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Survey and risk assessment of siloxanes in cosmetic products

Survey of chemical substances in consumer products No. 185

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Introduction

This project is a part of the Danish Environmental Protection Agency's measures to focus on the consumers' exposure to problematic chemical substances.

The purpose of the project is to collect knowledge of the use of siloxanes in cosmetic products and to clarify if the use of cosmetic products containing siloxanes constitutes a risk to environment and human health.

The project has been made between June and December 2019 by DHI and the Danish Technological Institute.

The project has been followed by a steering committee with the following members:

- Nellie Anne Martin, Danish Environmental Protection Agency
- Toke Winther, Danish Environmental Protection Agency
- Thit Aarøe Mørck, DHI
- Poul Bo Larsen, DHI
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Summary and conclusion

The purpose of this report is to build up knowledge about the use of silicone substances in cosmetic products and to investigate whether the use of cosmetic products containing these substances poses a risk to environment and to human health, and also to assess whether there are possible alternative substances that can replace problematic silicone substances. The silicone substances contained in cosmetic products are also referred to as siloxanes. Siloxanes consist of silicon, oxygen and alkane, which form part of the molecular siloxane structures in different structures. Siloxanes can be divided into acyclic and cyclic siloxanes, depending on their molecular structure. The *acyclic* siloxanes include linear and branched polymers such as the structures *methicone* or *dimethicone*. With regard to cyclic siloxanes, three or more of these structures are part of a ring structure.

According to current knowledge, the cyclic siloxanes include octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6), which are considered to be the most problematic siloxane compounds regarding environmental and human health effects. These siloxanes are problematic as they are associated with possible reproductive toxicity properties and because they are very slowly degradable in the environment.

This project is divided into three phases:

Phase 1: Suvey of the use of siloxanes in cosmetic products
Phase 2: Chemical analyses of siloxanes in cosmetic products purchased for the project
Phase 3: Hazard and risk assessment with regard to the human health and the environment

Mapping
The survey of the use of siloxanes in cosmetic products was made on the basis of a search in the Danish Consumer Council THINK Chemicals' app *"Kemiluppen"*. The app contains data on ingredients in cosmetic products that have been scanned by consumers. Based on an initial search in *Kemiluppen*, 82 different types of siloxanes declared in the products were identified. Of these, 12 siloxanes were selected for more in-depth assessment of their use based on their reported content in the products:

- *Cyclic siloxanes:* Cyclomethicone, D4, D5, D6
- *Acyclic siloxanes:* Amodimethicone, Cetyl peg/ppg-10/1 dimethicone, Dimethicone, Drometrizol trisiloxane, Peg-10 dimethicone, Peg-12 dimethicone, Phenyl trimethicone and trisiloxane.

The survey of the 12 selected siloxanes showed that they are primarily used in these product categories:

- Facial creams (day cream/lotion)
- Body care (cream/lotion/balm)
- Cosmetics (foundation)
- Hair care products (hair oil/cream/lotion/serum, shampoo, conditioner)
- Sun care products (cream/lotion/gel)

From literature searches and visits to various cosmetics websites, including the CosIng database, data were collected on the use and function of siloxane compounds in cosmetics. From

this it appeared that siloxanes are typically used in personal care products for hair and skin care, which was also the conclusion from the searches in Kemiluppen (see above). Siloxanes are stated to contribute to a number of desired product properties such as: antistastic effects, antifoaming effect, emollient effect, skin protection effect, glossy effect and as a solvent for other ingredients. In addition, the siloxanes are odourless and non-greasy, they help to make the product feel pleasant on the skin and they give a nice finish and even distribution of the product.

In order to assess the trend regarding the use and substitution of siloxanes, questionnaires were sent to a small selection of Danish cosmetics manufacturers and to two Danish industry associations. The responses indicated a general decline in the use of the cyclic siloxanes (cyclomethicone, D4, D5, D6) and attempts to substitute them, not least because of regulatory measures. The same trend could not be seen for the acyclic siloxanes. Furthermore, from the majority of the responses, a certain consumer demand for siloxane-free products was stated. As alternatives to the cyclic siloxanes were mentioned acyclic siloxanes/dimethicone and plant based substances such as oil esters, and also some undefined plasticizers were suggested.

Chemical analysis
Based on the survey, 50 specific cosmetic products from various selected product categories were purchased for analysis. Out of the 50 purchased products, 40 different products were selected for chemical analysis in the light of the product declaration. The products were analysed for their content of six specific siloxanes (D4, D5, D6, trisiloxane, drometrizol trisiloxane or phenyl trimethicone). In addition to the quantitative determination of the specific siloxanes, GC-MS screening was carried out to identify other siloxanes that could be relevant for further risk assessment concerning impact on the environment and consumer health.

The analysis of extracts from the cosmetic products was carried out by gas chromatography combined with GC-MS mass-selective detection (scan mode). Quantification was carried out by using a calibration curve based on reference standards for the six substances. Other siloxanes identified by comparison with the NIST library[1] were calculated either as D6 equivalents or trisiloxane equivalents. As a result, the quantitative determination of the siloxanes is less accurate than the analyses performed with reference substances.

25 out of 40 products were declared to have a content of cyclic siloxanes. Either as a single component of D4, D5 or D6, or a mixture of the three cyclic siloxanes. The results of the analyses indicate that low concentrations were found in most of the products (<0.6% for D4, <0.2% for D5, <1.7% for D6) – although that was not stated on the label. For most of the products with low concentrations of either D4, D5 or D6, at least one of the three (other) cyclic siloxanes is found in significant concentrations in the products. This suggests that the cyclic siloxanes added to the products are not pure substances but contain residues of other cyclic siloxanes. The cyclic siloxanes were also found as residues in dimethicone, probably because cyclic siloxanes can be used to make dimethicone.

According to Annex II of the Commission Regulation (EU) 2019/831 (from May 2019), D4 is banned for use in cosmetic products. However, five of the purchased products were declared to have a content of D4, and the analysis results showed a content of D4 between 2% and 40%. One product contained 23% D4, although D4 was not stated in the declaration. In addition, D4 was found in 17 other products with concentrations ranging from 0.005% to 0.59%.

Sixteen out of 40 products were declared to contain other siloxanes in addition to the siloxanes selected for quantitative analyses. With the exception of two products, the analysis results

[1] National Institute of Standards and Technology (NIST), USA. The NIST library is a databasse with mass spectra for more than 500,000 chemical compounds.

confirm the information stated on the product labels. Furthermore, a significant content of trisiloxane was found in one product although trisiloxane was not stated in the product declaration. For all products, screening analyses were carried out with GC-MS in order to identify siloxanes that were not stated in the declaration. Screening analyses showed a content of other cyclic siloxanes from D7 to D18 as well as D3. The linear siloxanes L4 to L20 were also identified in a number of products. In Dx and Lx, the number x refers to the number of Si-atoms that can be found in cyclic and linear siloxanes, respectively. In addition, one specific siloxane compound was identified, and in this report it is referred to as siloxane X.

Consumer risk assessment
To assess the human health risk associated with the use of the selected products, exposure estimates for the respective product types were made based on SCCS's (Scientific Committee on Consumer Safety) guidelines for cosmetic safety assessment. It should be noted that for products used on small children oral exposure was estimated as well in association with licking hands/fingers. For the selected siloxanes and dimethicone compounds, the hazard assessment was performed based on literature search and the latest expert reviews of the substances, such as assessments made by SCCS (the EU Scientific Committee for Consumer Product Safety) or by CIR (Cosmetic Ingredient Review Expert Panel). Based on the hazard assessment, the tolerable exposure level was calculated for the individual substances. For the siloxanes, the following critical effects could be identified as the basis for calculating the tolerable exposure levels:

D3: Effects on the liver
D4: Development of tumors in the uterus and effects on the liver. Adverse effects in lungs by inhalation.
D5: Development of tumors in the uterus and effects on the liver. Adverse effects in lungs by inhalation.
D6: Effects on the thyroid and liver. Adverse effects in lungs by inhalation.
Trisiloxane: Effects on the liver and biliary system.
Phenyl trimethicone: Teratogenic (old and very uncertain data).
Dimethicone: No harmful effects have been identified.
Drometrizol trisiloxane: No data available for assessment.

To make a risk assessment of each product, the tolerable concentration level of the different siloxanes was calculated based on the knowledge of the daily exposure to the product and based on the the tolerable exposure level of the specific siloxanes.

Based on this the ratio of the measured concentration in the product and the tolerable concentration level for each siloxane compound could be determined and expressed as a risk characterization ratio, RCR, for the siloxane:

RCR = measured concentration / tolerable concentration

If the measured concentrations exceed the tolerable concentrations (RCR> 1), this indicates that the use of the product may pose an unacceptable increased risk to the consumer.

For a total of 7 products, RCR values> 1 were found. This included 1 foundation, 1 hair conditioner, 1 hair oil, 1 body cream and 3 sunscreen products.

The foundation product was found to be critical only because of their phenyl trimethicone content with an RCR value of 1.1. However, the assessment of this substance is very uncertain as the toxicological test data for the substance is from the mid-1960s, i.e. data is far from meeting today's standards for testing. Furthermore, it is not known whether the test substance

used in the mid-1960s corresponds to the quality of phenyl trimethicone used in cosmetics today, so no clear conclusions can be made for this product.

Two pump spray products (1 hair conditioner, 1 hair oil) showed RCR values of 1.3 (sum of D5 and D6 content) and 3.1 (D4 content) respectively. However, when doing an actual testing and spraying with the two products, the initial assumptions for making exposure calculations were considered overly conservative and it was deemed unlikely that the products would pose a risk to the user.

The use of four products (2 sunscreens, 1 sun spray and 1 body cream) on infants resulted in RCR values of 1.2 to 75 based on the total content of the cyclic siloxanes D3, D4, D5 and D6. One of the sunscreens also contained phenyl trimethicone at a concentration resulting in an RCR value of 5.3, but as mentioned above the risk assessment of this substance is very uncertain. For adults only two of these products were found to pose a risk, as the exposure per kg bodyweight for adults is relatively lower than for children and consequently resulting in lower RCR values.

Several products, and in particular the sun care products, contained the approved UV filter drometrizol trisiloxane at concentrations up to 2.4%. Although it is an approved UV filter, there are no publicly available data for the substance that can form the basis for a risk assessment.

Environmental assessment
In connection with the environmental assessment, a hazard assessment of the selected siloxanes was carried out. D4 was assessed to have both PBT and vPvB properties. Cyclomethicone with a content of D4 above 3% is assesssed as a PBT substance and as a non PBT substance if the content of D4 is below 3%.

D5, trisiloxane and cyclomethicone were assessed to have vPvB properties, while phenyl trimethicone was assessed as a PBT substance. The substances D3, D6, dimethicone and drometrizole trisiloxane were characterised as having neither PBT nor vPvB properties.

Abiotic degrading (hydrolysis) is an important primary path for degrading siloxanes. The most important degrading products from the abiotic degrading processes have been identified to be dimthylsilanol, trimethylsilanol, dimethylsilanediol. Dimethylsilanol and trimethylsilanol can be hydrolysed to dimethylsilanediol, which probably is the final hydrolysis product. Dimethylsilanediol can biodegrade, but this will only happen very slowly with half life in soil in the range of years. Consequently, the degrading products should be characterised as P or vP.

All siloxanes are thus considered recalcitrant. Furthermore, as the degradation is a stepwise process, the total degradation time will increase with the molecular size. This means that polymer dimethicone must be expected to remain in the environment for considerably longer time than the cyclic and acyclic smaller siloxanes.

On the basis af the limited toxicity data to benthic and terrestrial organisms, it is not possible to prioritize the siloxanes with respect to their inherent toxicity to benthic and terrestrial organisms. The polymer dimethicone is however not toxic, as the substance is not bioavailable. In this connection, it must be mentioned that the polymer itself may contain low molecular siloxanes in a lower concentration, and that a small fraction of the dimethiocone eventually (and very slowly) will degrade into smaller siloxanes with similar toxicity as for the other siloxanes.

The siloxanes in the products were assigned an environmental impact score, which is calculated as the ratio of the PEC in the various environmental compartments (water, sediment, soil) to the hazard score. The lower the environmental impact score, the lower the environmental impact.

All in all it is not possible to make a priority on the basis of the environmental toxicity of the selected siloxanes due to limitation of environmental toxicity data.

Taking into account how the various siloxanes partition in the environment, the water phase is of relatively lower importance. It may be most relevant to prioritize according to the relative impact on the soil and the sediment compartments. Primarily products with drometrizol trisiloxane and phenyl trimethiocone showed the relatively highest impact on the soil compartment, whereas primarily products with D5 and D6 showed the relatively highest impact on the sediment compartment.

In connection with the current process of substuting cyclic siloxanes with dimethicone in cosmetic products, the question is whether this leads to improvement or deterioration of the environmental impact from the siloxanes. If it is presumed that the total concentration of siloxanes is not changed with the substitution process, then a consequence of this substitution process will be that larger amounts of substances released into the environment will remain in the environment. As a rule, dimethicone is not as toxic and bioaccumulative as the other minor siloxanes, but a fraction of the substance will ultimatively degrade into smaller parts, which will show similar toxicity and potential for bioaccumulation.

1. Introduction

1.1 Purpose

The purpose of the project with mapping and risk assessment of siloxanes in cosmetic products is to build up knowledge about the use of siloxanes in cosmetic products and to clarify if the use of cosmetic products including siloxanes pose a risk to environment and human health.

The most discussed siloxane compounds used in cosmetic products, and which are considered to be the most problematic siloxane compounds regarding environment and human health effects, are the cyclic compounds:

D4 - Octamethylcyclotetrasiloxane (CAS nummer 556-67-2):
D5 - Decamethylcyclopentasiloxane (CAS nummer 541-02-6)
D6 - Dodecamethylcyclohexasiloxane (CAS nummer 540-97-6)

A search from the Danish Consumer Council THINK Chemicals' app *"Kemiluppen"* (mid-2018) shows that D6 is registered as an ingredient in 221 cosmetic products (including 14 spray products), D5 in 793 (including 34 spray products), D4 in 22 (including 1 spray product) and cyclomethicone (D4/D5/D6) in 176 products. Apart from these the search also shows that a number of other siloxanes appear frequently in cosmetic products, including Drometrizole trisiloxane (approved UV filter), Ethyl trisiloxane, Trisiloxane, Disiloxane, Methicone an a number of derivatives of Methicone.

1.2 Method

As indicated in the project description the project was conducted in three phases:

Phase 1: Mapping
With the data from Kemiluppen the mapping should give an overview of which types of cosmetic products that contain siloxanes, and which siloxanes they contain, as well as establish how often Kemiluppen's users have scanned information about the specific products, which can give an idea of the consumer interest in the products. Subsequently, it is assessed for which consumer groups the products are intended, and also via a data search to clarify the function of the siloxanes in the products.

Phase 2: Chemical analyses
On the basis of knowledge gained in phase 1, a number of different cosmetic products with declaration of (or expected content of) cyclic and non-cyclic siloxanes are prioritised and purchased. The cosmetic products are analysed with regard to identification and content of a number of prioritised siloxane compounds, with the purpose that the analytical data can form the basis of both a risk assessment of the environment and of human health.

Phase 3: Health related and environment related hazard and risk assessment
By using relevant literature, expert statements/assessments and based on data obtained in phases 1 and 2, a hazard assessment, an exposure scenario and a risk assessment of the environment and of human health are made for the cosmetic products based on the content of siloxanes in the analysed products.

2. Mapping of siloxanes in cosmetic products

2.1 In general about siloxanes

Silicone compounds typically used in cosmetic products are also called siloxanes. The term siloxane is formed from the words silicium, oxygen and alkane, which are chemical elements and molecules included in the molecular structure of the siloxanes.

One group of siloxanes are formed by a *linear* polymer of *methicone*, which has the basic structure -(CH3)HSiO--, while *dimethicone* contains dimethylated linear polymers of the molecular basic structure -(CH3)2SiO-. For the *cyclic* siloxanes there are three or more of these molecular units linked together in a ring structure.

Furthermore, the linear and cyclic siloxanes may be coupled to a number of other chemical structures, which means that a large number of different siloxanes exists. When searching using the word *"methicone"* in the CosIng database* (the European Commission's database of cosmetic ingredients) 551 INCI-substances are identified (of which 505 included the word *dimethicone*). When searching using the word *"siloxane"* 49 INCI substances were identified.

*search made in June 2019 at:
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple).

2.2 Sorting and selecting siloxanes for the project

The purpose of mapping siloxanes in cosmetic products is to get information on which cyclic and acyclic siloxanes are used, in which product types, and for which purpose they are used. Since the cyclic siloxanes have come into focus because of the adverse effect on reproduction and not least due to the hazardous properties to the environment because of their slow degradation , it is furthermore the purpose to assess whether other linear siloxanes can be used instead. The mapping is to constitute the basis for selecting specific types of products for further analyses in order to identify and dertermine the concentration level of specific siloxanes in the products and further to make risk assessment of human health and the environment from the use of the products.

