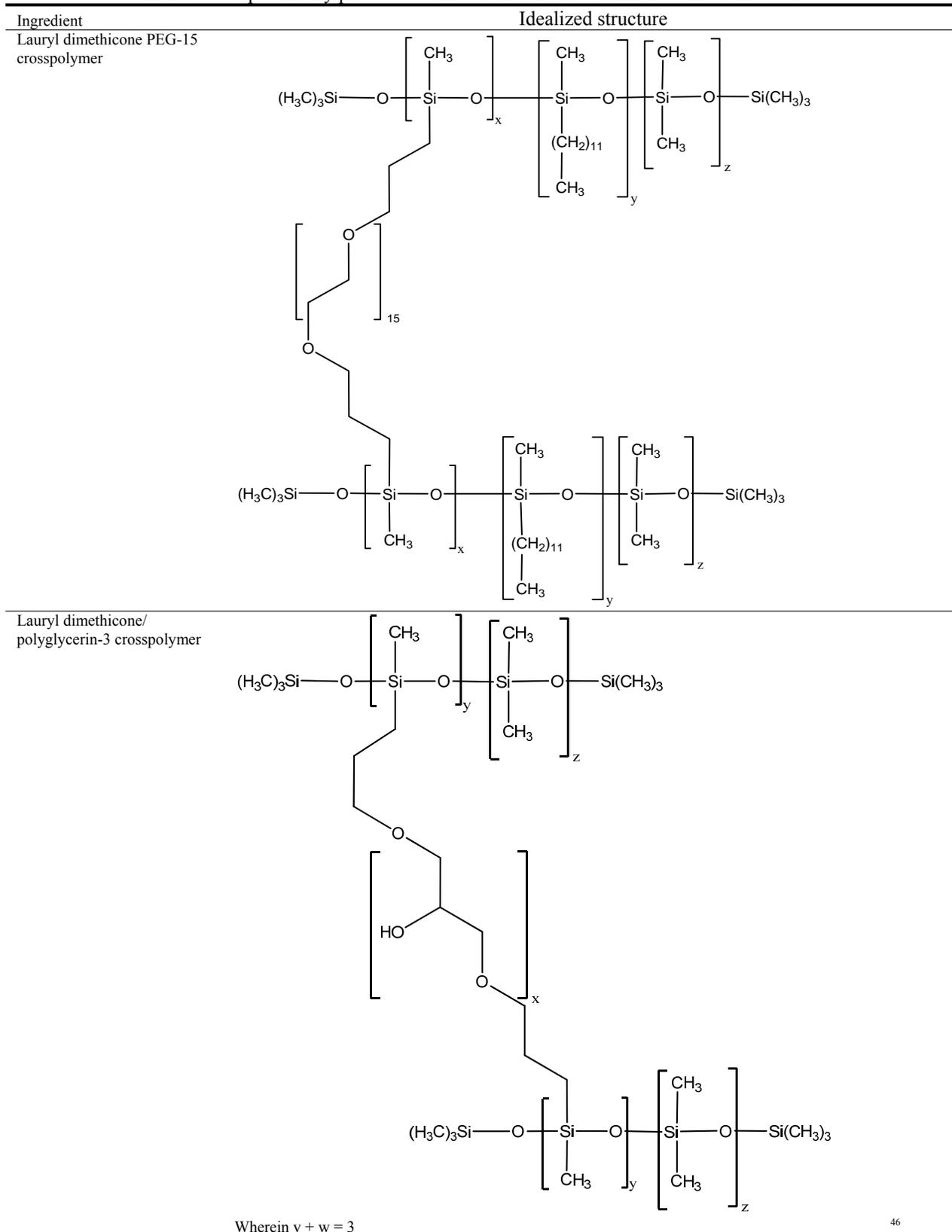


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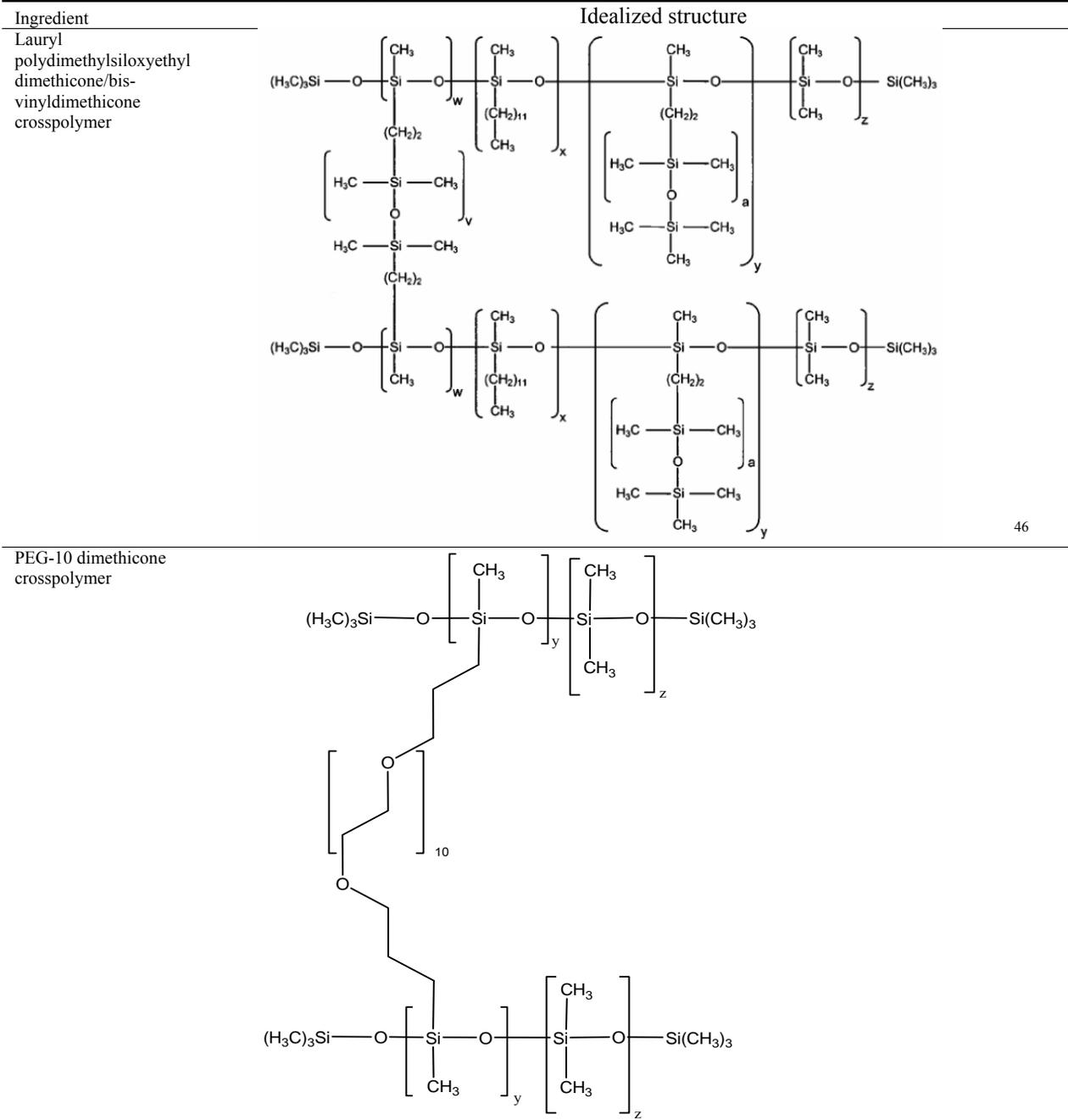


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Ingredient	Idealized structure
PEG-12 dimethicone crosspolymer	<p>The structure shows a dimethicone backbone consisting of three silicon atoms connected by oxygen atoms. The first silicon atom is bonded to three methyl groups and an oxygen atom. The second and third silicon atoms are part of repeating units, each bonded to two methyl groups and an oxygen atom. A polyethylene glycol (PEG) chain with 12 units is attached to the second silicon atom via an ether linkage. The third silicon atom is bonded to three methyl groups.</p>
PEG-8 dimethicone/polysorbate 20 crosspolymer	<p>The structure shows a dimethicone backbone consisting of three silicon atoms connected by oxygen atoms. The first silicon atom is bonded to three methyl groups and an oxygen atom. The second and third silicon atoms are part of repeating units, each bonded to two methyl groups and an oxygen atom. A polyethylene glycol (PEG) chain with 8 units is attached to the second silicon atom via an ether linkage. The third silicon atom is bonded to three methyl groups.</p>

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.

