Article

International Journal of Toxicology
2014, Vol. 33(Supplement 2) 65S-115S

DOI: 10.1177/1091581814524963
ijt.sagepub.com
SAGE

Safety Assessment of Dimethicone Crosspolymers as Used in Cosmetics

Lillian C. Becker[1], Wilma F. Bergfeld[2], Donald V. Belsito[2], Ronald A. Hill[2], Curtis D. Klaassen[2], Daniel C. Liebler[2], James G. Marks Jr[2], Ronald C. Shank[2], Thomas J. Slaga[2], Paul W. Snyder[2], and F. Alan Andersen[3]

Abstract

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

Keywords

cosmetics, safety, dimethicone crosspolymers

Introduction

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

- acrylates/bis-hydroxypropyl dimethicone crosspolymer;
- behenyl dimethicone/bis-vinyldimethicone crosspolymer;
- bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer;
- bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer;
- bis-vinyldimethicone crosspolymer;
- bis-vinyldimethicone/PEG-10 dimethicone crosspolymer;
- bis-vinyldimethicone/PPG-20 crosspolymer;
- butyldimethicone methacrylate/methyl methacrylate crosspolymer;
- C30-45 alkyl cetearyl dimethicone crosspolymer;
- C4-24 alkyl dimethicone/divinyldimethicone crosspolymer;
- C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer;
- cetearyl dimethicone crosspolymer;
- cetearyl dimethicone/vinyl dimethicone crosspolymer;
- cetyl dimethicone/bis-vinyldimethicone crosspolymer;
- cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer;
- crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer;
- dimethicone/bis-isobutyl PPG-20 crosspolymer;
- dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer;
- dimethicone crosspolymer;
- dimethicone crosspolymer-3;
- dimethicone/divinyldimethicone/silsesquioxane crosspolymer;
- dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer;
- dimethicone/PEG-10 crosspolymer;
- dimethicone/PEG-10/15 crosspolymer;
- dimethicone/PEG-15 crosspolymer;
- dimethicone/phenyl vinyl dimethicone crosspolymer;
- dimethicone/polyglycerin-3 crosspolymer;
- dimethicone/PPG-20 crosspolymer;
- dimethicone/titanate crosspolymer;
- dimethicone/vinyl dimethicone crosspolymer;
- dimethicone/vinyltrimethylsiloxysilicate crosspolymer;
- diphenyl dimethicone crosspolymer;

[1] Cosmetic Ingredient Review Scientific Analyst/Writer, Washington, DC, USA
[2] Cosmetic Ingredient Review Expert Panel Member, Washington, DC, USA
[3] Former Director, Cosmetic Ingredient Review, Washington, DC, USA

Corresponding Author:
Lillian J. Gill, Director, Cosmetic Ingredient Review, 1620 L. St, NW, Suite 1200, Washington, DC 20036, USA.
Email: cirinfo@cir-safety.org

- diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer;
- divinyldimethicone/dimethicone crosspolymer;
- hydroxypropyl dimethicone/polysorbate 20 crosspolymer;
- isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer;
- lauryl dimethicone PEG-15 crosspolymer;
- lauryl dimethicone/polyglycerin-3 crosspolymer;
- lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer;
- PEG-10 dimethicone crosspolymer;
- PEG-12 dimethicone crosspolymer;
- PEG-8 dimethicone/polysorbate 20 crosspolymer;
- PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer;
- PEG-12 dimethicone/PPG-20 crosspolymer;
- PEG-10 dimethicone/vinyl dimethicone crosspolymer;
- PEG-10/lauryl dimethicone crosspolymer;
- PEG-15/lauryl dimethicone crosspolymer;
- PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer;
- perfluorononyl dimethicone/methicone/amodimethicone crosspolymer;
- polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer;
- polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer;
- silicone quaternium-16/glycidoxy dimethicone crosspolymer;
- styrene/acrylates/dimethicone acrylate crosspolymer;
- trifluoropropyl dimethicone/PEG-10 crosspolymer;
- trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer;
- trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer;
- trimethylsiloxysilicate/dimethicone crosspolymer;
- vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer;
- vinyl dimethicone/lauryl dimethicone crosspolymer;
- vinyl dimethicone/methicone silsesquioxane crosspolymer;
- vinyldimethyl/trimethylsiloxysilicate/dimethicone crosspolymer;
- vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer.

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

Chemistry

Overview and Method of Manufacture

Definitions, functions in cosmetics, and CAS numbers for the ingredients addressed in this safety assessment are provided in Table 1.

These cosmetic ingredients are silicone elastomers comprising dimethicone copolymers cross-linked with a bifunctional agent. Idealized structures are shown in Figure 1.

For use in cosmetics, these crosspolymers are typically supplied to finishing houses as swollen gels (ie, trade name mixtures) that contain various oils (eg, silicone oils such as dimethicone).[3] The addition of hydrophilic components (eg, addition of polyethylene glycol [PEG] chains to produce dimethicone/PEG-10 crosspolymer) or hydrophobic components (eg, addition of long alkyl chains to produce behenyl dimethicone/bis-vinyldimethicone crosspolymer) affects both the chemical and the 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 cross-linking 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 cross-linking 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, which 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 cross-linking process.[3] For example, a dimethicone precursor polymer is made by the copolymerization of dimethyl siloxane units with methylhydrogen siloxane units. Accordingly, although we define dimethicone crosspolymer as "a polymer of dimethicone cross-linked with a C3 to C20 alkyl group," it is more likely that dimethicone crosspolymer is a methicone/dimethicone copolymer (methicone has 1 methyl and 1 hydrogen on each silicon in the polymer backbone. This contrasts with dimethicone, which has 2 methyl groups on each silicon in the polymer backbone) cross-linked with an α,ω-diene (ie, the double bonds are at the ends of the chain) that is 3 to 20 carbons long.

Physical and Chemical Properties

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

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

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

Table 1. Definitions and Functions of the Ingredients in This Safety assessment.[1,a]

Ingredient CAS no.	Definition	Function
Acrylates/bis-hydroxypropyl dimethicone crosspolymer	Acrylates/bis-hydroxypropyl dimethicone crosspolymer is a cross-linked polymer of bis-hydroxypropyl dimethicone and 1 or more monomers consisting of acrylic acid, methacrylic acid, or 1 of their simple esters. *Herein, simple esters means methyl, ethyl, propyl, or butyl esters.*	Absorbent, film former, skin protectant, viscosity-increasing agent—nonaqueous
Behenyl dimethicone/ bis-vinyldimethicone crosspolymer	Behenyl dimethicone/bis-vinyldimethicone crosspolymer is structurally defined. *It is a copolymer of behenyl dimethicone cross-linked with divinyl dimethicone.*	Skin-conditioning agent—emollient
Bis-phenylisopropyl phenylisopropyl dimethicone/ vinyl dimethicone crosspolymer	Bis-phenylisopropyl phenylisopropyl dimethicone/ vinyl dimethicone crosspolymer is a copolymer of phenylisopropyl dimethicone cross-linked with vinyl dimethicone.	Humectant
Bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer	Bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer is a cross-linked polymer of bis-vinyldimethicone partially cross-linked with methylhydrogen cyclic siloxanes and then further cross-linked with bis-methallyl PPG-20.	
Bis-vinyldimethicone crosspolymer	Bis-vinyldimethicone crosspolymer is structurally defined. *It is a copolymer of dimethicone cross-linked with divinyl dimethicone.*	None listed
Bis-vinyldimethicone/PEG-10 dimethicone crosspolymer	Bis-vinyldimethicone/PEG-10 dimethicone crosspolymer is a copolymer of PEG-10 dimethicone cross-linked 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 cross-linked polymer of bis-vinyldimethicone partially cross-linked with methylhydrogen cyclic siloxanes and the further cross-linked with bis-ally PPG-20.	Skin-conditioning agent—emollient; viscosity-increasing agent—nonaqueous
Butyldimethicone methacrylate/ methyl methacrylate crosspolymer	Butyldimethicone methacrylate/methyl methacrylate crosspolymer is a copolymer of butyl dimethicone methacrylate and methyl methacrylate monomers cross-linked 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 cross-linked 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 cross-linked with divinyldimethicone.	Dispersing agent—nonsurfactant, film former, skin-conditioning agent—occlusive, slip modifier, viscosity-increasing agent—nonaqueous
C30-45 alkyl dimethicone/ polycyclohexene oxide crosspolymer 330809-27-3 389082-70-6	C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer is C30-45 alkyl dimethicone cross-linked with a polyether made from vinyl cyclohexene oxide.	Dispersing agent—nonsurfactant, film former, skin-conditioning agent—occlusive, slip modifier, viscosity-increasing agent—nonaqueous
Cetearyl dimethicone crosspolymer 756876-51-4	Cetearyl dimethicone crosspolymer is a copolymer of cetearyl dimethicone cross-linked with vinyl cyclohexene oxide.	Film former; hair fixative

(continued)

Table 1. (continued)

Ingredient CAS no.	Definition	Function
Cetearyl dimethicone/vinyl dimethicone crosspolymer	Cetearyl dimethicone/vinyl dimethicone crosspolymer is a copolymer of cetearyl dimethicone cross-linked with vinyl dimethylpolysiloxane.	Film former; hair fixative
Cetyl dimethicone/ bis-vinyldimethicone crosspolymer	Cetyl dimethicone/bis-vinyldimethicone crosspolymer is structurally defined. *It is a copolymer of cetyl dimethicone cross-linked with divinyl dimethicone.*	Skin-conditioning agent—emollient
Cetyl hexacosyl dimethicone/ bis-vinyldimethicone crosspolymer	Cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer is a cross-linked 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 cross-linked with bis-vinyldimethicone.	Film former; hair-conditioning agent; hair fixative
Dimethicone/bis-isobutyl PPG-20 crosspolymer	Dimethicone/bis-isobutyl PPG-20 crosspolymer is a cross-linked polymer of hydrogen dimethicone cross-linked with bis-methallyl PPG-20.	Skin-conditioning agents—emollient; viscosity-increasing agent—nonaqueous
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 cross-linked with a C3 to C20 alkyl group.	Dispersing agent—nonsurfactant; emulsion stabilizer; hair fixative; viscosity-increasing agent—nonaqueous
Dimethicone crosspolymer-3	Dimethicone crosspolymer-3 is structurally defined. *It is a polymer of dimethicone, cross-linked with ethylene linkages to form cyclized-like repeat units.*	Skin-conditioning agent—miscellaneous; slip modifier
Dimethicone/ divinyldimethicone/ silsesquioxane crosspolymer	Dimethicone/divinyldimethicone/silsesquioxane crosspolymer is a cross-linked 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 cross-linked 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 cross-linked 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 cross-linked 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 cross-linked 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 cross-linked with phenyl vinyl dimethylpolysiloxane.	Viscosity-increasing agent—nonaqueous

(continued)

Table 1. (continued)

Ingredient CAS no.	Definition	Function
Dimethicone/polyglycerin-3 crosspolymer	Dimethicone/polyglycerin-3 crosspolymer is the polymer of dimethicone cross-linked 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 cross-linked polymer of hydrogen dimethicone cross-linked with bis-allyl PPG-20.	Skin-conditioning agent—emollient; viscosity-increasing agent—nonaqueous
Dimethicone/titanate crosspolymer	Dimethicone/titanate crosspolymer is the cross-linked 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 cross-linked with vinyl dimethylpolysiloxane.	Viscosity-increasing agent—nonaqueous
Dimethicone/ vinyltrimethylsiloxysilicate crosspolymer	Dimethicone/vinyltrimethylsiloxysilicate crosspolymer is a copolymer of dimethylpolysiloxane cross-linked with vinyltrimethylsiloxysilicate.	Film former; viscosity-increasing agent—nonaqueous
Diphenyl dimethicone crosspolymer	Diphenyl dimethicone crosspolymer is cross-linked diphenyl dimethicone. *Wherein the cross-linking agent is not disclosed.*	Skin-conditioning agent—miscellaneous; slip modifier
Diphenyl dimethicone/vinyl diphenyl dimethicone/ silsesquioxane crosspolymer	Diphenyl dimethicone/vinyl diphenyl dimethicone/ silsesquioxane crosspolymer is a cross-linked copolymer of diphenyl dimethicone, vinyl diphenyl dimethicone and silsesquioxane monomers.	Viscosity-increasing agent—nonaqueous
Divinyldimethicone/dimethicone crosspolymer	Divinyldimethicone/dimethicone crosspolymer is dimethicone cross-linked 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 cross-linked 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
Lauryl dimethicone PEG-15 crosspolymer	Lauryl dimethicone PEG-15 crosspolymer is a cross-linked copolymer formed from *diallyl* PEG-15 and lauryl dimethicone.	Surfactant-dispersing agent; surfactant-emulsifying agent; viscosity-increasing agent—aqueous
Lauryl dimethicone/ polyglycerin-3 crosspolymer	Lauryl dimethicone/polyglycerin-3 crosspolymer is a polymer of lauryl dimethicone cross-linked 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 cross-linked by bis-vinyldimethicone	Viscosity-increasing agent—nonaqueous
PEG-10 dimethicone crosspolymer	PEG-10 dimethicone crosspolymer is a cross-linked copolymer formed from *diallyl* PEG-10 and dimethicone	Viscosity increasing agent—nonaqueous

(continued)

Table 1. (continued)

Ingredient CAS no.	Definition	Function
PEG-12 dimethicone crosspolymer	PEG-12 dimethicone crosspolymer is a copolymer of PEG-12 dimethicone cross-linked 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 cross-linked 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 cross-linked with bis-methallyl PPG-20.	None reported
PEG-12 dimethicone/PPG-20 crosspolymer	PEG-12 dimethicone/PPG-20 crosspolymer is a cross-linked polymer of hydrogen dimethicone cross-linked 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 cross-linked 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 cross-linked 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 cross-linked 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 cross-linked with diallyl PEG-15.	Viscosity-increasing agent—nonaqueous
Perfluorononyl dimethicone/ methicone/amodimethicone crosspolymer	Perfluorononyl dimethicone/methicone/ amodimethicone crosspolymer is a cross-linked 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 cross-linked 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 cross-linked with a *di*allyl polyglyceryl-3.	Viscosity-increasing agent—nonaqueous
Silicone quaternium-16/glycidoxy dimethicone crosspolymer	Silicone quaternium-16/glycidoxy dimethicone crosspolymer is silicone quaternium-16 that has been cross-linked 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 1 or more monomers of acrylic acid, methacrylic acid or 1 of their simple esters cross-linked with divinylbenzene. *Herein, simple esters means methyl, ethyl, propyl, or butyl esters*	Skin-conditioning agent—miscellaneous
Trifluoropropyl dimethicone/ PEG-10 crosspolymer	Trifluoropropyl dimethicone/PEG-10 crosspolymer is a polymer of trifluoropropyl dimethicone cross-linked with PEG-10 diallyl ether.	Skin-conditioning agent—miscellaneous; surfactant-dispersing agent; surfactant-emulsifying agent; viscosity-increasing agent—nonaqueous

(continued)

Table 1. (continued)

Ingredient CAS no.	Definition	Function
Trifluoropropyl dimethicone/ trifluoropropyl divinyldimethicone crosspolymer	Trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer is a copolymer of trifluoropropyl dimethicone cross-linked with trifluoropropyl divinyldimethicone.	Skin-conditioning agent—miscellaneous; surfactant-dispersing agent; viscosity-increasing agent—nonaqueous
Trifluoropropyl dimethicone/ vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer	Trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer is a cross-linked copolymer of trifluoropropyl dimethicone, vinyl trifluoropropyl dimethicone and silsesquioxane monomers.	Viscosity-increasing agent—nonaqueous
Trimethylsiloxysilicate/ dimethicone crosspolymer	Trimethylsiloxysilicate/dimethicone crosspolymer is the product of the reaction between dimethicone and trimethylsiloxysilicate under conditions that produce rearrangement, condensation, and cross-linking 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 cross-linked with divinyl dimethicone.	Skin-conditioning agent—miscellaneous
Vinyl dimethicone/lauryl dimethicone crosspolymer	Vinyl dimethicone/lauryl dimethicone crosspolymer is lauryl dimethicone cross-linked with divinyl dimethicone.	Surfactant-dispersing agent; viscosity-increasing agent—nonaqueous
Vinyl dimethicone/methicone silsesquioxane crosspolymer	Vinyl dimethicone/methicone silsesquioxane crosspolymer is a copolymer of methicone silsesquioxane cross-linked with *bis*-vinyl dimethylpolysiloxane.	Viscosity-increasing agent—nonaqueous
Vinyldimethyl/ trimethylsiloxysilicate/ dimethicone crosspolymer	Monograph in development	None reported
Vinyldimethyl/ trimethylsiloxysilicate stearyl dimethicone crosspolymer	Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer is stearyl methicone cross-linked with *bis*-vinyldimethyl/ trimethylsiloxysilicate.	Absorbent; bulking agent; film former; viscosity-increasing agent—nonaqueous

[a]The italicized text represents additions made by CIR staff.

Table 2. Component Ingredients Previously Reviewed by CIR.

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

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

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

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

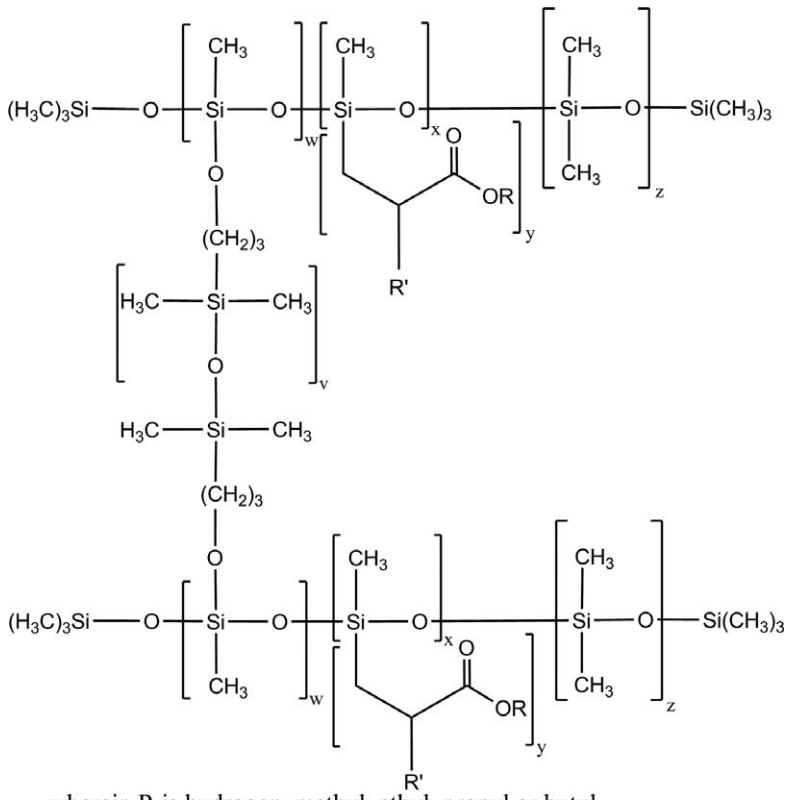
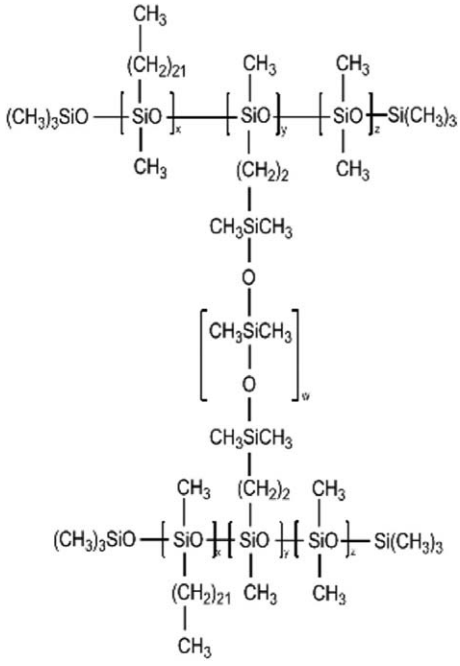
Ingredient	Idealized structure
Acrylates/bis-hydroxypropyl dimethicone crosspolymer	 wherein R is hydrogen, methyl, ethyl, propyl or butyl wherein R' is hydrogen or another dimethicone chain
Behenyl dimethicone/ bisvinyldimethicone crosspolymer	

Figure 1. Idealized structures of the dimethicone crosspolymers ingredients in this safety assessment. These idealized structures are merely generalized, 2-dimensional depictions of the true 3-dimensional frameworks that comprise these polymers. Although 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 1 example of the multitude of potentially produced connectivities found within these macromolecules.