As a starting point for this project, the Danish Environmental Protection Agency has made an initial search from *"Kemiluppen"* concerning use of siloxanes in cosmetic products. *"Kemiluppen"* is an app created in December 2015 by The Danish Consumer Council THINK, where consumers can scan a cosmetic product and via the app get information about the possible content of problematic chemical substances in the product. If the product is not yet included in the database, consumers can photograph a product's declaration list and submit the picture for assessment and thereby have the product included in *"Kemiluppen"*. Today *"Kemiluppen"* includes 18,000 cosmetic products of which approximately 12,000 are assumed to be currently on the market. The basic data that can be extracted from the the database is product name, which product category the product belongs to, the INCI-declaration list, and the number of scans consumers have made to search for information about the product in question. Since the app was created, more than 8 million scans have been made via the app, and the daily average for 2019 is approximately 4,800 scans. *"Kemiluppen"* forwards the information to the producers and importers, and the update of product declarations partly depends on reporting

from producers and importers and partly from the reportings from the consumers and from the testing of products performed by The Danish Consumer Council THINK.

Based on the initial search in *"Kemiluppen"* 1,231 products were identified on the Danish market, which was declared with one or more of a total of 12 siloxanes in which the term "*siloxane*" was included in the INCI name (see TABLE 1). Using the search "*methicone*" 4,340 products were identified, with one or more of 70 siloxanes on the declaration (see TABLE 2). Please note, that the two tables are solely arranged based on the used search word, and consequently the tables are not arranged after chemical structures, i.e. both acyclic and cyclic siloxanes appear in both tables.

TABLE 1. A total of 1,231 cosmetic products found by searching" siloxane-" in "Kemiluppen" distributed among 12 different substances.

"Siloxane"-search, substance	Number of products
Cyclotrisoloxan (D3)	3
Cyclotetrasiloxane (D4)	19
Cyclopentasiloxane (D5)	830
Cyclohexasiloxane (D6)	235
Disiloxane	12
Trisiloxane	40
Ethyl trisiloxane	10
Polydiethylsiloxane	2
Trimethyl pentaphenyl trisiloxane	1
Polyglyceryl-3 disiloxane dimethicone	1
Siloxanetriol alginat	1
Drometrizole trisiloxane	80

TABLE 2. A total of 4,340 cosmetic products found by searching "methicone-" in "Kemiluppen" distributed among 70 different substances.

"Methicone"-search, substance	Number of products
Acrylates/dimethicone copolymer	15
Aminoethylaminopropyl dimethicone	1
Amodimethicone	382
Bis(c13-15 alkoxy) pg-amodimethicone	5
Bisamino peg/ppg-41/3 aminoethyl pg-propyl dimethicone	37
Bis-aminopropyl dimethicone	29
Bis-cetearyl amodimethicone	18
Bis-diisopropanolamino-pg-propyl dimethicone/bis-isobutyl peg-14 copolymer	14
Bis-isobutyl peg/ppg-20/35/amodimethicone copolymer	4
Bis-peg/ppg-14/14 dimethicone	24
Bis-peg/ppg-16/16 peg/ppg-16/16 dimethicone	20
Bis-peg/ppg-20/20 dimethicone	3
Bis-peg-12 dimethicone	6
Bis-peg-15 methyl ether dimethicone	1
C24-28 alkyl dimethicone	1
C30-45 alkyl cetearyl dimethicone crosspolymer	10

”Methicone”-search, substance	Number of products
C30-45 alkyl dimethicone	10
Caprylyl methicone	18
Cetyl dimethicone	27
Cetyl peg/ppg-10/1 dimethicone	126
Cetyl triethylmonium dimethicone peg-8 succinate	6
Crotonic acid/vinyl c8-12 isoalkyl esters/va/bis-vinyldimethicone crosspolymer	1
Cyclomethicone	176
Dimethicone	2 372
Divinyldimethicone/dimethicone copolymer	14
Divinyldimethicone/dimethicone crosspolymer,	1
Hydroxypropyl dimethicone behenate	1
Hydroxypropyl dimethiconylpropyl acrylates copolymer	1
Lauryl dimethicone/polyglycerin-3 crosspolymer	2
Lauryl peg/ppg-18/18 methicone	29
Linoleamidopropyl pg-dimonium chloride phosphate dimethicone	4
Methicone	92
Methoxy peg/ppg-7/3 aminopropyl dimethicone	5
Methyl trimethicone	38
Nylon-611/dimethicone copolymer	1
Peg/ppg-14/4 dimethicone	6
Peg/ppg-15/15 acetate dimethicone	2
Peg/ppg-17/18 dimethicone	31
Peg/ppg-18/12 dimethicone	1
Peg/ppg-18/18 dimethicone	83
Peg/ppg-18/6 dimethicone	2
Peg/ppg-20/15 dimethicone	10
Peg/ppg-20/23 dimethicone	1
Peg/ppg-20/6 dimethicone	1
Peg/ppg-25/25 dimethicone	3
Peg/ppg-4/12 dimethicone	13
Peg-10 dimethicone	127
Peg-12 dimethicone	154
Peg-14 dimethicone	7
Peg-17 dimethicone	1
Peg-40/ppg-8 methylaminopropyl/hydroxypropyl dimethicone copolymer	5
Peg-7 amodimethicone	4
Peg-8 dimethicone	15
Perfluorononyl dimethicone	2
Perfluorononylethyl carboxydecyl peg-10 dimethicone	1
Pg-amodimethicone	3
Phenyl trimethicone	207
Phenylisopropyl dimethicone	2
Potassium dimethicone peg-7 panthenyl phosphate	11

”Methicone”-search, substance	Number of products
Ppg-12 dimethicone	2
Propoxytetramethyl piperidinyl dimethicone	2
Silica dimethicone silylate	6
Simethicone	51
Stearamidopropyl dimethicone	2
Stearoxy dimethicone	3
Stearyl dimethicone	23
Trideceth-9 pg-amodimethicone	3
Trimethylsiloxyamodimethicone	7
Trimethylsiloxyphenyl dimethicone	15
Vinyl dimethicone/methicone silsesquioxane crosspolymer	40

In this project, focus is on the use of both cyclic and acyclic siloxanes, as it is the intention to assess if some of the linear siloxanes can be used as substitute substances for the cyclic siloxanes.

Based on the tables above, the project group together with the Danish EPA selected 12 siloxanes for more in-depth reporting on their use.

Cyclic siloxanes:

Cyclomethicone

Octamethylcyclo-tetrasiloxane D4

Cycklopentasiloxane D5

Cyclohexasiloxane D6

Acyclic siloxanes:

Amodimethicone

Cetyl peg/ppg-10/1 dimethicone

Dimethicone

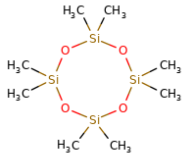
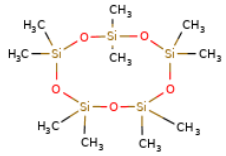
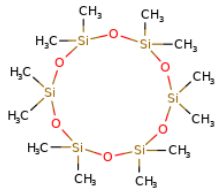
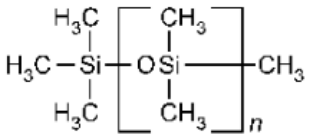
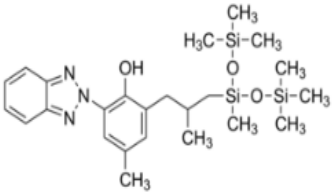
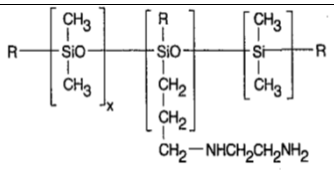
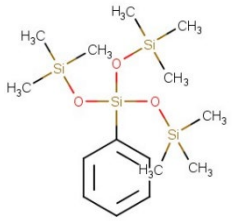
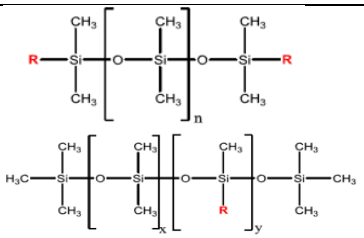
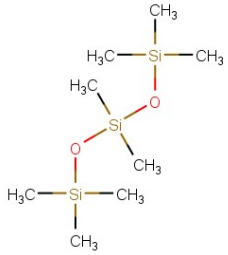
Drometrizol trisiloxane

Peg-10 dimethicone

Peg-12 dimethicone

Phenyl trimethicone

trisiloxane

INCI substance name (other names) CAS-No.	**Structure**	**INCI substance name (other names) CAS-No.**	**Structure**
Octamethylcyclo-tetrasiloxane (cylcotetrasiloxane) (D4) CAS 556-67-2		PEG-10 dimethi-cone No CAS No.	Se PEG/PPG-10/1 dimethicone, R: Polyethylene glycol
Cycklopentasilox-ane (Decamethylcyclo-pentasiloxane) (D5) CAS 541-02-6		PEG-12 dimethi-cone No CAS No.	Se PEG/PPG-10/1 dimethicone, R: Polyethylene glycol
Cyclohexasiloxane (Dodecamethylcy-clohexasiloxane) (D6) CAS 540-97-6		Dimethicone CAS 63148-62-9 CAS 9006-65-9 CAS 9016-00-6	
Cyclomethicone CAS 69430-24-6 CAS 556-67-2 CAS 541-02-6 CAS 540-97-6	Mixture of D4, D5, D6	Drometrizole trisiloxane CAS 155633-54-8	
Amodimethicone CAS 71750-80-6		Phenyl trimethi-cone CAS 2116-84-9	
PEG/PPG-10/1 di-methicone No CAS No.	 R: Polyethylene glycol or polypropyl-ene glycol	Trisiloxane (Trisiloxane, Oc-tamethyl) CAS 107-51-7	

2.3 Extract of the selected siloxanes

With specific focus on this project updated and detailed data extracts were made for the 12 selected siloxanes from *"Kemiluppen"* by the the Danish Consumer Council THINK. The following type of information was collected for products declared with one or more of the 12 selected siloxanes:

- Name of the product
- Product categori
- The product's INCI-content declaration
- How many consumer scans where made for each product category
- Target groups for the product with a special focus on products used for children under 3 years (the poduct name in some cases indicates child specific use)

The number of products, in which the individual substances can be found, deviates a little from the initial extracts from "Kemiluppen", which is due to the fact that the database is continuously updated.

2.4 Mapping of the use of 12 selected siloxanes

Overview tables (see Appendix 1) have been prepared for each of the 12 substances showing which product types each of the siloxane substances is used for. From these tables the product categories considered having the highest or most widely used exposure to consumers and the environment were identified. The following parameters were used as most relevant for assessing this:

- In which product categories is the substance used most frequently (if there are less than 5 products with the use of the siloxanes in a product category, they are not prioritised unless the products are targeted for instance for children).
- Products with are subject to large consumer interest (i.e. number of scannings in Kemiluppen).
- Exposure potential, i.e. if the product is a leave-on product (i.e. high exposure to the consumer) or a wash-off product (exposure to the environment).
- If the product is typically used often/on a daily basis.
- Typical content of the substance in % in the product and product volume applied.
- If multiple exposure routes can be anticipated when using the product (i.e. if the use besides dermal exposure may cause oral exposure or inhalation exposure as well).

Based on the extracts of data focusing on the 12 selected siloxanes, it was prioritised for each of the siloxanes which type of products was considered having the highest exposure potential towards the user and the environment.

Likewise, a literature search was made in EU's CosIng database as well as in the American Ingredient Review (CIR) database, which contain information such as the function of the cosmetic ingredients and knowledge about the typical concentrations (see **Error! Reference source not found.**).

2.4.1 Prioritising product categories for the individual siloxanes

A summary of the data of the 12 siloxanes and their use in the various product categories is presented below together with a priority of the product categories for further examination in this project.

TABLE 3. Top priority product categories for the substance Amodimethicone

Amodimethicone	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Hair care – Hair spray / hair spray / heat spray	14	4 949	+	+	D/I	K	-	+++ Inhalation and leave-on
Hair care -hair mousse	12	5 464	+	+	D	K/M	-	+++
Hair care - Balm / conditioner / treatment / mask	182	66 505	-	+	D	K/M/B	0.7-3 %	++/+++ Most products/consumer interest, limited exposure to the consumer, but exposure to the environment
Hair care-hairshampoo	86	49 850	-	+	D	K/M/B	-	+++ Many products (+ children) Exposure to the environment

TABLE 4. Top priority product categories for the substance Cetyl peg/ppg-10/1 dimethicone

Cetyl peg/ppg-10/1 dimethicone	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Facial care – BB/CC cream	8	5 923	+	+	D	K	0.034-15%	+++ High exposure
Cosmetic - Foundation	59	27 700	+	+	D	K	0.034-15%	+++ Many products, consumer interest

Body care - Cream / lotion / balm	11	2 953	+	+	D	K/M/B	0.034-15%	+++ Also children

TABLE 5. Top priority product categories for the substance Cyclomethicone

Cyclomethicone	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Facial care – day cream/lotion	23	13 236	+	+	D	K/M	1-82	+++ Daily use, potentially high conc. in the product
Baby care-baby lotion/-cream	1	395	+	+	D/O	B	-	+++ Only one product, but for children and high exposure
Hair care – hair oil / cream / lotion / serum	25	20 477	+	+/-	D	K/M	0.2-80	+++ Consumer interest
Soap and hygiene – Deodorant	71	74 238	+	+	D/I	K/M	5-56	+++ Many products, potentially high conc., inhalation of spray, high exposure to the environment

TABLE 6. Top priority product categories for the substance D4

D4	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Hair care - Balm / conditioner / treatment / mask	6	133	-	+/-	D	K/M	0.0007-2	++ Exposure to the environment

Hair care – Hair oil / cream / lotion / serum	12	3 054	+	+/-	D	K/M	0.2-2	+++ Most products with D4

TABLE 7. Top priority product categories for the substance D5

D5	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Facial care – BB/CC cream	21	14 550	+	+	D	K	1-61	+++
Facial care – day cream/lotion	69	32 621	+	+	D	K/M/B	1-61	+++ Many products, consumer interest, potentially high conc. Daily exposure
Hair care - Balm / conditioner / treatment / mask	73	19 334	-	+/-	D	K/M	0.009-89	+++ Exposure to the environment, many products, high conc.
Hair care – Hair oil / cream / lotion / serum	94	31 070	+	+/-	D	K/M	0.8-91	+++ Many products, potentially high conc. in the product
Cosmetics - Foundation	103	36 562	+	+	D	K	17-83	+++ Many products, potentially high conc., daily use
Body care - Cream / lotion / balm	98	38 374	+	+	D	K/M/B	0.3-88	+++ Children, potentially high conc., high consumer exposure
Sun care – Sun cream / - lotion / - gel	14	6 232	+	+	D	K/M/B	0.1-49	+++ high exposure, potentially high conc., Children

Soap and hygejne - Deodorant	101	74 290	+	+	D/I	K/M	0.4-19 10-60	+++ Many products, potentially high conc., inhalation of spray, high exposure to the environment

TABLE 8. Top priority product categories for the substance D6

D6	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Facial care – day cream/lotion	41	22 626	+	+	D	K/M	0.03-22	+++ Consumer interest, daily exposure
Cosmetics - Foundation	40	23 013	+	+	D	K	0.2-48	+++ Consumer interest, potential high concentration
Body care - Cream / lotion / balm	33	11 832	+	+	D	K/M/B	0.003-2	+++ High consumer exposure, children
Sun care – Sun cream / - lotion / - gel	9	6 555	+	+	D	K/M/B	0.03-4	+++ High consumer exposure, children
Sun care – Sun spray	12	6 599	+	+	D/I	K/M/B	0.6	+++ High exposure, children, exposure via respiratory system

TABLE 9. Top priority product categories for the substance Dimethiocone

Dimethiocone	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Facial care – Day cream / lotion	364	204 719	+	+	D	K/M	0.0001%- 10%	+++ Daily exposure, consumer interest, many products
Facial care – lip balm	13	13 898	+	+	D/O	K/M/B	0.6-20% (for lipstick)	+++ Oral/children
Facial care – Night cream	43	17 306	+	+	D	K	1-2%	+++ daily exposure
Hair care - Wax / mud / clay / paste / gum	29	6 773	+	+	D	M/K	10-80 % (div. hair preparations)	+++ Potential high concentration, daily exposure
cosmetick - Primer / fixer	43	20 338	+	+	D	K	24%	+++ Consumer interest, relatively high conc.
Body care - Cream / lotion / balm	322	199 163	+	+	D	M/K/B	0.5-10%	+++ Consumer interest, children, large amount per use, high consumer exposure
Sun care – Sun cream / - lotion / - gel	105	65 235	+	+	D	M/K/B	1-15%	+++ Many products, Consumer interest, children/ large amount per use, high consumer exposure
Sun care – Sun spray	12	5 224	+	+	D/I	M/K/B	1-15%	+++ Children/large amount per use/ inhalation

TABLE 10. Top priority product categories for the substance Drometrizol trisoloxan (the function of the substance in sun care products is as a UV-filter)

Drometrizol trisoloxane	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Sun care – Sun creme / - lotion / - gel	43	32 993	+	+	D	M/K/B	< 15%	+++ Consumer interest, High consumer exposure, children
Solpleje - Solspray	18	11 974	+	+	D/I	M/K/B	< 15%	+++ High consumer exposure, children, respiratory exposure

TABLE 11. Top priority product categories for the substance PEG-10 dimethicone

PEG-10 dimethicone	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Facial care – BB/CC cream	12	25 436	+	+	D	K/M	0.013-5.3	+++ Consumer interest, daily exposure
Facial care – day cream/lotion	13	3 500	+	+	D	K/M	0.013-5.3	+++
Cosmetics - Foundation	76	40 470	+	+	D	K	0.013-5.3	+++ Many products, Consumer interest

TABLE 12. Top priority product categories for the substance dimethicone

PEG-12 dimethicone	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Hair care / hair spray/ heat spray	52	14 402	+	+	D/I	K	0.0016-6.5	+++ Many products
Hairr care - Shampoo	28	3 708	-	+/-	D	K/M/B	0.0016-6.5	+++ Exposure to the invironment

TABLE 13. Top priority product categories for the substance Phenyl trimethicone

Phenyl trimethicone	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Hair care – Hair oil / cream/ lotion / serum	25	10 990	+	+/-	D	K/M	5-11	+++ Consumer interest
Cosmetics - Foundation	31	16 430	+	+	D	K	2-22	+++ Potential high conc, daily use

TABLE 14. Top priority product categories for the substance Trisiloxane

Trisiloxane	Number of products in Kemiluppen	Number of scannings in Kemiluppen	Leave on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women (K) Men (M) Children (B)	Conc. (CIR 2003)	Priority/comments
Facial care – day cream/lotion	12	8 413	+	+	D	M/K/B	-	+++ Daily exposure

2.4.2 Technical functions of the siloxanes

The siloxanes can have different technical functions in the cosmetic product. TABLE 15 below lists the various functions for the individual siloxanes, as indicated in Appendix 1.