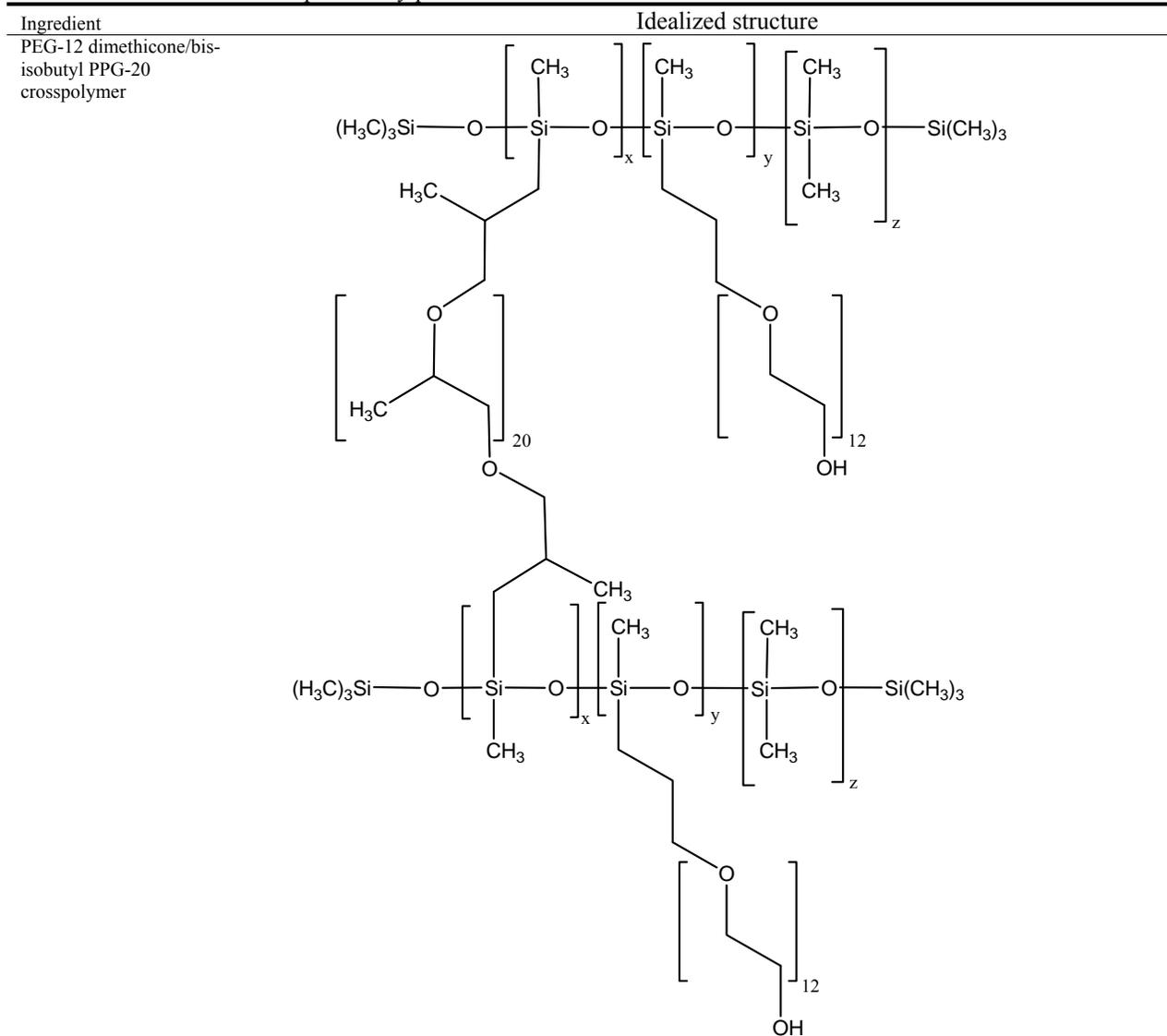


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