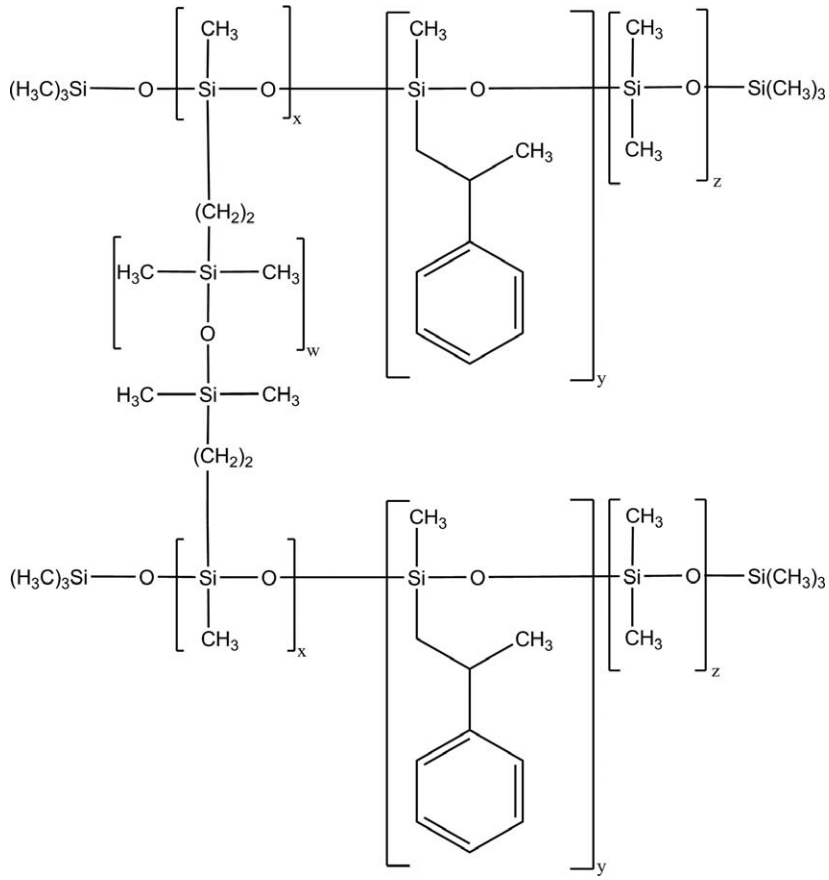
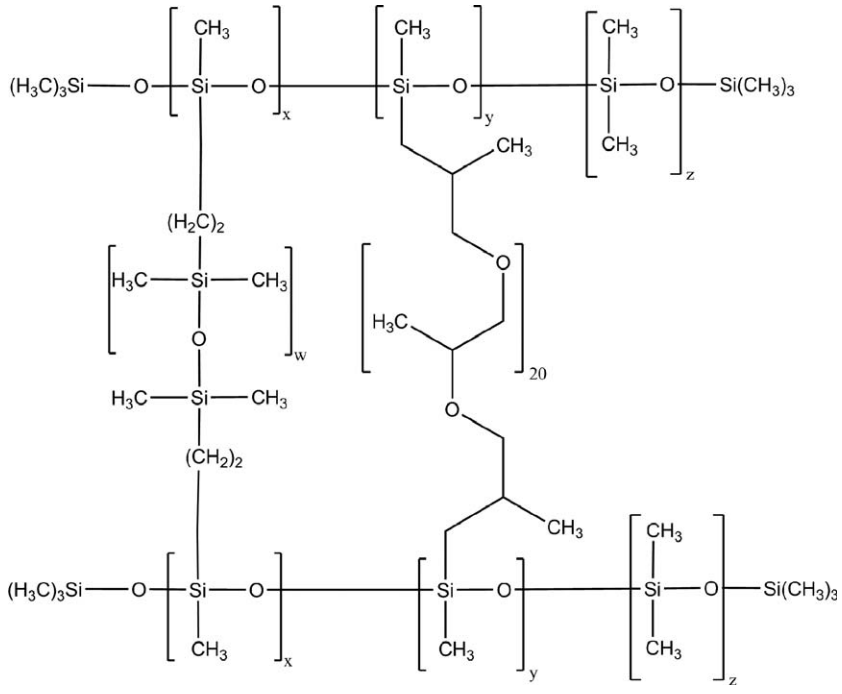
Ingredient	Idealized structure
Bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer	
Bis-vinyldimethicone/ bisisobutyl PPG-20 crosspolymer	

Figure 1. (continued)

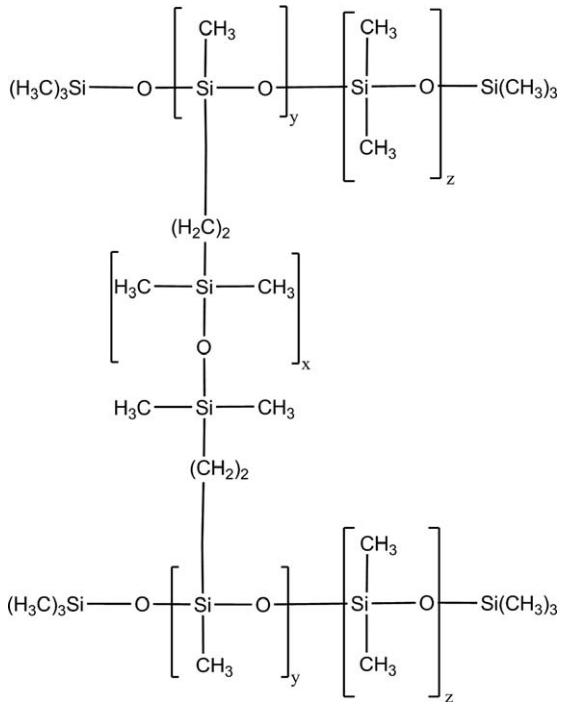
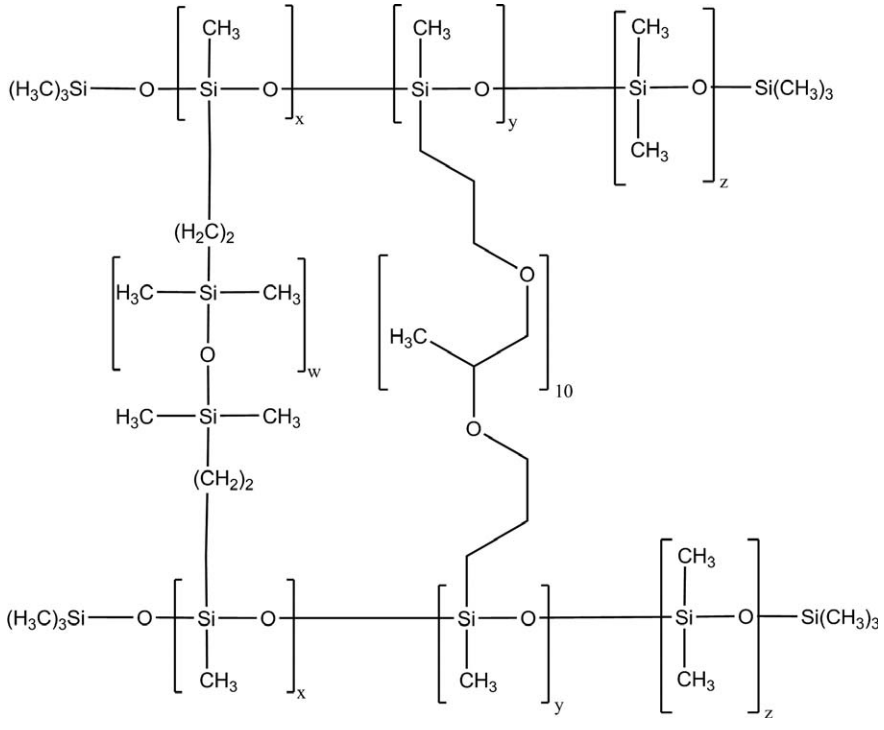
Ingredient	Idealized structure
Bis-vinyldimethicone crosspolymer	
Bis-Vinyldimethicone/ PPG-20 Crosspolymer	Bis-Vinyldimethicone/PPG-20 Crosspolymer is a crosslinked polymer of Bis-Vinyldimethicone partially crosslinked with methylhydrogen cyclic siloxanes and then further crosslinked with bis-allyl PPG-20. *The immense connectivity variability added by "methylhydrogen cyclic siloxanes" makes a structural representation of this ingredient quite challenging.*
Bis-vinyldimethicone/ PEG-10 dimethicone crosspolymer	

Figure 1. (continued)

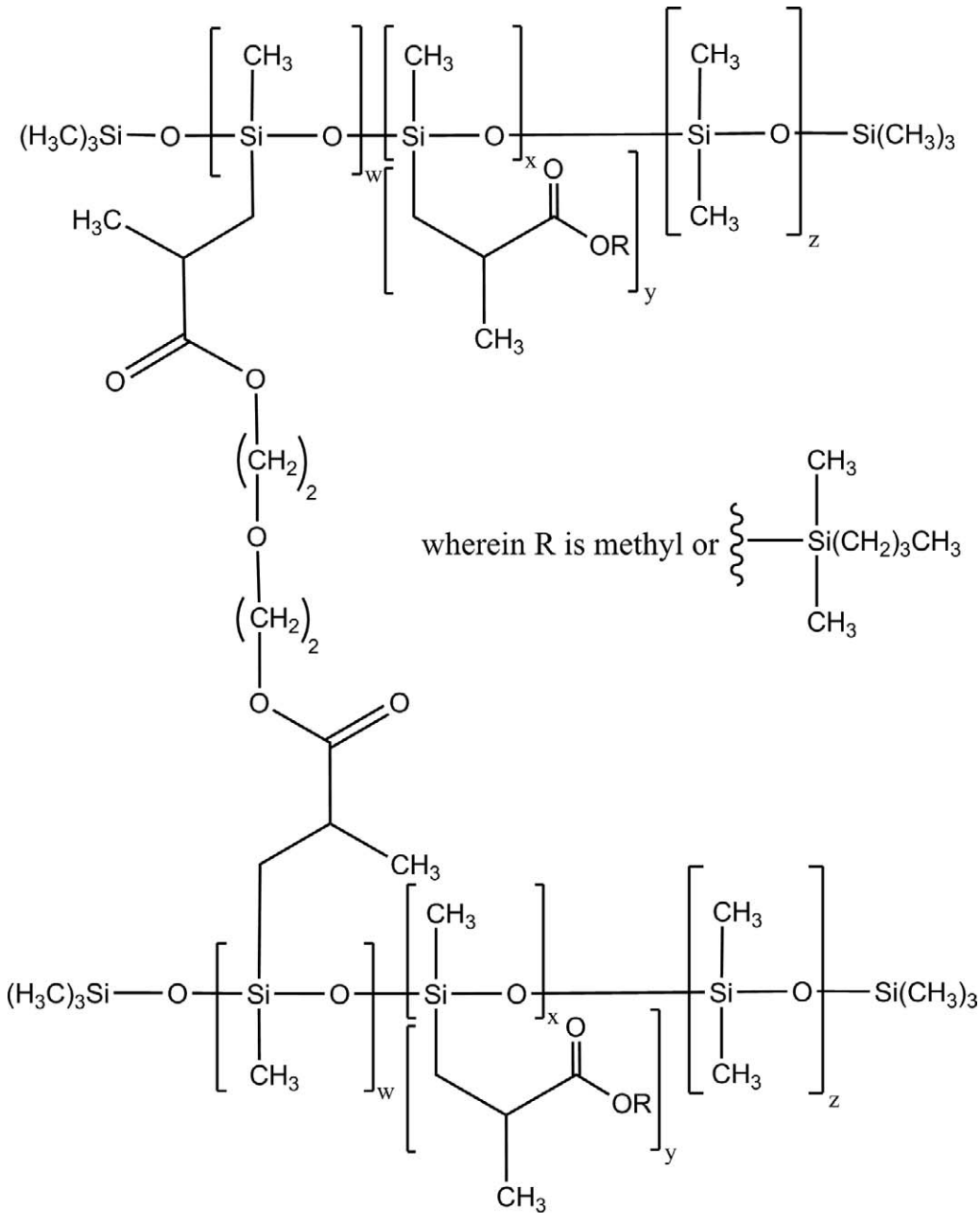
Ingredient	Idealized structure
Butyldimethicone methacrylate/methyl methacrylate crosspolymer	

Figure 1. (continued)

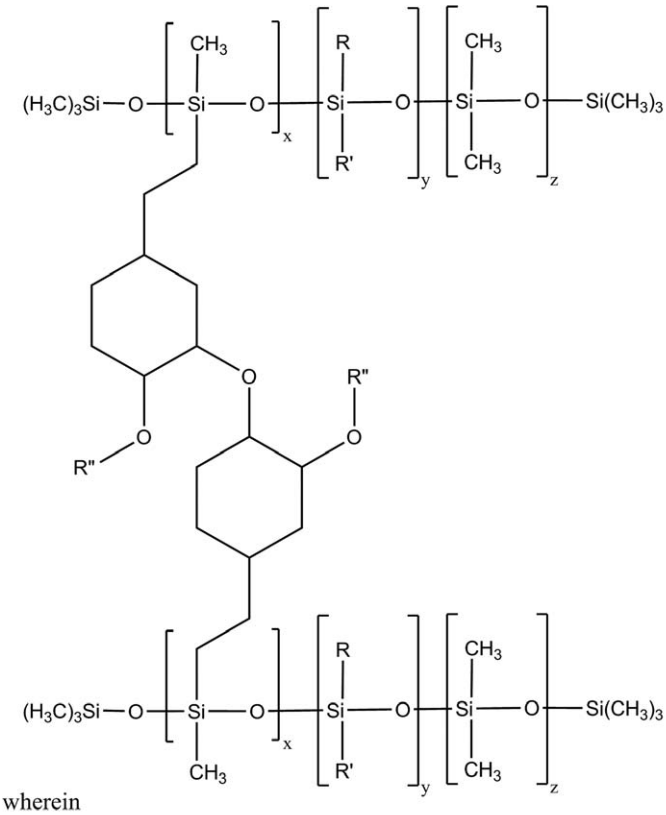
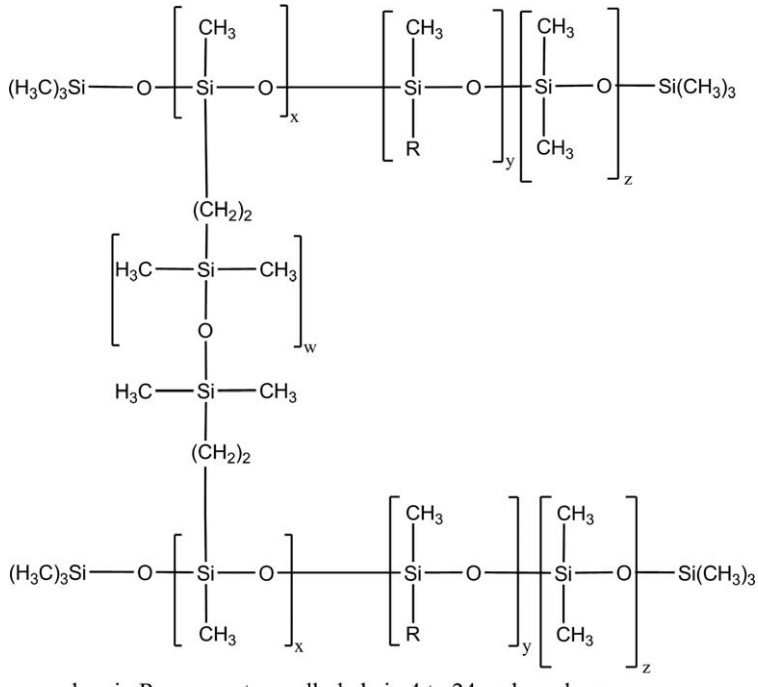
Ingredient	Idealized structure
C30-45 alkyl cetearyl dimethicone crosspolymer 443892-05-5	 wherein R represents an alkyl chain 30 to 45 carbons long R' repesents an alkyl chain 16 to 18 carbons long R" represents additional crosslinks through other vinyl cyclohexene oxide residues
C4-24 alkyl dimethicone/ divinyldimethicone crosspolymer	 wherein R represents an alkyl chain 4 to 24 carbons long

Figure 1. (continued)

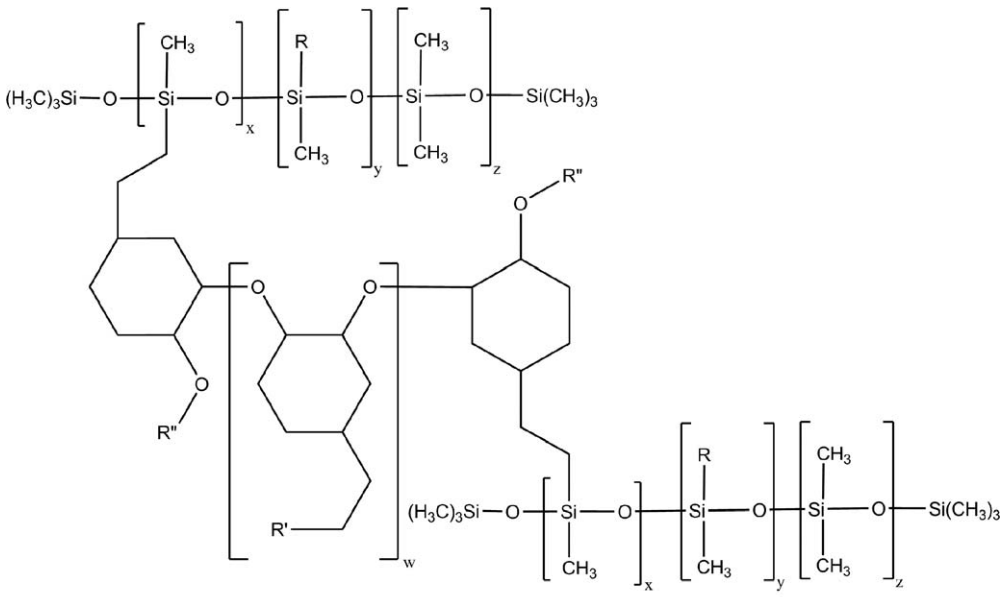
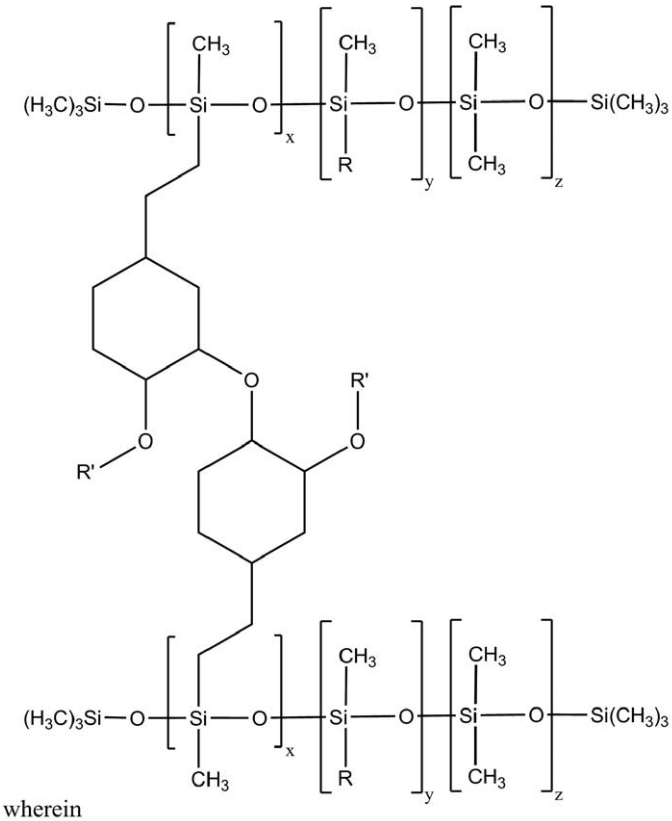
Ingredient	Idealized structure
C30-45 alkyl dimethicone/ polycyclohexene oxide crosspolymer 330809-27-3 389082-70-6	 wherein R represents an alkyl chain 30 to 45 carbons long R' repesents additional dimethicone backbones R" represents additional crosslinks through other vinyl cyclohexene oxide residues
Cetearyl dimethicone crosspolymer 756876-51-4	 wherein R repesents an alkyl chain 16 to 18 carbons long R' represents additional crosslinks through other vinyl cyclohexene oxide residues