TABLE 15 The technical function/use of the selected 12 siloxanes (for reference, see Appendix 1).

Cosmetic ingredient	Technical function in the product
Amodimethicone	Antistatic, hair conditioner, glossing, softener in creams.
Cetyl peg/ppg-10/1 dimethicone	Emulsifier and dispersant. For good adhesion to the skin.
Cyclomethicone	Hair- and skin conditioner, antistatic, softener or solvent. Typically used in personal care, hair products, antiperspirants, skin creams and shampoos.
D4	Hair- and skin conditioner, antistatic, softener and solvent. Typically used in personal care, hair products, antiperspirants, skin creams and shampoos.
D5	Hair- and skin conditioner, antistatic, softener and solvent. Typically used in personal care, hair products, antiperspirants, skin creams and shampoos.
D6	Hair- and skin conditioner, antistatic, softener and solvent. Typically used in personal care, hair products, antiperspirants, skin creams and shampoos.
Dimethicone	Antifoam, softener, skin protection, skin conditioner.
drometrizole trisiloxane	UV-filter
Peg-10 dimethicone	Conditioner in hair and skin care products
Peg-12 dimethicone	Conditioner in hair and skin care products
Phenyl trimethicone	Antifoam, conditioner in hair and skin care products
Trisiloxane	Antifoam, skin conditioner.

As it can be seen from TABLE 15 there is a considerable overlap between the functions of the substances in the cosmetic products, where the common denominator is the use in hair and skin care agents. The substances are typically used as softeners and as an antistatic agent.

However, two substances deviate from the others, as the use of the substance drometrizol trisiloxane is only indicated as UV-filter, while the substance cetyl peg/ppg-10/1 dimethicone is used as emulsifier and despersant.

2.5 Questionnaire survey

A questionnaire survey was made among the Danish trade organisations (VKH, Danish Detergents, Cosmetics and Household industry and the Cosmetics and Hygiene Industry) as well as a small subset of selected Danish cosmetics producers.

The purpose of the questionnaire was to map the use of siloxanes in cosmetic products and to examine how much attention the producers and distributors pay to siloxanes and possible substitution of these in the cosmetic products.

The questionnaire included 6 questions about the use of siloxanes in the trade, and whether it is possible to substitute especially the cyclic siloxanes.

A total of 14 responses to the questionnaires were received from trade organisations (including a response from Cosmetic Europe) and from producers and distributors.

In below TABLE 16 a short summary is given of the reponses to the questionnaires.

TABLE 16. Questions in questionnaire sent out via trade organisations

1	How do you experience the tendency regarding the use of cyclic siloxanes, including D4, D5 and D6, in cosmetic products the last 2-3 years? (Decreasing, Unchanged, Increasing)
	Decreasing: 12 Unchanged: 2 Increasing: 0
2	How do you experience the tendency regarding the use of linear siloxanes (e.g. dimethicone) in cosmetic products in the last 2-3 years? (Decreasing, Unchanged, Increasing)
	Decreasing: 5 Unchanged: 6 Increasing: 3
3	Do you presently experience in the trade an attempt to substitute the cyclic siloxanes? And if so, by which substances?
	Yes: 12 No: 1 No reply: 1
4	Which functions of the cyclic siloxanes can be difficult to achieve, if they are substituted?
	- Smooth shining look / sense without leaving the skin greasy - Easy to distribute on the skin - Good skin compatibility without being essentially dehydrating or degreasing on the skin - Low heat capacity, low heat conduction, low heat evaporation, give a warm feeling on the skin, evaporation of cyclic siloxanes does not induce cooling as other volatile substances - Volatility induce a good release of substances without leaving residues on skin or hair - Low chemical reactivity in low pH or aqueous products give a good stability at high temperature (80 ° C) and a prolonged durability - Lack of colour and odeur gives flexibility to add colour and perfume. - Optimal sensoric satisfaction
5	Do you find it likely that the use of cyclic siloxanes in cosmetics will be substituted by other types of siloxanes (e.g. dimethicone) in connection with the coming regulation under REACH?
	Yes: 12 No: 1 No reply: 1
6	Do you find that consumers demand siloxane-free products? If yes, does this demand concern specific siloxanes or siloxanes in general?
	Yes: 8 No: 5 No reply: 1

The majority replied that there has been a decrease in the use of cyclic siloxanes, including D4, D5 and D6, in cosmetic products over the last 2-3 years. However, there is some disagreement on whether or not there has also been a decrease in the use of linear siloxanes. Five of the survey participants replied that it is decreasing, whereas 6 replied that it is unchanged and 3 that it is increasing. The organisations who experience a decrease argue that the linear siloxanes, e.g. dimethicone, are increasingly used as replacement for the cyclic siloxanes.

All but one feel a tendency in the trade to seek substitution of the cyclic siloxanes by other substances. As possible substitutes are mentioned:

- Linear siloxanes/dimethicones
- Vegetable based ingredients such as oil esters
- Softeners

Linear siloxanes/dimethicones are by far the most mentioned substitute.

A number of properties of the cyclic siloxanes are mentioned, which are difficult to replace by other substances. In particular it is mentioned that the cyclic siloxanes leave skin and hair with a soft and shiny look without greasing. But also other properties are pointed out, such as the fact that it contributes to the ability to distribute the product on the skin etc.

A little more than half of the companies has experienced a consumer demand for siloxane-free products. This is also demanded from the distributors/intermediate producers. For the companies, which experience demands from the consumers, this is in relation to siloxanes in general, but several point out that this may be because the consumers do not know the difference between for instance cyclic and linear siloxanes.

All in all, it seems that the trade is very much aware of the content of cyclic siloxanes in their products, and that other substances are requested for substitution, e.g. dimethicone/linear siloxanes. However, some of the properties which the cyclic siloxanes contribute to the products are difficult to substitute.

2.6 Summary of mapping

2.6.1 Product types, number of products and number of scannings

TABLE 17 shows a list of each of the 12 selected siloxanes and the the product categories have been prioritized. The table also indicates the amount of products that are found within the categories, and how many times consumers have scanned the products within each category.

TABLE 17. Summary for the use of the substances within cosmetic product categories and number of products/numbers of consumer scannings within the categories. Data from the “Kemiluppen” database.

	Amodimethicone	Cetyl peg/ppg-10/1dimethi-cone	Cyclomethicone	D4	D5	D6	Dimethicone	Drometrizole trisiloxane	Peg-10 dimethicone	Peg-12 dimethicone	Phenyl trimethicone	Ttrisiloxane	Total (incl. possible overlap)
NUMBER OF PRODUCT TYPES in total	10	23	28	5	47	32	56	8	14	25	28	15	
NUMBER OF PRODUCTS in total	350	148	184	23	854	242	2458	85	142	159	214	39	
Prioritised product categories for the individual siloxanes indicating *number of products/numbers of scannings* in Kemiluppen for each substance													
Facial care – BB/CC cream		8 / 5923			21 / 14550				12 / 25436				41 / 45909
Facial care – Day cream / lotion			23 / 13236		69 / 32 621	41 / 22626	364 / 204719		13 / 3500			12 / 8 413	510 / 276702
Facial care – Lip balm							13 / 13898						13 / 13898

	Amodimethicone	Cetyl peg/ppg-10/1dimethicone	Cyclomethicone	D4	D5	D6	Dimethicone	Drometrizole trisiloxane	Peg-10 dimethicone	Peg-12 dimethicone	Phenyl trimethicone	Ttrisiloxane	Total (incl. possible overlap)
Facial care – Night cream							43 / 17306						43 / 17306
Baby care-baby lotion/-cream			1 / 395										1 / 395
Hair care – balm / conditioner / treatment / mask	182 / 66505			6 / 133	73 / 19334								261 / 85972
Hair care – Hair spray / hair spray / heat spray	14 / 4949									52 / 14402			66 / 19351
Hair care – Wax / mud / clay / paste / gum							29 / 6773						29 / 6773
Hair care - Hair mousse	12 / 5464												12 / 5464
Hair care – Hair oil / cream / lotion / serum			25 / 20477	12 / 3064	94 / 31070						25 / 10990		156 / 65601

	Amodimethicone	Cetyl peg/ppg-10/1dimethi-cone	Cyclomethicone	D4	D5	D6	Dimethicone	Drometrizole trisiloxane	Peg-10 dimethicone	Peg-12 dimethicone	Phenyl trimethicone	Ttrisiloxane	Total (incl. possible overlap)
Hair care-hair sham-poo	86 / 49850									28 / 3708			114 / 53558
Cosmetic – Founda-tion		59 / 2700			103 / 36 562	40 / 23013			76 / 40470		31 / 16430		309 / 119175
Cosmetic – Primer / fixer							43/ 20338						43 / 20338
Body care – Cream / lotion / balm		11 / 2 953			98 / 38374	33 / 11832	322 / 199163						464 / 252322
Sun care – Sun cream / - lotion / - gel					14 / 6232	9 / 6555	105 / 65235	43 / 32993	43 / 32993				214 / 142008
Sun care – Sun spray						12 / 6599	12 / 5224	18 / 11974	18 / 11974				60 / 35771
Soap and hygiene - Deodorant			71 / 74238		101 / 74290								172 / 148528

If the same product category is prioritised for several of the selected substances, this product type will be selected for further analysis.

From the mapping of the 12 selected siloxanes it can be seen that the siloxanes are most extensively used in the product categories:

- Facial care
    - Day cream/lotion
- Body care
    - Cream/lotion/balm
- Cosmetics
    - Foundation
- Hair care products and in particular:
    - Hair oil/cream/lotion/serum
    - Shampoo
    - Balm
- Sun care
    - Sun cream/-lotion/-gel

The product category facial care, day cream, is the category with most products containing one or more of the selected 12 siloxanes. The substance used in most products is dimethicone, which is used in 2,458 reported products from ”Kemiluppen”. D5 is det second most used substance with use in 854 products. The least used of the 12 selected siloxanes is D4, used in only 23 products distributed over a total of 5 product categories, mainly hair care products.

2.6.2 Exposure

2.6.2.1 Exposure route

Dermal exposure is relevant for all product types, having content of one or more of the 12 prioritised substances.

Inhalation exposure may be relevant for spray products within the category hair care, deodorants or the category for sun care.

Oral exposure is relevant for lipstick, lip balm and sun stick, but can also be relevant particularly for children in connection with body lotion/cream and sun care products, where licking around the mouth and licking of fingers may result in oral exposure.

In order to obtain assessment of more exposure routes than the dermal exposure route it is relevant to priorities spray products (inhalation) and lip substance/lip balm (oral exposure), and especially in relation to children´s oral exposure also to include body lotion/cream and sun care products.

2.6.2.2 Extent of exposure

When prioritising products, the selection of products should furthermore be made from the amount of exposure, as the selection of products with the highest exposure volume will have more interest in connection with risk assessment. Thus, leave-on products used in relatively large amounts and with high frequency (e.g. daily use of creams/lotion on larger areas of skin) will be more interesting than for instance hair dying products, which are wash-off products and which are not used on a daily basis, or makeup for small areas (eye shadow and eye lash products), which are only used in very small amounts.

Furthermore, some products will contain several of the siloxanes, which may lead to combined exposure resulting in combination effects from the substances.

2.6.3 Target groups

Children, and particularly children below 3 years, are considered a relevant target group for risk assessment for use of siloxanes in cosmetic products as small children may be more sensitive to the potential adverse effects from the substances, which is especially relevant for substances such as endocrine disruptors or chronic neurotoxicants. Also, small children will typically be relatively more exposed than adults as the body surface per kg bodyweight of children is higher than for adults, leading to higher exposure to cosmetic products for dermal application. Furthermore, the behaviour of small children will increase oral exposure to the products.

Pregnant women are considered as another target group for risk assessment, as their unborn baby may be exposed to product ingredients via the mother's exposure to a cosmetic product.

2.6.4 Environmental exposure/hazard

Environmental exposure to cosmetic ingredients should primarily focus on the used amount of the substances, i.e. products used frequently/daily and of a certain amount each time.

Unlike human exposure, wash-off products such as hand/body soap and shampoo will be particularly relevant, as these products will be released directly into the wastewater; they are used frequently and in relatively large amounts each time.

Another group of products which is particularly relevant is the sun care products for full body use, as the amount used is large and the environment may be directly exposed during bathing in freshwater or sea water.

Finally, products with high concentrations of the siloxanes or products used widely in the population will have an potential for increased release to the enviroment.

2.6.5 Prioritisation

Thus, from the considerations above the following aspects should be considered:

- Relevant siloxanes in the product type (section 2.2 og section 2.6.1)
- Number of products in the market (section 2.6.1.)
- Consumer interest/number of scannings (section 2.6.1.)
- Exposure conditions (section 2.6.2)
- Special target groups (section 2.6.3)
- Exposure to the environment (section 2.6.4)

Using these aspects for prioritisation the following product types were selected as relevant to further assessment in the project:

Facial care, day cream/lotion
Cyclomethicon, D5, D6, dimethicone, PEG 10 dimethicone, trisiloxane; many products/scannings, leave-on, high exposure.

Body care/lotion
Cetyl peg/ppg-10/1 dimethicone, D5, D6, dimethicone; many products/scannings, leave-on, high exposure incl. children.

Hair care, hair oil/cream/lotion/serum
Cyclomethicone, D4, D5, phenyl trimethicone; many products/scannings.

Hair care, balm/conditioner
Amodimethicone, D4, D5; many products/scannings.

Sun care, sun cream/lotion/gel
D5, D6, dimethicone, drometrizol trisiloxane, PEG 10 dimethicone; many products/scannings, leave-on, high exposure incl. children, oral exposure, exposure to the environment.

Sun care/sun spray
D6, dimethicone, drometrizol trisiloxane, PEG 10 trisiloxane; many products/scannings, leave-on, high exposure incl. children, inhalation and oral exposure, exposure to the environment.

Deodorants/antiperspirants
Cyclomethicone, D5; many products/scannings, high concentration, inhalation, exposure to the environment.

2.6.6 Selection of specific products

During the selection of specific products for further analysis of the content of siloxanes, 40 products were selected from “Kemiluppen” among the above product categories.

However, it was only possible to buy analytical reference substances for the ingredients:

Cyclomethicone
D4
D5
D6
Drometrizole trisiloxane
Phenyl trimethicone
Trisiloxane

which limited the focus on product types with the content of these substances, when specific products were selected for analysis.

A total of 40 specific products were selected for further chemical analysis from “Kemiluppen” within the prioritised product categories:

Facial cream/lotion (cyclomethicone, D5, D6, dimethicone, trisiloxane)	*3 products*
Foundation (D5, D6, phenyl trimethicone)	*4 products*
Body care:	
Creams/lotion (D5, D6, dimethicone)	*4 products*
Hair care:	
Balm/conditioner (D4, D5)	*5 products*
Hair spray (D5, dimethicone, phenyl trimethicone)	*3 products*
Hair oil/lotion (cyclomethicone, D4, D5, phenyl trimethicone)	*4 products*
Hair shampoo (dimethicone)	*3 products*
Sun care:	
Sun stick (dimethicone, drometrizole trisiloxane)	*2 products*
Sun spray (D6, dimethicone, drometrizole trisiloxane)	*3 products*
Sun cream/lotion (D5, D6, dimethicone, drometrizole trisiloxane)	*5 products*
Deodorant/antiperspirant (cyclomethicone, D5)	*4 products*

Products containing dimethicone were also prioritised even if a reference substance was not available for this polymer, as dimethicone may contain possible residue concentrations of cyclic siloxanes from the manufacturing process of dimethicone.

A total of 50 products in the above categories were purchased, 40 of these were then selected for chemical analysis after the actual declaration of the products had been studied. The products were primarily bought at three different netshops of Danish dealers, but it is estimated that the majority of the products can also be bought in physical shops on the Danish market.