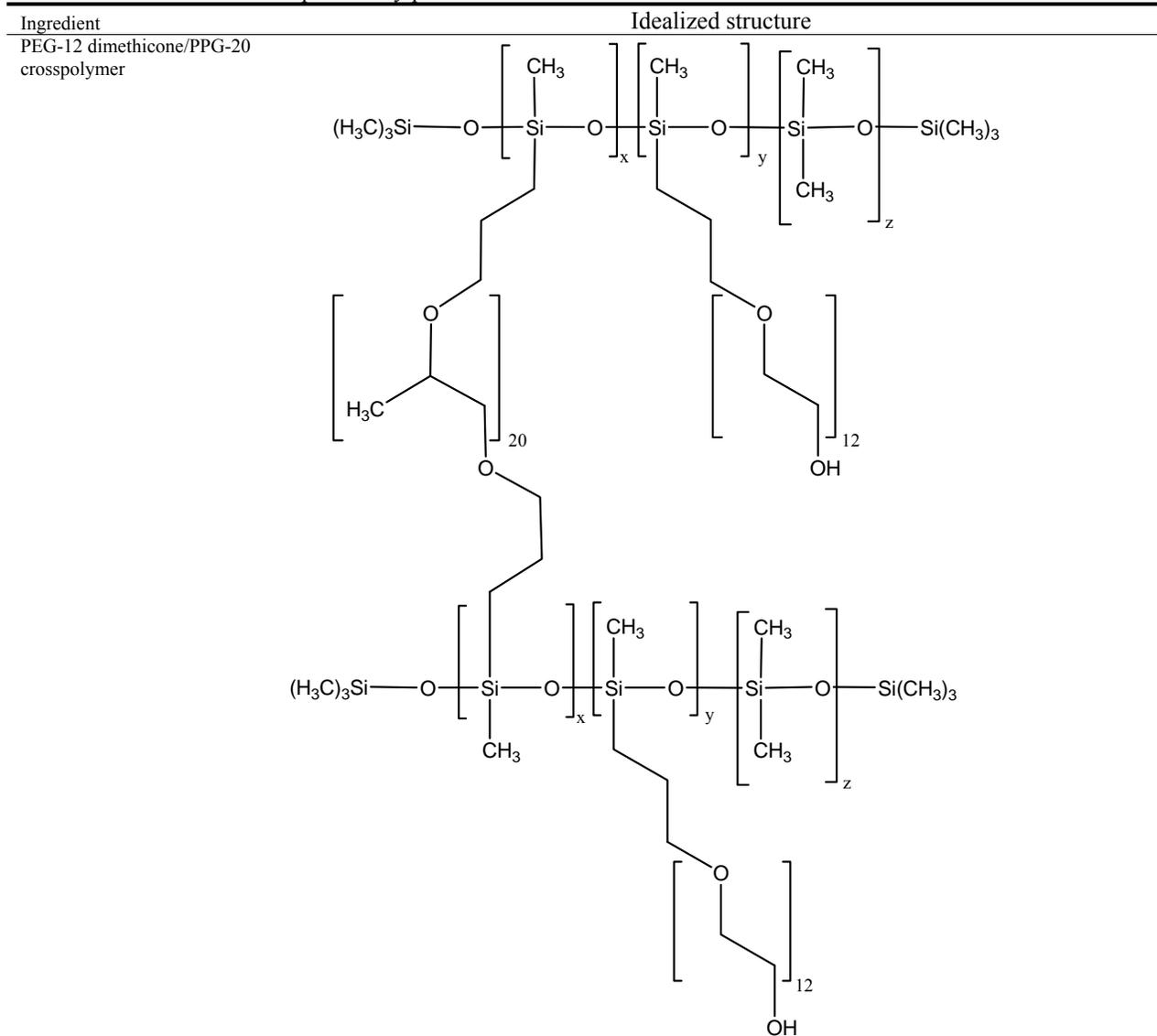
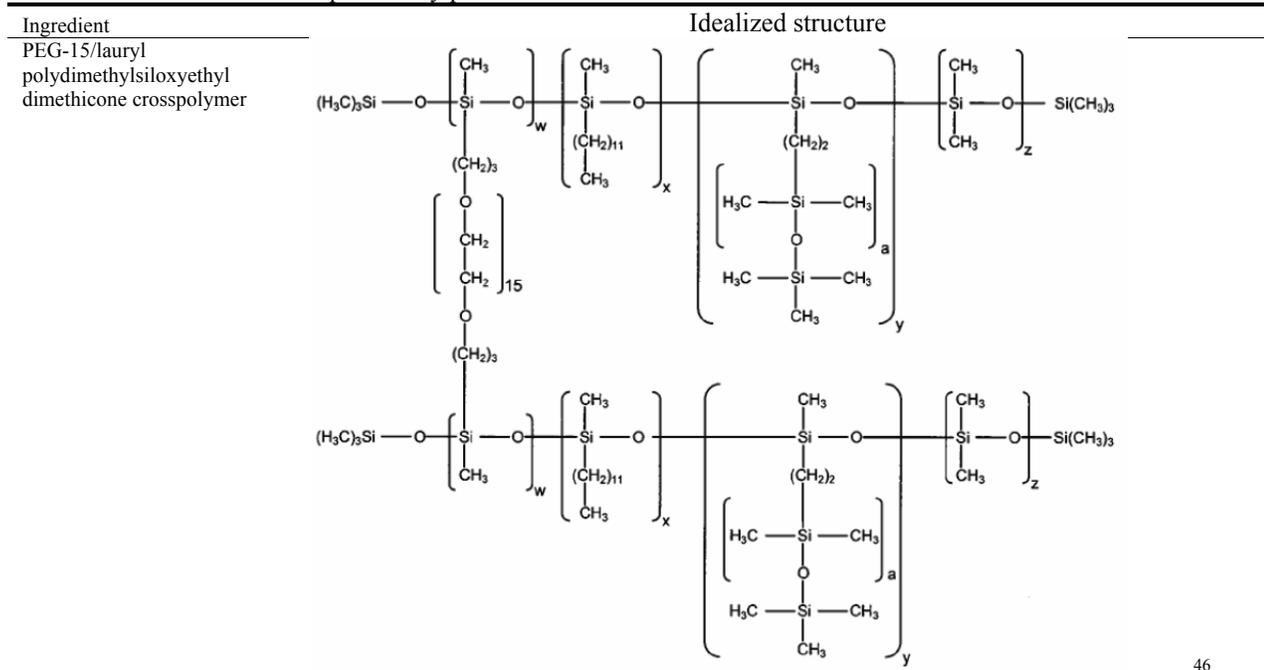