Figure 1. (continued)

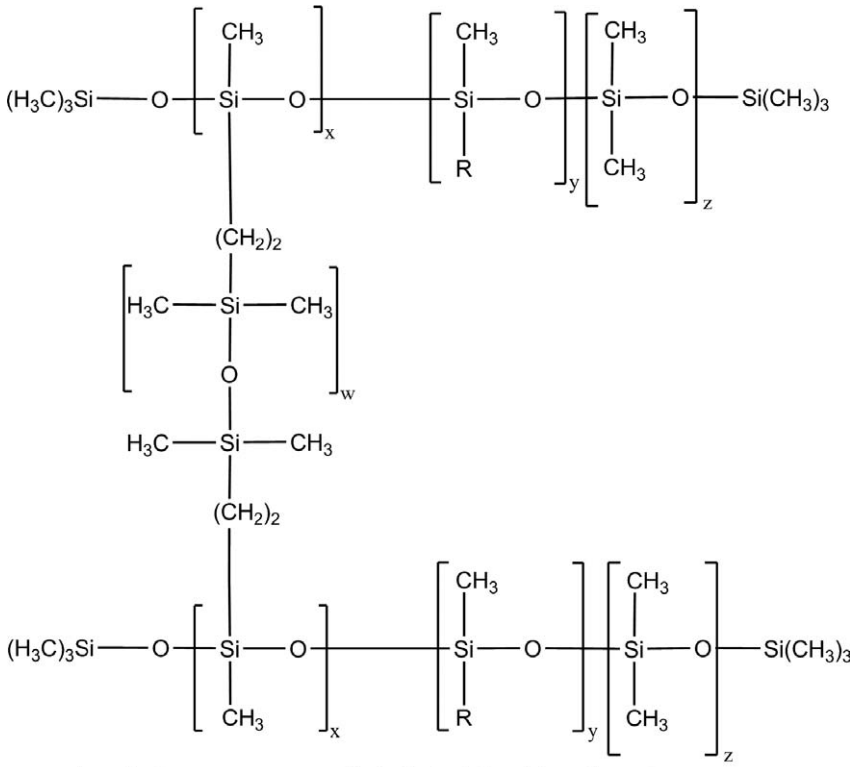
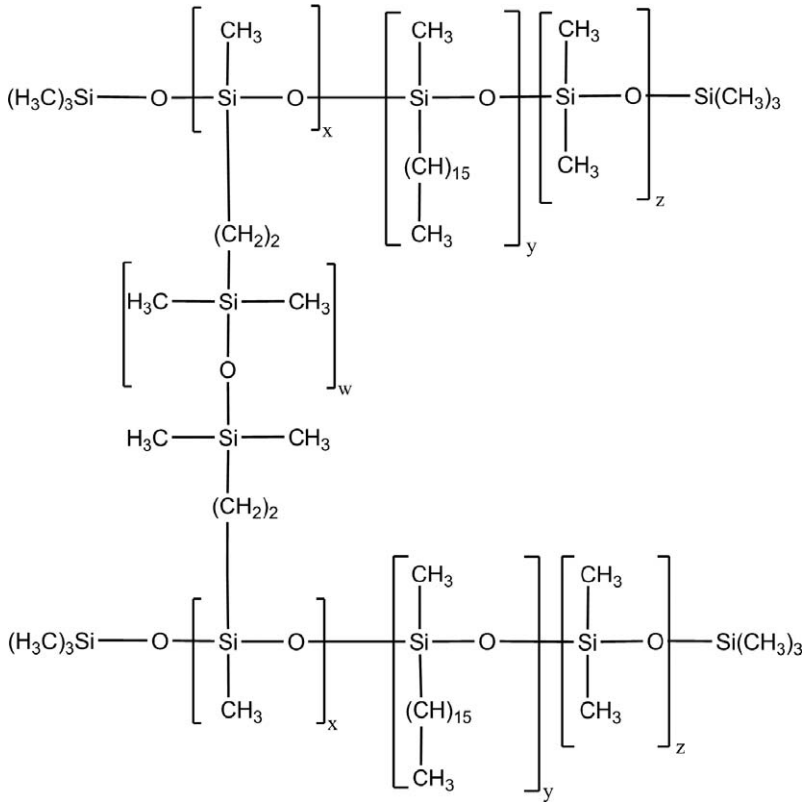
Ingredient	Idealized structure
Cetearyl dimethicone/vinyl dimethicone crosspolymer	 wherein R represents an alkyl chain 16 to 18 carbons long
Cetyl dimethicone/ bisvinyldimethicone crosspolymer	

Figure 1. (continued)

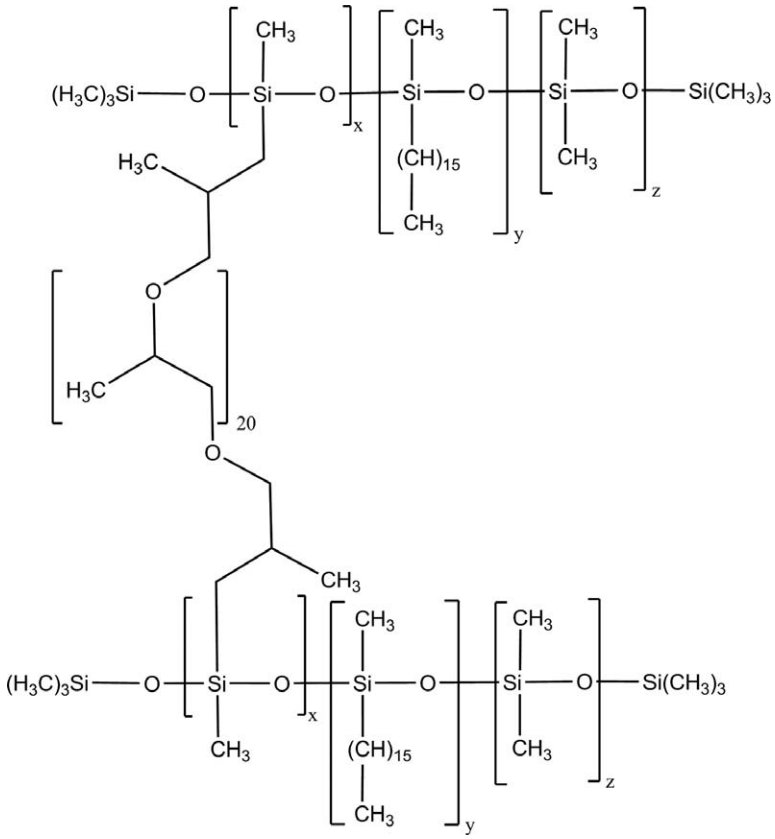
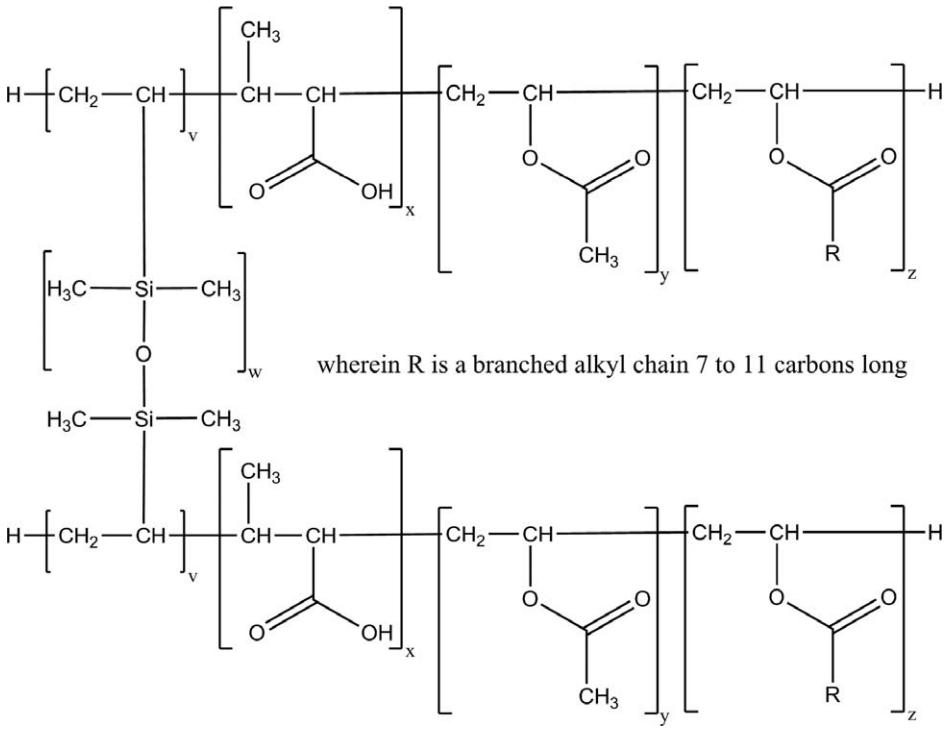
Ingredient	Idealized structure
Cetyl hexacosyl dimethicone/ bis-vinyldimethicone crosspolymer	
Crotonic acid/vinyl C8-12 isoalkyl esters/VA/ bisvinyldimethicone crosspolymer	

Figure 1. (continued)

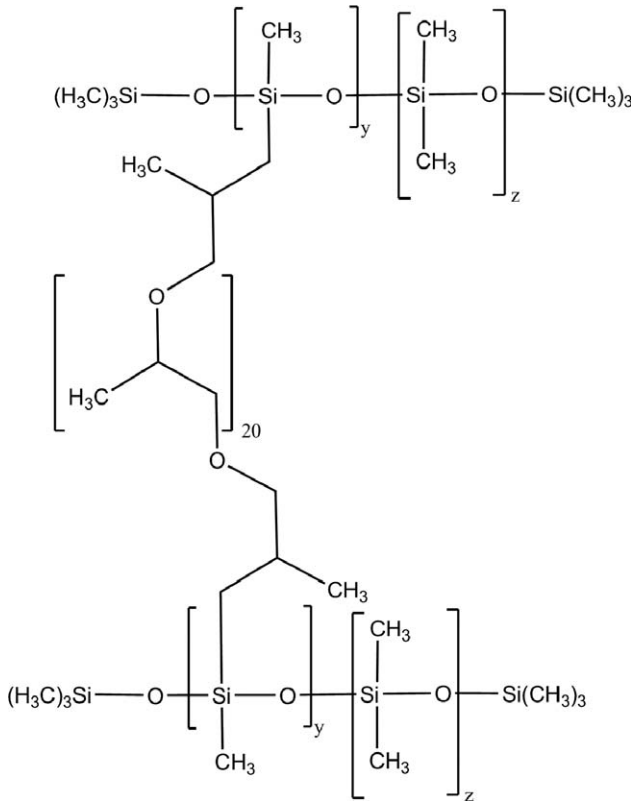
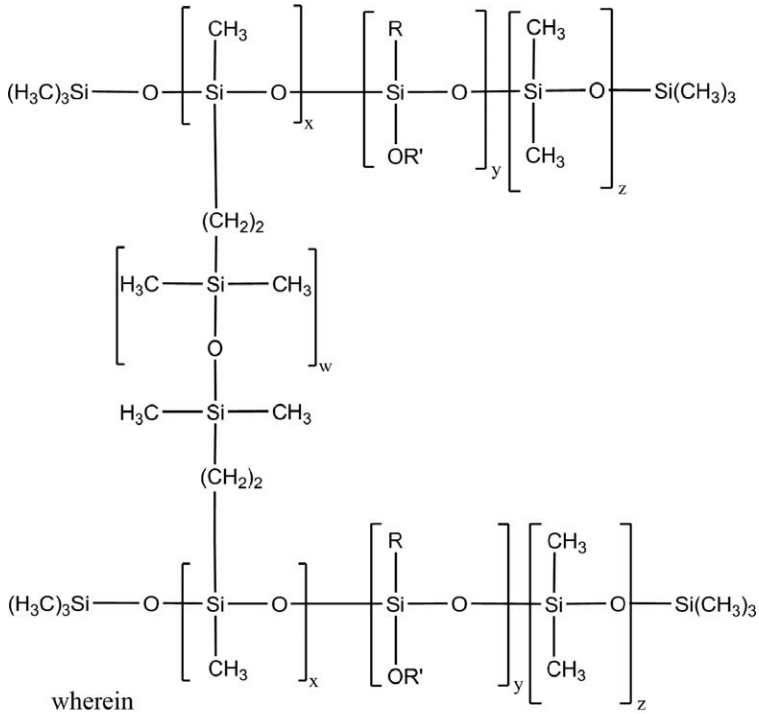
Ingredient	Idealized structure
Dimethicone/bis-isobutyl PPG-20 crosspolymer	
Dimethicone/ bisvinyldimethicone/ silsesquioxane crosspolymer	 wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones

Figure 1. (continued)

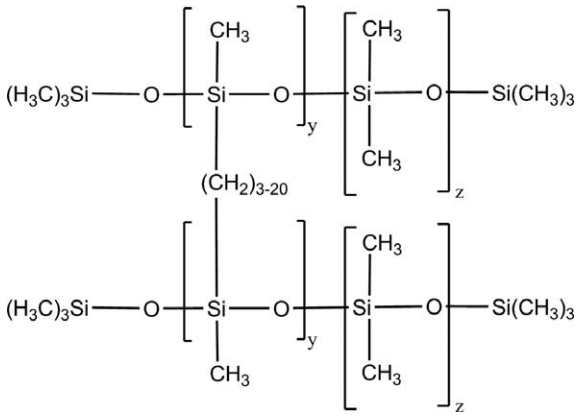
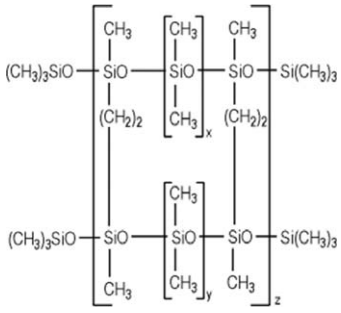
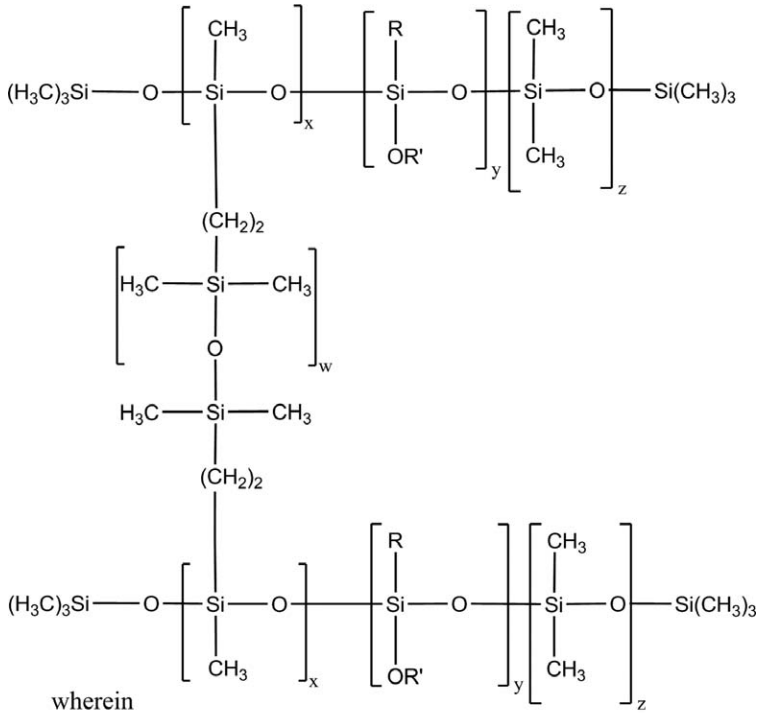
Ingredient	Idealized structure
Dimethicone crosspolymer 213629-14-2	
Dimethicone crosspolymer-3	
Dimethicone/divinyldimethicone/silsesquioxane crosspolymer	 wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones

Figure 1. (continued)

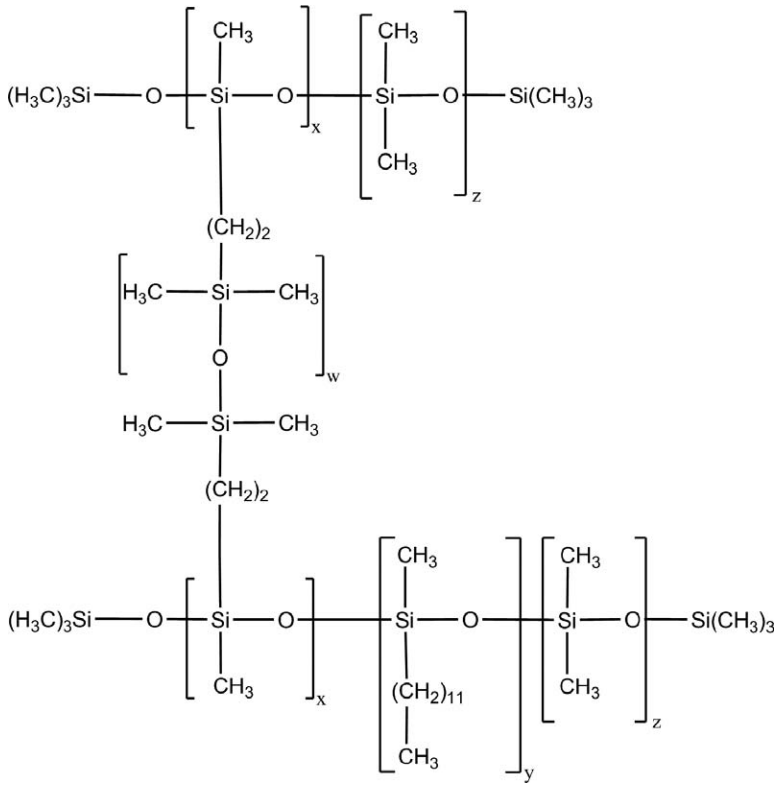
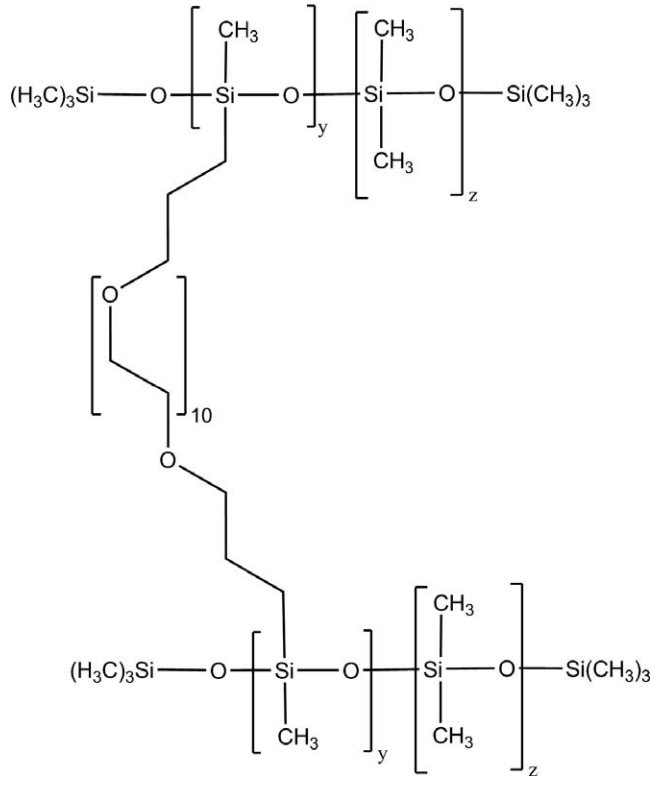
Ingredient	Idealized structure
Dimethicone/lauryl dimethicone/ bisvinyldimethicone crosspolymer	
Dimethicone/PEG-10 crosspolymer	