The substances given in brackets above indicate that the products are mainly selected because of the use of these substances in this product type. When selecting, the products having a declared content of siloxanes at the top of the declaration were preferred, as this indicates a high content of the substance. Also, specific products having several siloxanes on the declaration list were preferred for analysis.

2.6.7 Regulatory status of the selected siloxanes

Several of the selected siloxanes are subject to regulatory provisons either in connection with the cosmetic regulation, or in in connectiom with the CLP and the REACH regulation.
An overview of the regulatory status is given below in TABLE 18.

TABLE 18. Classification, restriction for use and current regulatory suggestions for limitations of use of the selected siloxanes.

Name CAS	Harmonised classification	REACH dossier classification	Specific current and coming limitations for use
Cyclic siloxanes			
D4 Octamethyl-cyclotetrasiloxane CAS: 556-67-2	Aquatic Chronic 4;H413 Repr. 2;H361 fertility	Flam. Liq. 3;H226 Repr. 2;H361 fertility Aquatic Chronic 4;H413	Banned for use in cosmetic products, Annex II in the Commission's regulation (EU) 2019/831 (applicable from May 2019). Use restriction, REACH Annex XVII: Banned in rinse-off cosmetic products in concentrations at or above 0.1%. Suggestion for limitation of use, REACH: Leave-on care products and other consumer products with D4/D5/D6 in concentrations > 0.1% cannot be marketed.
D5 Decamethyl- cyclopentasiloxane CAS: 541-02-6	-	No classification	Use restriction, REACH Annex XVII:: Banned in rinse-off cosmetic products in concentrations at or above 0.1%. Suggestion for limitation of use, REACH: Leave-on care products and other consumer products with D4/D5/D6 in concentrations > 0.1% cannot not be marketed
D6 Dodecamethyl- cyclohexasiloxane CAS: 540-97-6	-	No classification	Suggestion for limitation of use, REACH: Leave-on care products and other consumer products with D4/D5/D6 in concentrations > 0.1% cannot be marketed. Furthermore, wash-off and rinse-off cosmetic products with D6 in concentrations > 0.1% cannot not be marketed.
Cyclomethicone CAS:69430-24-6	-	Not registered	See D4/D5/D6 which are components in cyclomethicone.
Acyclic siloxanes			

Dimethicone (Dimethyl siloxane) 9006-65-9, 63148-62-9; 9016-00-6	-	Not registered	-
Drometrizole trisiloxane 155633-54-8	-	Not registered	Danish act No. 803 of 21/06/2013 and the Council's cosmetic regulation (EU) No. 1223/2009, Annex VI, approved as an UV-filter with a maximum content of 15 %.
Phenyl trimethicone 2116-84-9	-	No classification	-
Trisiloxane, Octamethyl- trisiloxane 107-51-7	-	Flam. Liq. 3;H226	Based on a REACH dossier evaluation: further testing according to Annex XI is requested from the REACH registrant.

3. Analysis of siloxanes in cosmetic products

3.1 Analysis of siloxanes

Based on the knowledge obtained in connection with mapping of the use of siloxanes in the different product categories of cosmetics, six specific siloxanes (TABLE 19) were selected for quantitative analysis. At the same time, the reference substances were selected on the basis of which substances can be analysed according to the analysis method of the laboratory described in section 3.1.2.

Three out of six of the specific siloxanes are cyclic siloxanes and form the three primary components in cyclemethicone (Appendix 1.3). The remaining three reference substances are linear or ramified siloxane compounds that are bound to the chemical structures with other functions than the molecular basic structure of siloxanes, $-(CH_3)_2SiO-$ (See TABLE 19).

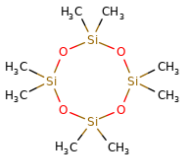
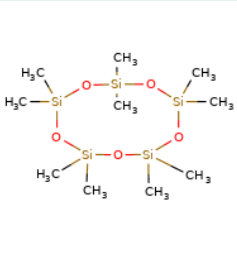
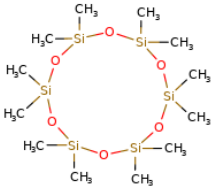
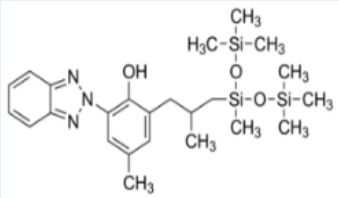
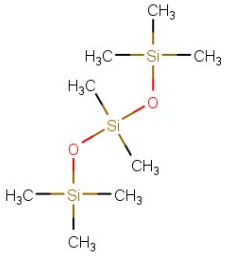
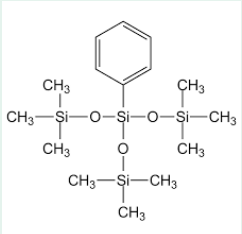
Apart from quantitative determination of specific siloxanes, a GC-MS screening was carried out in order to identify other siloxane compounds, which may be relevant for assessment of exposure via skin contact with or without oral intake of the product. As an example, short-chained, linear siloxanes could potentially be present, as in smaller amounts they could be a component from dimethicone. These short-chained linear siloxanes can be relevant to environmental and consumer risk assessment.

Dimethicone

Dimethicone, which by far is declared in most of the selected products, consists of linear siloxanes with varying chain-lengths (see Appendix 1.7). As the average molecular weight can vary from 5,000 to 100,000, which approximately corresponds to average chain-lengths from 67 to 1,351 units of $-(CH_3)_2SiO-$ (L67 – L1351), it is to be expected that the content of low molecular linear siloxanes also may vary in dimethicone.

As the analysis by GC-MS is limited to volatile and semi-volatile siloxane compounds, it will not be possible from the analysis results of linear siloxanes to estimate the content levels of dimethicone in the products. The results can only be used to obtain knowledge about the content of the low-molecular linear siloxanes, whose presence may be caused by addition of dimethicone to the products. From the analyses, cyclic siloxanes are also identified and they can be residual products in dimethicone.

TABLE 19. Reference substances of specific siloxanes used for quantitative determination

Siloxane	CAS-No.	Molecular structure
D4	556-67-2	
D5	541-02-6	
D6	540-97-6	
Drometrizole trisiloxane	155633-54-8	
Trisiloxane	107-51-7	
Phenyl trimethicone	2116-84-9	

3.1.1 Sample preparation

From the homogenised product, representative sub-samples were weighed for each product. Then the sub-sample was extracted with dichlormethan containing internal standard. Dilutions of extracts were subsequently made with dichlormethane containing internal standard in order to obtain a concentration of specific siloxanes that are within the calibaration area of the method.

3.1.2 Analytical method

The analysis of cosmetic products was carried out by gas chromatography combined with mass selective detection GC-MS (scan mode). Ions in the range of 100 – 800 m/z were detected. Quantification was carried out by calibration curve from specific siloxane compounds, which is indicated in TABLE 19. Other siloxane compounds, identified by means of the NIST library (see section below), were calculated as equivalents to one of the selected reference substances with similar chemical structure (TABLE 19). Therefore, quantification of the individual siloxanes analysed without available reference substance must be seen as semi-quantitative, as the response factor of the individual siloxanes may vary in the analysis.

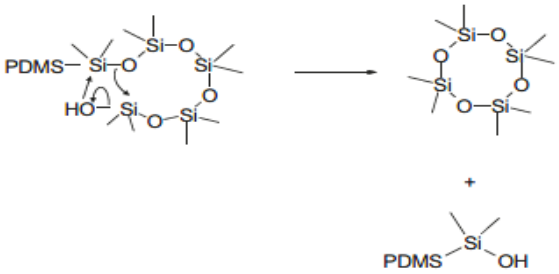
Detectable siloxanes in the products can be idendified by comparing current mass spectra with mass spectra in the NIST library, which is a database with mass spectra for more than 500,000 chemical compounds. In order to examine the agreement between a given spectrum and the NIST library, a hit rate is indicated between an unkown substance and the library reference. The hit rate is a mathematical calculation of the agreement between the reference spectrum of a substance in the NIST library and the spectrum of the substance in the analysis. The identification from the NIST library is considered to be indicative. For final positive identification a substance specific analysis with reference substances should be made.

The detection limit of siloxanes is 50 mg/kg, with the exception of the cyclic siloxanes D7 to D18, linar siloxanes and siloxane X (TABLE 21), where the detection limit is 5 mg/kg. Siloxane X is a siloxane compound that structurally is similar to phenyl trimethicone. The uncertainty of the analyses is in general estimated to 30% RSD and is highly matrice dependents. %RSD for double determination of each single product can be found in the table in Appendix 2.

When analysing cyclic siloxanes it is important especially to be aware of blind values. Blind values may arise as the cyclic siloxanes may e.g. be released by abrasion from the column material used for gas chromatographic analyses. Blind values are controlled by analysing blank tests containing neither test material nor reference material.

Cyclic siloxanes may form, if linear siloxanes with a free end-put hydroxyl group react with themselves and thereby release a cyclic siloxane (see Figur 3.1).[2] The released cyclic siloxanes may vary in size. If a product contains this type of linear siloxane, then there will be a risk of cyclic siloxanes forming in the product. The formation of cyclic siloxanes is a non-reversible reaction, and the reaction speed will increase as a function of temperature. It cannot be ruled out that above reaction also may occur during the analyses, as the linear siloxanes are subject to relatively high temperature during the analysis. Therefore, there is a risk of false positive. However, a review of the analysis results and the declaration of the products do not suggest that this is the case (see section 3.1.4.1).

[2] H.M.Brothers Jr. et. al., J. Chromatgr. A 1441 (2016) 116-125 og H.M.Brothers Jr. et al., International Journal of Cosmetic Science. 2017, 39, 580-588.



FIGUR 3.1 Release of cyclic siloxane (D4). PDMS = Polydimethylsiloxane. **Fejl! Bogmærke er ikke defineret.**

3.1.3 Overview of the analysis results

The analysis results are indicated in TABLE 20 as an average of two analysis results (double determination) carried out for each product.

TABLE 20. Analysis results (mg/kg) for content of siloxanes and siloxane compounds in cosmetic products (10.000 mg/kg = 1%). D = Dimethicone, DOH = Dimethiconol, A = Other polymers. [1)] Content is determined quantitatively. [2)] Content is determined semi-quantitatively. * Siloxane appears on the product declaration - means no indication.

Product type	Product No.	D4[1)]	D5[1)]	D6[1)]	Trisiloxane[1)]	Dromethrizole trisiloxane[1)]	Phenyl trimethicone[1)]	Siloxane X[2)]	D3[2)]	Sum of cyclic siloxanes[2)]	Size of cyclic siloxanes	Sum of linear siloxanes[2)]	Chain-lengths of siloxanes	Declaration of siloxane-polymers
Facial cream	1	<50	490	28 000*	<50	650	140*	<5	810	80	D7	2 600	L5-L15	D, A
	2	<50	90 000*	55 000*	<50	1 100	240	<5	2 600	110	D7	4 500	L5-L19	D, A
	3	200	70	<50	800*	210	130	<5	130	<5	-	2 600	L4-L18	D
Deodorant	36	260	369 000*	<50	<50	<50	<50	<5	<50	<5	-	<5	-	-
	37	5 900	910 000*	990	<50	<50	<50	<5	5 800	<5	-	<5	-	D
	38	400	319 000	1 400	<50	780	<50	<5	<50	<5	-	<5	-	D, DOH
Foundation	5	3 300	262 000*	12 000	<50	80	890	1 000	1 900	330	D7-D13	410	L5-L13	A
	6	410	14 000*	142 000*	<50	<50	<50	<5	5 300	370	D7-D14	90	L8-L13	A
	7	<50	70	100	<50	1 600	28 000*	5 700	1 200	240	D7-D10	8 800	L4-L16	-
	40	4 600	264 000*	13 000	57 000*	650	1 900	<5	1 700	290	D7	16 000	L7-L18	D
Hair balm	12	2 800	870 000*	7 900	<50	80	<50	<5	500	1 100	D7-D15	<5	-	DOH
	13	580	857 000*	11 000	<50	70	3 500*	3 200	2 000	640	D7-D13	90	L6	D
	15	260	66 000*	900	90	90	470*	600	470	<5	-	2 800	L5-L16	D, A
	16	340	280 000*	15 000	<50	<50	14 000*	6 700	160	<5	-	<5	-	-
	42	192 000*	232 000*	6 600*	<50	<50	<50	<5	11 000	960	D7-D18	240	L5-L13	DOH
	43	20 000*	298 000*	5 300	200 000	70	180	<5	5 000	1 200	D7-D18	30	L5	D, DOH
Hair spray	17	<50	<50	<50	<50	<50	1 900*	110	<50	<5	-	<5	-	-
	18	210	68 000*	610	<50	<50	<50	20	260	<5	-	<5	-	A
	19	<50	<50	<50	<50	<50	930*	830	100	<5	-	<5	-	A

Product type	Product No.	D4[1)]	D5[1)]	D6[1)]	Trisiloxane[1)]	Dromethrizole trisiloxane[1)]	Phenyl trimethicone[1)]	Siloxane X[2)]	D3[2)]	Sum of cyclic siloxanes[2)]	Size of cyclic siloxanes	Sum of linear siloxanes[2)]	Chain-lengths of siloxanes	Declaration of siloxane-polymers
Hair oil	20	398 000*	2 500*	<50	290	<50	<50*	<5	15 000	<5	-	<5	-	
	21	238 000*	150 000*	10 000	490	<50	<50	<5	16 000	1 000	D7-D14	<5	-	-
	22	450	>950 000	17 000	<50	100	<50	<5	470	1 200	D7-D14	80	L10	D
	23	50	158 000*	<50	130	<50	400*	410	280	<5	-	1 600	L6-L14	D, DOH, A
	44	<50	360*	530	200*	<50	<50*	10	<50	<5	-	<5	-	A, DOH
	45	<50	<50*	<50	<50	<50	<50	<5	<50	<5	-	<5	-	-
Hair sham-poo	24	<50	<50	<50	<50	<50	<50	<5	<50	<5	-	<5	-	D
	25	<50	<50	<50	<50	<50	<50	<5	<50	40	D11-D14	<5	-	D
	26	<50	<50	<50	<50	<50	<50	<5	60	140	D10-D15	<5	-	D
Body cream	8	<50	9 700*	230	<50	<50	<50	<5	100	<5	-	<5	-	D
	9	<50	1 700*	120	<50	<50	<50	<5	50	<5	-	<5	-	-
	10	60	570	32 000*	<50	<50	<50	<5	960	<5	-	<5	-	-
	11	<50	350	15 000*	<50	<50	<50	<5	70	<5	-	<5	-	-
	41	<50	<50	120	<50	80	90	<5	<50	<5	-	1 400	L5-L18	D
Sun cream	33	<50	<50	<50	<50	980*	<50	<5	50	<5	-	<5	-	D
	34	<50	<50	<50	<50	<50*	<50	<5	<50	<5	-	<5	-	D
	35	100	80	340	<50	3 400	740	<5	150	<5	-	25 000	L4-L21	D
	46	17 000*	160 000*	3 200*	<50	1 100	80	<5	2 900	170	D7-D8	26 000	L5-L20	D
Sun spray	28	<50	<50	<50	<50	6 900*	<50	<5	<50	<5	-	<5	-	-
	29	<50	1 800	2 3000*	<50	24 000*	270	<5	620	<5	-	2 500	L5-L14	D
	30	<50	<50	<50	<50	<50	<50	<5	<50	<5	-	<5	-	D

3.1.4 Review of quantitive analysis results

3.1.4.1 Cyclic siloxanes D4, D5 and D6

25 of 40 products were declared to have a content of cyclic siloxanes; either as a single component of D4, D5 or D6 or as a mixture of the three cyclic siloxanes.
The term cyclomethicone is used for mixtures of the three cyclic siloxanes D4, D5 and D6. It is consequently not possible to determine from the declaration on the product which cyclic siloxanes the products contain, if the product is declared with cyclomethicone.

The analysis results confirm the product declaration of all products except for one product (product 45), where cyclic siloxanes are mentioned. Furthermore, the analysis results indicate that most of the products have low concentrations (<0.6% for D4, <0.2% for D5, <1.7% for D6), although they have not been included in the declaration. In 21 out of 29 of the products with low concentrations of either D4, D5 or D6, at least one of the three (other) cyclic siloxanes were present in significant concentrations. That may be because the cyclic siloxanes that are added to the product are not pure but contain residues of other cyclic siloxanes. The cyclic siloxanes may also appear as residues in dimethicone, since cyclic siloxanes can be used for the production of that. However, product 7 is an exception, as residues of cyclic siloxanes (<0.01%) appear even if cyclic siloxanes or dimethicone are not stated on the declaration. However, in very low concentrations. The analyses showed that the product also contains the siloxane compound phenyl trimethicone and to a lesser extent another siloxane compound, which in this report is named siloxane X (see TABLE 21). Structurally, it resembles phenyl trimethicone.

As mentioned before, it is possible that cyclic siloxanes may form in the product, if the products contain a certain type of siloxanes (section 3.1.2). Dimethiconol contains siloxanes with free hydroxyl groups, which can particularly cause formation of cyclic siloxanes at intramolecular reaction. Therefore, products that contain dimethiconol and at the same time have a low content of cyclic siloxanes, are particularly interesting, as they indicate to which degree the formation occurs.