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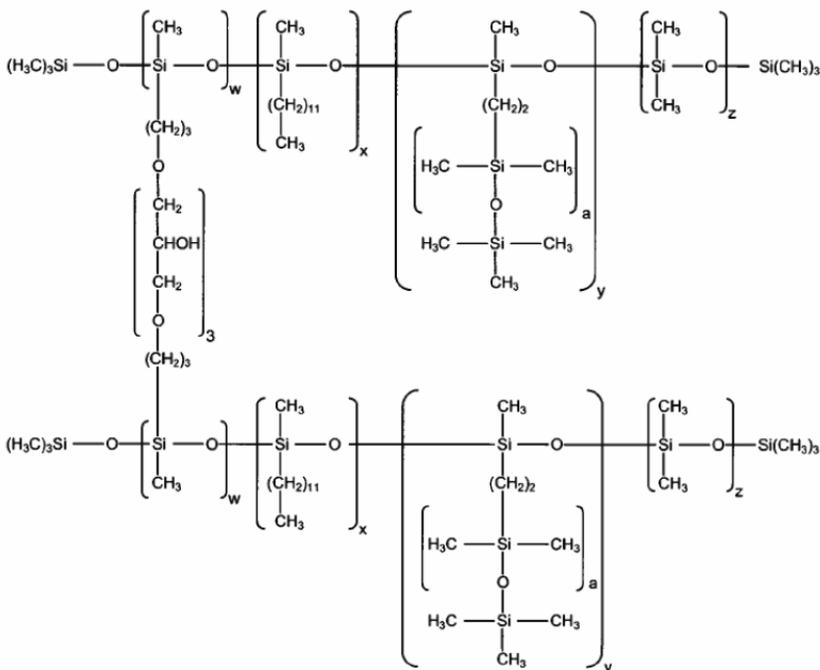
Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer

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.

Polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer

Polydimethylsiloxylethyl dimethicone/bis-vinyldimethicone crosspolymer is a copolymer of polydimethylsiloxylethyl dimethicone crosslinked with bis-vinyldimethicone. *The immense connectivity variability in this polymer makes a structural representation of this ingredient quite challenging.*

Polyglyceryl-3/lauryl polydimethylsiloxylethyl dimethicone crosspolymer



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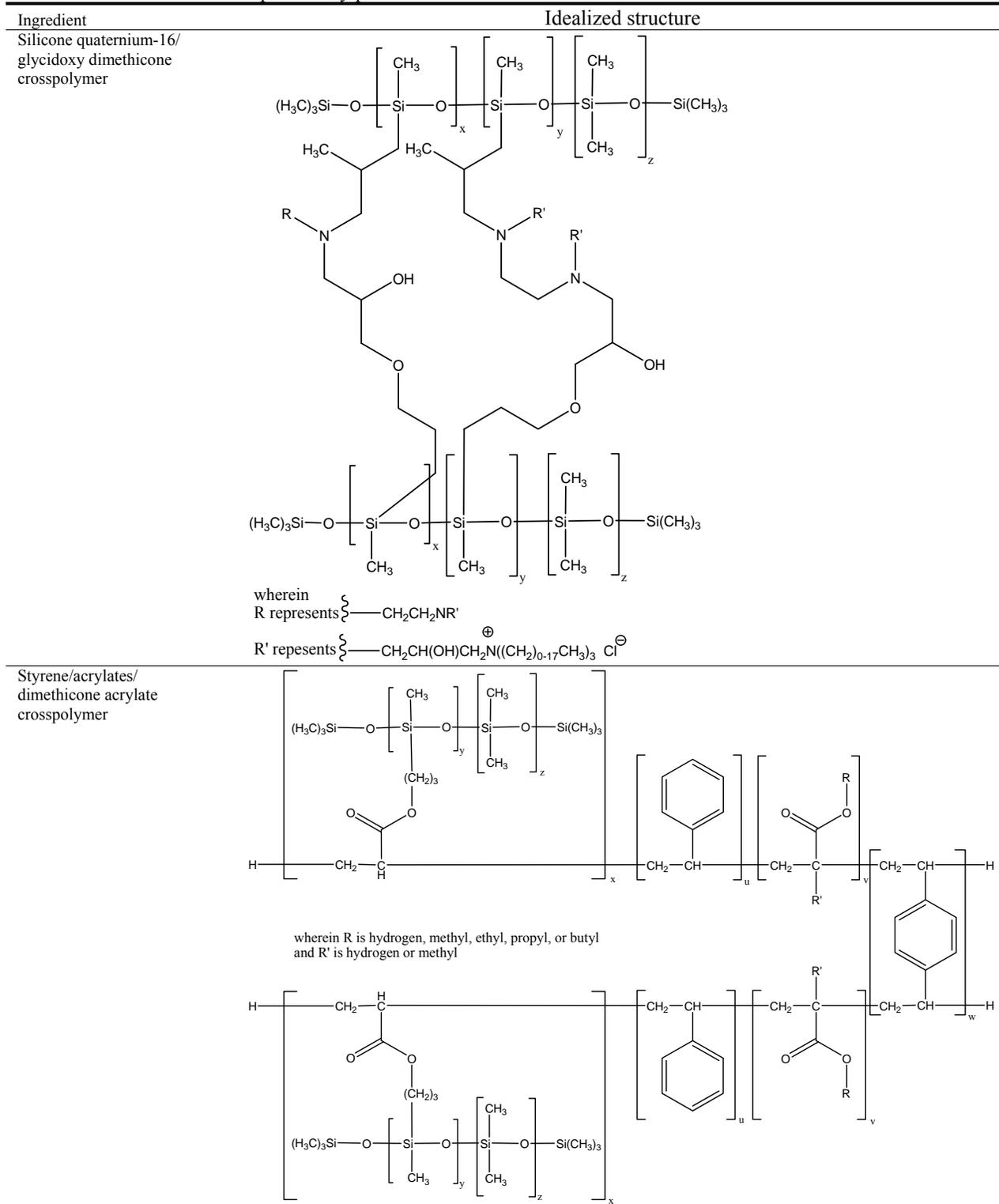