Figure 1. (continued)

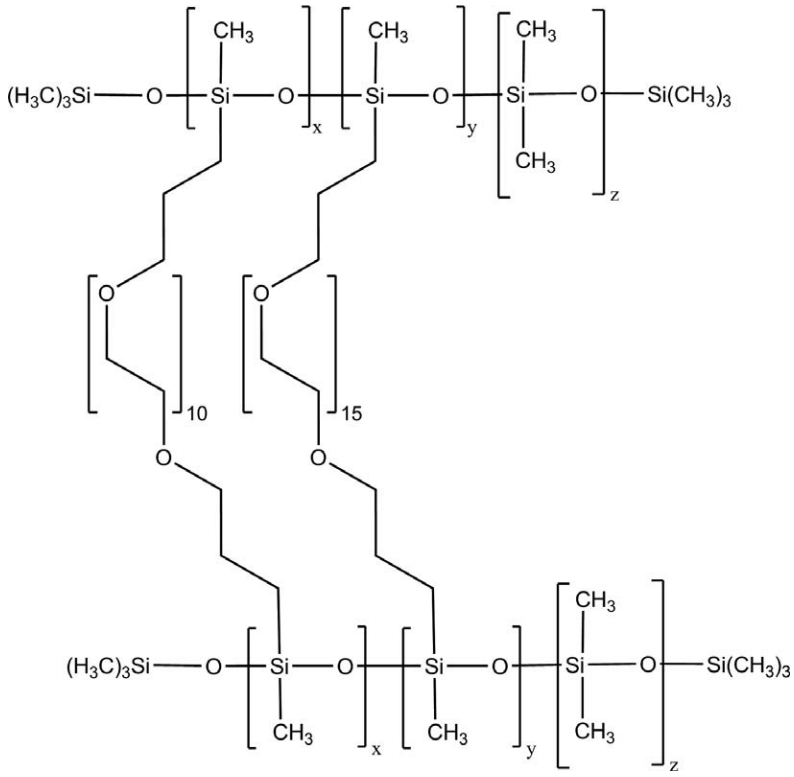
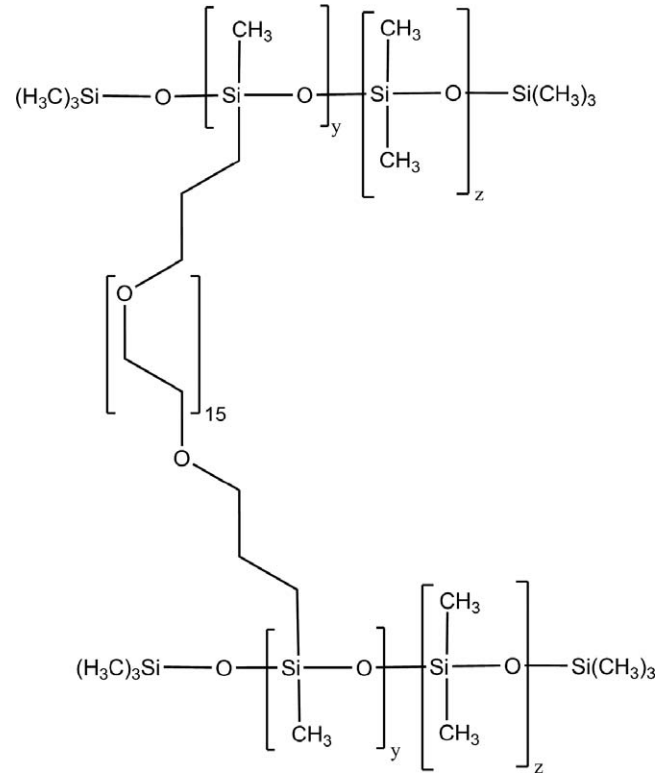
Ingredient	Idealized structure
Dimethicone/PEG-10/15 crosspolymer	
Dimethicone/PEG-15 crosspolymer	

Figure 1. (continued)

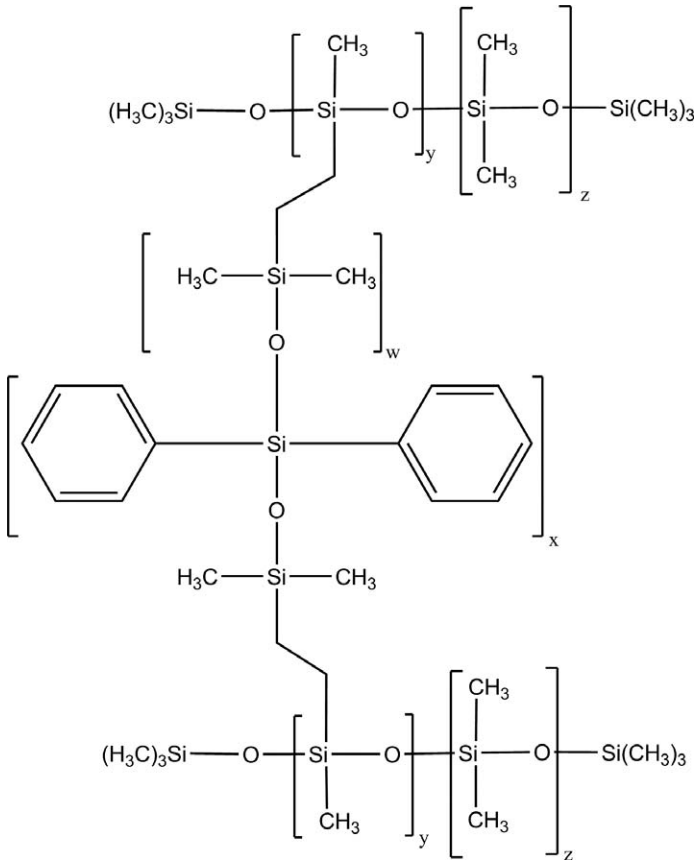
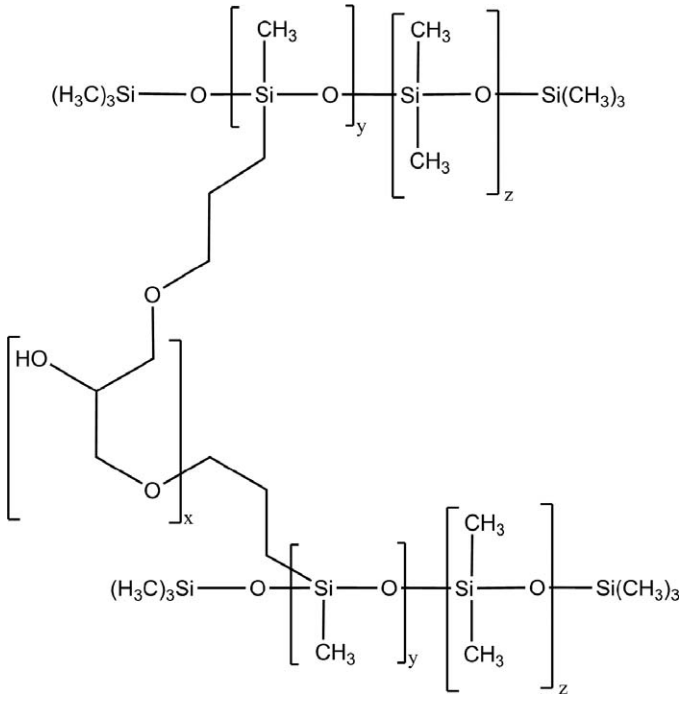
Ingredient	Idealized structure
Dimethicone/phenyl vinyl dimethicone crosspolymer	
Dimethicone/polyglycerin-3 crosspolymer	

Figure 1. (continued)

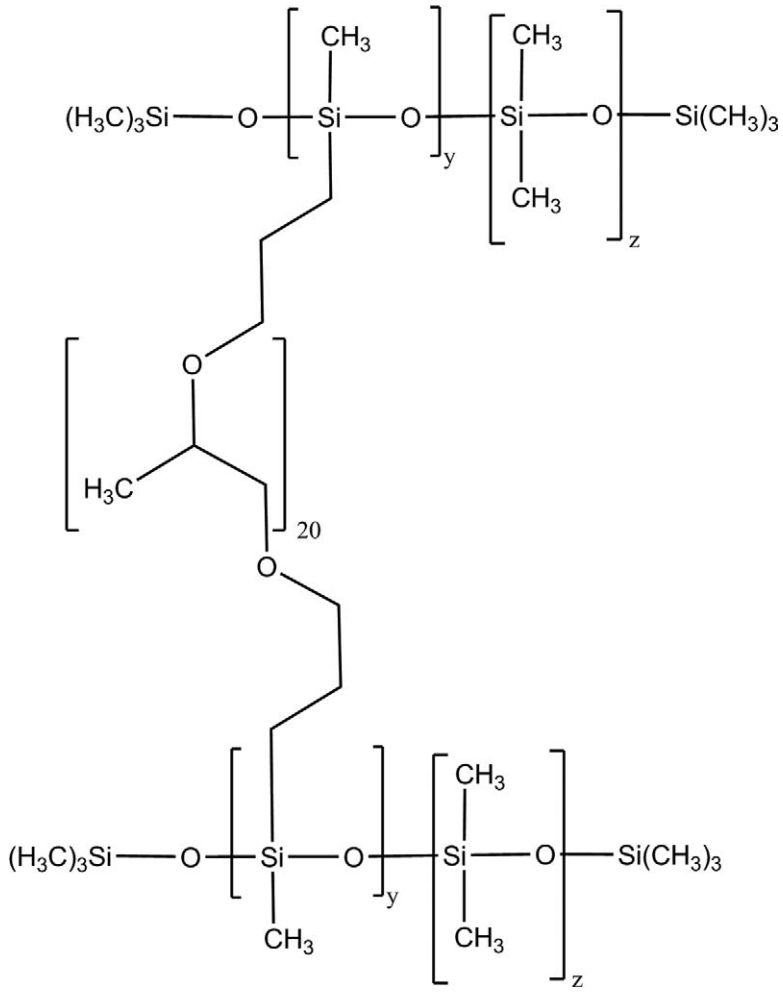
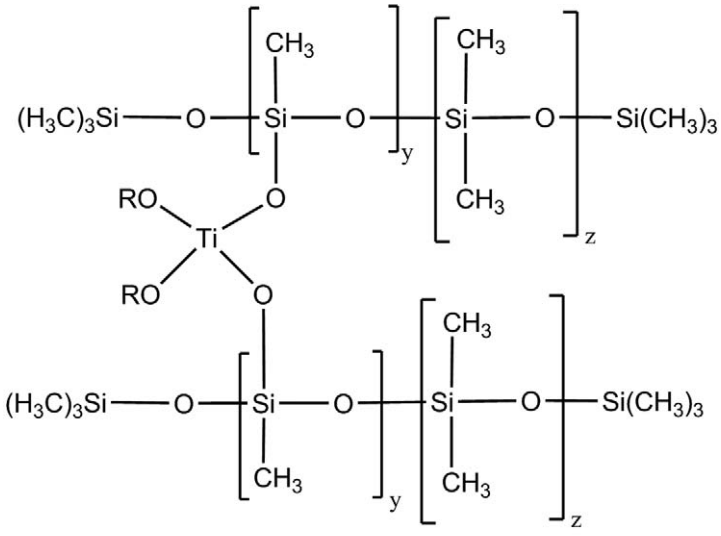
Ingredient	Idealized structure
Dimethicone/PPG-20 crosspolymer	
Dimethicone/titanate crosspolymer	 wherein R is isopropyl or an additional dimethicone crosslink

Figure 1. (continued)

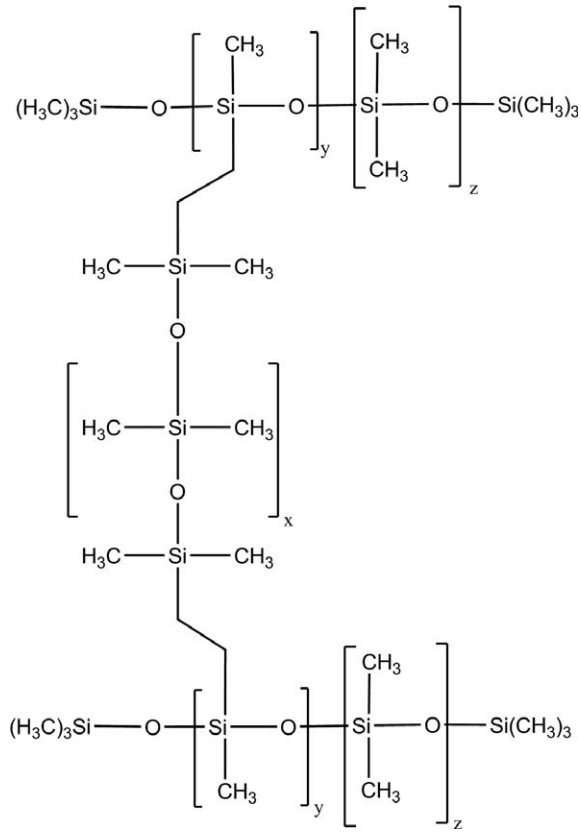
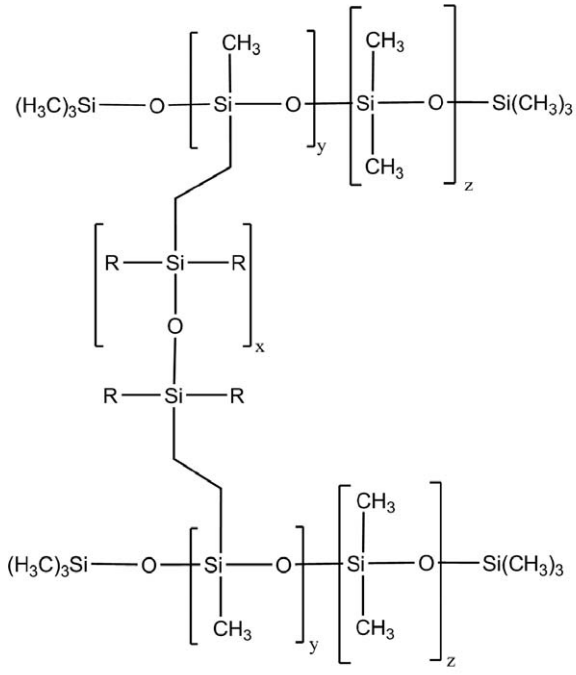
Ingredient	Idealized structure
Dimethicone/vinyl dimethicone crosspolymer	
Dimethicone/ vinyltrimethylsiloxysilicate crosspolymer	 wherein R represents a variable network of polysilicic acid units, which are endblocked with trimethylsilyl groups

Figure 1. (continued)

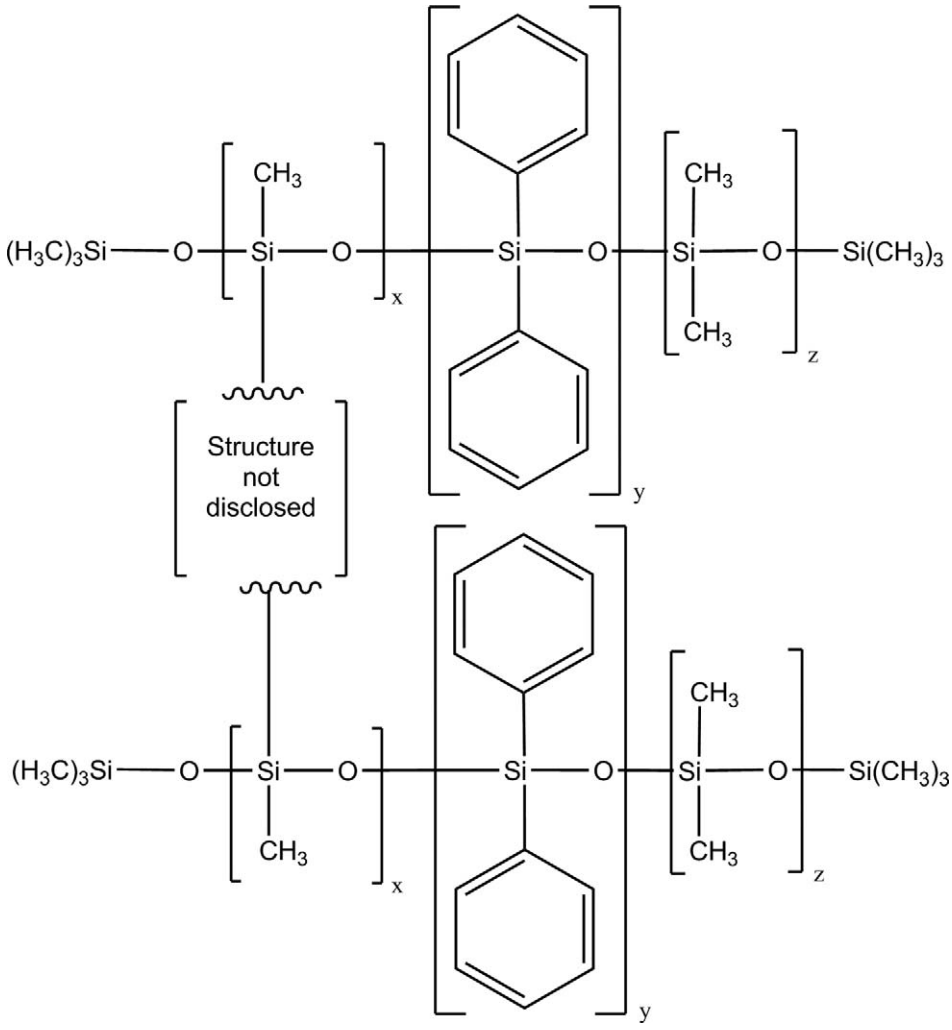
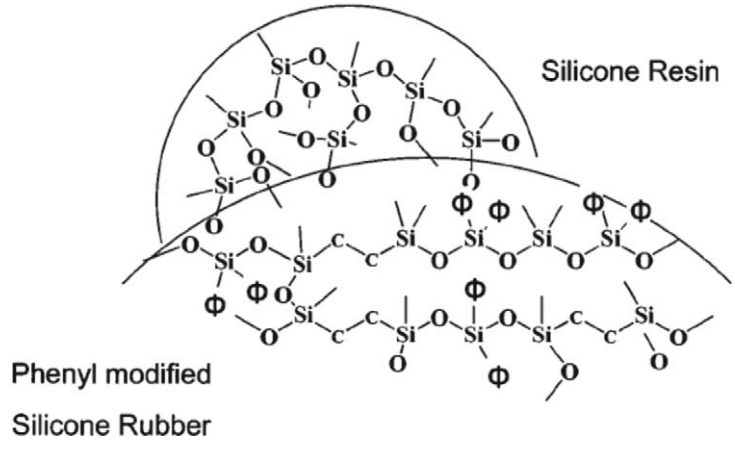
Ingredient	Idealized structure
Diphenyl dimethicone crosspolymer	
Diphenyl dimethicone/vinyl diphenyl dimethicone/ silsesquioxane crosspolymer	Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer is a crosslinked copolymer of diphenyl dimethicone, vinyl diphenyl dimethicone and silsesquioxane monomers. *The crosslinking connectivity here is unclear.*
	

Figure 1. (continued)

