Safety Assessment of Dimethicone, Methicone, and Substituted-Methicone Polymers, as Used in Cosmetics

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All interested persons are provided 60 days from the above release date (i.e., August 21, 2020) to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth.

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ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 30 Dimethicone, Methicone, and substituted-Methicone polymers; 20 of these ingredients were previously reviewed by the Panel, and 10 are reviewed herein for the first time. Most of these ingredients are reported to function as skin and hair conditioning agents. The Panel reviewed relevant new data, including frequency and concentration of use, as well as exposure type, and considered data from the previous report. The Panel concluded that these ingredients are safe in cosmetics in the present practices of use and concentration as described in this safety assessment when formulated to be non-irritating to the skin and eye.

INTRODUCTION

In 2003, the Expert Panel for Cosmetic Ingredient Safety (Panel) published a final report on the safety assessment of 20 Dimethicone, Methicone, and substituted-Methicone polymers.[1] Based on the available data, the Panel concluded that the ingredients named in that report are safe as used in cosmetic products. According to the Cosmetic Ingredient Review (CIR) Procedures, the Panel evaluates the conclusions of previously-issued reports approximately every 15 years. In December 2019, the Panel determined that this safety assessment should be re-opened due to an increase in the overall frequency of use for ingredients in this group. The Panel also determined that it is appropriate to include an additional 10 alkyl dimethicone and methicone ingredients (denoted in red below); the complete family of 30 ingredients comprises:

Amino Bispropyl Dimethicone
Aminopropyl Dimethicone
Amodimethicone
Amodimethicone Hydroxystearate
Behenoxy Dimethicone
C20-24 Alkyl Dimethicone
C20-24 Alkyl Methicone
C24-28 Alkyl Dimethicone
C24-28 Alkyl Methicone
C26-28 Alkyl Dimethicone
C26-28 Alkyl Methicone
C30-45 Alkyl Dimethicone
C30-45 Alkyl Methicone
C30-60 Alkyl Dimethicone
C32 Alkyl Dimethicone
Capryl Dimethicone
Caprylyl Methicone
Cetearyl Methicone
Cetyl Dimethicone
Dimethicone
Dimethoxysilyl Ethylenediaminopropyl Dimethicone
Hexyl Dimethicone
Hexyl Methicone
Hydroxypropyldimethicone
Methicone
Stearamidopropyl Dimethicone
Stearoxy Dimethicone
Stearyl Dimethicone
Stearyl Methicone
Vinyl Dimethicone

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*), the majority of the ingredients included in this assessment are reported to function as skin conditioning agents, hair conditioning agents, and/or viscosity increasing agents.[2] Additional functions are also reported for some ingredients (Table 1).

Excerpts from the summary of the 2003 report are included throughout the text of this re-review document, as appropriate, and are *identified by italicized text.* (This information is not included in the Summary section.) For complete and detailed information, please refer to the original report on the methicone polymer ingredients, which can be accessed on the CIR website (https://www.cir-safety.org/ingredients).

Panel safety assessments include relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the CIR website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties. Much of the data included in this safety assessment was found in an European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) report.[3] Please note that most of the toxicology studies described in that report were summaries, and it is those summary data that are reported in this safety assessment when ECETOC is cited.

CHEMISTRY

Definition

The ingredients in this report are all siloxane polymers. Each silicone atom is further substituted with hydrogen, methyl, or other substituents (Figure 1). "Methicone" (CAS No. 9004-73-3) means that most of the silicone atoms in the polymer backbone each have 1 methyl group and 1 hydrogen atom, while "Dimethicone" (CAS No. 9006-65-9) means that most silicone atoms in the polymer back bone have 2 methyl substituents. The remaining ingredients in this report have 1 or

2 of the substituents on the silicone atoms replaced with an alternative functional group (e.g., Hexyl Methicone (CAS No. 1873-90-1) is substituted with hexyl-chains (C6)). The definitions and idealized structures of all the ingredients included in this report are provided in Table 1

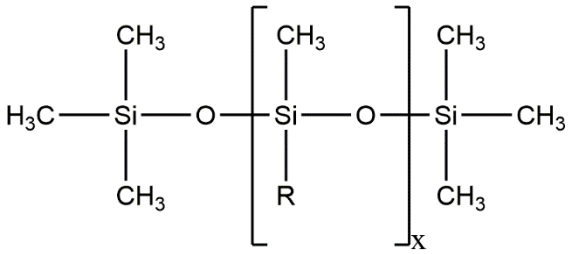


Figure 1. Methicones, wherein R is hydrogen, methyl, or other substituents

The polymerization of linear methicones, however, often results in a mixture of polymers (chains of variable lengths and molecular weights, including oligomers) and cyclic compounds.[4] Dimethicone is a mixture of fully methylated linear siloxane polymers end-blocked with trimethylsiloxy units.[2] Methicone is a linear monomethyl polysiloxane.[2] The other ingredients included in this review are siloxane polymers of Dimethicone and Methicone.

Viscosity is expressed in both dynamic and kinematic measurements, and is directly correlated with molecular weight and the degree of polymerization of a molecule, i.e., the longer the polymer chains, the more viscous the liquid polymer. Most of the viscosities reported in previous and current data have been described in kinematic centistokes (cSt; cm^2/s), and are converted to the standard, dynamic, Pascal*second (Pa·s; kg/m·s), where specific gravity, or relative density, values were available. To do this, the product of centistoke and specific gravity, or relative density, values, was divided by 1000, to attain Pa·s values. Specifically, a median reported relative density value of 950 has been used for the conversion of Dimethicone samples described in the ECETOC report.[3]

Physical Properties

Dimethicone is a white, almost odorless fluid polymer.[1] Specifications for Dimethicone stated that the color and odor are specified by the buyer. Also specified by the buyer are the refractive index at 25℃ (within the range of 1.4000 to 1.4035), and the kinematic viscosity (provided that the specified mean viscosity at 25℃ is not less than 20 centistokes [cs] and not greater than ± 5% of the specified mean). It contains 98.5% to 101.1% Dimethicone and the total acid number is 0.01 maximum. One supplier of Dimethicone noted that 100 and 350 cs fluids are generally used for cosmetics.

C30-45 Alkyl Dimethicone

C30-45 Alkyl Dimethicone is a an off-white solid, which occurs in small pellets, at standard temperature and pressure.[5] This ingredient has a melting point of 63 - 74 °C and is considered insoluble in water.

Hexyl Methicone

At atmospheric pressure, Hexyl Methicone is a liquid at 20 °C, has a melting/freezing point at < -20 °C, a boiling point at 232 °C, and a partition coefficient of log P_{ow} > 6.2 at 40 °C.[6] Additionally, Hexyl Methicone has a relative density of 0.83 at 20 °C and a water solubility of 0.011 mg/L at 20 °C.

Method of Manufacture

Stearoxy Dimethicone is produced by the reaction of dichloropolydimethylsiloxane with stearyl alcohol.[1] Dimethicone is produced by polymerization/equilibration. Cetyl Dimethicone is produced by hydrosilylation of C_{16} alpha-olefins. Stearyl Dimethicone is produced by hydrosilylation of C_{18} alpha-olefins.

No additional methods of manufacture data were found in the published literature, and unpublished data were not submitted.

Impurities

One supplier of these ingredients noted that Stearoxy Dimethicone, Dimethicone, Cetyl Dimethicone, and Stearyl Dimethicone contain no antioxidants or preservatives.[1] Heavy metals are at 5 ppm maximum, and D4/D5 cyclomethicone is at less than 1%.

C30-45 Alkyl Dimethicone

The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) noted that C30-45 Alkyl Dimethicone can potentially contain residual monomers which are classified as hazardous according to the *Globally*

Harmonised System of Classification and Labelling of Chemicals (GHS).[5] As per Australian chemical manufacturing guidelines; however, these are not present above the cut off concentrations for classification.

No additional impurities data were found in the published literature, and unpublished data were not submitted.

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics is collected from manufacturers and reported by cosmetic product category in the FDA Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by the cosmetic industry in response to a survey, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

Frequency and concentration of use has generally increased for these ingredients since they were originally reviewed, with some of the increases being quite significant. According to 2020 VCRP survey data, the frequency of use of Dimethicone has increased from 1659 reported uses in 1998 to 14,050 reported uses in 2020, and the number of uses reported for Methicone increased from none reported in 1998 to 654 uses reported in 2020 (Table 2).[7] Although the overall increase in the reported maximum concentration of use of Dimethicone is not substantial (from 80% to 85%), increases in concentration according to exposure type are substantial.[8] For example, increases in maximum use concentrations of Dimethicone were very large for products resulting in dermal contact (30% in 1999 to 85% in 2019), application to the eye area (13% in eyebrow pencils, in 1999, to 37.8% in eyeliners, in 2019), incidental ingestion via lipstick formulations (20% in 1999 to 71.3% in 2019), and incidental inhalation (16% in perfume sprays, in 1999, to 85% in moisturizing sprays in 2019, and from 30% to 53% for face powders).

Of the recently included ingredients, Caprylyl Methicone has the highest overall frequency of use (234), with 43 reported uses in moisturizing formulations. Nine methicone ingredients which are not reported to be in use are listed in Table 3. A survey of use concentration data for the 10 alkyl dimethicone and methicone ingredients that were added to the report is currently underway, and those data will be included once received.