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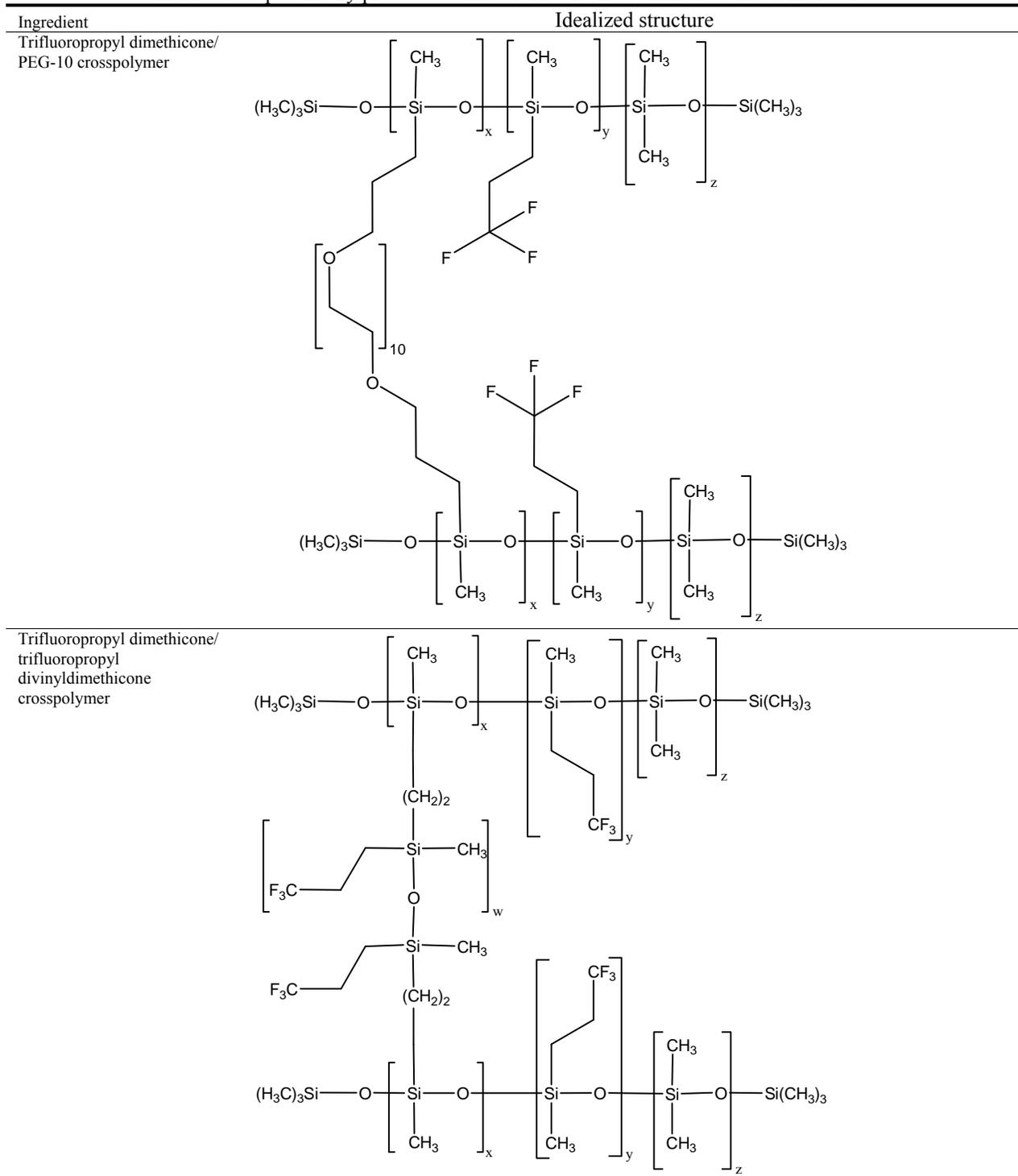