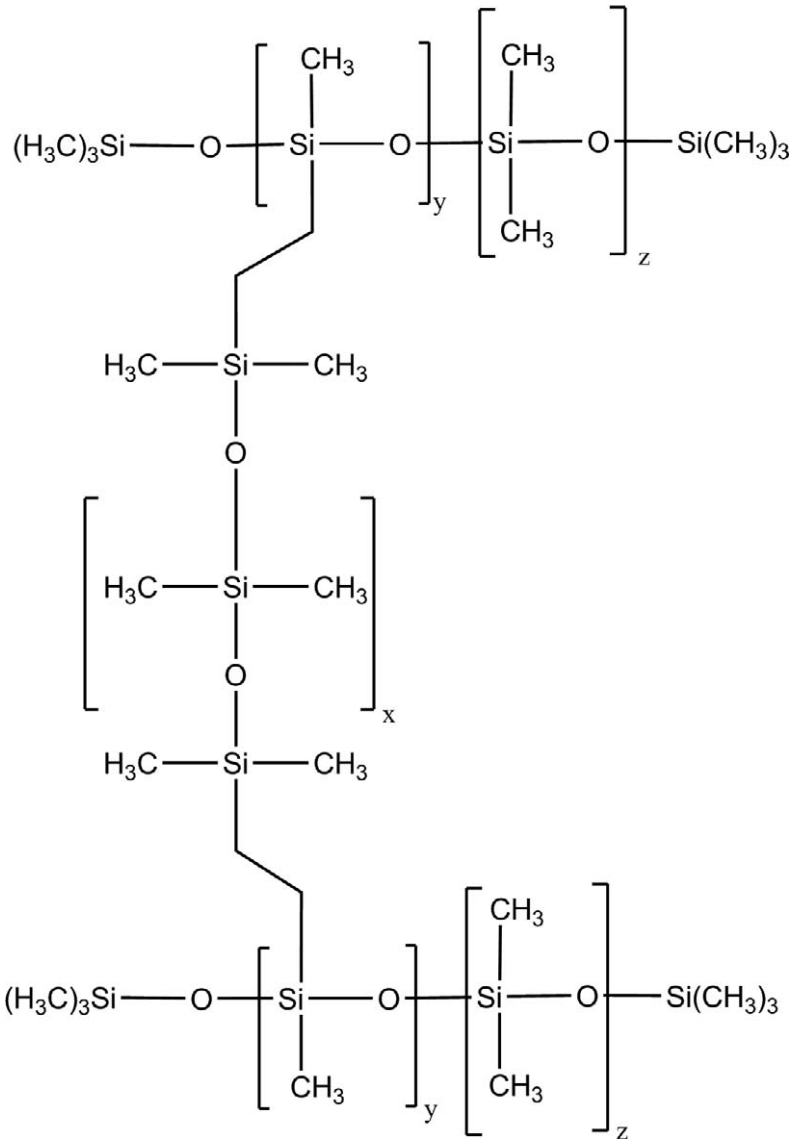
Ingredient	Idealized structure
Divinyldimethicone/ dimethicone crosspolymer	
Hydroxypropyl dimethicone/ polysorbate 20 crosspolymer	Hydroxypropyl Dimethicone/Polysorbate 20 Crosspolymer is a copolymer of Hydroxypropyldimethicone and Polysorbate 20 crosslinked with Succinic Acid. *The immense connectivity variability added by Polysorbate 20 makes a structural representation of this ingredient quite challenging.*
Isopropyl titanium triisostearate/ 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. *The immense connectivity variability in this polymer makes a structural representation of this ingredient quite challenging.*

Figure 1. (continued)

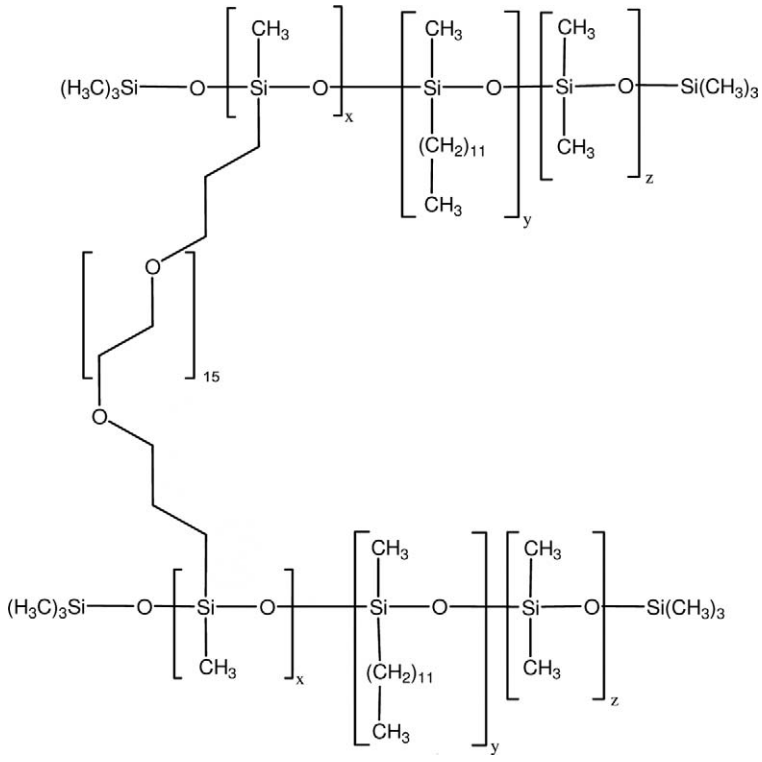
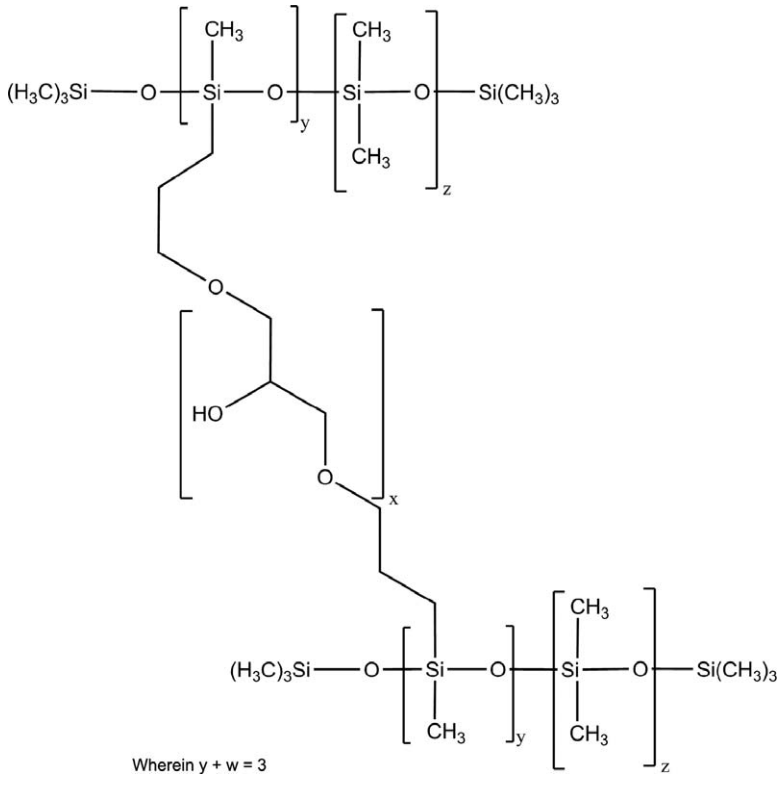
Ingredient	Idealized structure
Lauryl dimethicone PEG-15 crosspolymer	
Lauryl dimethicone/ polyglycerin-3 crosspolymer	

Figure 1. (continued)

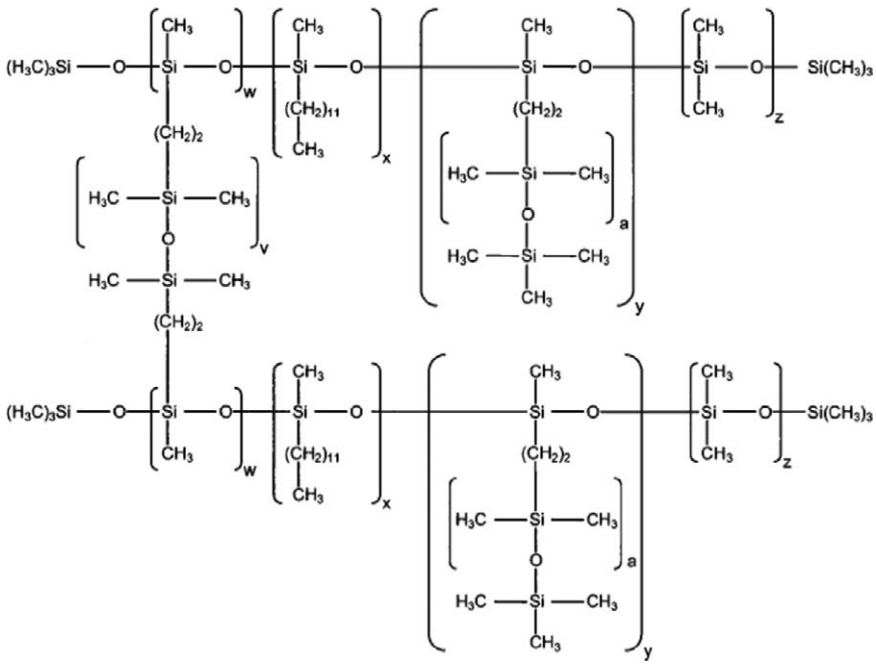
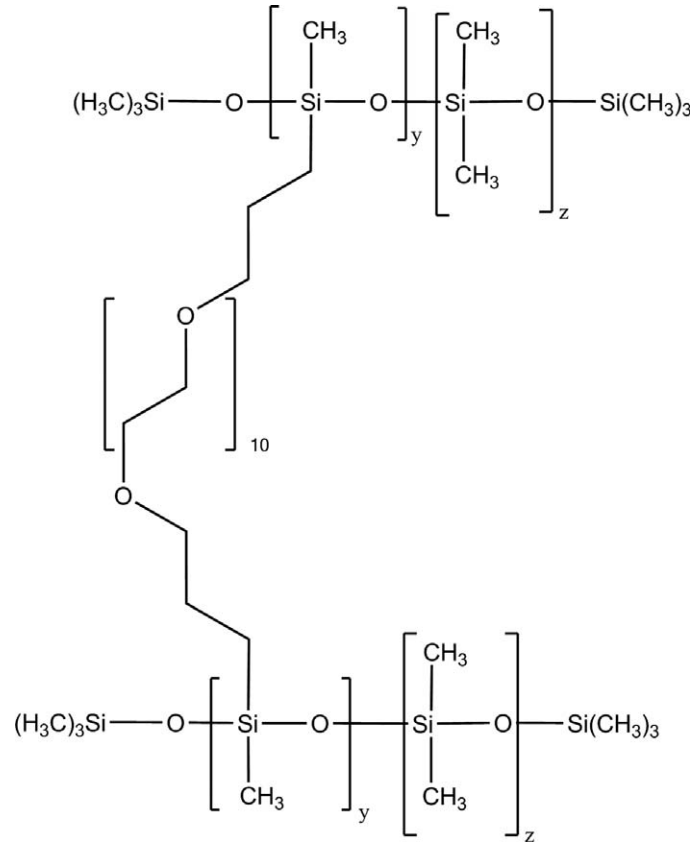
Ingredient	Idealized structure
Lauryl polydimethylsiloxyethyl dimethicone/ bisvinyldimethicone crosspolymer	
PEG-10 dimethicone crosspolymer	

Figure 1. (continued)

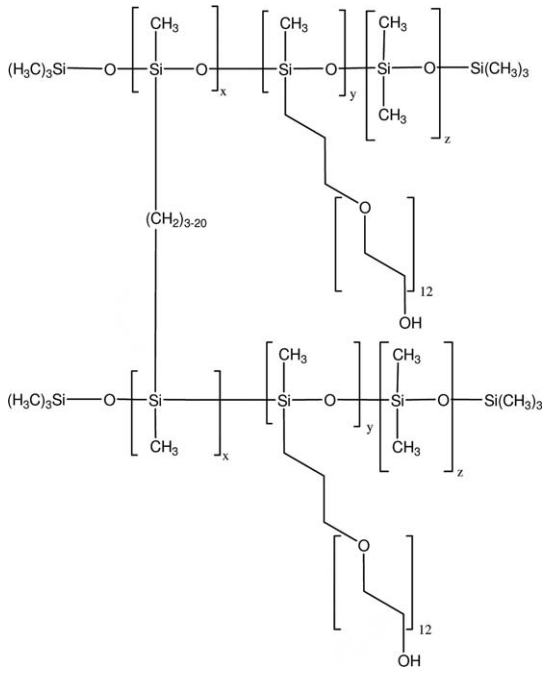
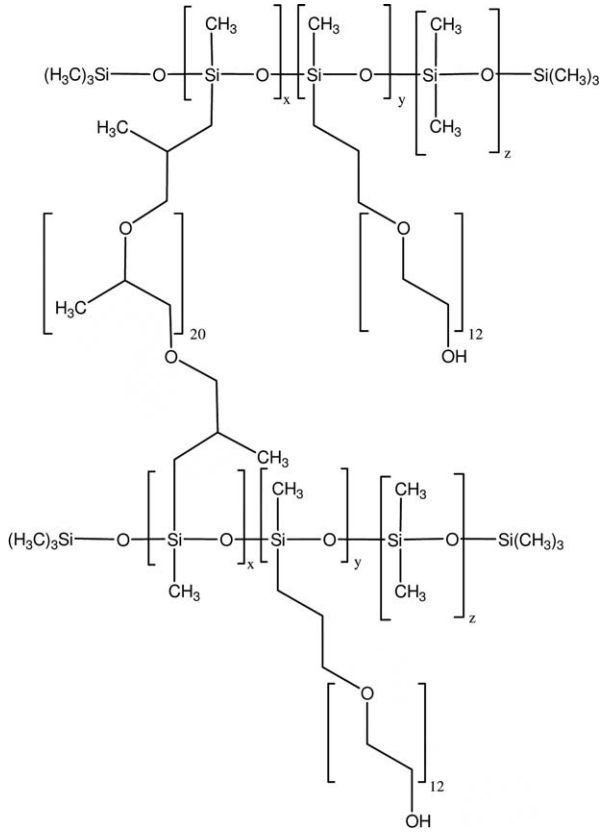
Ingredient	Idealized structure
PEG-12 dimethicone crosspolymer	
PEG-8 dimethicone/ polysorbate 20 crosspolymer	PEG-8 dimethicone/polysorbate 20 crosspolymer is a copolymer of a complex mixture of esters formed from the reaction of PEG-8 dimethicone and polysorbate 20 crosslinked with Succinic Acid. *The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

Figure 1. (continued)

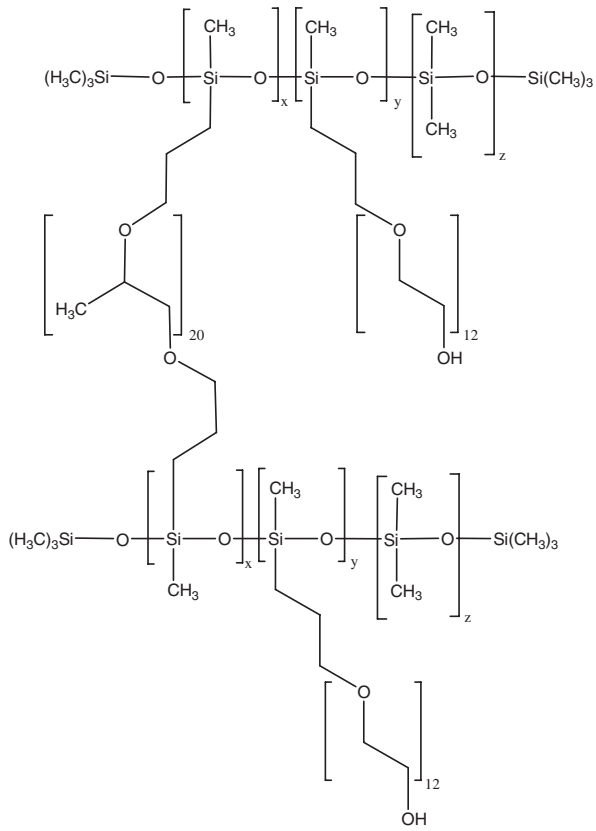
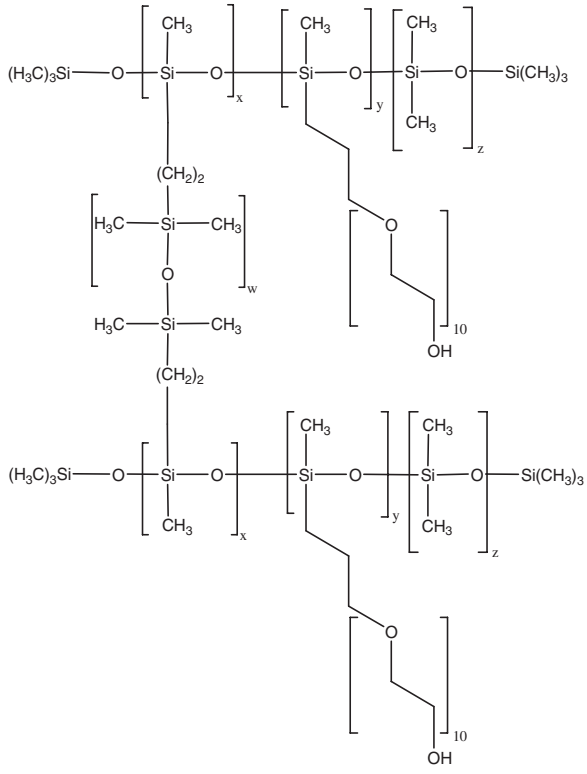
Ingredient	Idealized structure
PEG-12 dimethicone/PPG-20 crosspolymer	
PEG-10 dimethicone/vinyl dimethicone crosspolymer	

Figure 1. (continued)

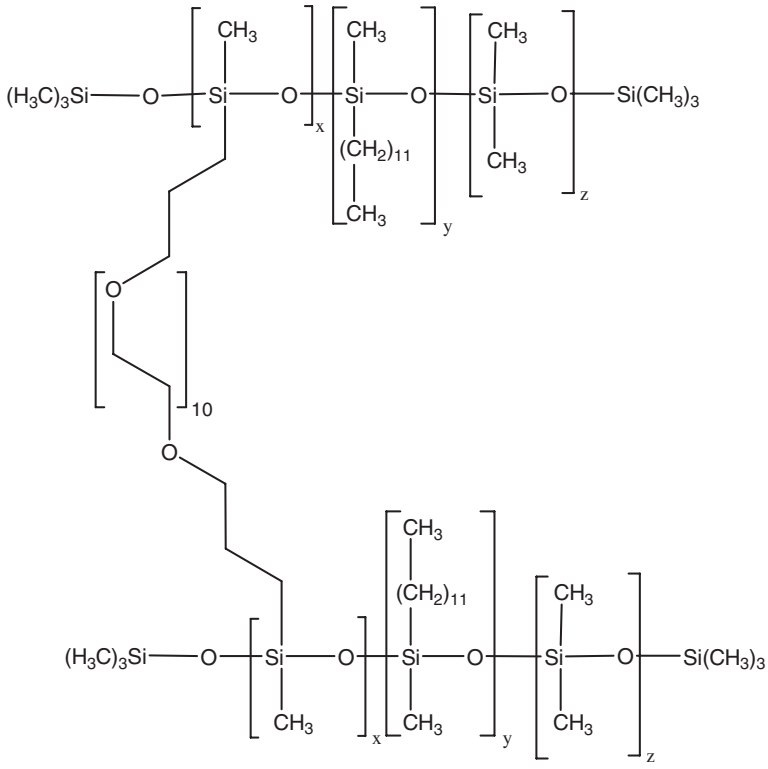
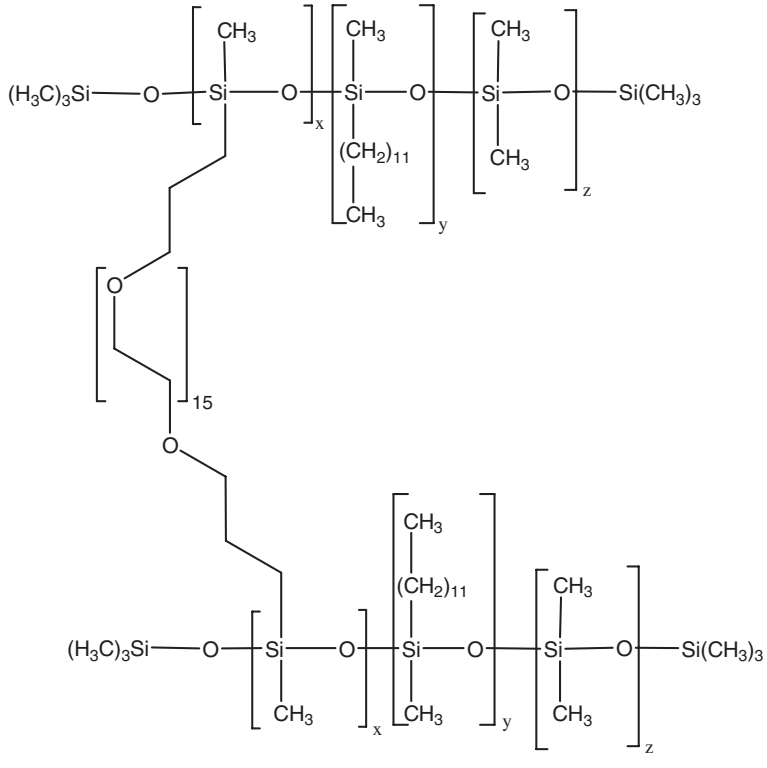
Ingredient	Idealized structure
PEG-10/lauryl dimethicone crosspolymer	
PEG-15/lauryl dimethicone crosspolymer	