The ingredients named in this report are not restricted from use in any way under the rules governing cosmetic products in the European Union.[9]

Non-Cosmetic

Dimethicone

The allowable concentration of use of Dimethicone as an active ingredient in the formulation of skin protectant drug products for over-the-counter human use is 1 - 30%. [21 CFR § 347.10] Dimethicone has been used as a physical barrier method of eradicating head lice and eggs.[10,11] Dimethicone use is also prevalent in condom lubricants, and is taken orally as an anti-flatulence agent.[3,12,13] Dimethicone is also used industrially, in various construction sealants, rubber, and paints.[3]

In 2008, at the Joint Expert Committee on Food Additives (JECFA) of the World Health Organization (WHO) the established acceptable daily intake (ADI) level for Dimethicone of 0 - 1.5 mg/kg was withdrawn, due to variability in safety data, and was temporarily replaced with 0 - 0.8 mg/kg, while concerns about ocular toxicity resulting from molecular weight and viscosity-dependent absorption and toxicity were evaluated.[12] As of 2011, the original ADI of 0 - 1.5 mg/kg was reinstated.[12]

TOXICOKINETIC STUDIES

Penetration

Dimethicone

Penetration of Dimethicone (9.5 kg/m·s and 332.5 kg/m·s) was examined in female human abdominal skin and vaginal tissue.[3] Both viscosities were applied in infinite doses for 96 h to the donor side of split-thickness human abdominal skin sections (reference standard) and full-thickness human vaginal tissue mounted in Franz in vitro diffusion cells. (The identification of the vehicle and receptor fluid was not provided.) The dermal flux rate for Dimethicone (332.5 kg/m·s) in abdominal skin was 0.3 ng/cm^2/h, compared to 2 ng/cm^2/h for vaginal tissue; while the flux rates for Dimethicone (9.5 kg/m·s) in abdominal skin were 0.2 ng/cm^2/h and 6 ng/cm^2/h for vaginal tissue. The authors concluded that there was a low penetration rate, which occurred more rapidly in vaginal tissue, for both viscosities.

In a dermal penetration study, the authors sought to determine if Dimethicone interacts with and alters the stratum corneum (SC) lipid microstructure.[14] Excised human SC tissue samples were obtained from the inner thigh of a healthy 50

year-old woman and the abdomen of a healthy 26 year-old man. An in vitro model lipid system containing SC fatty acids was also used to mimic the skin barrier. These tissue samples were rinsed with 0.001% m/m trypsin inhibitor and stored for 48 h in 76% humidity, at ambient temperature, to achieve an approximately 20% hydration level. The hydrated samples were then treated for 20 minutes in various viscosities of excess Dimethicone (332.5, 475, 950, or 19,000 kg/m·s) at 37 ºC, removed with a cellulose tissue, and analyzed for change using thermal profile, x-ray diffraction, polarized light microscopy, and transmission electron microscopy. All results indicated that Dimethicone did not disturb or interact with the liquid crystalline structure of the upper layer of the epidermis, and hence is not likely to penetrate the skin barrier.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Several acute pharmacokinetic studies in dogs, rats, and a monkey reported minimal gastrointestinal absorption of Dimethicone and up to 99.99% recovery of the administered dose via excretion.[1] In a repeated dose study, beagle dogs were fed 91% Dimethicone at a dose of 300 mg/kg/d for 120 d in the diet. Although one female showed atrophy of the spleen, and another female had slightly reddened rugae near the stomach and mucus in the intestine, Dimethicone was not detected in any organs or considered absorbed.

Animal

Dimethicone

In a study examining dermal absorption and distribution, an occlusive patch containing [^{14}C]-Dimethicone (332.5 kg/m·s) was applied to male CD rats (number not provided) for 24 h.[3] After the initial 24-h exposure period, animals were removed from the metabolism cages, the occlusive patch was removed, and the exposure site was washed. The animals were re-wrapped with a non-occlusive bandage and returned to metabolism caging for continued monitoring and collection of biologic samples. The animals were killed 72 h after their initial exposure and the exposure sites were carefully excised. Radioactivity tracing demonstrated that 70% of the administered dose was found on the patch materials, 11.4% was present at the site of application, and none was found in the blood. Minimal amounts were found in the feces (0.01%) and carbon dioxide traps (0.001%).

Human

In human studies, absorption was seen in humans following ingestion of a Dimethicone sample containing low-molecular-weight polymers.[1] Dermal upper back exposure to Dimethicone for 10 d did not increase blood or urine silicone concentrations in men.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Dermal

The dermal LD_{50} for Dimethicone was > 2 g/kg in rats and rabbits.[1] The dermal LD_{50} for Methicone was > 20 ml/kg in rabbits. The dermal LD_{50} for Vinyldimethicone was > 16 ml/kg in rabbits.

C30-45 Alkyl Dimethicone

An acute dermal exposure study with C30-45 Alkyl Dimethicone was performed, in rats, according to the US Toxic Substances Control Act (US TSCA) [40 CFR § 798.1100] Test Guideline (TG).[5] The LD_{50} in rats was reported to be > 2000 mg/kg bw.[5] (No further details, including viscosity, were provided.)

Dimethicone

Undiluted, Dimethicone (54,150 kg/m·s) was applied to the shaved backs of 5 male and 5 female adult New Zealand White rabbits at a dose of 2000 mg/kg bw.[3] The test site was occluded and Dimethicone was in contact with the skin for 24 h. After exposure, the residual test material was removed with Dimethicone (332.5 kg/m·s)-moistened gauze. The rabbits were frequently observed on the day of treatment and at least once a day during a follow-up 14-d observation period. No signs of systemic toxicity were observed during the study, and no rabbits died during this study. Under the conditions of this study, the acute LD_{50} of Dimethicone in adult male and female rabbits was considered to be > 2000 mg/kg bw.

A single, 2008 mg/kg bw dermal application of Dimethicone (332.5 kg/m·s) was made on 5 male and 5 female Sprague Dawley (SD) rats, in accordance with the Organization for Economic Cooperation and Development (OECD) TG 402.[3] The test substance was spread over approximately 10% of the total body surface and was held in place with a bandage for 24 h. Test sites were rinsed with lukewarm water at the end of the application period; animals were monitored for mortality and clinical signs for 14 d, before necropsy. No mortality and noticeable abnormalities were observed. The dermal LD_{50} in this study was determined to be > 2008 mg/kg bw.

Oral

Dimethicone, Methicone, and Vinyldimethicone were not acutely toxic following oral exposure.[1] Methicone had an oral LD_{50} of > 64 ml/kg in male albino rats. Vinyldimethicone had an oral LD_{50} of > 16.0 ml/kg in Sprague Dawley rats. Greasy-textured fur was noted in the rats, while one rat had pneumonia and pleuritis observed at necropsy.

Dimethicone

Five male and 5 female Sprague-Dawley rats were administered a single dose of 2000 mg/kg bw Dimethicone (57,000 kg/m·s) in corn oil by gavage (concentration not reported).[3] No overt signs of systemic toxicity were observed over the course of a 14 day post-dose observation period. All of the rats gained weights, no animals died during the study, and no gross necropsy lesions were observed. The acute oral LD_{50} of Dimethicone in male and female rats was determined as > 2000 mg/kg bw.

Inhalation

Two dogs, seven guinea pigs, and seven rats were exposed to a "200 fluid" aerosol of Dimethicone at a concentration of 2.12 mg/L for 6 h.[1] Three guinea pigs died during the study, and all necropsied animals had hyperemic lungs with hemorrhagic areas. Vapor exposure to Methicone, at a concentration of 0.78 mg/L for 8h, and Vinyldimethicone, at a near-saturation concentration (no further details provided) for 6 h, did not cause mortality or lesions in rats. Aerosolized Hexyl Methicone was administered by whole-body inhalation exposure to Fischer F344/N rats for 4 h, at varied target doses ranging from 1.0 mg/L- 5.0 mg/L with particles having a mass median aerodynamic diameter (MMAD) of 0.27µm-0.29µm. All rats exposed to the 5.0 mg/L dose (0.27 µm MMAD) died, while a portion died at the other doses. Lesions at necropsy of the rats who died included dark red or mottled lungs and/or fluid filled trachea. The calculated LC_{50} for both sexes was 1.8 mg/L.

Dimethicone

An acute aerosol inhalation study of Dimethicone (95,000 kg/m·s)was performed in a similar fashion to OECD TG 403.[3] Groups of 5 Wistar rats were exposed for 4 h, nose-only, to solutions of 25% Dimethicone dissolved in petroleum ether, or to two other solvents, in separate control groups (control solvents not named). Rats were exposed to mean Dimethicone concentrations of 4315 mg/m^3 at a mass median particle size (MMPS) of 1.55 µm, or 11,582 mg/m^3 and a MMPS of 0.846 µm. During, and after, the 14-d observation period, no mortality or clinical symptoms were attributed to Dimethicone exposure. The LC_{50} was determined to be > 11,582 mg/m^3.

Dimethicone (9500 kg/m·s) dissolved in dichloromethane was used to perform an acute aerosol inhalation toxicity study, in accordance with OECD TG 403.[3] Groups of 5 Wistar rats were tested with concentrations of either 153.3, 322.0, 445.6, or 694.8 mg/m^3 Dimethicone, with MMPS up to 1.8 µm. Duration of exposure was not provided; however, according to OECD TG 403, exposure can be up to 6 h (nose-only) in rats. No mortality or toxic effects were observed during the 14-d observation period or at necropsy. The LC_{50} was determined to be > 695 mg/m^3.

Short Term Toxicity Studies

Dermal

No adverse reactions were found in rabbits following short-term dermal dosing with 6% to 25% Dimethicone.[1] Rats were dermally dosed with either 0.04% Dimethicone (18.92 kg/m·s), or a solution containing 5% each of four linear/cyclic dimethylpolysiloxanes for 4 wk. No macroscopic changes were noted. Changes were seen in serum total cholesterol concentrations, and dermal dosing resulted in less silicon accumulation in the fat when compared to oral administration.

Dimethicone

Three groups of 10 New Zealand white rabbits (number per sex not specified) were dermally administered Dimethicone (332.5 kg/m·s) via an occlusive patch for 4 wk (28 d) at dosages of 0, 100, 300, or 1000 mg/kg/d.[3] On a daily basis, rabbits were examined for dermal irritation prior to application, and were exposed to the test material for 6 h prior to patch removal. Body weight was measured twice a week, and blood samples were taken for hematology and blood chemistry evaluations on day 29 for males and day 30 for females. No deaths or adverse events related to the treatment occurred. Body weight, hematology, blood chemistry, and gross and microscopic evaluation of selected organs showed no changes that were considered of toxicological significance. The no-observable-adverse-effect-level (NOAEL) for dermal application of Dimethicone in rabbits in this study was therefore considered to be 1000 mg/kg/d.