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Ingredient	Idealized structure
Trifluoropropyl dimethicone/ vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer	<p>wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones</p>
Trimethylsiloxysilicate/ dimethicone crosspolymer	<p>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. <i>The immense connectivity variability in this polymer makes a structural representation of this ingredient quite challenging.</i></p>
Vinyl dimethicone/ lauryl/ behenyl dimethicone crosspolymer	

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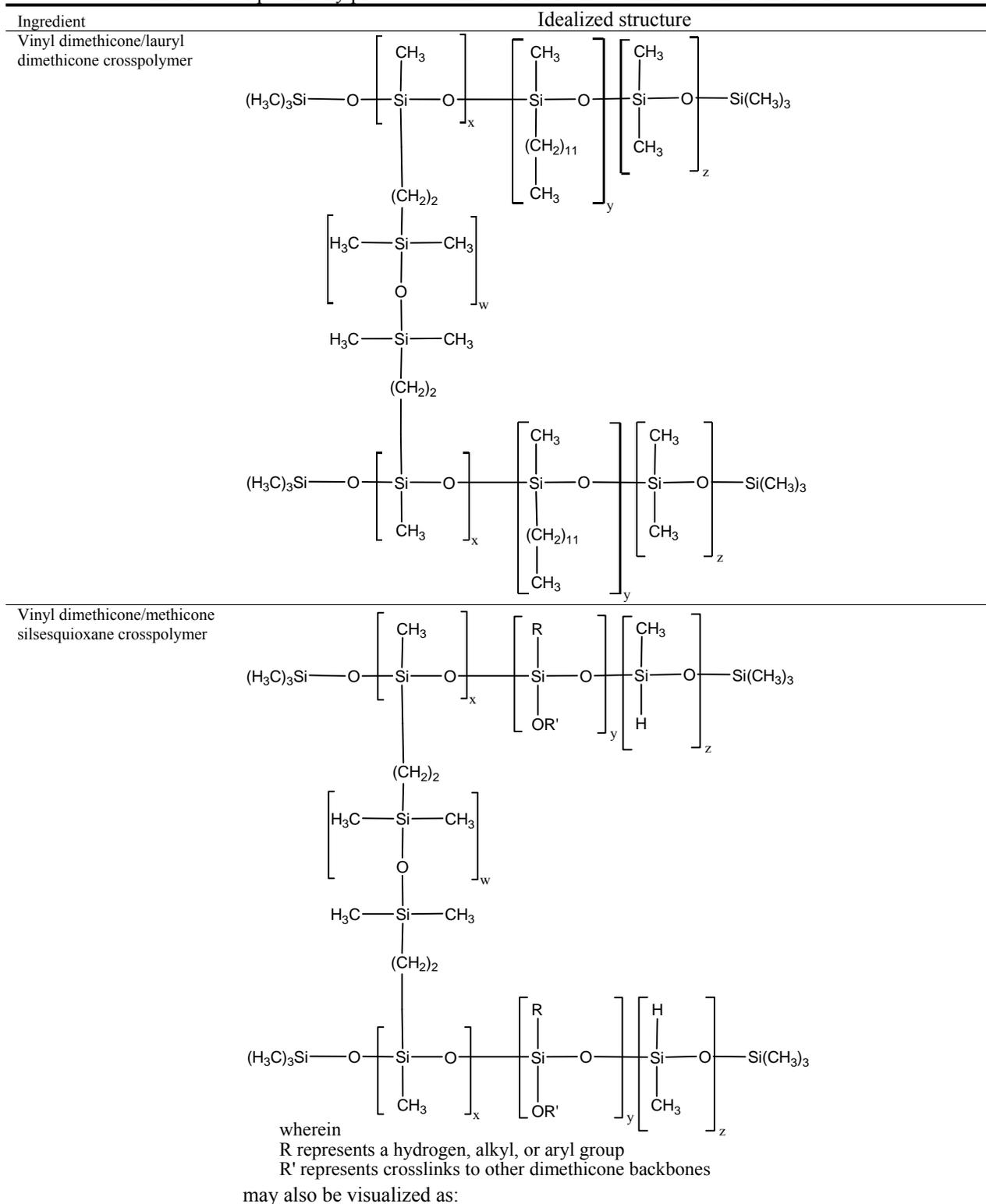
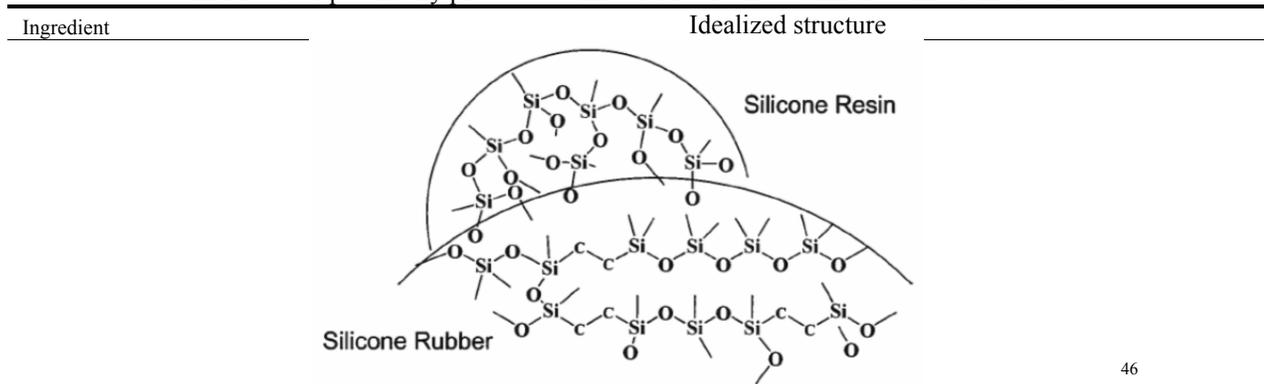