Figure 1. (continued)

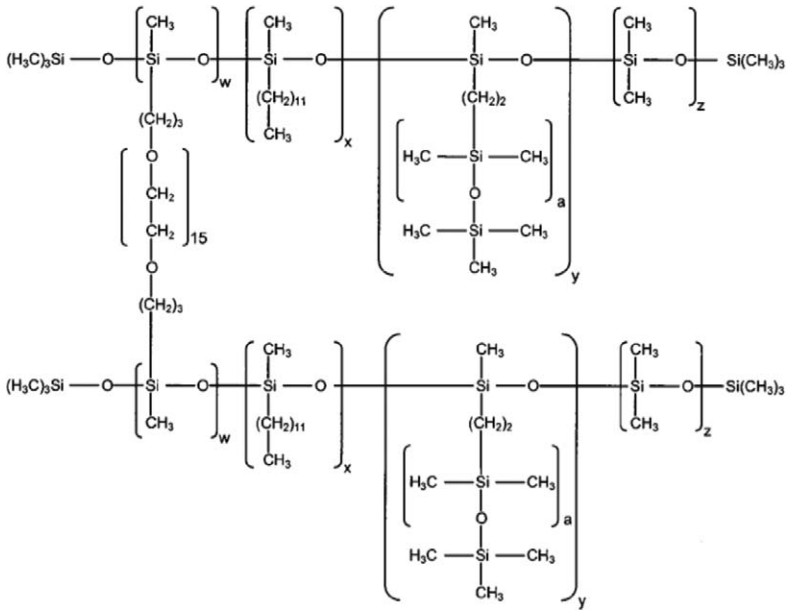
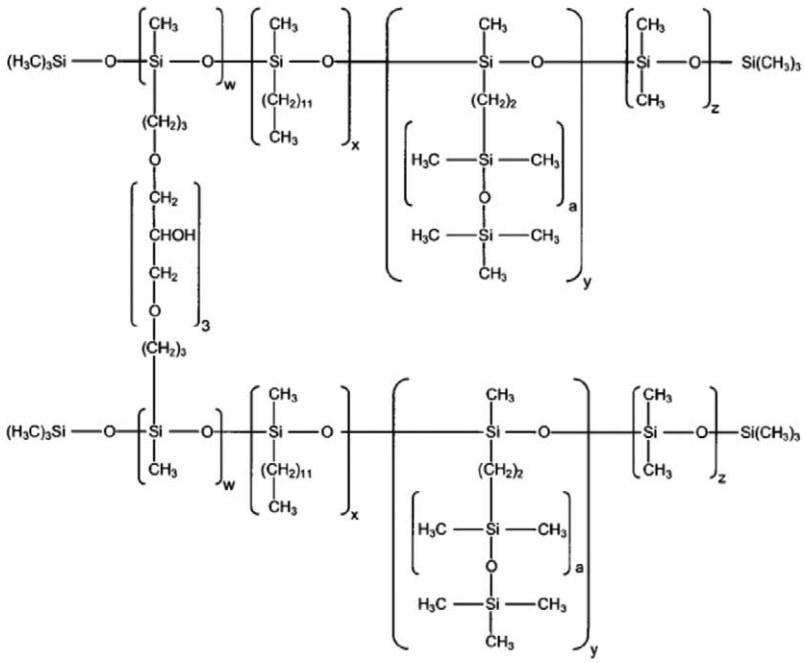
Ingredient	Idealized structure
PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer	
Perfluorononyl dimethicone/ methicone/amodimethicone crosspolymer	Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer is a crosslinked silicone polymer that is formed by reacting a copolymer of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

Figure 1. (continued)

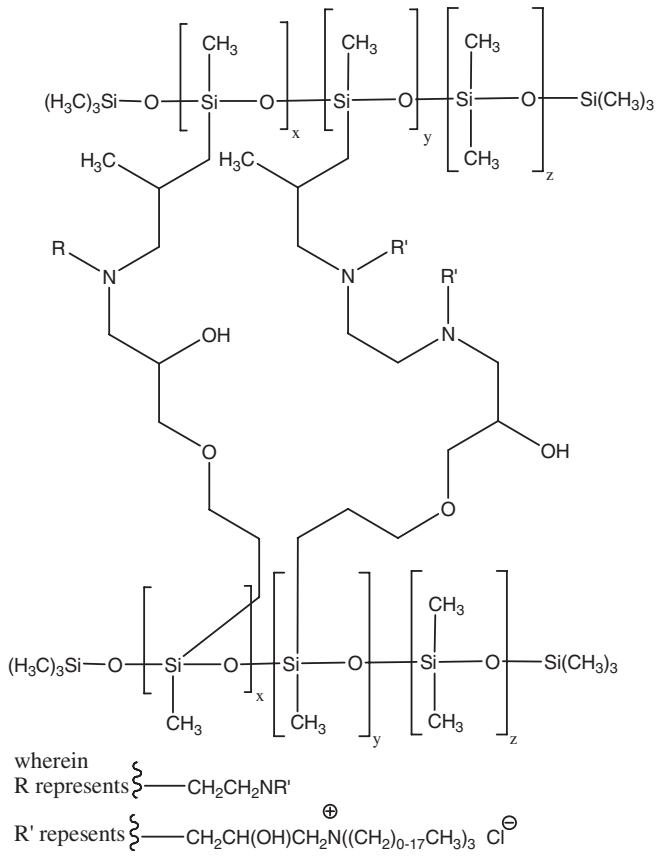
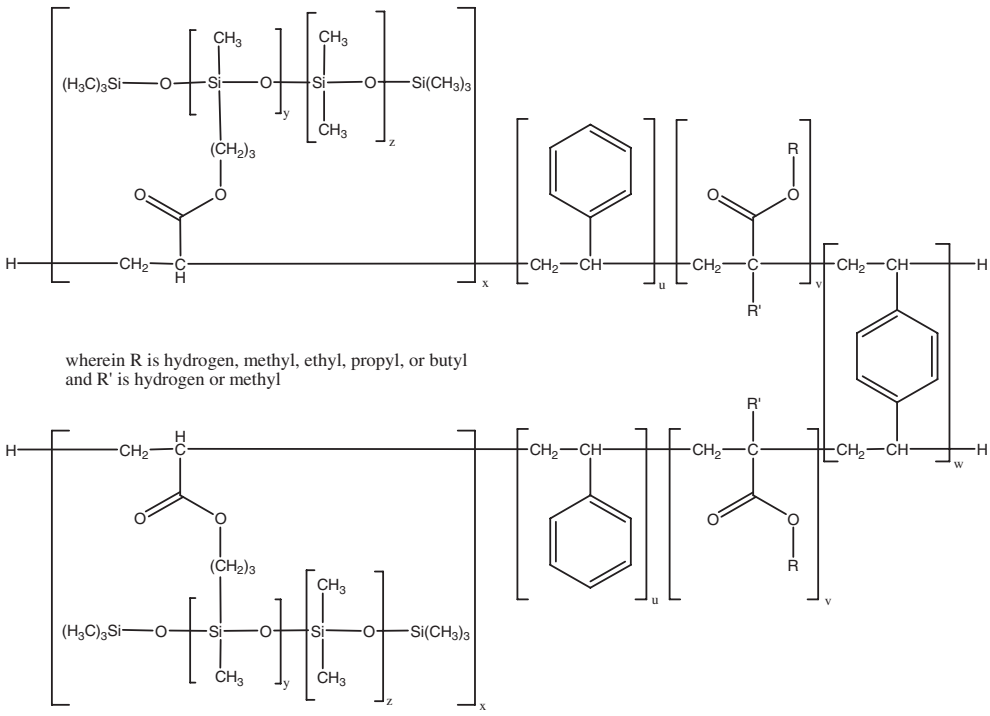
Ingredient	Idealized structure
Silicone quaternium-16/ glycidoxy dimethicone crosspolymer	
Styrene/acrylates/ dimethicone acrylate crosspolymer	

Figure 1. (continued)

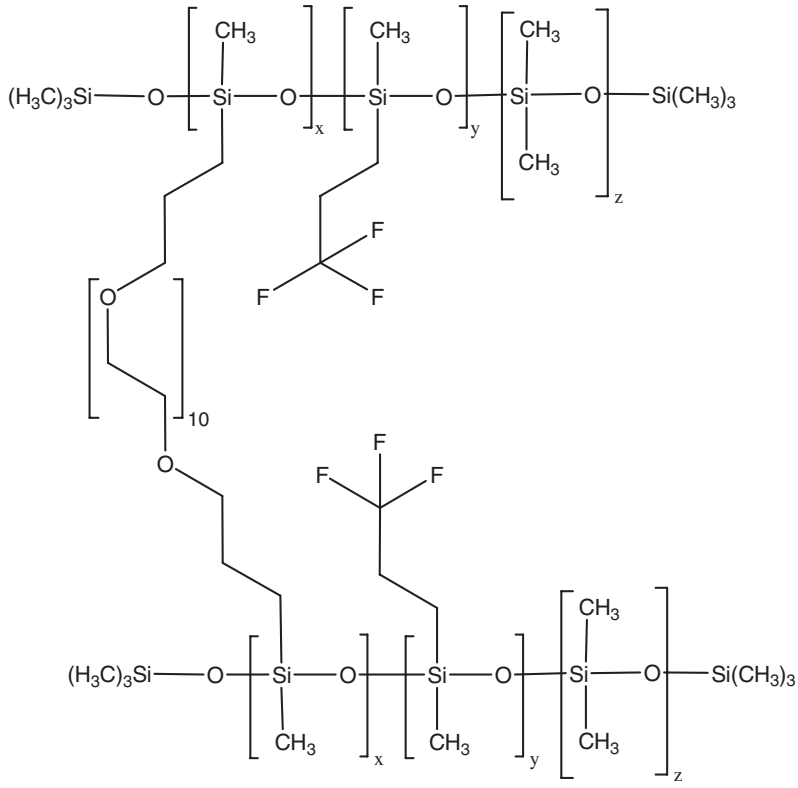
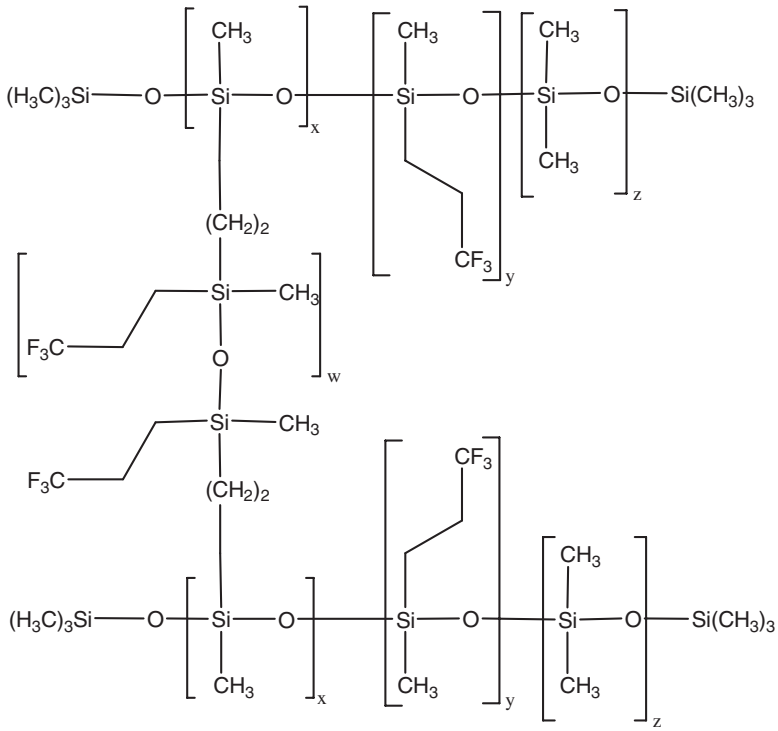
Ingredient	Idealized structure
Trifluoropropyl dimethicone/ PEG-10 crosspolymer	
Trifluoropropyl dimethicone/ trifluoropropyl divinyldimethicone crosspolymer	

Figure 1. (continued)

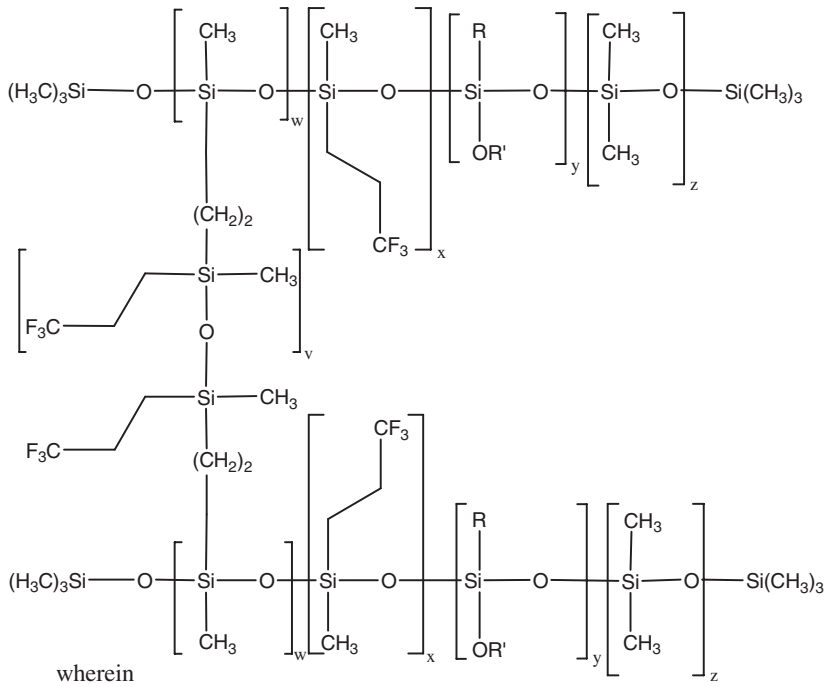
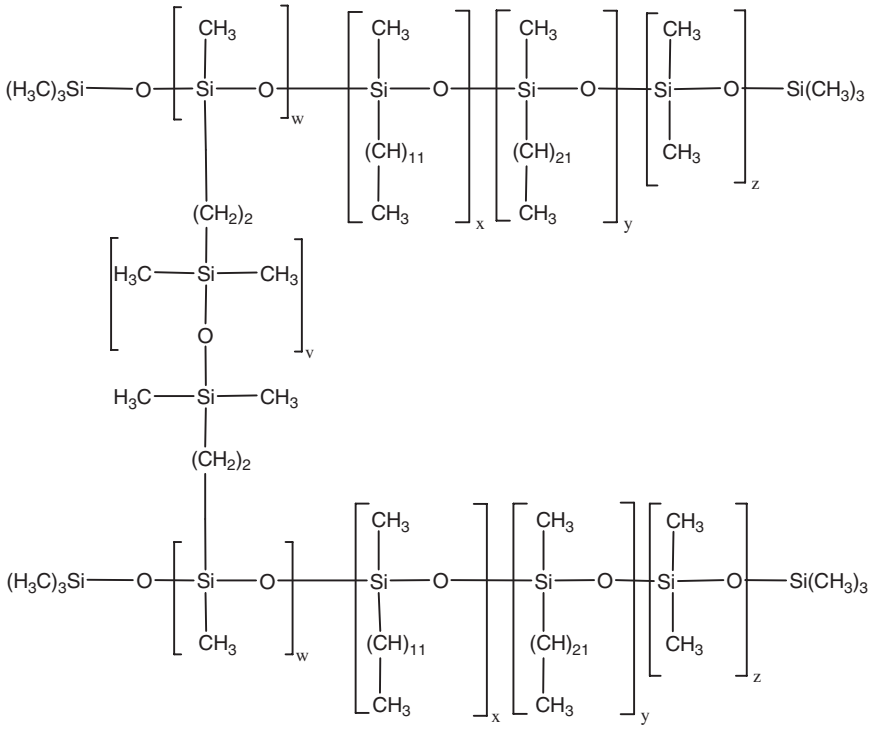
Ingredient	Idealized structure
Trifluoropropyl dimethicone/ vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer	 wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones
Trimethylsiloxysilicate/ dimethicone crosspolymer	Trimethylsiloxysilicate/dimethicone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

Figure 1. (continued)