In 6 of the purchased products (product 12, 23, 38, 42, 43 and 44), dimethiconol is stated on the product declaration. When reviewing the analysis results of cyclic siloxanes in the products with dimethiconol it is seen that the 6 products contain several different cyclic siloxanes. However, as 5 out of 6 products contain more than 15% D5 (product 12, 23, 38, 42 and 43), it is not possible to determine if the content of cyclic siloxanes exists in these products as free D5 or as a concequence of the formation from dimethiconol.

Tests to change the temperature on the injection port of the gas chromatograph had no effect in terms of possible formation of cyclic siloxanes. Theoretically, an increase in temperature should give increased formation of cyclic siloxanes, whereas a reduction in temperature should give reduced formation of cyclic siloxanes. This was not observed, and it is therefore estimated that the effect was not substantial during the current series of analyses. Product 44, which is also based on dimethiconol, only shows a content of D5 and D6 in very low concentrations (<0.05 %). That indicated that cyclic siloxanes are not created during the analyses.

D4
Five products have a declared content of D4 (product 20, 21, 42, 43 and 46). The analysis results confirm the declaration of the five products, as the content of D4 in these products is 2 - 40%. Apart from the mentioned five products, D4 was found in 17 other products, where D4 is not declared. The content of D4 in these products is 0.005 - 0.59%, and a content of D5 and/or D6 is also seen.

As it can bee seen in TABLE 18 in section 2.6.7, D4 may not be used in cosmetic products according to Annex II in the Commission's Regulation (EU) 2019/831. However, article 17 in the Regulation does concede that the unintentional presence of a small amount of a prohibited substance may be allowed, when it is assured that it is safe to use the product. However, the next Regulation regarding D4 and D5 in wash-off products under REACH does not have a similar concession. The limit value is set at 0.1%.

D5
According to the D5 analysis results, 29 products contain D5 with a content of between 0.007% to above 95% (see TABLE 20). D5 is stated on the declaration of 20 of the products. Two products contain more than 31% of D5 (product 22 and 38), and D5 is not included in the declaration. However, the declarations do indicate that the product contains cyclomethicone. According to the declaration, product 21 contains D5 and cyclomethicone. A single product (product 45) is declared to contain D5 although the analyses did not show any presence of D5 in the product.

Currently, there are no restrictions on the use/content of D5 in cosmetic products, but as mentioned in the section about D4, the content of D5 must not surpass 0.1% in wash-off products from 31 January 2020. In this project, D5 >0.1% was found in all 6 hair balm products, but as they are leave-on products (not to be washed off) they would not come within that regulation. However, there is a REACH proposal concerning the content of D4, D5 and D6 in leave-on cosmetic products (and D6 in wash-off) (see TABLE 18) - also with a limit value of 0.1%. The proposal has not yet been adopted.

D6
The analysis results of D6 show that 26 products contain D6 at a level of 0.001 - 14% (see TABLE 20). D6 is stated on the declaration of 8 of the products, and the analysis results show a content of 0.3 - 14%. Furthermore, the declarations of three of the products (product 21, 22 and 38) included cyclomethicone. The analysis results of these three products show a content of D6 in the range of 0.14 – 1.5%.

Currently, there are no restrictions on the use/content of D6 in cosmetic products, but there is a REACH proposal concerning the content of D6 in cosmetic products (see TABLE 18). If the proposal is adopted, then the content of D6 must not surpass 0.1%. In this project, a content of D6 >0.1% has been seen in 5 hair balm products (12, 13, 16, 42 and 43).

Cyclomethicone
Three products have a declared content of cyclomethicone (product 21, 22 and 38). The analysis results of these products showed that the products contain D4, D5 and D6. However, D4 and/or D5 are the primary components with a content of more than 15%. The content of D6 in these three products is lower than 1.5%.

No specific rules exist for cyclomethicone, but as cyclomethicone contains D4, D5 and D6, the content of these must comply with the current substance limits. Product 21 has a D4 content of 23.8%, and as described above, it is illegal to market the product.

3.1.4.2 Trisiloxane, drometrizole trisiloxane and phenyl trisiloxane
16 of the 40 products were declared to contain trisiloxane, drometrizole trisiloxane and/or phenyl trisiloxane, and they were chosen for quantitative analyses. With the exception of two products (product 20 and 44), the analysis results confirm the declarations on the products. Furthermore, a considerable content of trisiloxane was found in one single product, and trisiloxane had not been stated on the declaration of the product (product 43).

Trisiloxane

Two products have a declared content of trisiloxane (product 40 and 44). The analysis results confirm the declaration of the products; however, the content of one of the products is only 0.02%, whereas the other product contains 5.7%. One product (product 43) contains 20% trisiloxane, but trisiloxane does not appear on the declaration. Apart from the four mentioned products, trisiloxane was found in five other products. The content of trisiloxane in these products is 0.009 – 0.05%. The presence of trisiloxane in low concentrations in products may be due to the use of dimethicone in the products. At present, there are no restrictions on the use/content of trisiloxane in cosmetic products.

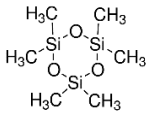
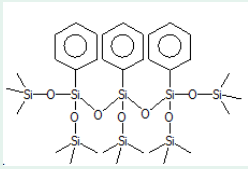
Drometrizole trisiloxane
Three products have a declared content of drometrizole trisiloxane (product 28, 29 and 33) with a content of 0.01 – 2.4% (see TABLE 20). Apart from the mentioned four products, drometrizole trisiloxane was found in 15 other products. The content of drometrizole trisiloxane in these products is 0.007 – 0.3%. The substance is an approved UV filter, and none of the products surpass the upper content limit of 15% as stated in the cosmetics regulations.

Phenyl trimethicone
The analysis results of phenyl trimethicone show that 17 products contain phenyl trimethicone with a content of 0.008 – 2.8% (see TABLE 20). In connection with 8 of these products, phenyl trimethicone is stated on the declaration. Two products do not contain phenyl trimethicone although it is stated on the declaration (product 20 and 44). At present, there are no restrictions on the use/content of phenyl trimethicone in cosmetic products.

3.1.5 Review of results of GC-MS screening

Screening analyses were carried out by GC-MS for all products with the purpose of identifying siloxanes that are not declared on the products (see TABLE 21). The screening analyses showed a content of other cyclic siloxanes from D7 to D18 as well as D3. Linear siloxanes L4 to L20 were also identified for a number of products. Furthermore, a single siloxane compound, siloxane X, was identified. The analysis results are indicated in TABLE 20.

TABLE 21. Siloxanes identified by GC-MS-screening.

Siloxane	CAS-No.	Molecule formula /structure
D3	541-05-9	
D_n, n = 7,..,18 (cyclic siloxanes)	-	$D_n = (CH_3)_2SiO$
L_n, n = 4,…20 (linear siloxanes)	-	$L_n = (CH_3)_3SiO\text{-}((CH_3)_2SiO)_{n-2}\text{-}Si(CH_3)_3$
Bis[trimehtylsiloxy]trimethylsiloxyphenylsiloxane (Siloxane X)	-	

The content of identified siloxanes mentioned above is calculated against one of the reference substances included in the analysis (TABLE 19). Consequently, the screening results must be considered as semi-quantitative. The response factor from the analysis of certain substances is close to the response factor of the specific siloxane, whereas the response factor of other substances is far from that and will consequently result in a more uncertain determination of

the concentration in the sample. On that basis, the content of linear siloxanes is stated as a sum with information about which chain-lengths were observed. The content is indicated as trisiloxane equivalents, as the content is calculated according to the standard of trisiloxane. Therefore, siloxane results identified by GC-MS screening are not directly comparable to other quantitative results.

3.1.5.1 Other cyclic siloxane compounds

The analysis results of D3 show that 29 products contain D3 with a content of 0.005-1.5% (see TABLE 20). D3 results are semi-quantitative, as calculations are made from the reference substance D4. Furthermore, a number of major cyclic siloxanes were found. Their content has been stated as a sum and calculated from the reference substance D6. The sum does not surpass 0.12% in the products.

In general, the cyclic siloxanes appear with a variation of sizes at the same time. Typically, they also appear in products with a high content of one of the three cyclic siloxanes D4, D5 or D6 and/or in products declared to contain dimethicone.

3.1.5.2 Other linear siloxane compounds

Like the cyclic siloxanes (section 3.1.5.1), the linear siloxanes appear with varying chain-lengths typically at the same time and have been found in a large number of the products. Contents of up to 2.6% have been seen, and that is a sum calculated from the reference substance trisiloxane. Results of the linear siloxanes are consequently semi-quantitative.

Products with a content of linear siloxanes correlate with the products being declared to contain dimethicone with the exception of a single product (product 17). Some products, such as shampoo, are declared with dimethicone, although the analyses did not detect any linear siloxanes. That may be due to a very low content of dimethicone, and therefore the content of minor linear siloxanes is comparably lower and below the detection limit.

The composition of dimethicone, as used in the products, may vary as the average molecular weight can be 5 000 – 100 000. At the same time, the linear siloxanes that can be detected by GC-MS are limited. Therefore, the analysis results cannot assess the combined content of dimethicone. Another analysis technique would be needed for that task.

3.1.5.3 Siloxane compounds with other functions

The siloxane compound siloxane X (TABLE 21) was identified in 10 products with a content of 0.001 – 0.7%. The siloxane compound appeared in products that also contain phenyl trimethicone. The two siloxane compounds have structural similarities. The siloxane X results are semi-quantitative, as calculations were carried out on the basis of the reference substance phenyl trimethicone.

4. Risk assessment for consumers

4.1 Exposure assessment

For exposure assessment of the chosen products, the starting point is the guidelines for risk assessment of cosmetic products from EU´s scientific committee for safety of consumer products (SCCS Notes of Guidance, 10th edition, 2018). Exposure estimates for a number of cosmetic product categories are indicated and used further as indicated in TABLE 22 below.

For the product types where the dermal exposure is regarded as relevant to children, the exposure estimate is converted to this taking into account the higher surface to body weight ratio of children. Within body care and sun protection, where an oral exposure to children is considered to be likely, exposure estimates are indicated for oral exposure from children's sucking behaviour on fingers/hands. Furthermore, for products creating aerosols in connection with use (e.g. pump sprays and pressure spray cans) estimates are indicated for exposure by inhalation. Further details regarding calculation of these exposure estimates are given below in the table.

TABLE 22 Exposure estimates for dermal and oral exposure as well as inhalation for the selected products

Product category	Dermal	Dermal	Oral	Inhalation
	Adult	Converted to child 1 year*	Children 1-2 years	Conc. 2 min (mg/m^3) Conc. 18 min (mg/m^3) Dose mg/kg bw/day
Facial day cream/lotion		-	-	-
Daily amount (g/day)	1.54			
Retention factor	1.00			
Daily exposure (g/day)	1.54			
Daily exposure (mg/kg bw/ day)	24.14			
Foundation		-	-	-
Daily amount (g/day)	0.51			
Retention factor	1.00			
Daily exposure /g/day)	0.51			
Daily exposure (mg/kg bw/ day)	7.90			
Body care, creams/lotion		-	-	-
Daily amount (g/day)	7.82			
Retention factor	1.00			
Daily exposure (g/day)	7.82			
Daily exposure (mg/kg bw/ day)	123.2	197	11	
Hair balm/conditioner		-	-	
Daily amount (g/day)	3.92			
Retention factor	0.01			1 960 mg/m^3
Daily exposure (g/day)	0.04			392 mg/m^3
Daily exposure (mg/kg bw/ day)	0.67			2.39 mg/kg bw/day

Hair spray, spray, pressure tank		-	-	
Daily amount (g/day)	6.8			
Retention factor	0.1			3 400 mg/m^3
Daily exposure (g/day)	0.68			680 mg/m^3
Daily exposure (mg/kg bw/day)	11			4.08 mg/kg bw/day
Hair spray, spray, pump spray		-	-	
Daily amount (g/day)	3.6			
Retention factor	0.1			1 800 mg/m^3
Daily exposure (g/day)	0.36			360 mg/m^3
Daily exposure (mg/kg bw/day)	6			2.16
Hair oil-lotion (hair styling products)	4.0	-	-	
Daily amount (g/day)	0.1			2 000 **mg/m^3**
Retention factor	0.4			400 **mg/m^3**
Daily exposure (g/day)	5.74			2.4 mg/kg bw/day
Daily exposure (mg/kg bw/day)				
Hair shampoo		-	-	-
Daily amount (g/day)	29.13	18.230.01		
Retention factor	0.01	0.18		
Daily exposure (g/day)	0.29	18		
Daily exposure (mg/kg bw/day)	4.1			
Sun cream/lotion				
Daily amount (g/day)	18.0	2 x 9 g*		
Retention factor	1	1		
Daily exposure (g/day)	18.0	18.0 g		
Daily exposure (mg/kg bw/day)	300	1 385	79	
Sun spray, pump spray				
Daily amount (g/day)	18.0			
Retention factor	1			90 mg/m^3
Daily exposure (g/day)	18.0			18 mg/m^3
Daily exposure (mg/kg bw/day)	300			0.11 mg/kg bw/day
Deodorant/antiperspirant, non-spray	1.50	-	-	-
Daily amount (g/day)	1.00			
Retention factor	1.50			
Daily exposure (g/day)	22.08			
Daily exposure (mg/kg bw/day)				
Deodorant/antiperspirant spray		-	-	
Daily amount (g/day)	0.69			
Retention factor	1.00			345 mg/m^3
Daily exposure (g/day)	0.69			69 mg/m^3
Daily exposure (mg/kg bw/day)	10.0			0.41 mg/kg bw/day

* Indicated as worst-case exposure Danish EPA (2017).

Dermal exposure

When calculating exposure to children for body lotion the starting point was the exposure to adults of 123.2 mg/kg bw/day. SCCS (2018) indicates that the total skin area in proportion to the body weight is approx. 1.6 times higher for a 1 year old child compared to adults, which consequently corresponds to an exposure of 1.6 x 123.2 mg/kg bw/day = 197 mg/kg bw/day.

Similar ratio is used for hair shampoo that may be used both as shower gel (18.67 g/day, adult person) and hair shamppo (10.46 g/day), i.e. 29.13 g/day for an adult person..

Oral exposure
It is estimated, that oral exposure from body creams/lotions and sun creams/lotion is likely for small 1-2 year old children as oral exposure from lips and via sucking of fingers/hands is considered especially relevant for this age group. Default values in RIVM[3] (2014) suggest, that the hand area of 1-2 year old children is 5.7% of the total body area and thus, the oral contribution is calculated to be 5.7% of the skin exposure.

Inhalation
SCCS (2018) does not indicate specific exposure parameters for inhalation of cosmetic products in spray or powder form but refers to a publication of Stealing et al. (2014), which recommends using a so-called two-box exposure model for cosmetic spray products. In this model it is assumed that the exposure in the first 2 minutes comes from inhalation of a relatively concentrated aerosol mist distributed in 2 m^3 air closest to the user, while exposure in the subsequent 18 minutes comes from staying in a (bath)room, after the aerosol has been distributed evenly in the room's volume of 10 m^3.

Based on this scenario the concentration of aerosols in the air can be calculated, as it is assumed from a worst case scenario that the total sprayed product volume remains airborne and is distributed evenly in 2 m^3 and 10 m^3 cubic volume respectively:

Conc. (during first 2 minutes) = sprayed product amount (mg)/ 2 m^3

Conc. (during subsequent 8 minutes) = sprayed product amount (mg)/ 10 m^3

Exposure expressed as mg/kg bw/day via inhalation can be calculated from the following calculation formula:

Adults:
$D_{inhalation}$ (mg/kg bw/day) =
(Amount spray (mg) / 2 m^3) x 0.013 m^3/min (inhalation minute volume) x 2 min/ 60 kg
+ (Amount spray (mg) / 10 m^3) x 0.013 m^3/min (inhalation minute volume) x 18 min/ 60 kg

$D_{inhalation}$ (mg/kg bw/day) = 0.00022 x amount spray (mg) + 0.00039 Amount spray (mg)
$D_{inhalation}$ (mg/kg bw/day) = 0.0006 x Amount spray (mg)/ kg lw/day

This means that the sprayed amount of product can be multiplied by 0.0006 in order to obtain the inhalation dose in mg/kg bw/day.

It is assessed that the above can be used as a worst-case estimate for airborne exposure of hair spray products in pressure containers as well as in pump sprays, as these products in general are aimed at small size particles to be distributed in the best possible way in the hair.

For sun protection, where spraying is done directly on the skin and the palm of the hand for further distribution, the exposure assessment is considered to be conservative, as the aerosols here are considerably bigger. It is therefore considered likely, that only a smaller part of the product corresponding to 1% of the sprayed amount may be subject to inhalation.

[3] The National Institute for Public Health and the Environment in the Netherlands

4.2 Hazard assessment

For the selected siloxane and dimethicone compounds, a hazard assessment was made based on literature searches and from expert assessments of the substances, e.g. assessment made by SCCP (EU´s scientific committee for safety of consumer products) or by CIR (Cosmetic Ingredient Review Expert Panel).