Oral

Mongrel dogs were fed with up to 3.0 g/kg/d of 83% Dimethicone for 12 wk.[1] The liver of dosed dogs had bile pigment deposits in Kupfer and hepatic cells, which were proportional to the daily dose received.

Dimethicone

In a 28-d oral toxicity study, Dimethicone (9.5 kg/m·s and 332.5 kg/m·s) was administered to groups of 10 CDF-(F344)-CrlBr rats in the diet, at concentrations of 10,000 to 100,000 ppm (1 - 10%).[3] No mortality or adverse clinical signs of toxicity were noted during observation or upon necropsy . Test article related symptoms consisted of dose-related increase in matting of male and female rat fur, increased incidence of corneal opacity and inflammation, and significantly decreased mean triglycerides and low-density-lipoprotein levels (LDL) at higher doses (≥ 2.5%). These symptoms were not regarded as adverse effects and the NOAEL of Dimethicone in the rat diet was determined to be > 100,000 ppm.

Inhalation

A cat, rabbit, guinea pig, two rats, and four mice were sprayed for 4 h with an atomizer containing 10 ml/kg of a sample of Dimethicone (140 cm^2/s; dynamic viscosity or specific gravity values were not available) for 29 d.[1] During the 6-wk post-dosing observation period, no exposure-related adverse effects were seen in the cat, rabbit, guinea pig, and rats. All four mice died – one after the 20th exposure, and the three others during the post-dosing period. The link between treatment and death was uncertain and the authors concluded that Dimethicone inhalation is harmless.

Subchronic Toxicity Studies

Oral

Mice and rats were dosed for 90 days with up to 10% Dimethicone without adverse effect.[1] In one rat study, in which animals received 0.1%, 0.3%, or 1.0% Dimethicone for 120 d, changes in body weight or spleen weight were observed in the 1.0% Dimethicone dosage group.

Dimethicone

Groups of 10 male and 10 female Sprague-Dawley rats were fed Dimethicone (33.25, 332.5, or 950 kg/m·s) at concentrations of 1, 5, or 10% in the diet and were observed for 90 days.[1,3] After 90 days, the animals were killed, necropsied, and examined for gross and microscopic effects. No signs of systemic toxicity were seen during the study or during post-study pathologic examination. Anal leakage of Dimethicone was detected in the high dose groups and in those rats that were fed more viscous Dimethicone. Food consumption was increased in the mid and high dose groups, for all three viscosities. Observations of slight chronic corneal inflammation, opacity, and neovascularization was observed in the eyes of the rats, regardless of dosage, and was regarded as a local ocular effect resulting from contact with the feed.

Chronic Toxicity Studies

Oral

No significant differences were observed in the organ weights of Wistar rats that were fed 0.3 % Dimethicone in the diet for 2 years.[1] Pulmonary lesions, changes in the ovaries and uterus, and mild fatty changes in the liver and tubular epithelium of the kidneys was observed in all treated rats. Rats and rabbits which were fed 1% Dimethicone in the diet (50 or 350 cm^2/s; dynamic viscosity or specific gravity values were not available) for up to 1 yr did not exhibit signs of systemic toxicity.

Dimethicone

Four groups of 30 male Fischer 344 rats and 4 groups of 30 female Fischer 344 rats were administered Dimethicone (9.5 kg/m·s) in the diet at doses of 0 (control), 100, 300, or 1000 mg/kg bw/d, respectively, for 12 mos.[3,15] Four groups of 10 males and 4 groups of 10 females from each treatment group were necropsied after 12 mos of Dimethicone administration. Four groups of 20 male and 4 groups of 20 female rats from each treatment group were observed for chronic recovery for 12 mos after the 12-month treatment period. Test article-related toxicological effects in necropsied rats were limited to increased incidence of ocular opacities in ≥ 300 mg/kg bw/d for females and 1000 mg/kg bw/d group for males. Similarly, in the chronic recovery group, there was an increased eye opacity for all treated male groups, without dose correlation. This result was further supported by microscopic findings of keratitis and corneal dystrophy. The no-observed-effect-level (NOEL) for systemic toxicity of Dimethicone was determined to be equal to the highest tested dose, 1000 mg/kg bw/d.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Dimethicone was tested in numerous oral-dose (using rats) and dermal-dose (using rats, rabbits, monkeys) reproductive and developmental toxicity studies.[1] In an oral study with rats, 3.3 mL/kg/d Dimethicone was administered directly to the stomach for 6 d. Males treated with 1 of 3 Dimethicone samples (no further details provided) had significantly decreased body weight and/or decreased testes or seminal vesicles weights. No treatment-related adverse findings were noted in pregnant females or fetuses, dosed orally, via diet, and dermally. In an intergenerational study, a motor oil containing an unspecified amount of Dimethicone was applied undiluted in doses of 0.1, 0.4, and 1.5 mL/kg, to the shaved backs of the parental (P1) and first generation (F_1) of Sprague-Dawley rats, daily for an 8-wk premating period, 3-wk mating period, and

throughout gestation and lactation. Mortality was significantly increased on day 0 in the 0.4 mL/kg group, and absolute testes weight was significantly reduced in the adult F_1 male rats of the 1.5 mL/kg group, beginning wk 7, but the relative testes to body weight ratio was not significantly different from controls.

No additional developmental and reproductive toxicity studies were found in the published literature, and unpublished data were not submitted.

GENOTOXICITY

Dimethicone tested negative for genotoxic effects in multiple Ames tests, at up to 5000 µg/plate, bacterial reverse mutation assays, at up to 79% in formulation, micronucleus tests, at up to 5 g/kg, and in mouse cell and Chinese hamster ovary (CHO) assays, at up to 10,000 µg/ml, both with and without metabolic activation.[1]

In Vitro

C30-45 Alkyl Dimethicone

A bacterial reverse mutation assay was performed with C30-45 Alkyl Dimethicone in accordance with OECD TG 471.[5] The test substance was found to be non-mutagenic. (No further details were provided.)

Dimethicone

Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, and *Escherichia coli* strains WP2 uvrA and WP2 uvrA (pKM 101) were tested with Dimethicone (57,000 kg/m·s) in a bacterial reverse mutation assay, in the presence and absence of metabolic activation.[3] The assay was performed in two stages, in which a range-finding study, and consequent initial and independent repeat assays were used to evaluate the mutagenic potential of Dimethicone. Based on the toxicity assay, the maximum dose tested was 5000 µg per plate. Although precipitate was observed at ≥ 500 or at ≥ 1500 µg per plate, no appreciable toxicity was observed; and Dimethicone was considered non-mutagenic, under these study conditions.

CARCINOGENICITY

Dimethicone tested negative for carcinogenicity in both an oral (up to 2.5% Dimethicone in diet for 76 wk) and a dermal carcinogenicity study (lifetime application; 50 µl of the test article (motor oil) that contained an unspecified amount of Dimethicone) using mice.[1] *One treated mouse in the dermal study had a palpable skin mass at the application site during wk 65, which regressed by wk 67; no application site dermal neoplasms were microscopically confirmed in either treated or control mice.*

Dimethicone

The carcinogenic potential of a silicone resin containing 92% Dimethicone and 8% silica (300-1050 cm^2/s; dynamic viscosity or specific gravity values were not provided) was evaluated using groups of 50 male and 50 female F344/DuCrj rats.[16] The rats were given diets containing 0, 1.25, or 5.0% of the test article for 104 weeks. Animals were monitored twice daily for signs of toxicity, and body weight was measured alternate weeks. During the study, there were no significant differences in appearance or behavior between the control and treatment groups. Survival rates were also not significantly different between both groups. The relative organ weight percentage for livers in male rats that received 5.0 % test article in the diet were significantly lower than those of the livers in male control rats. Lower relative kidney, brain, and heart organ weight percentages were also considered to be statistically significant in treated female rat compared to female control rats. There was a statistically significant, 2 - 18%, increase in the incidence of parafollicular cell (C-cell) adenomas in female rats within the highest dosage group (5.0%); however, according to previous carcinogenic assays done by the National Toxicology Program, the naturally occurring incidence of C-cell adenomas ranges from 0 - 34%. The male 5.0% dosage group experienced a decreased incidence of prostate cancer (8% vs. 22% in controls); however, values for prostatic intraepithelial neoplasias (PINs) were similar across groups. The prostate cancer incidence of the control group was relatively high (compared to historical results elsewhere); thus, the difference between treatment and control groups were considered incidental.

In a long-term toxicity study, 3 groups of 20 male and 20 female F344 rats were observed for oncogenic effects associated with oral administration of Dimethicone (9.5 kg/m·s) doses of 100, 300, or 1000 mg/kg bw/d for up to 24 mos.[15] Slightly increased incidence of corneal opacity was observed in male rats dosed at 1000 mg/kg bw/d and in female rats dosed at 100 and 1000 mg/kg bw/day, as well as an overall increase in minimal to mild keratitis in all male and female rats (statistical significance not mentioned). A statistically significant increase in the incidence of islet cell adenomas was observed in the 100 mg/kg bw male dosage group; however, the lack of effect in female groups, high incidence of islet cell adenomas in controls (even when assigned to recover for 12 mos) suggested that that these effects were independent of Dimethicone exposure. No neoplastic changes were observed and the NOEL for oncogenicity of Dimethicone was determined to be 1000 mg/kg bw/d.