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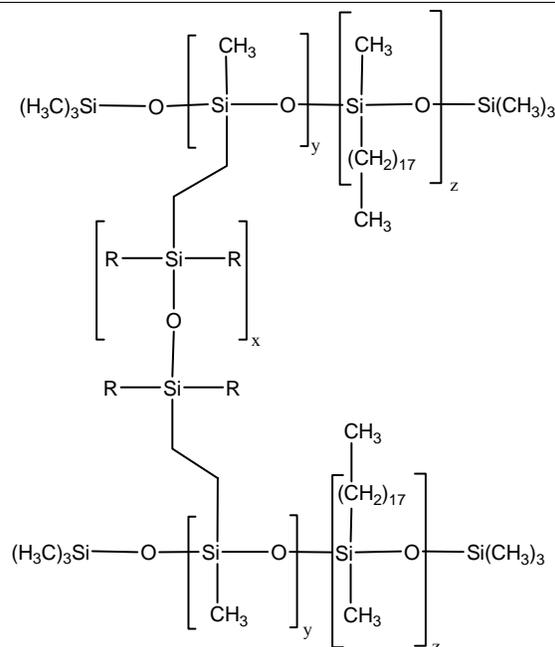


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Vinyldimethyl/
trimethylsiloxysilicate/
dimethicone crosspolymer

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

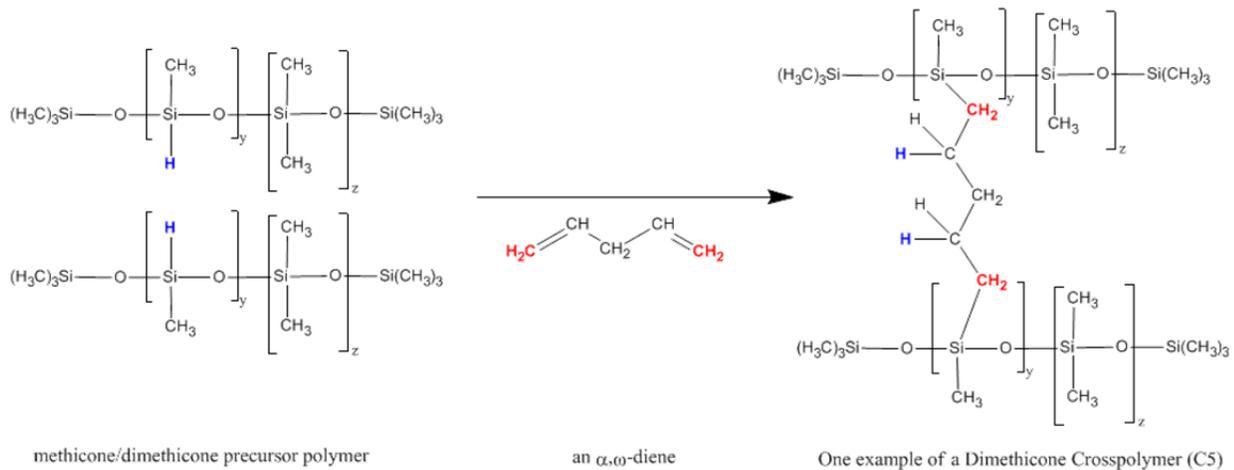


Figure 2. Example of the hydrosilylation-crosslinking of a dimethicone precursor polymer.

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