For hazard assessment of a substance, the critical effects of the substance are identified, and the NOAEL value, which will form the basis of the risk assessment, is identified. Subsequently, a tolerable exposure level for the substance is calculated:

Tolerable exposure level = NOAEL/reference MoS (Margin of Safety)

According to SCCS (2018), a reference MoS consists of a number of uncertainty factors to be considered at extrapolation from animal experimental data to humans, humans' diversity in terms of sensitivity, as well as relevance and quality of test data. Typically, a reference MoS of 100 to ensure a safe human exposure level, if the NOAEL used for the estimation is from a 90 day experimental animal study.

Details regarding hazard assessments including calculations of the tolerable exposure levels of the selected siloxanes can be seen in Appendix 2, while an extract is given below in TABLE 23.

Dimethicone

Assessments by an American expert group "Cosmetic Ingredient Review Expert Panel" from 2003 and 2020 (CIR 2003 and 2020) together with ECETOC (2011) areconsidered to form the best basis for the hazard assessment. From the data presented a NOAEL of 1000 mg/kg bw/day was determined based on a long-term 2-year study, in which rats were dosed with dimethicone through the diet. The NOAEL as well as the calculated tolerable exposure level can be seen below.

Exposure route (critical effect)	NOAEL/NOAEC (mg/kg bw/day)	Uncertainty factor	Tolerable exposure level (mg/kg bw/day)	Reliability
Oral (no effect seen)	1000	100	10	High

Cyclomethicone

See the assessments below for D3, D4, D5 and D6.

D3 (hexamethylcyclotrisiloxane)

The REACH registration of the substances is considered the best basis for the hazard assessment. On the basis of this, an oral NOAEL of 25 mg/kg bw/day concerning effect on the liver weight can be determined from a 14 day study test and a LOAEC of 136 mg/m^3 can be determined from a 90 day inhalation study with rats, also with regard to effect on the liver. The calculated tolerable exposure levels can be seen below.

Exposure route (critical effect)	NOAEL/NOAEC	Uncertainty factor	Tolerable exposure level	Reliability
Inhalation (liver effect)	136 mg/m^3 (LOAEC) eq. 24 mg/m^3 continuous exposure	75	0.32 mg/m^3	High

Oral (liver effect)	25 mg/kg bw/day	600	0.04 mg/kg bw/day	High
Dermal (liver effect)	136 mg/m^3		0.22 mg/kg bw/day*	Reliable unknown skin absorption

*To calculate the tolerable dermal exposure, extrapolation from inhalation data to dermal exposure is made, as first-pass effect in the liver does not influence the toxicity as may be the case in the oral study. Adjustment is made for a lower dermal absorption rate with a factor of 2.

D4 (octamethylcyclotetrasiloxane)

D4 is a toxicologically, well-tested substance and meets the REACH data requirements for highest tonnage level (above 1000 tons per year).

In 2010 EU´s expert group for consumer safety, SCCS, published a toxicological assessment of D4 and D5. This assessment is considered to form the best basis for the hazard assessment of D4. Furthermore, the Danish Environmental Protection Agency has assessed the substance in 2010 with the aim to determine a health based air quality criterion. Based on these data, a NOAEC of 150 ppm (eq. 1816 mg/m^3) can be determined from a cancer inhalation study with rats where tumors in the uterus and effects on the liver (increased liver weight) occurred at higher levels. From the same test, a LOAEC of 35 ppm (420 mg/m^3) can be determined based on inflammatory effects in the lungs at this exposure level. In addition, this substance is considered to be an endocrine disruptor (CeHoS 2018). The calculated tolerable exposure levels can be seen below.

Exposure route (critical effects)	NOAEL/NOAEC	Uncertainty factor	Tolerable exposure level	Reliability
Inhalation (lung effects)	420 mg/m^3 (LOAEC) eq. 75 mg/m^3 continuous exposure	75	1.0 mg/m^3	High reliability
Converted to systemic internal dose (uterus tumors)	1816 mg/m^3 eq. 17.8 mg/kg bw/day	100	0.178 mg/kg bw/day	High reliability
Oral (uterus tumors, liver effects)	0.178 mg/kg bw/day	-	0.34 mg/kg bw/day *	High reliability
Dermal (uterus tumors, liver effects)	0.178 mg/kg bw/day		35.6 mg/kg bw/day **	High reliability

* The oral absorption of D4 is estimated to be up to 52%, and the tolerable oral exposure level is consequently calculated on the basis of the tolerable internal dose from inhalation.
** The dermal absorption of D4 is estimated to be 0.5%, and the tolerable dermal exposure level is consequently calculated on the basis of the tolerable internal dose.

D5 (decamethylcyclotetrasiloxane)

In 2016 EU´s expert group for consumer safety, SCCS, published a toxicological assessment of D5. Data from this assessment is used as a basis for this hazard assessment.

From a 90-day inhalation study with rats, a NOAEC of 49 ppm (corresponding to 744 mg/m^3) can be determined based on local effects in lungs and nasal mucous membranes as well as enlarged liver. From a cancer inhalation study with rats, a NOAEC of 40 ppm (corresponding to 607 mg/m^3) can be seen as a result of increased occurrence of tumors in the uterus at higher exposure levels. The calculated tolerable exposure levels can be seen below.

Exposure route (critical effect)	NOAEL/NOAEC	Uncertainty factor	Tolerable exposure level	Reliability
Inhalation (lung effects, liver effects)	744 mg/m^3 eq. 133 mg/m^3 continuous	25	5.3 mg/m^3	High reliability
Inhalation (uterus tumors)	607 mg/m^3 eq. 108 mg/m^3 continuous	25	4.3 mg/m^3	High reliability
Converted to systemic internal dose	607 mg/m^3 eq. 3 mg/kg bw/day	100	0.03 mg/kg bw/day	High reliability
Oral (uterus tumors and liver effects)	0.03 mg/kg bw/day	-	0.3 mg/kg bw/day *	High reliability
Dermal (uterus tumors and liver effects)	0.03 mg/kg bw/day	-	50 mg/kg bw/day **	High reliability

* The oral absorption of D5 is estimated to be 10%, and the tolerable oral exposure level is consequently calculated on the basis of the tolerable internal dose.

** The dermal absorption of D5 is estimated to be 0.06%, and the tolerable dermal exposure level is consequently calculated on the basis of the tolerable internal dose.

D6 (dodecamethylcyclotetrasiloxane)

It is estimated that the REACH registration of the substance (updated June 2019) forms the best basis for an assessment of the substance. Based on data from this, a LOEL of 100 mg/kg bw/day can be determined with regard to effects on the thyroid gland and liver in a 28 days' oral exposure test with rats and a NOAEC of 18.2 mg/m^3 in terms of harmful local effects in lungs and effects in the liver (fat accumulation) in a 90 days' inhalation test with rats. The calculated tolerable exposure levels can be seen below.

Exposure way (critical effect)	NOAEL/NOAEC	Uncertainty factor	Tolerable exposure level	Reliability
Inhalation (lung effect, liver)	18.2 mg/m^3 Sv.t. 3.3 mg/m^3 continuous	25	0.13 mg/m3	High reliability
Oral (liver, thyroid effect)	100 mg/kg bw/day	300	0.33 mg/kg bw/day	High reliability
Dermal (liver, thyroid effect)	0.33 mg/kg bw/day	-	165 mg/kg bw/day*	Reliable

* The dermal absorption of D6 is estimated to be 0,03%, and the tolerable dermal exposure level is consequently calculated on the basis of the tolerable oral internal dose at an absorption of 15%.

Phenyl trimethicone

It was only possible to find toxicological data for the substance from a safety assessment made by Cosmetic Ingredient Review Expert Panel in 1986 based mainly on a number of unpublished data (CIR 1986). Based on these, a dose of 200 mg/kg bw/day for repeated dermal exposure can be considered as a LOAEL, because a number of resorptions and a reduced number of viable offsprings were seen with rabbits dosed from day 6 to day 18 in the gestation period. The calculated exposure levels can be seen below.

Exposure route (critical effect)	NOAEL/NOAEC	Uncertainty factor	Tolerable exposure level	Reliability
Dermal (congenital malformation)	200 mg/kg bw/day	1000	0.2 mg/kg bw/day	Low

Trisiloxane (octamethyltrisiloxane)

Data from the REACH registration is considered to be the best basis for a hazard assessment of this substance. Based on data from the REACH registration an oral NOAEL of 25 mg/kg bw/day can be determined in relation to effects on the liver and the biliary system based on a 28 days in rats. Also, a NOAEC of 3869 mg/m^3 in relation to the same type of effects could be found from a 90-day inhalation study in rats. The calculated tolerable exposure levels can be seen below.

Exposure way (critical effect)	NOAEL/NOAEC	Uncertainty factor	Tolerable exposure level	Reliability
Inhalation (effects liver, biliary system)	3 869 mg/m^3 eq. 967 mg/m^3 continuous exp.	25	38 mg/m3	High reliability
Oral (effects liver, biliary system)	25 mg/kg bw/day	300	0.083 mg/kg bw/day	High reliability
Dermal (effects liver, biliary system)	13 mg/kg bw/day	-	130 mg/kg bw/day *	Realiable

*The tolerable dermal exposure level is extrapolated from the tolerable exposure level for inhalation using a 10 times lower absorption rate compared to inhalation.

Drometrizole trisiloxane

No toxicological data on drometrizole trisiloxane are available from SCCS, CIR, Toxline, Pubchem or from US EPA's comptox database. Furthermore, the substance is not REACH registered. In 2015 the Danish Environmental Protection Agency made an assessment of a number of cosmetic sunscreens, and also in this publication no available toxicological data for the substance were found (Danish Environmental Protection Agency, 2015).

Consequently, it is not possible to make neither a hazard assessment nor a risk assessment of the substance, which according to the cosmetics regulation is an approved UV filter.

Summary

The calculated tolerable exposure levels and the critical effects for the substances in question are summarised in the below TABLE 23 together with classifications of the substances.

TABLE 23 tolerable exposure levels for selected siloxane compounds.

Name CAS	REACH dossier HH Classification	Calculated tolerable exposure O, D, Inh Reliability*, **, ***	Critical effects
Dimethicone (Dimethyl siloxane) 9006-65-9, 63148-62-9; 9016-00-6	Not registered	O: 10 mg/kg bw/day*** D: negligible absorption Inh: no data	No effects observed
Trisiloxane, Octamethyltrisiloxane 107-51-7	Not classified	O: 0.083 mg/kg bw/day*** D:130 mg/kg bw/day** Inh: 38 mg/m^3***	Effect on the liver and biliary system

Name CAS	REACH dossier HH Classification	Calculated tolerable exposure O, D, Inh Reliability*, **, ***	Critical effects
Phenyl trimethicone 2116-84-9	Not classified	O: - D: 0.2 mg/kg bw/day* Inh: -	Developmental toxicity
D3 Hexamethylcyclotrisiloxane 541-05-9	Not classified	O: 0.04 mg/kg bw/day*** D: 0.22 mg/kg bw/day** Inh: 0.32 mg/m^3***	Liver effects Liver effects Liver effects
D4 Octamethylcyclotetrasiloxane 556-67-2	Repr.2, H361 fertility	O: 0.34 mg/kg bw/day*** D: 35.6 mg/kg bw/day*** Inh: 1.0 mg/m^3***	Uterus tumors, Liver effects Uterus tumors, Liver effects Lung effects
D5 Decamethylcyclopentasiloxane 541-02-6	Not classified	O: 0.30 mg/kg bw/day*** D: 50 mg/kg bw/day*** Inh: 4.3 mg/m^3*** 5.4 mg/m^3***	Uterus tumors, Liver effects Uterus tumors, Liver effects Uterus tumors, Lung effects, Liver effects
D6 Dodecamethylcyclohexasiloxane 540-97-6	Not classified	O: 0.33 mg/kg bw/day*** D: 165 mg/kg bw/day** Inh: 0.13 mg/m^3***	Thyroid effects; Liver effects Thyroid effects; Liver effects Lung effects, Liver effects
Cyclomethicone 69430-24-6	Not registered	See D3, D4, D5 and D6	See D3, D4, D5 and D6
Drometrizole trisiloxane 155633-54-8	Not registered	O: - D:- Inh:-	No available toxicological data

**** high reliability ** reliable * low reliability*

In cases where several of the above substances are present at the same time in a cosmetic product, and some of the substances have the same effects (i.e. same critical effect), this has to be considered in the risk assessment. In such cases the principle of additivity of the risk coefficients will be used in order to avoid underestimation of the combined risk.

For the siloxanes D3, D4, D5 and D6 it can be seen that the tolerable exposure levels are calculated considering liver effects both for dermal as well as for oral exposure and in these cases also the combined risk from both exposure routes has to be considered.

The same applies for the substances D4 and D5, both having uterus tumors as critical effect in relation to both oral and dermal exposure.

For the substances trisiloxane, D3, D5 and D6 the critical effects are liver effects in relation to inhalation exposure. Furthermore, effects in the lungs are seen as critical for the substances D4, D5 and D6 and additive effects must therefore be taken into account for this effect also.

4.2.1 Risk characterisation

In connection with risk characterisation it is considered the most practical approach to assess the extensive amount of analytical results in TABLE 20 by comparing the found concentrations of the substances to calculated tolerable concentrations in the individual product types.

When knowledge is available about the tolerable exposure level of an ingredient and the exposure of the product on which it is used is known, the tolerable concentration in the product can be calculated as:

TE (Y) (mg/kg bw/day) = Eksp(P) (mg/kg bw/day) x TC(Y) (mg Y/mg P)

TC(Y) (mg Y/mg P) = TE(Y) (mg/kg bw/day) / Eksp(P) (mg/kg bw/day)

where

TE(Y): tolerable exposure level for the siloxane compound Y, (mg/kg bw/day)

Eksp(P): the daily exposure with the product P, (mg/kg bw/day)

TC(Y): the tolerable concentration of Y in the product P, (mg Y/mg P)

Example: Tolerable concentration of D3 in facial day cream:
For D3, a tolerable exposure level for dermal exposure of 0.22 mg/kg bw/day was determined, and according to TABLE 22 the daily exposure from facial cream can be set at 24.14 mg/kg bw/day. The tolerable concentration in facial cream can then be calculated:

TC(Y) (mg Y/mg P) = TE(Y) (mg/kg bw/day) / Eksp(P) (mg/kg bw/day)

TC(D3) (mg D3 /mg facial cream) =0.22 mg/kg bw/day / 24.14 mg/kg bw/day

TC(D3) = 0.0091 mg D3/ mg facial cream = 9100 mg D3/ kg facial cream

Since the analysis results are indicated in mgY/kgP, it is more practical to convert the tolerable concentration from mgY/mgP to mgY/kg P by multiplying the value by 10^6 (1 000 000 mg/kg).

Using this method for the tolerable exposure level for dermal, oral and inhalation and dividing these evalues by the daily exposure from the individual product types, the tolerable concentration can be calculated for all siloxane compounds in the respective product types.

Next step in the risk assessment will then be to compare the measured concentrations to the tolerable concentrations. If the measured concentrations exceed the tolerable concentrations this implies that the use of the product may cause an unacceptable increased risk to the consumer. The ratio between measured concentration and tolerable concentration may be expressed by the risk characterisation ratio, RCR:

RCR = measured concentration / tolerable concentration

The RCR methodology is applicable for both adult use of a cosmetic product as well as use of the product for small children. However, the toletable concentration in the product may be different as the exposure on a body weight basis (mg /kg bw/day) is different due to differences in use volume of the product as well as differences in body weight of the user.

This type of risk characterisation ratio is a transcription of the risk characterisation ratio used in connection with risk assessment of industrial chemicals under REACH, as RCR here is described as:

RCR = exposure (mg/kg bw/day) / DNEL mg/kg bw/day

RCR values exceeding the value of 1 indicates that the measured concentration is above the tolerable concentration and thus, indicate a potential risk for the consumer. However, before a more final conclusion can be made it is important to evaluate to which extent high or low degree og uncertainties pertaining to the exposure assessment or to the derivation of a tolerable exposure level for the substance, as this may hamper the validity of the assessment and the conclusion.

DNEL (Derived No Effect Level) is the same as a tolerable exposure level. As ”measured concentration” of a substance in the cosmetic product is directly proportional to ”exposure” of the substance, and as there is the same proportional relation between the “tolerable concentration” and the tolerable exposure (DNEL-value), the RCR value will be the same. Thus, the RCR value will be the same whether you use the concentration level in the product or the dose expressed in mg/kg bw/day.

The advantage of expressing the risk in an RCR value is that for substances with similar adverse effects (e.g. affecting the same target organ or having the same mode of action) the RCR values can be added up. I.e. for effects on the same target organ and if it cannot be shown by concrete mode of action (MoA) data that the effects are **not** additive, we use an additive approach for our risk assessment. This is considered a reasonable and balanced assumption as different or similar MoAs may either be non-additive, additive or even result in synergistic responses.
Further, several of the siloxanes are closely related, i.e. with high degree of similarity in relation to chemical structure and physicochemical properties. As they further affect the same target organs with comparable effects this very much support an additive approach.

In this way it is possible to assess if the combined exposure to the substances leads to an RCR value above 1 and consequently poses a risk to the consumer.