OTHER RELEVANT STUDIES

Immunotoxicity

Dimethicone

Four groups of 20 female A.SW (*H-2^s-T18^b-/SnJ*) mice received a single 0.5-ml intraperitoneal injection (i.p.) of one of the following: phosphate-buffered saline (PBS) as the negative control, pristane (2,6,10,14-tetramethylpentadecane) as the positive control, silicone gel (taken from a mammary implant), or Dimethicone (970 kg/m·s).[17] A pretest bleed was taken via orbital puncture prior to injection, after which blood samples were obtained post-injection once a month for 6 mos. The mice were killed after 6 mos of observation, and peritoneal macrophages were collected by lavage. Additionally, immunoprecipitation, fluorescent antinuclear antibody (FANA) microscopy, macrophage culture, kidney pathology, and enzyme-linked immunosorbent assay (ELISA) immunoglobin analyses were performed. Although Dimethicone-treated mice did not produce lupus-associated antinuclear antibodies (observed in the controls) various antibody isotopes were observed within 2 mos of injection. Immunoglobulin M (IgM) levels remained elevated compared to controls, and IgG1 and IgE serum levels were significantly elevated at 4 mos in comparison to 5 - 6 mos for the controls. Macrophages from negative control mice secreted little interleukin-6 (IL-6), a pro-inflammatory cytokine, while pristane-, silicone gel-, and Dimethicone-treated mice spontaneously secreted IL-6 and also produced greater, dose-dependent amounts of IL-6 when cultured with lipopolysaccharide. Suspected silicone droplets and expanded vacuoles within the glomeruli of treated mice kidneys also indicated capacity for systemic accumulation.

DERMAL IRRITATION AND SENSITIZATION

Irritation

Most dermal irritation studies using rabbits classified Dimethicone as a minimal irritant.[1] Studies that scored reactions according to the Draize scale reported PIIs (primary irritation index) of ≤ 2.8(with test samples containing 5% to 100% Dimethicone). Vinyl Dimethicone was not irritating to rabbits following a 4-hr exposure.

C30-45 Alkyl Dimethicone

A skin irritation test using C30-45 Alkyl Dimethicone was performed, in rabbits, in accordance with US TSCA [40 CFR § 798.4470].[5] The test substance was determined to be non-irritating. (No further details were provided).

Dimethicone

Three rabbits and 3 guinea pigs were exposed to a non-occlusive, daily application of 0.5 ml of Dimethicone (100 cm^2/s; dynamic viscosity or specific gravity values were not provided) to a 2.5 cm^2 patch of closely shaven skin for 10 d.[18] No erythema or signs of skin irritation or inflammation was noted in the animals.

In an acute dermal toxicity study, undiluted, Dimethicone (57,000 kg/m·s) was applied to the shaved backs of 5 male and 5 female adult New Zealand White rabbits, under occlusion, for 24 h, at a dose of 2000 mg/kg bw.[3] Erythema was observed at the application site in all ten rabbits, but resolved by the 7th day of observation.

Sensitization

Dimethicone (tested undiluted and at 79%) was not a sensitizer in four assays using mice and guinea pigs.[1] It was not a sensitizer at 5.0% in a clinical HRIPT using 83 panelists.

Human

Dimethicone

In a human repeat insult patch test (HRIPT), Dimethicone (11,875 kg/m·s) was tested neat as a negative control, and was used as a vehicle for a 5% (v/v) solution of an unspecified test substance.[3] Sodium lauryl sulfate (0.1% aqueous solution) was used as a positive control. Of the 115 subjects enrolled, 106 completed the study; no subjects withdrew due to adverse reactions to the test substance. Induction consisted of 9 consecutive applications, where 0.2 ml of Dimethicone was applied under a semi-occlusive dressing for 24 h. The test sites were evaluated in the following 48 - 72 h. After the 9th application, there was a 10 to 15-day non-treatment period. Challenge occurred in the sixth week of the study, where the substance was applied to an unexposed site for 24 h; this site was graded after 24 - 48 h. No evidence of sensitization to Dimethicone, as a control or vehicle, was observed.

OCULAR IRRITATION

Most ocular irritation studies using rabbits classified Dimethicone as a mild to minimal irritant.[1] The most common finding was a conjunctival reaction. However, a few studies reported severe reactions. Similar to Dimethicone, Methicone and Vinyldimethicone also produced conjunctival reactions.

C30-45 Alkyl Dimethicone

The ocular irritancy potential of C30-45 Alkyl Dimethicone was tested, in rabbits, in accordance to US TSCA [40 CFR § 798.4500].[5] Slight conjunctivae effects were observed, but resolved within 24 h of exposure. The test substance was determined to be non-irritating. (No further details were provided).

Dimethicone

Sixteen adult pigmented rabbits were tested for corneal tolerance of Dimethicone.[19] One eye of each animal was treated (the other eye served as a control) by forming a hanging suture in the lid which allowed 0.7 - 1.0 ml of generically produced, as well as medical-grade, Dimethicone at varying viscosities (485-12,125 kg/m·s) to remain on the eye for 3 - 6 h. Medical-grade Dimethicone (970 kg/m·s), which is produced with higher manufacturing, biocompatibility, and safety standards for use in pharmaceuticals and medical devices, was included to assess if it would elicit a variable eye irritation response. The oil was only replaced if the eye cup leaked or if the animal moved. The eyes were examined with fluorescein by slit lamp immediately after treatment, and were either enucleated immediately or 3 - 7 days later. Compared to the control eye, which was treated with a saline balanced salt solution, the eyes treated with Dimethicone exhibited increased epithelial and whole corneal thickness, which persisted for several days and was most noticeable ≥ 3 days post-treatment. Although there appeared to be better ocular tolerance for the medical-grade Dimethicone, it also caused some corneal changes; under light microscopy, all eyes treated with Dimethicone showed various degrees of intracellular epithelial and stromal edema. The authors concluded that both non-medical grade and medical-grade Dimethicone are mildly irritating to the corneal epithelium.

The ocular irritancy of Dimethicone was evaluated in a study using groups of either 3 mice, 3 guinea pigs, or 3 rabbits to test 5 separately-manufactured samples of Dimethicone (100 cm^2/s; dynamic viscosity or specific gravity values unavailable).[18] For the test, a drop of Dimethicone was instilled once daily for 10 days into the lower eyelid of the animals, and conjunctival irritancy and reflex response to light and touch were observed for 15 days. The first sample did not produce inflammation or ocular opacity; however, all tested guinea pigs died by day 8 - 10. The second sample caused inflammation in the eye of one rabbit after 10 days, while 2 guinea pigs and 1 rabbit died. The eyes of animals treated with the second sample were also opaque. Since no other differences besides a slightly more acidic profile in the first 2 tested samples were observed (0.17 mg potassium hydroxide vs. 0.1 mg potassium hydroxide required to neutralize acid), the authors opined that ocular irritancy and inflammatory effects of silicone fluids may be dependent upon the acidity of the samples.

MUCOUS MEMBRANE IRRITATION STUDIES

A mucoadhesive paste (53% Dimethicone) was introduced (0.5 g) via syringe into the vaginal cavity of six albino rabbits.[1] Two control rabbits were dosed with a sodium chloride solution. Tissue was scored according to the Draize scale (maximum score of 8) at 24, 48, and 72 h post dosing. Erythema was noted in three rabbits at 24 h, and in one rabbit at 48 h after treatment. None had erythema at 72 h. No edema or signs of toxicity were observed. The irritation score for the paste was 0.22.

Dimethicone

Five samples of Dimethicone (100 cm^2/s; dynamic viscosity or specific gravity values unavailable), each not requiring more than 0.1 mL of 0.05 N alcoholic KOH to neutralize 15 g of the fluid, were tested for irritation of vaginal mucosa.[18] A sample of 0.05 ml of Dimethicone was instilled into the vagina of rats (number of animals not specified) daily for 8 days, the vaginal mucous membrane was observed to determine irritancy, and the effect on leukocyte count was determined. A 77.8 - 88% increase in leukocytes was observed in the vaginal smears of rats treated with two samples of Dimethicone. A similar increase was observed for rats instilled with formaldehyde as the reference irritant. The authors concluded that 2 of the silicone samples with a higher acidity (0.17) and acid value of 0.3 were more likely to be mucous membrane irritants than the other samples (0.05 - 0.10 acidity; acid values were not provided).

CLINICAL STUDIES

Case Reports

Dimethicone

A 23-day old, premature twin male infant suffering with nasal congestion was accidentally sprayed intranasally with diaper rash protectant spray (instead of nasal saline spray), which listed 10% Dimethicone as the only active ingredient.[20] The child went into a choking and coughing spell, and was rushed to the emergency department. After 2 h, he was still in respiratory distress, wherein his oxygen saturation had dropped to 85% and his chest x-ray showed diffuse bilateral infiltrates, suggestive of bilateral chemical pneumonitis. By the 3rd day, he developed an eosinophilia of 31 - 37%, with an absolute eosinophilic count of 3100 - 4250 per µl. He was treated with frequent saline bronchial lavages and chest physical therapy to remove mucus plugs blocking his endotracheal tube and was weaned off the ventilator by the 7th day after

exposure. Referring to the Expert Panel evaluation that Dimethicone is safe for cosmetic use and when inhaled short term,[1] the researchers were of the opinion that Dimethicone did not cause the patient's symptoms. They found that the inactive ingredients of the product were aloe oil extract, caprylic/capric triglyceride, mineral oil, Peruvian balsam oil, shea liquid, and tocopheryl acetate/vitamin E. The authors concluded that the massive dose of mineral oil exposure was the most likely cause for acute pneumonitis, as was the Peruvian balsam oil for eosinophilia.

SUMMARY

According to the *Dictionary*, these 30 methicone ingredients are reported to function in cosmetics as skin conditioning agents, hair conditioning agents, and/or viscosity increasing agents. Of the ingredients in this report, Dimethicone and Methicone have the greatest frequency of use, according to 2020 VCRP data. Reported use for Dimethicone increased from 1659 formulations in 1998 to 14,050 in 2020, and reported frequency of use of Methicone increased from no reported uses in 1998 to use in 654 formulations in 2020. The highest concentration of use reported in 2019 was for Dimethicone, at a concentration of 85% in moisturizing products; the maximum concentration of use reported previously for Dimethicone was 80%.

Penetration of Dimethicone (9.5 kg/m·s and 332.5 kg/m·s) in human abdominal and vaginal tissue was examined after a 96-h application. A low penetration rate was observed for both viscosities, with more rapid penetration in vaginal tissue. In a dermal penetration study, the interaction of Dimethicone with the SC lipid microstructure in healthy excised human tissue was evaluated. All results indicated that Dimethicone did not disturb or interact with the upper layer of epidermis, and is not likely to penetrate the skin barrier. Male rats were exposed to both occlusive and non-occlusive patches of [^{14}C]-Dimethicone to observe dermal absorption and excretion over 3 days. Radioactivity tracing demonstrated that 11.4% of the applied dose was at the site of application and minimal amounts were found in feces and carbon dioxide traps.