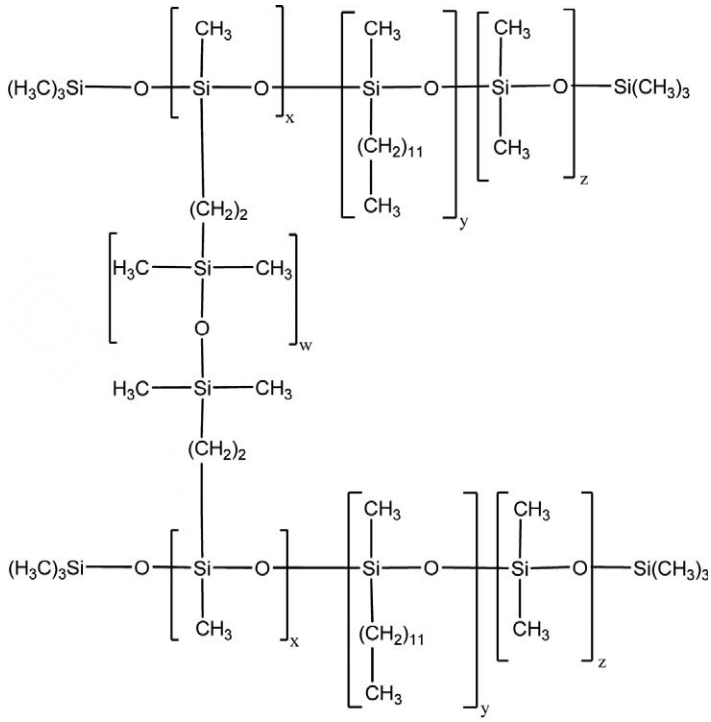
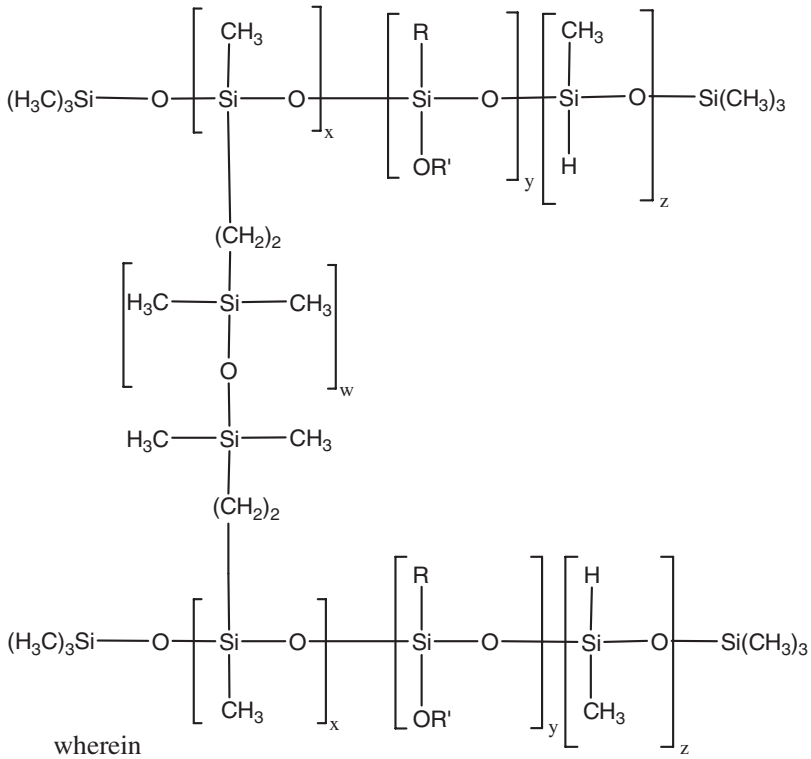
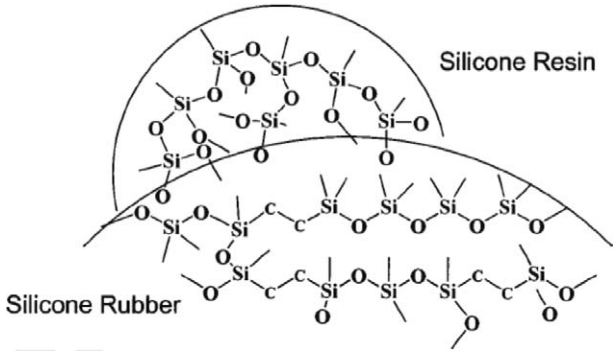
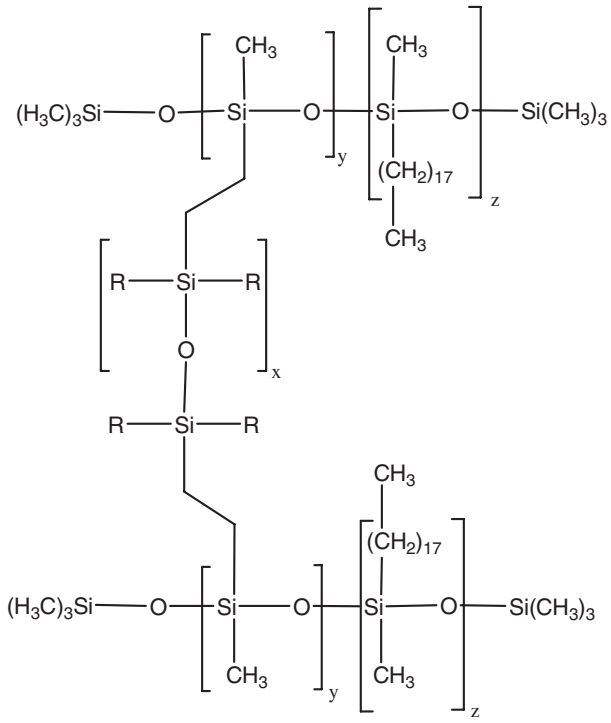
Ingredient	Idealized structure
Vinyl dimethicone/lauryl dimethicone crosspolymer	
Vinyl dimethicone/methicone silsesquioxane crosspolymer	 wherein R represents a hydrogen, alkyl, or aryl group R' represents crosslinks to other dimethicone backbones may also be visualized as:

Figure 1. (continued)

Ingredient	Idealized structure
	
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

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

Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer. Vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer (20% in isododecane) is stable for at least 1 year with no special storage requirements.[10] The mixture with isododecane reportedly creates a semitransparent gel with thixotropic properties.

Particle Size

Dimethicone/divinyldimethicone/silsesquioxane crosspolymer was reported in a patent to be spherical-shaped particles with

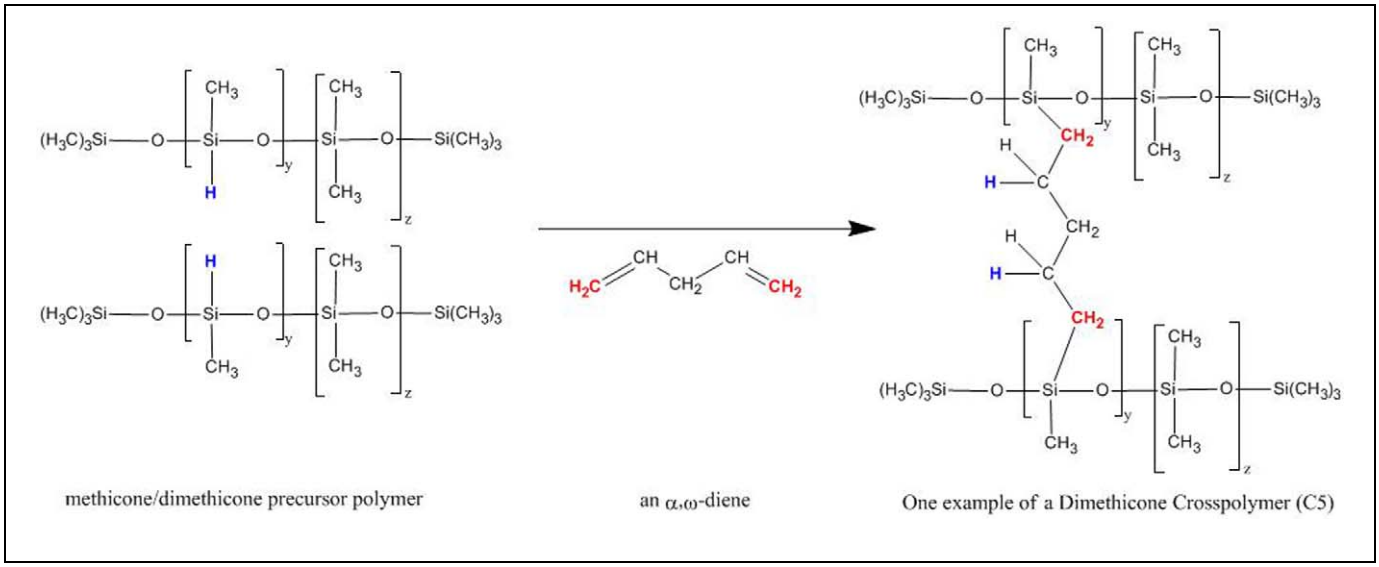


Figure 2. Example of the hydrosilation cross-linking of a dimethicone precursor polymer.

diameters ranging from 2 to 10 μm.[11] In finished products, even in those that are powders, these particles generally aggregate stably to produce much larger particles.

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

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 included *tert*-butanol (<100 ppm), isododecane (<1000 ppm), vinyl acetate (≤100 ppm), vinyl tert-decanoate (≤2000 ppm), crotonic acid (≤200 ppm), and trace amounts of isopropanol and ethyl acetate.

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

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

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

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

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

Use

Cosmetic

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

Table 3. Chemical and Physical Properties of Dimethicone Crosspolymers.

Property	Value	Reference
Acrylates/bis-hydroxypropyl dimethicone crosspolymer		
No data were discovered or submitted		
Behenyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted		
Bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer		
No data were discovered or submitted		
Bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer		
No data were discovered or submitted		
Bis-vinyldimethicone crosspolymer		
No data were discovered or submitted		
Bis-vinyldimethicone/PEG-10 dimethicone crosspolymer		
No data were discovered or submitted		
Bis-vinyldimethicone/PPG-20 crosspolymer		
No data were discovered or submitted		
Butyldimethicone methacrylate/methyl methacrylate crosspolymer		
No data were discovered or submitted		
C30-45 alkyl cetearyl dimethicone crosspolymer		
No data were discovered or submitted		
C4-24 alkyl dimethicone/divinyldimethicone crosspolymer		
No data were discovered or submitted		
C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer		
No data were discovered or submitted		
Cetearyl dimethicone crosspolymer		
No data were discovered or submitted		
Cetearyl dimethicone/vinyl dimethicone crosspolymer		
No data were discovered or submitted		
Cetyl dimethicone/bis-vinyldimethicone crosspolymer		
Physical form	Liquid	46
Water solubility 1% and 10%	Insoluble	46
Other solubility isopropyl alcohol 1% and 10%	Insoluble	46
Mineral spirits 1% and 10%	Soluble	
Mineral oil 1% and 10%	Soluble	
Aromatic solvents 1% and 10%	Soluble	
Cyclomethicone 1% and 10%	Soluble	
Cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted		
Crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer		
Physical form	Granules	4
Density, g/cm^3	1122	4
Water solubility	Dispersible	4
Other solubility cyclopentasiloxane	Insoluble	4
Dimethicone	Insoluble	
Isopropanol	1%-10% soluble	
Ethanol	Soluble	
Acetone	Soluble	
Isopropyl myristate	Insoluble	
Ethyl acetate	Soluble	
Butyl acetate	1%-10% soluble	
Dimethicone/bis-isobutyl ppg-20 crosspolymer		
No data were discovered or submitted		
Dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer		
No data were discovered or submitted		
Dimethicone crosspolymer		
No data were discovered or submitted		
Dimethicone crosspolymer-3		
No data were discovered or submitted		
Dimethicone/divinyldimethicone/silsesquioxane crosspolymer		
Physical form	Powder	12
Color	Off white	12
Odor	Typical	12
Vapor pressure, mm Hg @ 25°C	<0.1	6
Boiling point, °C	>300 (decomposes)	6
Water solubility, g/L @ °C and pH	Insoluble	6
Dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted		
Dimethicone/PEG-10 crosspolymer		
No data were discovered or submitted		
Dimethicone/PEG-10/15 crosspolymer		
No data were discovered or submitted		
Dimethicone/PEG-15 crosspolymer		
No data were discovered or submitted		
Dimethicone/phenyl vinyl dimethicone crosspolymer		
No data were discovered or submitted		
Dimethicone/polyglycerin-3 crosspolymer		
No data were discovered or submitted		
Dimethicone/PPG-20 crosspolymer		
No data were discovered or submitted		
Dimethicone/titanate crosspolymer		
No data were discovered or submitted		
Dimethicone/vinyl dimethicone crosspolymer		
No data were discovered or submitted		
Dimethicone/vinyltrimethylsiloxysilicate crosspolymer		
No data were discovered or submitted		
Diphenyl dimethicone crosspolymer		
No data were discovered or submitted		
Diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer		
No data were discovered or submitted		
Divinyldimethicone/dimethicone crosspolymer		
No data were discovered or submitted		
Hydroxypropyl dimethicone/polysorbate 20 crosspolymer		
No data were discovered or submitted		
Isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer		
No data were discovered or submitted		
Lauryl dimethicone PEG-15 crosspolymer		
No data were discovered or submitted		
Lauryl dimethicone/polyglycerin-3 crosspolymer		
No data were discovered or submitted		
Lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted		
PEG-10 dimethicone crosspolymer		
No data were discovered or submitted		
PEG-12 dimethicone crosspolymer		
No data were discovered or submitted		
PEG-8 dimethicone/polysorbate 20 crosspolymer		
No data were discovered or submitted		
PEG-12 dimethicone/PPG-20 crosspolymer		
No data were discovered or submitted		
PEG-12 dimethicone/PPG-20 crosspolymer		
No data were discovered or submitted		
PEG-10/lauryl dimethicone crosspolymer		
No data were discovered or submitted		
PEG-15/lauryl dimethicone crosspolymer		
No data were discovered or submitted		
PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer		
No data were discovered or submitted		
Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer		
No data were discovered or submitted		
Polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer		
No data were discovered or submitted		
Polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer		
No data were discovered or submitted		
Silicone quaternium-16/glycidoxy dimethicone crosspolymer		
No data were discovered or submitted		

(continued)

(continued)

Table 3. (continued)

Property	Value	Reference
Styrene/acrylates/dimethicone acrylate crosspolymer		
No data were discovered or submitted		
Trifluoropropyl dimethicone/PEG-10 crosspolymer		
No data were discovered or submitted		
Trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer		
No data were discovered or submitted		
Trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer		
No data were discovered or submitted		
Trimethylsiloxysilicate/dimethicone crosspolymer		
No data were discovered or submitted		
Vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer		
No data were discovered or submitted		
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		

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%, and 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, and 11 deodorants; body paint sprays up to 0.3%) and in 12 rinse-off products (0.007%-5%).
- Dimethicone crosspolymer 3 was reported to be used in 52 leave-on products (0.02%-2%; including 13 eye products) and in rinse-off products (0.2%).
- Dimethicone/divinyldimethicone/silsesquioxane crosspolymer was reported to be used in 14 leave-on products (0.5%-5%).
- Dimethicone/PEG-10/15 crosspolymer was reported to be used in 51 leave-on products (0.03%-3%) and in a hair conditioner (0.8%).
- Dimethicone/phenyl vinyl dimethicone crosspolymer was reported to be used in 10 leave-on products (0.8%-2%).
- Dimethicone/vinyl dimethicone crosspolymer was reported to be used in 444 leave-on products (0.003%-46%; including 1 baby product, 59 eye products, 9 lipsticks, and 47 products that may be inhaled) and 13 rinse-off products (0.06%-37%).
- Dimethicone/vinyltrimethylsiloxysilicate crosspolymer was reported to be used in 14 leave-on products (0.04%-6%; including eye products).
- Diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer was reported to be used in 13 leave-on products (0.1%-7%; up to 7% in face powders).
- Divinyldimethicone/dimethicone crosspolymer was reported to be used in 4 leave-on products (0.007%) and up to 0.7% in rinse-off products.
- Lauryl dimethicone/polyglycerin 3 crosspolymer was reported to be used in 3 rinse-off products (2%).
- PEG-10 dimethicone crosspolymer was reported to be used in 15 leave-on products (0.6%-2%).
- PEG-12 dimethicone crosspolymer was reported to be used in 28 leave-on products (0.3%-2%; 17 deodorants) and 3 rinse-off products (0.3%).
- PEG-15/lauryl dimethicone crosspolymer was reported to be used in 4 leave-on products (up to 2%) and 3 rinse-off products.
- Silicone quaternium-16/glycidoxy dimethicone crosspolymer was reported to be used in 2 leave-on products (0.003%) and 4 rinse-off products (1%-3%).
- Vinyl dimethicone/lauryl dimethicone crosspolymer was reported to be used in 3 leave-on products (0.3%-2% including lipstick) and in rinse-off products up to 0.09%.
- Vinyl dimethicone/methicone silsesquioxane crosspolymer was reported to be used in 104 leave-on products (0.1%-20%; mostly in make-up products) and 1 rinse-off product (0.5%-0.6%).

VCRP[15] data were only available for:

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

Council[16] data were only available for:

- Cetyl dimethicone/vinyldimethicone crosspolymer was reported to be used in leave-on and rinse-off products up to 0.005% including eye shadow, bath soap and detergents, and shaving cream.
- Dimethicone/PEG-10 crosspolymer was reported to be used in leave-on products (0.5%; foundations).

Table 4. Frequency of Use According to Duration and Exposure of Dimethicone Crosspolymers.[13,14,a]

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

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

(continued)

- 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 the Council survey for:

- acrylates/bis-hydroxypropyl dimethicone crosspolymer;
- bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer;
- bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer;

Table 4. (continued)

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

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

(continued)

- 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;

Table 4. (continued)

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

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

(continued)

- diphenyl dimethicone crosspolymer;
- hydroxypropyl dimethicone/polysorbate 20 crosspolymer;
- lauryl dimethicone PEG-15 crosspolymer;
- lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer;
- PEG-8 dimethicone/polysorbate 20 crosspolymer;
- PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer;
- PEG-12 dimethicone/PPG-20 crosspolymer;
- polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer;

Table 4. (continued)

Use type	PEG-10 dimethicone/vinyl dimethicone crosspolymer		PEG-10/lauryl dimethicone crosspolymer		PEG-15/lauryl dimethicone crosspolymer		Perfluorononyl dimethicone/methicone/ amodimethicone crosspolymer	
	Uses	Maximum concentration, %	Uses	Maximum concentration, %	Uses	Maximum concentration, %	Uses	Maximum concentration, %
Total/range	7	NR	NR	0.5-0.7	7	0.7-2	NR	0.7
Duration of use								
Leave-on	7	NR	NR	0.5-0.7	4	0.7-2	NR	0.7
Rinse-off	NR	NR	NR	0.6	3	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	1	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	0.7
Incidental inhalation—sprays	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation—powders	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	7	NR	NR	0.5-0.7	7	0.7-2	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	0.7
Baby	NR	NR	NR	NR	NR	NR	NR	NR

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

Abbreviations: NR, not reported; totals, rinse-off + leave-on product uses.
[a]Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum of total uses.

- PEG-15/lauryl polydimethylsiloxyethyl dimethicone;
- polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer;
- trifluoropropyl dimethicone/PEG-10 crosspolymer;
- trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer;
- trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer;
- trimethylsiloxysilicate/dimethicone crosspolymer;
- vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer;
- vinyldimethyl/trimethylsiloxysilicate/dimethicone crosspolymer;

- vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer.

Dimethicone crosspolymer and dimethicone/vinyl dimethicone crosspolymer are used in cosmetic products that may be sprays, including hair and body paint products, and could possibly be inhaled. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 μm, with propellant sprays yielding a greater fraction of droplets/particles below 10 μm compared with pump sprays.[17,18] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal region and would not be respirable (ie, they would not enter the lungs) to any appreciable amount.[19,20] There is some evidence indicating that deodorant spray products can release substantially larger fractions of particulates having aerodynamic equivalent diameters in the range considered to be respirable.[21] However, the information is not sufficient to determine whether significantly greater lung exposures result from the use of deodorant sprays compared to other cosmetic sprays. None of the deodorants containing these ingredients were reported to be sprays.

Toxicokinetics

Absorption, Distribution, Metabolism, and Excretion

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

Toxicological Studies

Acute Toxicity

Dermal—nonhuman

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

Oral—nonhuman

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

Inhalation—nonhuman

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

In vitro

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

Repeated Dose Toxicity

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

Oral—nonhuman

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 on body weight or food consumption. Macroscopic findings at necropsy were unremarkable. The mean absolute liver and relative liver weights in all test article-treated female groups was increased in a dose-dependent manner. However, only the high-dose group values were statistically significant. The authors concluded that oral administration of dimethicone/bis-isobutyl PPG-20 crosspolymer to rats for 14 consecutive days was well tolerated at all doses.[23]

Reproductive and Developmental Toxicity

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

Genotoxicity

In Vitro

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

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

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

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

Dimethicone/phenyl vinyl dimethicone crosspolymer. Dimethicone/phenyl vinyl dimethicone crosspolymer (~16%) was not mutagenic to *S typhimurium* (strains TA98, TA100, TA1535,

and TA1537) and *E coli* (strain WP3uvrA) with or without metabolic activation.[25]

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

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

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

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

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

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

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

Polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer. Polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer (100%; 2500 μg/plate) was not mutagenic to *S typhimurium* (strains TA98, TA100, TA1535, and TA1537) and *E coli* (strain WP3uvrA) with or without metabolic activation.[33]

Carcinogenicity

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

Irritation and Sensitization

Irritation

Dermal—nonhuman

Dimethicone crosspolymer. Dimethicone crosspolymer (100%; 0.5 mL) was not dermally irritating when administered to female New Zealand White rabbits (n = 3) under semiocclusion for 4 hours.[5]

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

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

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

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

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

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

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

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

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

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

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

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

Vinyl dimethicone/methicone silsesquioxane crosspolymer. Vinyl dimethicone/lauryl dimethicone crosspolymer (100%; 0.5 mL) had a PPI of 0.25 when administered under occlusion to intact and abraded skin of New Zealand White rabbits (n = 6).[36] The authors concluded that the test article was not a primary irritant.