4.2.2 Risk characterisation of dermal exposure

The first step is as mentioned to find the tolerable concentrations for the various siloxane compounds in the different product types. Using the method described above this can be calculated as indicated below in TABLE 24.

TABLE 24 Dermal exposure, tolerable exposure levels for individual substances and associated tolerable product concentrations.

Substance:		**D3**	**D4**	**D5**	**D6**	**Dimethicone**	**Trisiloxane**	**Phenyl trimethicone**
Tolerable dermal exposure (mg/kg bw/day):		**0.22**	**35.6**	**50**	**165**	**-**	**130**	**0.2**
Critical effects/target organ:		**Liver effect**	**uterus tumors and liver effect**	**uterus tumors and liver effect**	**liver/ thyroid**		**Liver/biliary system**	**Developmental effects**
	Daily dermal exposure to the product (mg/kg bw/day)	---------- Tolerable concentration in the product mg/kg ----------						
Product category								
Facial day cream/lotion	24.14	$9.1x10^3$	$1.5x10^6$	$2.1x10^6$	$6.8x10^6$	-	$5.4x10^6$	8290
Foundation	7.90	$2.8x10^4$	$4.5x10^6$	$6.3x10^6$	$2.1x10^7$	-	$1.7x10^7$	$2.5x10^4$
Body care. Creams/ lotion	123.2	1 786	$2.9x10^5$	$4.1x10^5$	$1.3x10^6$	-	$1.1x10^6$	1620
Child	197	1 116	$1.8x10^5$	$2.5x10^5$	$8.4x10^5$		$6.6x10^5$	1020
Hair balm/conditioner (retention factor: 0,01)	0.67	$3.2x10^5$	$5.3x10^6$	$7.5x10^7$	$2.5x10^8$	-	$1.9x10^8$	$3.0x10^5$
Revised Hair balm/conditioner (leave-in retention factor: 0,1)*	6.7	$3.2x10^4$	$5.3x10^5$	$7.5x10^6$	$2.5x10^7$	-	$1.9x10^7$	$3.0x10^4$
Hair spray, spray, pressure container	11	$2.0x10^4$	$3.2x10^6$	$4.5x10^6$	$1.5x10^7$	-	$1.2x10^7$	$1.8x10^4$
Hair spray, spray, pump spray	6	$3.6x10^4$	$5.9x10^6$	$8.3x10^6$	$2.8x10^7$	-	$2.2x10^7$	$3.3x10^4$
Hair oil/lotion	5.74	$3.8x10^4$	$6.2x10^6$	$8.7x10^6$	$2.9x10^7$	-	$2.3x10^7$	$3.5x10^4$
Hair shampoo	4.1	$5.4x10^4$	$8.7x10^6$	$1.2x10^7$	$4.0x10^7$	-	$3.2x10^7$	$4.9x10^4$
Child	18	$1.2x10^4$	$2.0x10^6$	$2.7x10^6$	$9.2x10^6$	-	$7.2x10^6$	$1.1x10^4$
Sun cream/lotion	300	734	$1.2x10^5$	$1.6x10^5$	$5.5x10^5$	-	$4.3x10^5$	670

Child	1 385	158	$2.6x10^4$	$3.6x10^4$	$1.2x10^5$		$9.4x10^4$	140
Sun spray, pump spray	300	734	$1.2x10^5$	$1.6x10^5$	$5.5x10^5$	-	$4.3x10^5$	670
Child	1 385	158	$2.6x10^4$	$3.6x10^4$	$1.2x10^5$		$9.4x10^4$	140
Deodorant/antiperspirant	22.08	$1.0x10^4$	$1.6x10^6$	$2.3x10^6$	$7.5x10^6$	-	$5.9x10^6$	9060
Deodorant/antiperspirant spray	10.0	$2.2x10^4$	$3.6x10^6$	$5.0x10^6$	$1.7x10^7$	-	$1.3x10^7$	$2x10^4$
Deodorant/antiperspirant Ethanol based	20.63	$1.1x10^4$	1.7x106	$2.4x10^6$	$8.0x10^6$	-	$6.3x10^6$	9690

*as the purchased hair balms were all regarded as leave-in products when assessment was made of the individual products, the exposure and the tolerable concentration are calculated on the basis of a retention factor of 0.1 for the products (like for hair oil/lotion) instead of 0.01 as indicated in TABLE 22.

It should be noted, that in the cases where the tolerable exposure to a concentration is higher than the actual exposure to the entire product, a tolerable concentration is obtained above 1000 000 mg/kg which is of course not possible. Nevertheless, these values are used for calculation purposes in the risk assessment and the RCR calculations. A given content in the product may still cause a certain contribution to an RCR value, which may be significant when adding RCR values for several similar substances at the same time in the product.

In TABLE 25 below, the tolerable exposure concentrations have been put in relation to the measured concentrations in the products, and RCR for the ingredients in the individual products have been calculated. For the individual products substances with effects on the same organ have been added up (see TABLE 21 with indication of critical effects/organs for dermal exposure from the individual siloxane compounds). The RCR for the substances D3, D4, D5, D6 and trisiloxane has been added for liver effects, as these effects are regarded as additive and relevant to humans, and the RCR values for uterus tumors for D4 and D5 have been added in order to obtain an assessment of the combined risk in terms of impact to the liver and development of uterus tumors. When making additions, RCR values <0.01 are not included as contributions at this level must be considered to be insignificant. Values where the detection limit is indicated as ”<50” in TABLE 20 are not included in the below table, but just replaced with the notation ”-”.

TABLE 25. Risk assessment at skin contact for adults and children (indicated by the letter "C" in the relevant columns) indicates risk characterisation ratio for children's exposure)

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
1	Facial cream									
	Analysis conc., mg/kg	810	-	490	28 000	-	140	350		
	Tolerable conc. mg/kg	$9.1x10^3$	-	$2.1x10^6$	$6.8x10^6$	-	8290	-		
	RCR	0.09	-	<0.01	<0.01	-	0.02	-	0.09	< 0.01
2	Facial cream									
	Analysis conc., mg/kg	2 600	-	90 000	55 000	-	240	1100		
	Tolerable conc. mg/kg	$9.1x10^3$	-	2.1x106	6.8x106	-	8290	-		
	RCR	0.28	-	0.04	<0.01	-	0.03	-	0.32	0.04
3	Facial cream									
	Analysis conc., mg/kg	130	200	70	-	800	130	210		
	Tolerable conc. mg/kg	$9.1x10^3$	$1.47x\ 10^6$	$2.1x10^6$	-	$5.4x10^6$	8290	-		
	RCR	0.01	<0.01	<0.01	-	<0.01	0.02	-	0.01	<0.01
36	Deodorant									
	Analysis conc., mg/kg	-	260	369 000	-	-	-	-		
	Tolerable conc. mg/kg	-	$1.6x10^6$	$2.3x10^6$	-	-	-	-		
	RCR	-	<0.01	0.16	-	-	-	-	0.16	0.16

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
37	Deodorant									
	Analysis conc., mg/kg	5 800	5 900	910 000	990	-	-	-		
	Tolerable conc. mg/kg	$1.0x10^4$	$1.6x10^6$	$2.3x10^6$	$7.5x10^6$	-	-	-		
	RCR	0.58	<0.01	0.40	<0.01	-	-	-	0.98	0.40
38	Deodorant Spray, pressure container									
	Analysis conc., mg/kg	-	400	319 000	1 400	-	-	780		
	Tolerable conc. mg/kg	-	$3.6x10^6$	$5.0x10^6$	$1.7x10^7$	-	-	-		
	RCR	-	<0.01	0.06	<0.01	-	-	-	0.06	0.06
5	Foundation									
	Analysis conc., mg/kg	1 900	3 300	262 000	12 000	-	890	80		
	Tolerable conc. mg/kg	$2.8x10^4$	$4.5x10^6$	$6.3x10^6$	$2.1x10^7$	-	$2.5x10^4$	-		
	RCR	0.07	<0.01	0.04	<0.01	-	0.04	-	0.11	0.04
6	Foundation									
	Analysis conc., mg/kg	5 300	410	14 000	142 000	-	-	10		
	Tolerable conc. mg/kg	$2.8x10^4$	$4.5x10^6$	$6.3x10^6$	$2.1x10^7$	-	-	-		
	RCR	0.19	<0.01	<0.01	<0.01	-	-	-	0.19	<0.02
7	Foundation									
	Analysis conc., mg/kg	1 200	40	70	100	-	28 000	1 600		
	Tolerable conc. mg/kg	$2.8x10^4$	$4.5x10^6$	$6.3x10^6$	$2.1x10^7$	-	$2.5x10^4$	-		
	RCR	0.049	<0.01	<0.01	<0.01	-	**1.1**	-	0.04	0.01

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
40	Foundation Analysis conc., mg/kg Tolerable conc. mg/kg RCR	1 700 $2.8x10^4$ 0.06	4 600 $4.5x10^6$ <0.01	264 000 $6.3x10^6$ 0.04	13 000 $2.1x10^7$ <0.01	57 000 $1.6x10^7$ <0.01	1 900 $2.5x10^4$ 0.08	650 - -	0.10	0.04
12	Hair balm Analysis conc., mg/kg Tolerable conc. mg/kg RCR	500 $3.2x10^4$ 0.02	2 800 $5.3x10^6$ <0.01	870 000 $7.5x10^6$ 0.12	7 900 $2.5x10^7$ <0.01	- - -	- - -	80 - -	0.14	0.12
13	Hair balm Analysis conc., mg/kg Tolerable conc. mg/kg RCR	2 000 $3.2x10^4$ 0.06	580 $5.3x10^6$ <0.01	857 000 $7.5x10^6$ 0.11	11 000 $2.5x10^7$ <0.01	- - -	3 500 $3.0x10^4$ 0.12	70 - -	0.18	0.11
15	Hair balm Analysis conc., mg/kg Tolerable conc. mg/kg RCR	470 $3.2x10^4$ 0.01	260 $5.3x10^6$ <0.01	66 000 $7.5x10^6$ <0.01	900 $2.5x10^7$<0.01	90 $1.9x10^7$ <0.01	470 $3.0x10^4$ 0.02	90 - -	0.01	0.01
16	Hair balm Pump spray									

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
	Analysis conc., mg/kg	160	340	280 000	15 000	-	14 000	-		
	Tolerable conc. mg/kg	$3.2x10^4$	$5.3x10^6$	$7.5x10^6$	$2.5x10^7$	-	$3.0x10^4$	-		
	RCR	0.01	<0.01	0.04	<0.01	-	0.47	-	0.05	0.04
42	Hair balm Analysis conc., mg/kg Tolerable conc. mg/kg RCR	11 000 $3.2x10^4$ 0.34	192 000 $5.3x10^6$ 0.04	232 000 $7.5x10^6$ 0.03	6 600 $2.5x10^7$ <0.01	- - -	- - -	- - -	0.41	0.07
43	Hair balm									
	Analysis conc., mg/kg	5 000	20 000	298 000	5 300	200 000	180	70		
	Tolerable conc. mg/kg	$3.2x10^4$	$5.3x10^6$	$7.5x10^6$	$2.5x10^7$	$1.9x10^7$	$3.0x10^4$	-		
	RCR	0.16	<0.01	0.04	<0.01	0.01	0.006	-	0.21	0.04
17	Hair spray Spray pressure container									
	Analysis conc., mg/kg	-	-	-	-	-	1 900	-		
	Tolerable conc. mg/kg	-	-	-	-	-	$1.8x10^4$	-		
	RCR	-	-	-	-	-	0.11	-	-	-
18	Hair spray pump spray									
	Analysis conc., mg/kg	260	210	68 000	610	-	-	-		
	Tolerable conc. mg/kg	$3.6x10^4$	$5.9x10^6$	$8.3x10^6$	$2.8x10^7$	-	-	-		

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
	RCR	<0.01	<0.01	<0.01	<0.01	-	-	-	<0.01	<0.02
19	Hair spray									
	pump spray									
	Analysis conc., mg/kg	100	40	40	40	-	930	-		
	Tolerable conc. mg/kg	$3.6x10^4$	$5.9x10^6$	$8.3x10^6$	$2.8x10^7$	-	$3.3x10^4$	-		
	RCR	<0.01	<0.01	<0.01	<0.01	-	0.03	-	<0.01	<0.01
20	Hair oil									
	Pump spray									
	Analysis conc., mg/kg	15 000	398 000	2 500	-	290	-	-		
	Tolerable conc. mg/kg	$3.8x10^4$	$6.2x10^6$	$8.7x10^6$	-	$2.3x10^7$	-	-		
	RCR	0.40	0.06	<0.01	-	<0.01	-	-	0.46	0.06
21	Hair oil									
	Analysis conc., mg/kg	16 000	238 000	150 000	10 000	490	-	-		
	Tolerable conc. mg/kg	$3.8x10^4$	$6.2x10^6$	$8.7x10^6$	$2.9x10^7$	$2.3x10^7$	-	-		
	RCR	0.42	0.04	0.02	<0.01	<0.01	-	-	0.48	0.06
22	Hair oil									
	Analysis conc., mg/kg	470	450	>950 000	17 000	-	-	100		
	Tolerable conc. mg/kg	$3.8x10^4$	$6.2x10^6$	$8.7x10^6$	$2.9x10^7$	-	-	-		
	RCR	0.01	<0.01	<0.11	<0.01	-	-	-	0.01	<0.11
23	Hair oil									
	Analysis conc., mg/kg	280	50	158 000	-	130	400	-		

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
	Tolerable conc. mg/kg	$3.8x10^4$	$6.2x10^6$	$8.7x10^6$	-	$2.3x10^7$	$3.5x10^4$	-		
	RCR	<0.01	<0.01	0.02	-	<0.01	0.01	-	0.02	0.02
44	Hair oil									
	Analysis conc., mg/kg	-	-	360	530	200	-	-		
	Tolerable conc. mg/kg	-	-	$8.7x10^6$	$2.9x10^7$	$2.3x10^7$	-	-		
	RCR	-	-	<0.01	<0.01	<0.01	-	-	<0.01	<0.01
45	Hair oil									
	Analysis conc., mg/kg	-	-	-	-	-	-	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-
24	Hair shampoo									
	Analysis conc., mg/kg	-	-	-	-	-	-	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-
25	Hair shampoo									
	Analysis conc., mg/kg	-	-	-	-	-	-	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-
26	Hair shampoo									
	Analysis conc., mg/kg	60	-	-	-	-	-	40		
	Tolerable conc. mg/kg	$5.4x10^4$/ $1.2x10^4$C	-	-	-	-	-	-		
	RCR	<0.01/<0.01C	-	-	-	-	-	-		-

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect <0.01/ <0.01C	Cumulated RCR uterus tumors (D4 + D5)
8	Body cream									
	Analysis conc., mg/kg	100	-	9 700	230	-	-	-		
	Tolerable conc. mg/kg	1786/ 1116C	-	$4.1x10^5$/ $2.5x10^5$	$1.3x10^6$/ $8.4x10^5$	-	-	-		
	RCR/ RCRC	0.061/ 0.09C	-	0.02/ 0.04C	<0.01/ <0.01C	-	-	-	0.08/ 0.13C	0.02/ 0.04C
9	Body cream									
	Analysis conc., mg/kg	50	-	1 700	120	-	-	-		
	Tolerable conc. mg/kg	1786/ 1116C	-	$4.1x10^5$/ $2.5x10^5$	$1.3x10^6$/ $8.4x10^5$	-	-	-		
	RCR/ RCRC	0.03/ 0.05C	-	<0.01/<0.01C	<0.01/ <0.01C	-	-	-	0.03/ 0.05C	<0.01/<0.01C
10	Body cream									
	Analysis conc., mg/kg	960	60	570	32 000	-	-	-		
	Tolerable conc. mg/kg	1786/ 1116C	$2.9x10^5$/ $1.8x10^5$	$4.1x10^5$/ $2.5x10^5$	$1.3x10^6$/ $8.4x10^5$	-	-	-		
	RCR/ RCRC	0.54/ 0.87C	<0.01/<0.01C	<0.01/<0.01C	0.02/ 0.04C	-	-	-	0.54/ 0.87C	<0.01/<0.01C
11	Body cream									
	Analysis conc., mg/kg	70	-	350	15 000	-	-	-		
	Tolerable conc. mg/kg	1786/ 1116C	-	$4.1x10^5$/ $2.5x10^5$	$1.3x10^6$/ $8.4x10^5$	-	-	-		
	RCR/ RCRC	0.04/ 0.06C	-	<0.01/<0.01C	0.01/0.02C	-	-	-	0.04/ 0.08C	<0.01/<0.01C

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
41	Body cream									
	Analysis conc., mg/kg	-	-	-	120	-	90	80		
	Tolerable conc. mg/kg	-	-	-	$1.3x10^6$/ $8.4x10^5$	-	1620/ 1020	-		
	RCR/ RCRC	-	-	-	<0.01/ <0.01C	-	0.06/ 0.09C	-	<0.01/ <0.01C	-/-
33	Sun cream									
	Analysis conc., mg/kg	50	-	-	-	-	-	980		
	Tolerable conc. mg/kg	734/ 158C	-	-	-	-	-	-		
	RCR/ RCRC	0.07/ 0.32C	-	-	-	-	-	-	0.07/ 0.32C	-
34	Sun cream									
	Analysis conc., mg/kg	-	-	-	-	-	-	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR/ RCRC	-	-	-	-	-	-	-	-	-
35	Sun cream									
	Analysis conc., mg/kg	150	100	80	340	-	740	3 400		
	Tolerable conc. mg/kg	734/ 158C	$1.2x10^5$/ $2.6x10^4$	$1.6x10^5$/ $3.6x10^4$	$5.5x10^5$/ $1.2x10^5$	-	670/ 140	-		
	RCR/ RCRC	0.20/ 0.95C	<0.01/ <0.01C	<0.01/ <0.01C	<0.01/<0.01C	-	**1.1/ 5.3C**	-	0.20/0.95C	-/-
46	Sun cream									
	Analysis conc., mg/kg	2 900	17 000	160 000	3 200	-	80	1 100		
	Tolerable conc. mg/kg	734/ 158C	$1.2x10^5$/	$1.6x10^5$/	$5.5x10^5$/	-	670/ 140	-		

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole-trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
			$2.6x10^4$	$3.6x10^4$	$1.2x10^5$					
	RCR/ RCRC	**4.0/ 18C**	0.14/ 0.66C	**1.0/ 4.4C**	<0.01/0.03C	-	0.12/ 0.55C	-	**5.0/ 22C**	**1.1/ 5.1C**
28	Sun spray									
	Pump spray									
	Analysis conc., mg/kg	-	-	-	-	-	-	6 900		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR/ RCRC	-	-	-	-	-	-	-	-	-
29	Sun spray									
	Analysis conc., mg/kg	620	-	1 800	23 000	-	270	24 000		
	Tolerable conc. mg/kg	734/ 158C	-	$1.6x10^5$/ $3.6x10^4$	$5.5x10^5$/ $1.2x10^5$	-	670/ 140	-		
	RCR/ RCRC	0.84/ **3.9C**	-	<0.01/ 0.05C	0.04/0.19C	-	0.40/ **1.9C**	-	0.88/ **4.0C**	<0.01/ 0.05C
30	Sun spray									
	Analysis conc., mg/kg	-	-	-	-	-	-	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR/ RCRC	-	-	-	-	-	-	-	-	-

RCR-values above 1 are indicated in **bold** writing

It should be noted, that risk assessment for children was only made for the product categories hair shampoo, body cream/lotion and sun cream/lotion, as the other cosmetic product categories are intended for adults. An exception is product No. 45 which was intended for small children with cradle cap in the scalp, but in this product no content of siloxanes was seen.