The acute dermal LD_{50} of C30-45 Alkyl Dimethicone was determined to be > 2000 mg/kg bw in rats. Undiluted, Dimethicone (54,150 kg/m·s) was applied, under occlusion, to the shaved backs of 5 male and 5 female New Zealand white rabbits at a dose of 2000 mg/kg bw for 24 h. No mortality and signs of toxicity were observed and the acute dermal LD_{50} was determined to be > 2000 mg/kg bw in rabbits. A single, 2008 mg/kg bw dermal application did not cause mortality or noticeable abnormalities in 5 male and 5 female Sprague-Dawley rats; under these study conditions the acute dermal LD_{50} was determined to be > 2008 mg/kg bw. Three groups of 10 New Zealand white rabbits were exposed to an occlusive patch of Dimethicone (332.5 kg/m·s) for 28 d at doses up to 1000 mg/kg/d. No deaths or adverse events related to the exposure occurred, and the NOAEL for dermal application in rabbits was determined to be 1000 mg/kg/d.

Five male and female Sprague-Dawley rats were administered a single oral dose of 2000 mg/kg bw Dimethicone in corn oil. No toxic effects or gross necropsy lesions were observed, and the acute LD_{50} was determined to be > 2000 mg/kg bw in rats. In a 28-d oral toxicity study, Dimethicone was administered at up to 10% (100,000 ppm) in the diet of CDF-(F344)-CrlBr rats. Test article related symptoms included matted fur, increased incidence of corneal opacity, and significantly decreased mean triglycerides and LDL levels at higher doses. These symptoms were not considered adverse effects and the NOAEL of Dimethicone was determined > 100,000 ppm. Groups of 10 male and 10 female Sprague-Dawley rats were fed up to Dimethicone (950 kg/m·s) at concentrations of 1, 5, or 10% for 90 days (dose not reported). Neither systemic toxicity nor clinical pathology occurred, and observations of slight corneal inflammation were regarded as local effects from contact with the feed. Four groups of 30 male and 30 female Fischer 344 rats were administered Dimethicone (9.5 kg/m·s), in their diet, at doses up to 1000 mg/kg bw/d for 12 mos. Amongst the treated rats, four groups of 10 male and 10 female rats were necropsied after 12 mos, while four groups of 20 male and 20 female rats were observed for recovery 12 mos after the treatment period. In both necropsied and recovery groups there was an increase in ocular opacity, and the NOEL for systemic toxicity was determined to be 1000 mg/kg bw/d.

Groups of 5 Wistar rats were exposed for 4 h, nose-only, to solutions of 25% Dimethicone (95,000 kg/m·s) dissolved in petroleum ether, or to two other solvents, in separate control groups (control solvents not named). No mortality or clinical symptoms were attributed to Dimethicone exposure, and the LC_{50} was determined to be > 11,582 mg/m^3. Dimethicone (9500 kg/m·s) dissolved in dichloromethane was tested for acute inhalation toxicity, at doses up to 694.8 mg/m^3, in Wistar rats. No mortality or toxic effects were observed, and the LC_{50} was determined to be > 695 mg/m^3.

A bacterial reverse mutation assay was performed with C30-45 Alkyl Dimethicone; the test substance was not found to be non-mutagenic. In a bacterial reverse mutation assay, *S. typhimurium* tester strains TA98, TA100, TA153, TA1537, and *E. coli* strains WP2 uvrA and WP2 uvrA (pKM 101) were tested with Dimethicone (57,000 kg/m·s), at a maximum dose of 5000 µg per plate, in the presence and absence of metabolic activation. Although precipitate was observed at ≥ 500 or ≥ 1500 µg per plate, Dimethicone was considered non-mutagenic under these study conditions.

The carcinogenic potential of a silicone resin containing Dimethicone was evaluated by feeding 50 male and 50 female F344/DuCrj rats diets containing up to 5.0% of the test article for 104 weeks. There was a statistically significant, 2 - 18% increase in the incidence of C-cell adenomas in female rats in the highest dosage group, while the male rats in the highest

dosage group experienced a decreased incidence of prostate cancer compared to the control group. The incidence of prostate cancer in the control group was relatively high, and thus the difference between treatment and control groups was considered incidental.

Three groups of 20 male and 20 female F344 rats were observed for oncogenic effects upon administration of Dimethicone (10 cm^2/s; dynamic viscosity or specific gravity unavailable) at doses of 100, 300, or 1000 mg/kg bw/d for up to 24 mos. Slightly increased incidence of corneal opacity was observed at the maximum dose, as well as a statistically significant increase in islet adenomas among males in the 100 mg/kg bw group. However, the lack of increased islet adenomas in female rats and the high incidence amongst control rats suggested that these effects were independent of Dimethicone exposure. The NOEL for oncogenicity of Dimethicone was determined to be 1000 mg/kg bw/d.

Twenty female A.SW mice received a single 0.5-ml i.p. injection of Dimethicone, while 3 groups of 20 mice were injected with either saline, pristane or silicone gel, to evaluate immunological reactions over 6 mos. Dimethicone-treated mice produced various antibody isotopes within 2 mos of injection, spontaneously secreted and produced greater, dose-dependent amounts of IL-6, and showed silicone droplets and expanded vacuoles within kidney glomeruli. The authors therefore hypothesized that silicone gels and Dimethicone are capable of inciting a local and systemic chronic inflammatory response.

A skin irritation test using C30-45 Alkyl Dimethicone (test concentration not specified) was performed in rabbits; the test substance was determined to be non-irritating. Dimethicone did not cause dermal irritation or inflammation in rabbits and guinea pigs. In an HRIPT, Dimethicone was tested neat (as a negative control), and as used as a vehicle for a 5% solution of an unspecified test substance, in 106 subjects. No evidence of sensitization to Dimethicone, as a control or vehicle, was observed.

The ocular irritancy potential of C30-45 Alkyl Dimethicone was tested, in rabbits; slight conjunctivae were observed, but resolved in within 24 h of exposure, and the test substance was deemed non-irritating. Sixteen rabbits were exposed for to up to 6 h with 0.7 - 1.0 ml of generic or medical-grade Dimethicone, in one eye, to test for variance in ocular irritancy. All eyes treated with either generic or medical-grade Dimethicone evidenced mild irritation corneal epithelium. In a study using groups of 3 mice, guinea pigs, or rabbits, 5 separately manufactured samples of Dimethicone (100 cm^2/s; dynamic viscosity or specific gravity values unavailable) were instilled into the lower eyelid of the animals once daily for 10 days. All guinea pigs exposed to the first sample died by days 8 - 10, and the second sample caused corneal inflammation in one rabbit after 10 days, and death in another rabbit and 2 guinea pigs. Both samples of Dimethicone had a slightly more acidic profile, suggesting that the ocular irritancy and inflammatory effects of silicone fluids may be acidity-dependent.

The potential for five samples 0.5 ml of Dimethicone (100 cm^2/s; dynamic viscosity or specific gravity values unavailable) to cause vaginal mucosa irritation was tested in rats for 8 days. An ~88% increase in leukocytes was observed in the vaginal smears of rats treated with two Dimethicone samples. A similar increase was observed in rats treated with formaldehyde. Irritation outcomes for each Dimethicone sample were deemed to be affected by higher acidity and acid values.

A 23-day old, premature twin male infant experienced severe respiratory distress, acute pneumonitis, and eosinophilia as a result of intranasal exposure to a 10% Dimethicone spray. Although Dimethicone was listed as the active ingredient, mineral oil and Peruvian balsam oil were determined as the causative agents for the severe reaction.

DISCUSSION

In accordance with the CIR Procedures & Support to the Expert Panel for Cosmetic Ingredient Safety, the Panel evaluates the conclusions of previously-issued reports approximately every 15 years. In 2003, the Panel published a final report on the safety assessment of 20 Dimethicone, Methicone, and substituted-Methicone polymers, and concluded that the ingredients named in that report are safe as used in cosmetic products. Due to dramatic increases in frequency of use, and increases in concentrations of use for certain exposure types, especially for Dimethicone in products that could result in incidental inhalation, the Panel determined to reopen this safety assessment. In addition to the ingredients previously reviewed, the Expert Panel Clustering and Read Across Working Group considered related polymers for inclusion in this report; the Working Group determined it was appropriate to include 10 additional polymers that have not yet been reviewed, due to chemical similarity and similarity of use.

The Panel noted that Dimethicone is now reported to be used at 85% in moisturizing spray formulations; in the original assessment, the greatest reported maximum use concentration in spray products was 16% in perfumes. Additionally, the Panel noted that some of these polymers are used in powders, which could also possibly be inhaled. Nevertheless, the Panel found that the absence of exposure-related effects from a study reported in the original assessment, in which several species were sprayed with an atomizer containing 10 mL/kg Dimethicone for 29 d, mitigated concern for use of these ingredients in cosmetic products that could be incidentally inhaled. Also, the Panel noted that in aerosol products, 95% – 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the

nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredient is used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at https://www.cir-safety.org/cir-findings.

Furthermore, the Panel noted that Dimethicone is now being used at, or above, concentrations at which ocular irritation was observed in studies cited in the original assessment. The Panel was also concerned with the results from an ocular irritation study included in the present assessment, in which mortality in test animals occurred following instillation of 100% Dimethicone (970 kg/m·s) in the eye. The Panel remarked that mortality occurring during an ocular irritation study is very unusual, and toxicologically implausible. Subsequently, the Panel distinguished the difference between instilling 37.8% pure Dimethicone in the eye, as opposed to using a cosmetic product containing 37.8% Dimethicone, in which ocular contact is not intended. However, the Panel stated that manufacturers should be cognizant of incidental/accidental exposure to the eye, and specified that products containing the ingredients included in this report must be formulated to be non-irritating to the eye. In addition to concentrations of use, the Panel noted high variability in the viscosity of these ingredients, and the need for cosmetic manufacturers to indicate the viscosities at which these ingredients are formulated.