Dermal—human

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

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

Ocular

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

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

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

Sensitization

Dermal—nonhuman

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

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

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

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

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

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

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

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

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

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

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

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

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

Dermal—human

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

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

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

Dimethicone/vinyl dimethicone crosspolymer. In 2 modified HRIPTs (n = 107), a facial lotion containing dimethicone/vinyl dimethicone crosspolymer (1%) was not sensitizing.[39]

Summary

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

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

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

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

Reported use and use concentration data were available for:

- behenyl dimethicone/bis-vinyldimethicone crosspolymer;
- C30-45 alkyl cetearyl dimethicone crosspolymer;
- C4-24 alkyl dimethicone/divinyldimethicone crosspolymer;
- cetearyl dimethicone crosspolymer;
- dimethicone/bis-isobutyl PPG-20 crosspolymer;
- dimethicone crosspolymer;
- dimethicone crosspolymer-3;
- dimethicone/divinyldimethicone/silsesquioxane crosspolymer;
- dimethicone/PEG-10/15 crosspolymer;
- dimethicone/phenyl vinyl dimethicone crosspolymer;
- dimethicone/vinyl dimethicone crosspolymer;
- dimethicone/vinyltrimethylsiloxysilicate crosspolymer;
- diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer;
- divinyldimethicone/dimethicone crosspolymer;
- lauryl dimethicone/polyglycerin-3 crosspolymer;
- PEG-10 dimethicone crosspolymer;
- PEG-12 dimethicone crosspolymer;
- PEG-15/lauryl dimethicone crosspolymer;
- silicone quaternium-16/glycidoxy dimethicone crosspolymer;
- vinyl dimethicone/lauryl dimethicone crosspolymer;
- vinyl dimethicone/methicone silsesquioxane crosspolymer.

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

- C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer;
- Dimethicone/polyglycerin-3 crosspolymer;
- isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer;
- PEG-10 dimethicone/vinyl dimethicone crosspolymer was reported to be used in 7 leave-on products;
- styrene/acrylates/dimethicone acrylate crosspolymer.

Use concentration data were only available for:

- cetyl dimethicone/bis-vinyldimethicone crosspolymer;
- dimethicone/PEG-10 crosspolymer;
- dimethicone/PPG-20 crosspolymer;
- PEG-10/lauryl dimethicone crosspolymer;
- perfluorononyl dimethicone/methicone/amodimethicone crosspolymer.

There were no reported uses or use concentrations for:

- acrylates/bis-hydroxypropyl dimethicone crosspolymer;
- bis-phenylisopropyl phenylisopropyl dimethicone/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;
- cetyl dimethicone/bis-vinyldimethicone crosspolymer;
- cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer;
- crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer;
- dimethicone/divinyldimethicone/silsesquioxane crosspolymer;
- dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer;
- dimethicone/PEG-15 crosspolymer;
- dimethicone/titanate crosspolymer;
- diphenyl dimethicone crosspolymer;
- hydroxypropyl dimethicone/polysorbate 20 crosspolymer;
- lauryl dimethicone PEG-15 crosspolymer;
- lauryl dimethicone/polyglycerin-3 crosspolymer;
- lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer;
- PEG-8 dimethicone/polysorbate 20 crosspolymer;
- PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer;
- PEG-12 dimethicone/PPG-20 crosspolymer;
- PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer;
- polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer;
- polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer;
- trifluoropropyl dimethicone/PEG-10 crosspolymer;
- trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer;
- trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer;
- trimethylsiloxysilicate/dimethicone crosspolymer;
- vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer;
- vinyldimethyl/trimethylsiloxysilicate/dimethicone crosspolymer;
- vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer.

Dimethicone crosspolymer had a dermal LD_{50} of >2000 mg/kg in rabbits. The oral LD_{50} of dimethicone crosspolymer was >2000 mg/kg for rats. The acute inhalation LC_{50} of crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer at 10% over 4 hours 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 to 5000 μg/plate.

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

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

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

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

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

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

Discussion

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

There was a lack of toxicokinetics, repeated dose toxicity, carcinogenicity, and reproductive/developmental toxicology data for the dimethicone crosspolymers in this safety assessment. The Panel was not concerned about these gaps in information because these ingredients are large polymers that will not penetrate the skin. Also, the silicone backbone is stable under anticipated conditions of use and these ingredients do not contain monomers above the levels of toxicological concern. There are multiple animal irritation and sensitization studies as well as 2 HRIPT studies that were negative for effects. Ames tests were negative for 3 of these ingredients.

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

- α-Methylstyrene;
- bis-vinyldimethicone;
- methyl methacrylate;
- butyldimethylsilylmethacrylate;
- vinyl cyclohexene oxide;

- vinyl acetate;
- α,ω-Divinyl alkenes (C4-20);
- bis-vinyl phenylmethyldimethicone;
- allyl alcohol;
- isobutanol;
- titanium species used in cross-linking [(0-IPr)4 or (0-iPr)2Cl2];
- unidentified diamine cross-linking agent in silicone quaternium-16/glycidoxy dimethicone crosspolymer;
- styrene;
- divinylbenzene;
- allyl polyglyceryl-3;
- bisvinyl trifluoroproyl methicone (if n $\sim \leq 8$).

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

The Panel discussed the issue of incidental inhalation exposure from face powders, foot powders, and sprays, perfumes, and hair sprays. The data available from 1 acute inhalation exposure study indicated that the LC_{50} for crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone is greater than 5.29 mg/L. The Panel concluded that the sizes of a substantial majority of the particles of these ingredients, as manufactured, are larger than the respirable range and/or aggregate and agglomerate to form much larger particles in formulation. These ingredients are reportedly used at concentrations up to 20% in spray and up to 46% in powder cosmetic products that may become airborne. The Panel noted that 95% to 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, these ingredients are not likely to cause direct toxic effect in the upper respiratory tract, based on the chemical and biological properties of the dimethicone crosspolymers. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. The Panel considered other data available to characterize the potential for dimethicone crosspolymers to cause genotoxicity, irritation, and sensitization. They noted the lack of systemic toxicity in acute oral exposure studies, little or no irritation or sensitization in multiple tests of dermal and ocular exposure, and the absence of genotoxicity in multiple Ames tests. In addition, these ingredients are large macromolecules, insoluble in water, and chemically inert under physiological conditions or conditions of use, which supports the view that they are unlikely to be absorbed or cause local effects in the respiratory tract. A detailed discussion of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at http://www.cir-safety.org/cir-findings.

Conclusion

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

- acrylates/bis-hydroxypropyl dimethicone crosspolymer*;
- behenyl dimethicone/bis-vinyldimethicone crosspolymer;
- bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer*;
- bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer*;
- bis-vinyldimethicone crosspolymer*;
- bis-vinyldimethicone/PEG-10 dimethicone crosspolymer*;
- bis-vinyldimethicone/PPG-20 crosspolymer*;
- butyldimethicone methacrylate/methyl methacrylate crosspolymer*;
- C30-45 alkyl cetearyl dimethicone crosspolymer;
- C4-24 alkyl dimethicone/divinyldimethicone crosspolymer;
- C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer;
- cetearyl dimethicone crosspolymer;
- cetearyl dimethicone/vinyl dimethicone crosspolymer;
- cetyl dimethicone/bis-vinyldimethicone crosspolymer*;
- cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer*;
- crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer*;
- dimethicone/bis-isobutyl PPG-20 crosspolymer;
- dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer*;
- dimethicone crosspolymer;
- dimethicone crosspolymer-3;
- dimethicone/divinyldimethicone/silsesquioxane crosspolymer;
- dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer*;
- dimethicone/PEG-10 crosspolymer;
- dimethicone/PEG-10/15 crosspolymer;
- dimethicone/PEG-15 crosspolymer*;

- dimethicone/phenyl vinyl dimethicone crosspolymer;
- dimethicone/polyglycerin-3 crosspolymer;
- dimethicone/PPG-20 crosspolymer;
- dimethicone/titanate crosspolymer*;
- dimethicone/vinyl dimethicone crosspolymer;
- dimethicone/vinyltrimethylsiloxysilicate crosspolymer;
- diphenyl dimethicone crosspolymer*;
- diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer;
- divinyldimethicone/dimethicone crosspolymer;
- hydroxypropyl dimethicone/polysorbate 20 crosspolymer*;
- isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer;
- lauryl dimethicone PEG-15 crosspolymer*;
- lauryl dimethicone/polyglycerin-3 crosspolymer*;
- lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer*;
- PEG-10 dimethicone crosspolymer;
- PEG-12 dimethicone crosspolymer;
- PEG-8 dimethicone/polysorbate 20 crosspolymer*;
- PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer*;
- PEG-12 dimethicone/PPG-20 crosspolymer*;
- PEG-10 dimethicone/vinyl dimethicone crosspolymer;
- PEG-10/lauryl dimethicone crosspolymer;
- PEG-15/lauryl dimethicone crosspolymer;
- PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer*;
- perfluorononyl dimethicone/methicone/amodimethicone crosspolymer;
- polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer*;
- polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer*;
- silicone quaternium-16/glycidoxy dimethicone crosspolymer;
- styrene/acrylates/dimethicone acrylate crosspolymer;
- trifluoropropyl dimethicone/PEG-10 crosspolymer*;
- trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer*;
- trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer*;
- trimethylsiloxysilicate/dimethicone crosspolymer*;
- vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer*;
- vinyl dimethicone/lauryl dimethicone crosspolymer;
- vinyl dimethicone/methicone silsesquioxane crosspolymer;
- vinyldimethyl/trimethylsiloxysilicate/dimethicone crosspolymer*;
- vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer*.

*Not reported in use. If ingredients in this group to be in current use are 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.

Authors' Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1620 L. St, NW, Suite 1200, Washington, DC 20036, USA.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: The articles in this supplement were sponsored by the Cosmetic Ingredient Review. The Cosmetic Ingredient Review is financially supported by the Personal Care Products Council.

References

1. Gottschalck TE, Breslawec HP. *International Cosmetic Ingredient Dictionary and Handbook*. 14th ed. Washington, DC: Personal Care Products Council; 2012.
2. Nair B, Elmore AR, Berfeld WF, et al. Final report on the safety assessment of stearoxy dimethicone, dimethicone, methicone, amino bispropyl dimethicone, aminopropyl dimethicone, amodimethicone, amodimethicone hydroxystearate, behenoxy dimethicone, C24-28 alkyl methicone, C30-45 alkyl methicone, C30-45 alkyl dimethicone, cetearyl methicone, cetyl dimethicone, dimethoxysilyl ethylenediaminopropyl dimethicone, hexyl methicone, hydroxypropyldimethicone, stearamidopropyl dimethicone, stearyl dimethicone, stearyl methicone, and vinyldimethicone. *Int J Toxicol*. 2003;22(suppl 2):11-35.
3. Starch MS, Fiori JE, Lin Z. Beyond rheology modification: hydrophilically modified silcone elastomers provide new benefits. *J Cosmetic Sci*. 2003;54(2):193-205.
4. Wacker Chemie AG. *Product dossier Belsil® P101 (Crotonic Acid/Vinyl 8-12 Isoalkyl Esters/VA/Bis-Vinyldimethicone Crosspolymer* [pamphlet]. Burghausen, Germany: Wacker Chemie AG; 2011.
5. National Industrial Chemicals Notification and Assessment Scheme. Full public report: Polymer in DOW CORNING 9040 Silicone Elastomer Blend. Sidney, Australia, National Occupational Health and Safety Commission; 2000:1-19. http://www.nicnas.gov.au/PUBLICATIONS/CAR/NEW/PLC/PLC0100FR/plc189fr.pdf. Accessed April 17, 2012.
6. Grant Industries. Product information: dimethicone/divinyldimethicone/silsesquioxane crosspolymer. Unpublished data submitted by the Personal Care Products Council; 2012:12.
7. Wacker Chemie AG. *Product dossier Wacker-Belsil® RG100 (Cylcopentasiloxane (and) Dimethicone/Vinyltrimethylsiloxysilicate Crosspolymer)* [pamphlet]. Burghausen, Germany: Wacker Chemie AG; 2010.
8. CosmetoScope. PEG-12 Dimethicone; March 1, 2010. http://www.cosmetoscope.com/2010/03/peg-12-dimethicone/. Accessed February 8, 2011.

9. Shin-Etsu. Shin-Etsu silicone: silicone products for personal care: Shin-Etsu unique materials (Includes chemical and physical properties of a number of dimethicone crosspolymer ingredients). Unpublished data submitted by Personal Care Products Council; 2010.
10. Wacker Chemie AG. *Product dossier Wacker-Belsil® RG90 (Isodecane (and) Vinyldimethyl/Trimethylsiloxysilicate Stearyl Dimethicone Crosspolymer* [pamphlet]. Burghausen, Germany: Wacker Chemie AG; 2010.
11. Wang J, Hung JL, Hrubec TJ, et al. United States Patent Application Publication: topical cosmetic composition containing hybrid silicone composite powder (US2005/0112072 A1) Unpublished data submitted by the Personal Care Products Council; 2005.
12. Grant Industries. Product information: Gransil EPSQ dimethicone/divinyldimethicone/silsesquioxane crosspolymer. Unpublished data submitted by the Personal Care Products Council; 2011:12.
13. Personal Care Products Council. Updated concentration of use by FDA product category: dimethicone crosspolymers. Unpublished data submitted by Personal Care Products Council;2012:12.
14. U.S. Food and Drug Administration. FDA Database. *Cosmetic Production Formulation and Frequency of Use Data Submitted to the Voluntary Cosmetic Registration Program (VCRP)*. Washington, DC: FDA. Data submitted in response to FOIA request; 2012.
15. U.S. Food and Drug Administration. FDA database. *Cosmetic Production Formulation and Frequency of Use Data Submitted to the Voluntary Cosmetic Registration Program (VCRP)*. Washington, DC: FDA; 2010.
16. Personal Care Products Council. Concentration of use by FDA product category: dimethicone crosspolymer ingredients. Unpublished data submitted by Personal Care Products Council; 2012:11.
17. Johnsen MA. The Influence of Particle Size. *Spray Technol Mark*. 2004;14(11):24-27.
18. Rothe H. Special aspects of cosmetic spray safety evaluation. Unpublished information presented to the 26 September CIR Expert Panel. Washington, DC; 2011.
19. Bremmer HJ, Prud'homme de Lodder LCH, van Engelen JGM. General Fact Sheet: limiting conditions and reliability, ventilation, room size, body surface area; Updated version for ConsExpo 4; 2006:1-31. http://www.rivm.nl/bibliotheek/rapporten/320104002.pdf. Accessed August 24, 2011. Report No. RIVM 320104002/2006.
20. Rothe H, Fautz R, Gerber E, et al. Special aspects of cosmetic spray safety evaluations: principles on inhalation risk assessment. *Toxicol Lett*. 2011;205:(2):97-104.
21. Bremmer HJ, Prud'homme de Lodder LCH, van Engelen JGM. Cosmetics Fact Sheet: to assess the risks for the consumer; Updated version for ConsExpo 4; 2006:1-77. http://www.rivm.nl/bibliotheek/rapporten/320104001.pdf. Accessed August 24, 2011. Report No. RIVM 320104001/2006.
22. AMA Laboratories Inc.Agar diffusion cytotoxicity test of Gransil EPSQ (dimethicone/divinyldimethicone/silsesquioxane crosspolymer). AMA Ref. No. MS06.CYTOTOX.K9528.GII. Unpublished data submitted by the Personal Care Products Council; 2006.
23. Silicones Environmental Health and Safety Council. Summary of health data for cosmetic ingredient review: dimethicone crosspolymer ingredients. Unpublished data submitted by Silicones Environmental Health and Safety Council. Summary of Dow Corning reports as follows: 2011-I0000-63817, 2011-I0000-64264; 2010-I0000-62764; 2010-I0000-63290, 2010-I0000-63291, 2010-I0000-63410, 2010-I0000-63442, 2010-I0000-63443, 2010-I0000-63445, -63411, 2010-I0000-62425, 2010-I0000, 1999-I0000-46222, 1999-I0000-46260, 1999-I0000-46165, 2002-I0000-51793, 1999-I0000-46259, 1999-I0000-46455, 2002-I0000-51792, 1999-I0000-46532; 2012:6.
24. Shin-Etsu. Summary of safety studies on a test ingredient containing 24% dimethicone/PEG-10/15 crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
25. Shin-Etsu. Summary of safety studies on a test ingredient containing 16% dimethicone/phenyl vinyl dimethicone crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
26. Shin-Etsu. Summary of safety studies on a test ingredient containing 40% dimethicone/polyglycerin-3 crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
27. Shin-Etsu. Summary of safety studies on a test ingredient containing 24% dimethicone/vinyl dimethicone crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
28. Shin-Etsu. 2012. Summary of safety studies on a test ingredient containing diphenyl/vinyl diphenyl dimethicone/silsesquioxane crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
29. Shin-Etsu. Summary of safety studies on a test ingredient containing 40% lauryl dimethicone/polyglycerin-3 crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
30. Shin-Etsu. Summary of safety studies on lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
31. Shin-Etsu. Summary of safety studies on PEG-15/lauryl dimethicone crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
32. Shin-Etsu. Summary of safety studies on PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
33. Shin-Etsu. Summary of safety studies on polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
34. Shin-Etsu. Summary of safety studies on a mixture of PEG-10/lauryl dimethicone crosspolymer and PEG-15/Lauryl Dimethicone Crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
35. Shin-Etsu. Summary of safety studies on vinyl dimethicone/lauryl dimethicone crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
36. Shin-Etsu. Summary of safety studies on vinyl dimethicone/methicone silsesquioxane crosspolymer. Unpublished data submitted by Personal Care Products Council; 2012.
37. Cassidy SL, Stanton E. In vitro eye irritation studies on organosilicon compounds. *Cutan Ocul Toxicol*. 1997;16:(1):45-60.

38. AMA Laboratories Inc. 50 Human subject repeat insult patch test skin irritation/sensitization evaluation (occlusive patch) of Gransil EPSQ (dimethicone/divinyldimethicone/silsesquioxane crosspolymer). AMA Ref. No. MS04.RIPT.K99. Unpublished data submitted by the Personal Care Products Council; 2006.
39. Clinical Research Services. Summary of an HRIPT of a facial lotion containing 1% dimethicone/vinyl dimethicone crosspolymer (row 1 irritation results, row 2 sensitization results). Unpublished data submitted by Personal Care Products Council; 2006:1.
40. Fiume MZ, Berfeld WF, Belsito DV, et al. Final report on the safety assessment of acrylates copolymer and 33 related cosmetic ingredients. *Int J Toxicol*. 2002;21:(suppl 3):1-50.
41. Berfeld WF, Belsito DV, Hill RA, et al. Final Report of the Cosmetic Ingredient Review Expert Panel: Amended Safety Assessment of Triethylene Glycol and Polyethylene Glycols (PEGs)-4, -6, -7, -8, -9, -10, -12, -14, -16, -18, -20, -32, -33, -40, -45, -55, -60, -75, -80, -90, -100, -135, -150, -180, -200, -220, -240, -350, -400, -450, -500, -800, -2M, -5M, -7M, -9M, -14M, -20M, -23M, -25M, -45M, -65M, -90M, -115M, -160M and -180M and any PEGs $\geq$ 4 as used in Cosmetics. Washington, DC: Cosmetic Ingredient Review; 2010:1-49.
42. Elder RW. Final report on the safety assessment of polysorbates 20, 21, 40, 60, 65, 80, 81, and 85. *J Am Coll Toxicol*. 1984;3:(5):1-82.
43. Berfeld WF, Belsito DV, Klaassen CD, et al. Final report on the safety assessment of propylene glycol and polypropylene glycols. *J Am Coll Toxicol*. 1994;13:(6):437-491.
44. Fiume MZ, Berfeld WF, Belsito DV, et al. *Final Amended Report of the Cosmetic Ingredient Review Expert Panel: Safety Assessment of Propylene Glycol, Tripropylene Glycol, and PPGs as Used in Cosmetics*. Washington, DC: Cosmetic Ingredient Review; 2010:1-31.
45. Becker LC, Bergfeld WF, Belsito DV, et al. *Final Safety Assessment: Silylates and Surface Modified siloxysilicates as used in Cosmetics*. Washington, DC: Cosmetic Ingredient Review; 2011:1-25.
46. Siltech Corporation. *Siltech: Innovative Silicone Specialties* [pamphlet]. Toronto, Ontario: Siltech Corporation; 2012.