The Panel also noted that the potential exists for dermal irritation with the use of products formulated using Dimethicone, Methicone, and substituted-Methicone polymers. The Panel specified that products containing these ingredients must be formulated to be non-irritating.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that the following 30 Dimethicone, Methicone, and substituted-Methicone polymers are safe as used in cosmetics, when formulated to be non-irritating to the skin and the eye:

Amino Bispropyl Dimethicone
Aminopropyl Dimethicone
Amodimethicone
Amodimethicone Hydroxystearate*
Behenoxy Dimethicone
C20-24 Alkyl Dimethicone
C20-24 Alkyl Methicone
C24-28 Alkyl Dimethicone
C24-28 Alkyl Methicone
C26-28 Alkyl Dimethicone
C26-28 Alkyl Methicone
C30-45 Alkyl Dimethicone
C30-45 Alkyl Methicone
C30-60 Alkyl Dimethicone
C32 Alkyl Dimethicone
Capryl Dimethicone
Caprylyl Methicone
Cetearyl Methicone
Cetyl Dimethicone
Dimethicone
Dimethoxysilyl Ethylenediaminopropyl Dimethicone
Hexyl Dimethicone
Hexyl Methicone*
Hydroxypropyldimethicone*
Methicone
Stearamidopropyl Dimethicone*
Stearoxy Dimethicone
Stearyl Dimethicone
Stearyl Methicone
Vinyl Dimethicone

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

TABLES

Table 1. Definitions, idealized structures, and functions[2, CIR Staff]

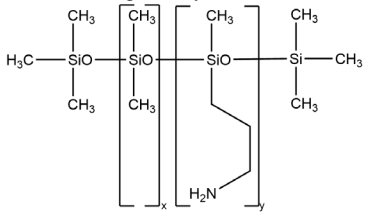
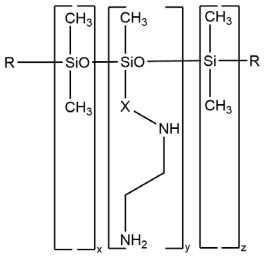
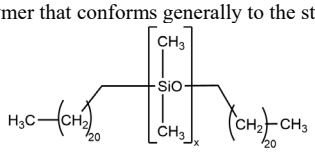
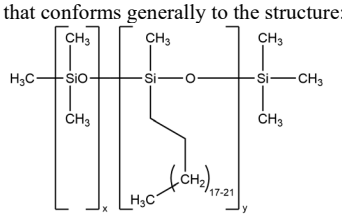
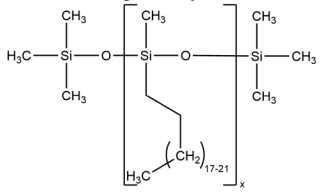
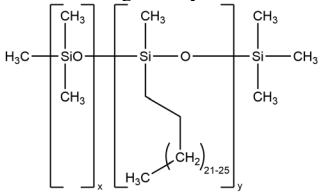
Name & CAS No.	Definition & Structure	Function(s)
Amino Bispropyl Dimethicone 189959-16-8	a complex three-dimensional siloxane polymer formed by the reaction between dimethiconol and 3-(trimethoxysilyl)-*N*-[3-(trimethoxysilyl)propyl]-1-propanamine.	Hair-conditioning agent
Aminopropyl Dimethicone 99363-37-8	the siloxane polymer that conforms generally to the structure: 	Hair-conditioning agent Skin-conditioning agent—miscellaneous
Amodimethicone 106842-44-8 68554-54-1 71750-79-3	a siloxane polymer that contains amino functional groups. It conforms generally to the structure:  where R=OH or CH_3, and X represents the propyl, isopropyl, or isobutyl group.	Hair-conditioning agent
Amodimethicone Hydroxystearate	the salt of Amodimethicone and Hydroxystearic Acid.	Hair-conditioning agent
Behenoxy Dimethicone	a dimethyl siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—emollient
C20-24 Alkyl Dimethicone 200074-76-6	is the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—occlusive Viscosity increasing agent—nonaqueous
C20-24 Alkyl Methicone 200074-77-7	is the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent – emollient Viscosity increasing agent-- nonaqueous
C24-28 Alkyl Dimethicone 192230-29-8	is the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—occlusive Viscosity increasing agent--nonaqueous

Table 1. Definitions, idealized structures, and functions[2, CIR Staff]

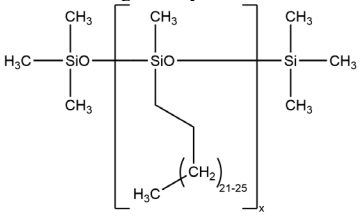
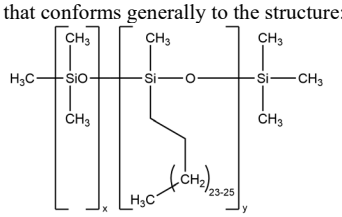
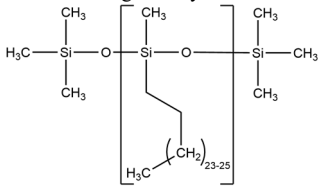
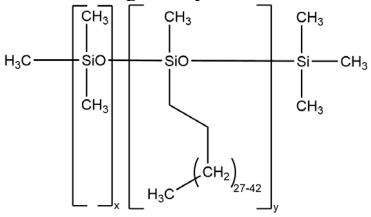
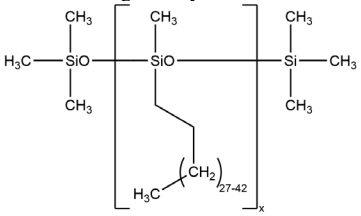
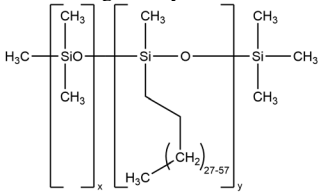
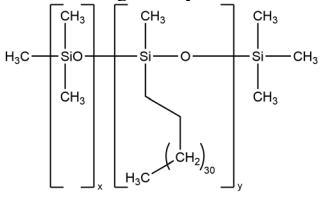
Name & CAS No.	Definition & Structure	Function(s)
C24-28 Alkyl Methicone 189378-12-9	the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—emollient Viscosity increasing agent—non-aqueous
C26-28 Alkyl Dimethicone	is the siloxane polymer that conforms generally to the structure: 	Hair-conditioning agent Skin conditioning agent--occlusive
C26-28 Alkyl Methicone 189378-12-9	is the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent --occlusive
C30-45 Alkyl Dimethicone	the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—occlusive
C30-45 Alkyl Methicone 189378-12-9 246864-88-0	the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—occlusive Viscosity increasing agent—non-aqueous
C30-60 Alkyl Dimethicone	the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—occlusive Viscosity increasing agent – non-aqueous
C32 Alkyl Dimethicone	is the silicone polymer that conforms generally to the structure: 	Skin- conditioning agent--emollient

Table 1. Definitions, idealized structures, and functions[2, CIR Staff]

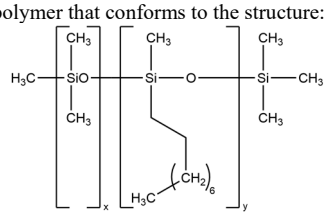
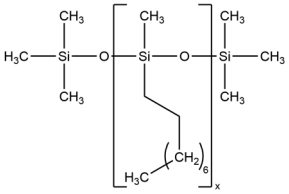
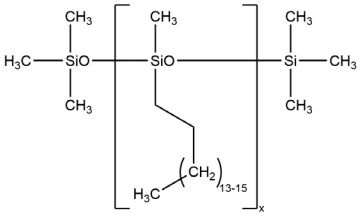
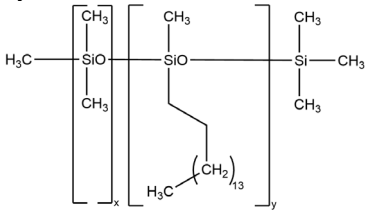
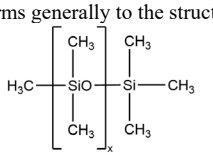
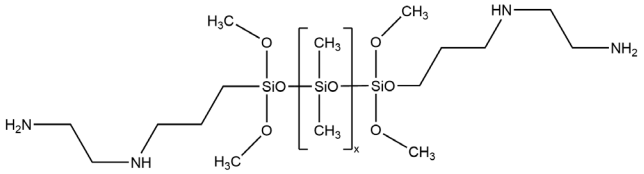
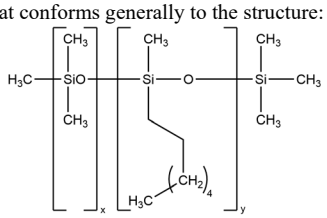
Name & CAS No.	Definition & Structure	Function(s)
Capryl Dimethicone	is a dimethyl siloxane polymer that conforms to the structure: 	Skin-conditioning agent--emollient
Caprylyl Methicone 17955-88-3	is the siloxane polymer that conforms to the structure: 	Skin-conditioning agent--occlusive
Cetearyl Methicone	a siloxane polymer that conforms to the structure: 	Skin-conditioning agent—occlusive
Cetyl Dimethicone 191044-49-2	a dimethyl siloxane polymer that conforms to the structure: 	Antifoaming agent Skin-conditioning agent—emollient and occlusive
Dimethicone 141-62-8 141-63-9 63148-62-9 9006-65-9 9016-00-6 107-52-8	a mixture of fully methylated linear siloxane polymers end blocked with trimethylsiloxy units. It conforms generally to the structure: 	Antifoaming agent Skin protectant Skin-conditioning agent—occlusive Solvent
Dimethoxysilyl Ethylenediaminopropyl Dimethicone 71750-80-6	the siloxane polymer that conforms generally to the structure: 	Hair conditioning agent
Hexyl Dimethicone	the siloxane polymer that conforms generally to the structure: 	Hair conditioning Skin conditioning agents - - miscellaneous

Table 1. Definitions, idealized structures, and functions[2, CIR Staff]

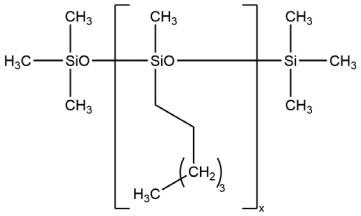
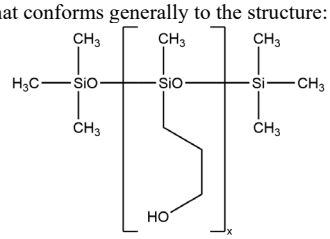
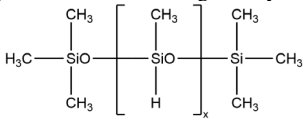
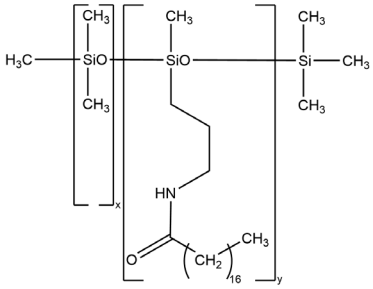
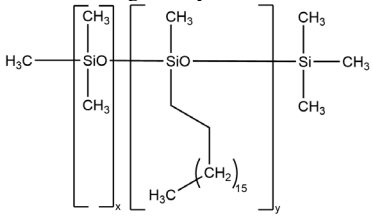
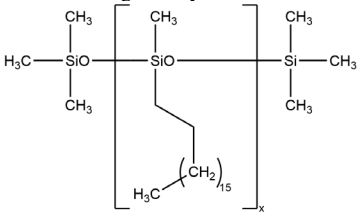
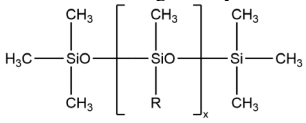
Name & CAS No.	Definition & Structure	Function(s)
Hexyl Methicone 1873-90-1	the siloxane polymer that conforms to the structure: 	Skin-conditioning—emollient
Hydroxypropyldimethicone 102782-61-6	the siloxane polymer that conforms generally to the structure: 	Hair-conditioning Skin-conditioning—miscellaneous
Methicone 63148-57-2 9004-73-3	a linear monomethyl polysiloxane. It conforms generally to the structure: 	Skin-conditioning agent—occlusive Surface modifier
Stearamidopropyl Dimethicone	the siloxane polymer that conforms to the structure: 	Corrosion inhibitor Film former
Stearoxy Dimethicone 68554-53-0	a polymer of dimethylpolysiloxane with some methyl groups replaced by stearoxy groups.	Skin-conditioning agent—emollient
Stearyl Dimethicone 67762-83-8	the siloxane polymer that conforms generally to the formula: 	Skin-conditioning agent—occlusive
Stearyl Methicone	the siloxane polymer that conforms generally to the structure: 	Skin-conditioning agent—occlusive
Vinyl Dimethicone 53529-60-5	a derivative of Dimethicone where some of the methyl groups have been replaced with vinyl groups. The vinyl groups can occur at the ends of the siloxane chain or pendant to the siloxane chain. It conforms generally to the structure:  wherein R is a methyl or vinyl group, and at least one vinyl group is present.	Not reported

Table 2. Current and historical frequency and concentration of use according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2020[7]	**1998[1]**	**2019[8]**	**1999[1]**	**2020[7]**	**1998[1]**	**2019[8]**	**1999[1]**
	Amino Bispropyl Dimethicone				**Aminopropyl Dimethicone**			
Totals*	**1**	**NR**	**NR**	**NR**	**57**	**NR**	**0.001-3**	**NR**
Duration of Use								
Leave-On	*1*	*NR*	*NR*	*NR*	*36*	*NR*	*0.001-3*	*NR*
Rinse-Off	*NR*	*NR*	*NR*	*NR*	*21*	*NR*	*0.3-0.66*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR	NR	NR	NR	1	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	NR	NR	16[a]; 6[b]	NR	0.1-0.5[a]	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	6[b]	NR	NR	NR
Dermal Contact	NR	NR	NR	NR	15	NR	0.001-3	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	Not spray: 0.001	NR
Hair - Non-Coloring	1	NR	NR	NR	36	NR	0.1-0.66	NR
Hair-Coloring	NR	NR	NR	NR	5	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
	Amodimethicone				**Behenoxy Dimethicone**			
Totals*	**1387**	**166**	**0.0051-5**	**0.0004-3**	**13**	**3**	**0.5**	**2-3**
Duration of Use								
Leave-On	*449*	*29*	*0.0051-4*	*0.0004-0.7*	*12*	*2*	*0.5*	*2*
Rinse-Off	*937*	*137*	*0.06-5*	*0.6-3*	*1*	*1*	*NR*	*3*
Diluted for (Bath) Use	*1*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	1	NR	NR	NR	5	NR	NR	NR
Incidental Ingestion	2	NR	NR	NR	2	NR	NR	NR
Incidental Inhalation-Spray	11; 208[a], 10[b]	3; 9[a]	0.3-2; 0.15-4[a]	0.0004-0.7[a]	4[a]; 1[b]	NR	NR	2[a]; 2[b]
Incidental Inhalation-Powder	1; 10[b]	NR	0.05[c]	NR	1[b]	NR	0.5[c]	2[b]
Dermal Contact	77	1	0.0051-0.49	NR	11	NR	0.5	2-3
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	1240	121	0.06-5	0.0004-3	NR	3	NR	NR
Hair-Coloring	68	44	0.18-1.3	2	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	43	NR	NR	NR	2	NR	NR	NR
Baby Products	2	NR	NR	NR	NR	NR	NR	NR
	C20-24 Alkyl Dimethicone				**C24-28 Alkyl Methicone**			
Totals*	**38**	**NA**	**SIP**	**NA**	**NR**	**NR**	**NR**	**2**
Duration of Use								
Leave-On	*38*	*NA*	*SIP*	*NA*	*NR*	*NR*	*NR*	*2*
Rinse-Off	*NR*	*NA*	*SIP*	*NA*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NA*	*SIP*	*NA*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	1	NA	SIP	NA	NR	NR	NR	NR
Incidental Ingestion	29	NA	SIP	NA	NR	NR	NR	2
Incidental Inhalation-Spray	3[a]; 4[b]	NA	SIP	NA	NR	NR	NR	NR
Incidental Inhalation-Powder	4[b]	NA	SIP	NA	NR	NR	NR	NR
Dermal Contact	9	NA	SIP	NA	NR	NR	NR	NR
Deodorant (underarm)	NR	NA	SIP	NA	NR	NR	NR	NR
Hair - Non-Coloring	NR	NA	SIP	NA	NR	NR	NR	NR
Hair-Coloring	NR	NA	SIP	NA	NR	NR	NR	NR
Nail	NR	NA	SIP	NA	NR	NR	NR	NR
Mucous Membrane	29	NA	SIP	NA	NR	NR	NR	2
Baby Products	NR	NA	SIP	NA	NR	NR	NR	NR

Table 2. Current and historical frequency and concentration of use according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2020[7]	**1998[1]**	**2019[8]**	**1999[1]**	**2020[7]**	**1998[1]**	**2019[8]**	**1999[1]**
	C26-28 Alkyl Dimethicone				**C30-45 Alkyl Dimethicone**			
Totals*	**13**	**NA**	**SIP**	**NA**	**66**	**NR**	**0.16-5.1**	**2**
Duration of Use								
Leave-On	*11*	*NA*	*SIP*	*NA*	*64*	*NR*	*0.16-5.1*	*2*
Rinse-Off	*2*	*NA*	*SIP*	*NA*	*2*	*NR*	*0.5*	*NR*
Diluted for (Bath) Use	*NR*	*NA*	*SIP*	*NA*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	10	NA	SIP	NA	13	NR	0.16-5.1	NR
Incidental Ingestion	1	NA	SIP	NA	36	NR	0.4-2.9	NR
Incidental Inhalation-Spray	NR	NA	SIP	NA	3[a]; 5[b]	NR	2.3[a]	2[a]
Incidental Inhalation-Powder	NR	NA	SIP	NA	5[b]	NR	4; 0.5-4[c]	NR
Dermal Contact	9	NA	SIP	NA	24	NR	0.16-5.1	2
Deodorant (underarm)	NR	NA	SIP	NA	NR	NR	NR	NR
Hair - Non-Coloring	2	NA	SIP	NA	2	NR	0.5-2.3	NR
Hair-Coloring	NR	NA	SIP	NA	NR	NR	NR	NR
Nail	NR	NA	SIP	NA	NR	NR	NR	NR
Mucous Membrane	1	NA	SIP	NA	36	NR	0.4-2.9	NR
Baby Products	NR	NA	SIP	NA	NR	NR	NR	NR
	C30-45 Alkyl Methicone				**C30-60 Alkyl Dimethicone**			
Totals*	**71**	**NR**	**0.0054-2.2**	**NR**	**2**	**NA**	**SIP**	**NA**
Duration of Use								
Leave-On	*50*	*NR*	*0.0054-2.2*	*NR*	*2*	*NA*	*SIP*	*NA*
Rinse-Off	*21*	*NR*	*NR*	*NR*	*NR*	*NA*	*SIP*	*NA*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NA*	*SIP*	*NA*
Exposure Type								
Eye Area	12	NR	NR	NR	NR	NA	SIP	NA
Incidental Ingestion	13	NR	NR	NR	NR	NA	SIP	NA
Incidental Inhalation-Spray	7[a]; 5[b]	NR	NR	NR	2[b]	NA	SIP	NA
Incidental Inhalation-Powder	5[b]	NR	0.0054-2.2[c]	NR	2[b]	NA	SIP	NA
Dermal Contact	52	NR	0.0054-2.2	NR	2	NA	SIP	NA
Deodorant (underarm)	NR	NR	NR	NR	NR	NA	SIP	NA
Hair - Non-Coloring	3	NR	NR	NR	NR	NA	SIP	NA
Hair-Coloring	NR	NR	NR	NR	NR	NA	SIP	NA
Nail	2	NR	NR	NR	NR	NA	SIP	NA
Mucous Membrane	13	NR	NR	NR	NR	NA	SIP	NA
Baby Products	NR	NR	NR	NR	NR	NA	SIP	NA
	Caprylyl Methicone				**Cetearyl Methicone**			
Totals*	**234**	**NA**	**SIP**	**NA**	**45**	**1**	**0.75-1.1**	**0.5-1**
Duration of Use								
Leave-On	*226*	*NA*	*SIP*	*NA*	*45*	*1*	*0.75-1.1*	*0.5-1*
Rinse-Off	*8*	*NA*	*SIP*	*NA*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NA*	*SIP*	*NA*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	51	NA	SIP	NA	2	NR	NR	NR
Incidental Ingestion	20	NA	SIP	NA	NR	1	NR	0.6-1
Incidental Inhalation-Spray	1; 63[a]; 38[b]	NA	SIP	NA	34[a];6[b]	NR	0.75[a]	0.5[b]
Incidental Inhalation-Powder	10; 38[b]	NA	SIP	NA	6[b]	NR	1.1[c]	0.5[b]
Dermal Contact	204	NA	SIP	NA	43	NR	0.9-1.1	0.5
Deodorant (underarm)	NR	NA	SIP	NA	NR	NR	NR	NR
Hair - Non-Coloring	9	NA	SIP	NA	2	NR	0.75	NR
Hair-Coloring	NR	NA	SIP	NA	NR	NR	NR	NR
Nail	1	NA	SIP	NA	NR	NR	NR	NR
Mucous Membrane	20	NA	SIP	NA	NR	1	NR	0.6-1
Baby Products	NR	NA	SIP	NA	NR	NR	NR	NR

Table 2. Current and historical frequency and concentration of use according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2020[7]	**1998[1]**	**2019[8]**	**1999[1]**	**2020[7]**	**1998[1]**	**2019[8]**	**1999[1]**
	Cetyl Dimethicone				**Dimethicone**			
Totals*	**233**	**27**	**0.001-11.8**	**0.5-10**	**14,050**	**1659**	**0.0000014-85**	**0.0001-80**
Duration of Use								
Leave-On	*228*	*26*	*0.1-11.8*	*0.5-10*	*12,426*	*1333*	*0.002-85*	*0.0001-80*
Rinse-Off	*5*	*1*	*0.001-6*	*NR*	*1616*	*320*	*0.0000014-23.4*	*0.001-10*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*8*	*6*	*2.5-3*	*NR*
Exposure Type								
Eye Area	64	5	1-6	0.5	1976	111	0.25-37.8	0.3-13
Incidental Ingestion	14	NR	1.1-10	4-5	347	12	0.4-71.3	0.001-20
Incidental Inhalation-Spray	38[a]; 6[b]	4[a]; 2[b]	0.5-4[a]	2[a]; 2[b]	119; 4763[a]; 2430[b]	56; 336[a]; 299[b]	1-85; 0.3-63.5[a]; 1-2.9[b]	0.2-16; 0.3-15[a]; 0.0001-10[b]
Incidental Inhalation-Powder	19; 6[b]	2; 2[b]	6; 0.1-11.8[c]	0.9-3; 2[b]	482; 2430[b]; 31[c]	87; 299[b]; 7[c]	0.33-53; 1-2.9[b]; 0.5-66.9[c]	0.3-30; 0.0001-10[b]; 2[c]
Dermal Contact	210	24	0.001-11.8	0.9-10	11,377	1313	0.0022-85	0.0001-30
Deodorant (underarm)	NR	NR	NR	NR	33[a]	9[a]	spray: 2-18.6; not spray: 5-40	0.5-23[a]
Hair - Non-Coloring	7	1	0.5-6	NR	1522	249	0.0000014-63.5	0.08-80
Hair-Coloring	NR	NR	NR	NR	291	29	0.00015-3.3	0.5
Nail	NR	NR	NR	NR	397	36	0.002-75	0.001-3
Mucous Membrane	14	NR	0.001-10	4-5	442	54	0.0022-71.3	0.001-20
Baby Products	NR	NR	5	NR	34	8	0.21-10	2
	Dimethoxysilyl Ethylenediaminopropyl Dimethicone				**Hexyl Dimethicone**			
Totals*	**NR**	**NR**	**0.043-2.1**	**NR**	**NR**	**NA**	**0.17**	**NA**
Duration of Use								
Leave-On	*NR*	*NR*	*0.043*	*NR*	*NR*	*NA*	*0.17*	*NA*
Rinse-Off	*NR*	*NR*	*2.1*	*NR*	*NR*	*NA*	*NR*	*NA*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NA*	*NR*	*NA*
Exposure Type								
Eye Area	NR	NR	NR	NR	NR	NA	0.17	NA
Incidental Ingestion	NR	NR	NR	NR	NR	NA	NR	NA
Incidental Inhalation-Spray	NR	NR	0.043[a]	NR	NR	NA	NR	NA
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NA	NR	NA
Dermal Contact	NR	NR	NR	NR	NR	NA	0.17	NA
Deodorant (underarm)	NR	NR	NR	NR	NR	NA	NR	NA
Hair - Non-Coloring	NR	NR	0.043	NR	NR	NA	NR	NA
Hair-Coloring	NR	NR	2.1	NR	NR	NA	NR	NA
Nail	NR	NR	NR	NR	NR	NA	NR	NA
Mucous Membrane	NR	NR	NR	NR	NR	NA	NR	NA
Baby Products	NR	NR	NR	NR	NR	NA	NR	NA
	Methicone				**Stearoxy Dimethicone**			
Totals*	**654**	**NR**	**0.00014-3.6**	**0.009-5**	**44**	**21**	**0.8-1.5**	**0.1-3**
Duration of Use								
Leave-On	*635*	*NR*	*0.00014-3.6*	*0.009-5*	*43*	*20*	*0.8-1.5*	*0.1-3*
Rinse-Off	*18*	*NR*	*0.15-0.46*	*0.05-0.3*	*1*	*1*	*NR*	*0.5*
Diluted for (Bath) Use	*1*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	166	NR	0.1-3.6	0.02-0.9	9	NR	NR	2-3
Incidental Ingestion	91	NR	0.36	0.06	10	NR	0.8	3
Incidental Inhalation-Spray	7[a]; 21[b]	NR	NR	0.3[b]	7[a]; 8[b]	6[a]; 10[b]	NR	0.1; 0.2-3[a]; 2[b]
Incidental Inhalation-Powder	92; 21[b]	NR	0.064-1.5; 0.048-1.9[c]	0.08-5; 0.3[b]; 0.3[c]	8[b]	1; 10[b]	NR	2[b]
Dermal Contact	505	NR	0.00014-3.6	0.01-5	32	21	1.5	0.5-3
Deodorant (underarm)	NR	NR	spray: 0.25	NR	NR	NR	NR	NR
Hair - Non-Coloring	10	NR	0.46	NR	1	NR	NR	0.1-0.2
Hair-Coloring	5	NR	NR	0.3	NR	NR	NR	NR
Nail	24	NR	0.0035-2.5	0.009	NR	NR	NR	NR
Mucous Membrane	95	NR	0.36	0.06	10	NR	0.8	3
Baby Products	NR	NR	0.46	0.3	NR	NR	NR	NR

Table 2. Current and historical frequency and concentration of use according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2020[7]	**1998[1]**	**2019[8]**	**1999[1]**	**2020[7]**	**1998[1]**	**2019[8]**	**1999[1]**
	Stearyl Dimethicone				**Stearyl Methicone**			
Totals*	**183**	**7**	**0.2-8.3**	**0.8-6**	**1**	**NR**	**NR**	**NR**
Duration of Use								
Leave-On	*176*	*6*	*0.2-8.3*	*0.8-6*	*1*	*NR*	*NR*	*NR*
Rinse-Off	*7*	*1*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	46	2	3.6-8.3	0.8-6	NR	NR	NR	NR
Incidental Ingestion	25	2	0.38-2.6	4-6	NR	NR	NR	NR
Incidental Inhalation-Spray	3; 28[a]; 35[b]	1[a]	0.38[a]	4[b]	NR	NR	NR	NR
Incidental Inhalation-Powder	2; 35[b];	NR	0.2-2.3[c]	4[b]	NR	NR	NR	NR
Dermal Contact	149	3	0.2-8.3	1-6	1	NR	NR	NR
Deodorant (underarm)	NR	NR	not spray:1.2	NR	NR	NR	NR	NR
Hair - Non-Coloring	9	NR	0.3	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	25	2	0.38-2.6	4-6	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
	Vinyl Dimethicone							
Totals*	**1**	**NR**	**NR**	**NR**				
Duration of Use								
Leave-On	*1*	*NR*	*NR*	*NR*				
Rinse-Off	*NR*	*NR*	*NR*	*NR*				
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*				
Exposure Type								
Eye Area	NR	NR	NR	NR				
Incidental Ingestion	1	NR	NR	NR				
Incidental Inhalation-Spray	NR	NR	NR	NR				
Incidental Inhalation-Powder	NR	NR	NR	NR				
Dermal Contact	NR	NR	NR	NR				
Deodorant (underarm)	NR	NR	NR	NR				
Hair - Non-Coloring	NR	NR	NR	NR				
Hair-Coloring	NR	NR	NR	NR				
Nail	NR	NR	NR	NR				
Mucous Membrane	1	NR	NR	NR				
Baby Products	NR	NR	NR	NR				

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

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

[b] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories.

[c] It is possible these products are powders, but it is not specified whether the reported uses are powders

NR – no reported use

NA – Ingredient was not included in the original safety assessment.

SIP – survey in progress

Table 3. Methicone ingredients not reported to be in use

Amodimethicone Hydroxystearate
C20-24 Alkyl Methicone*
C24-28 Alkyl Dimethicone*
C26-28 Alkyl Methicone*
C32 Alkyl Dimethicone*
Capryl Dimethicone*
Hexyl Methicone
Hydroxypropyldimethicone
Stearamidopropyl Dimethicone

*concentration of use survey is currently being conducted

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