Facial cream
For the three facial creams analysed, low RCR values were seen in general. The highest RCR values obtained were 0.28 for D3 content and 0.29 for phenyl trimethicone content in product No. 2.
None of the examined facial creams is estimated to form a risk at dermal contact.

Deodorant
For the three examined deodorants (one pressure container spray (product No. 38) and two roll-on products) it was seen, that product No. 37 has an RCR value of 0.40 for content of D5 and 0.58 for content of D3. As both substances have the same toxicological target organ, these RCR values can be added up so that a combined RCR of 0.98 is reached, which is an RCR value which can just be accepted, also because the used value for dermal absorption is estimated to be conservative.
Further data on skin absorption would be required for a more precise risk assessment of this product.

Foundation
For the three examined foundation products it can be seen, that product No. 7 has a RCR value of 1.1 for content of phenyl trimethicone, which might indicate that there is an unacceptable risk from this substance in the product.
However, the reliability of the calculated tolerable exposure level for phenyl trimethicone and thereby the tolerable concentration must be considered to be very limited, as the toxicological data are very old (from 1966/67). This means that the testing has been performed under conditions which are very far from today's standard, and furthermore, it is uncertain whether the phenyl trimethicone quality used in the testing corresponds to the qualities used today in cosmetics.

Hair balm

For product No. 42 the highest RCR value of 0.34 is seen on the basis of content of D3, and when RCR values for the other liver toxic siloxanes D3 and D4 are added, a cumulated RCR value of 0.41 is seen.
For the analysed hair balm products no unacceptable risk levels have been obtained.

Hair spray
For the analysed hair spray products no unacceptable risk levels have been obtained.

Hair oil
From the data of the six hair oil products, the content of D3 in product No. 20 and No. 21 result in RCR values of 0.40 and 0.42 respectively. For the other siloxanes the RCR values are much lower.

For the analysed hair oil products no unacceptable risk levels have been obtained for the dermal exposure.

Hair shampoo
All three examined hair shampoo products show very low RCR values <0.01 for the found solixane compounds.
For the analysed shampoo products no unacceptable risk levels have been obtained.

Body cream/lotion
From the five analysed products, product No. 10 resulted in the highest RCR values as the content of D3 showed RCR values of 0.54 and 0.87 for adult and children, respectively.

Thus, no concern for potential risk could be identified from dermal exposure alone from the analysed body cream/lotion products.

Sun cream/sun spray
From the seven sun protection products (creams and spray products), increased RCR values above 1 were seen for product No. 35, 46 and 29.

For product No. 35 an RCR value of 0.95 was reached for content of D3 in connection with exposure to children, whereas a RCR value of 0.20 was found for adults. It should be noted that the value for tolerable dermal exposure for D3 is based on an *estimated* dermal absorption of 50% in relation to absorption by inhalation, which may be considered as a rather conservative approach supporting the conclusion of no risk.

Product 35 showed RCR values of 5.3 and 1.1 for phenyl trimethicone for exposure to children and adults, respectively However, the reliability of the calculated tolerable exposure level for phenyl trimethicone and thereby the tolerable concentration must be considered to be very limited, as the toxicological data are very old (from 1966/67). This means that the testing has been performed under conditions which are very far from today's standard, and furthermore, it is uncertain whether the phenyl trimethicone quality used in the testing corresponds to the qualities used today in cosmetics. So, the reliability of the calculated tolerable exposure level and also the tolerable concentration for phenyl trimethicone is considered to be too limited for a final conclusion.

For product No. 46, RCR values of 1 and above were seen for the substances D3 and D5 for both children and adult for all the substances. Highest values were seen for D3 with RCR values of 18 and 4.0. Also, RCR values of 5.1 and 1.1 for children and adults respectively were seen when the RCR values for the tumorigenic substances D4 and D5 are added. By adding up RCR values for liver effect, values of 22 and 5.0 for children and adults respectively were seen. Based on such high RCR values, the product must be considered to form a risk for children as well as adults.

For product 29, RCR values of 3.9 and 0.84 were obtained for content of D3 in connection with exposure to children and adults respectively. It should be noted, that the value for tolerable dermal exposure for D3 is based on an *estimated* dermal absorption of 50% in relation to absorption by inhalation which may be considered as a rather conservative approach. However, a risk to children cannot be excluded.

For product 29, a RCR value of 1.9 for phenyl trimethicone were seen for children. However, the reliability of the calculated tolerable exposure level and also the tolerable concentration for phenyl trimethicone is considered to be too limited for a final conclusion.

Sun product No. 29 contains the highest level of the approved UV-filter drometrizole trimethicone, and the analysed level of 2.4 % lies considerable below the regulatory maximum limit of 15%. However, it is not possible to make a specific risk assessment for this substance, as it has not been possible to find toxicological information on the substance.

Overview
Above, RCR values above 1 for dermal exposure to adults from the following products were found:

Product No.	Product type	Siloxanes*	RCR
7	Foundation	PTM	1.1
35	Sun cream	PTM	1.1
46	Sun cream	D3	4.0

PTM: phenyl trimethicone

* Adding up RCR values for siloxanes with similar toxic response, higher RCR values are obtained for instance for risk of liver effects, but for the sake of readability only siloxanes where an identified RCR >1 is indicated in the table. Also, cumulated RCR values are not indicated, as this would not have resulted in additional products with a risk.

RCR values above 1 for dermal exposure to children were found from the following products:

Product No.	Product type	Siloxanes*	RCR
29	Sun spray	D3	3.9
		PTM	1.9
35	Sun cream	PTM	5.3
46	Sun cream	D3,	18
		D5	4.4

*Only siloxanes with an RCR>1 are indicated. PTM: phenyl trimethicone

4.2.3 Risk characterisation of oral exposure of children

As previously mentioned, the first step is to find the tolerable concentrations for the various siloxane compounds in the different product types. From the above method this can be calculated as indicated in TABLE 26 below. The tolerable concentrations are solely calculated from exposure estimates for small children's oral intake in connection with sucking fingers/hands, while the oral exposure route for adults is considered to be insignificant compared to the dermal exposure.

TABLE 26 Oral exposure, children and tolerable exposure levels for single substances and associated tolerable product concentrations.

Substance		D3	D4	D5	D6	Dimethicone	Trisiloxane	Phenyl trimethicone
Tolerable oral exposure (mg/ kg bw/day):		**0.04**	**0.34**	**0.30**	**0.33**	**-**	**0.083**	**-**
Critical effects/target organs:		Liver effect	Uterus tumors and liver effect	Uterus tumors and liver effect	liver/ thyroid		liver/biliary system	
Product category	**Daily oral exposure with the product mg/kg bw/day**	**---------- Tolerable concentration in the product mg/kg ----------**						
Body care								
Cream / lotion	11	$3.6x10^3$	3.1x104	$2.7x10^4$	$3.0x10^4$	-	$7.5x10^3$	-
Sun cream, lotion	79	506	$4.3x10^3$	$3.8x10^3$	$4.2x10^3$	-	$1.1x10^3$	-
Sun spray, pump spray	79	506	$4.3x10^3$	$3.8x10^3$	$4.2x10^3$	-	$1.1x10^3$	-

It should be noted that in the cases where the tolerable exposure to a substance is higher than the actual exposure to the entire product, a tolerable concentration of more than 1000 000 mg/kg is calculated, which is not possible. Nevertheless, these values may be used for calculation reasons in the risk assessment and the RCR calculations, as a given content in the product, even below the tolerable exposure level still makes up a certain contribution in terms of an RCR value, which may have impact when adding up RCR values for several substances in the product with similar toxicity.

Below in TABLE 27 the tolerable exposure concentrations are put in relation to the measured concentrations in the products, and RCR for the ingredients in the individual products are calculated. In the individual products, substances with effects on the same organ are added up (see TABLE 21 with indication of critical effects/organs for oral exposure of the individual siloxane compounds). RCR for the substances D3, D4, D5, D6 and trisiloxane are added for liver effects, and the RCR values for uterus tumors for D4 and D5 are added in order to establish the combined risk in terms of effect on the liver and induction of uterus tumors. When adding up, the value <0,01 is not included as contributions of this level must be considered insignificant. Values where the detection limit is indicated as "<50" in TABLE 20 are not included in the below table, but simply replaced by the "-".

TABLE 27. Risk assessment oral exposure to children

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
8	Body cream									
	Analysis conc., mg/kg	100	-	9 700	230	-	-	-		
	Tolerable conc. mg/kg	$3.6x10^3$	-	$2.7x10^4$	$3x10^4$	-	-	-		
	RCR	0.03	-	0.36	<0.01	-	-	-	0.39	0.36
9	Body cream									
	Analysis conc., mg/kg	50	-	1 700	120	-	-	-		
	Tolerable conc. mg/kg	$3.6x10^3$	-	$2.7x10^4$	$3x10^4$	-	-	-		
	RCR	0.01	-	0.06	<0.01	-	-	-	0.07	0.06
10	Body cream									
	Analysis conc., mg/kg	960	60	570	32000	-	-	-		
	Tolerable conc. mg/kg	$3.6x10^3$	$3.1x10^4$	$2.7x10^4$	$3x10^4$	-	-	-		
	RCR	0.27	<0.01	0.02	**1.1**	-	-	-	**1.4**	0.02

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
11	Body cream									
	Analysis conc., mg/kg	70	-	350	15000	-	-	-		
	Tolerable conc. mg/kg	$3.6x10^3$	-	$2.7x10^4$	$3x10^4$	-	-	-		
	RCR	0.02	-	0.01	0.50	-	-	-	0.53	0.01
41	Body cream									
	Analysis conc., mg/kg	-	-	-	120	-	90	80		
	Tolerable conc. mg/kg	-	-	-	$3x10^4$	-	-	-		
	RCR	-	-	-	<0.01	-	-	-	<0.01	-
33	Sun cream									
	Analysis conc., mg/kg	50	-	-	-	-	-	980		
	Tolerable conc. mg/kg	506	-	-	-	-	-	-		
	RCR	0.10	-	-	-	-	-	-	0.10	-
34	Sun cream									
	Analysis conc., mg/kg	-	-	-	-	-	-	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-
35	Sun cream									
	Analysis conc., mg/kg	150	100	80	340	-	740	3 400		
	Tolerable conc. mg/kg	506	$4.3x10^3$	$3.8x10^3$	$4.2x10^3$	-	-	-		
	RCR	0.30	0.02	0.02	0.08	-	-	-	0.40	0.04
46	Sun cream									
	Analysis conc., mg/kg	2 900	17 000	160 000	3 200	-	80	1 100		

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
	Tolerable conc. mg/kg	506	$4.3x10^3$	$3.8x10^3$	$4.2x10^3$	-	-	-		
	RCR	**5.7**	**3.9**	**42**	0.77	-	-	-	**52**	**46**
28	Sun pray									
	Pump spray									
	Analysis conc., mg/kg	-	-	-	-	-	-	6900		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-
29	Sun spray									
	Analysis conc., mg/kg	620	-	1800	23000	-	270	24000		
	Tolerable conc. mg/kg	506	-	$3.8x10^3$	$4.2x10^3$	-	-	-		
	RCR	**1.2**	-	0.47	**5.5**	-	-	-	**7.2**	0.47
30	Sun spray									
	Analysis conc., mg/kg	-	-	-	-	-	-	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-

RCR values above 1 are indicated in **bold** writing

Body cream/lotion
Among the 5 products, the highest RCR values are seen for D6, and for product No. 10 an RCR value of 1.1 for the oral exposure to children is seen. A combined oral RCR of 1.4 is obtained for liver effects when the RCR values for D3 and D6 are added.

The calculation of the tolerable exposure level for D6 on the basis of liver effects is considered reliable but conservative, as the authors reporting the study evaluated that liver effects could not be considered as adverse. Also, it can be discussed whether it is realistic that children make a thorough sucking of the covered hands on a daily basis, which is the basis for the the exposure assessment. Finally, it must also be pointed out that the combined RCR value has a relatively limited exceedance of the value of 1. So, overall the justication for the oral scenario alone constituting a risk is considered as relatively weak.

Sun cream/lotion
Among the 7 products, products No. 46 and No. 29 exceed an RCR value of 1.

For product No. 46, significantly increased RCR values are seen for D3, D4 and D5 as values of 5.7 / 3.9 / 42 were obtained. If the RCR values for effect on the liver and uterus tumors are added, cumulated RCR values of 52 (D3+D4+D5+D6) for liver effects and 46 (D4+D5) for uterus tumors can be calculated.
Based on these high RCR values children´s oral exposure to this product is considered to result in an unacceptable risk, even though the exposure estimate can be considered as conservative.

For product No. 29, RCR values of 1.2 and 5.5 are obtained for D3 and D6 respectively. Combined RCR of 7.2 concerning risk of liver effects can be obtained, when the RCR values for D3 and D6 are added.

Overview
Above, RCR values above 1 for oral exposure to children from the products were found:

Product No.	Product type	Siloxanes	RCR
10	Body cream	D3, D6	1.1 (D6) 1.4 (D3+D6)
29	Sun spray	D3, D6	1.2 (D3) 5.5 (D6) 7.2 (D3+D6)
46	Sun cream	D3, D4, D5, D6	5.7 (D3) 3.9 (D4) 42 (D5) 52 (D3+D4+D5+D6) 46 (D4+D5)

*Only siloxanes found with an RCR >1 are indicated

4.2.4 Risk characterisation of combined dermal and oral exposure of children

In order to assess the combined risk in connection with use of the products on children, the RCR values for dermal exposure is added to the RCR values for oral exposure for the individual products. When adding, the value <0,01 is not included as contributions at this low level are considered to be insignificant.

TABLE 28. Risk assessment for combined dermal and oral exposure to children

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
8	Body cream									
	RCR dermal	0.09	-	0.04	<0.01	-	-	-	0.13	0.04
	RCR oral	0.03	-	0.36	<0.01	-	-	-	0.39	0.36
	RCR total	0.12	-	0.40	<0.02	-	-	-	0.52	0.40
9	Body cream									
	RCR dermal	0.05	-	<0.01	<0.01	-	-	-	0.05	<0.01
	RCR oral	0.01	-	0.06	<0.01	-	-	-	0.07	0.06
	RCR total	0.06	-	0.06	<0.01	-	-	-	0.12	0.06
10	Body cream									
	RCR dermal	0.87	<0.01	<0.01	0.04	-	-	-	0.9	<0.01
	RCR oral	0.27	<0.01	0.02	**1.1**	-	-	-	**1.4**	0.02
	RCR total	**1.2**	<0.01	0.02	**1.1**	-	-	-	**2.3**	0.02
11	Body cream									
	RCR dermal	0.06	-	<0.01	0.02	-	-	-	0.08	<0.01
	RCR oral	0.02	-	0.01	0.50	-	-	-	0.53	0.01
	RCR total	0.08	-	0.01	0.52	-	-	-	0.61	0.01
41	Body cream									
	RCR dermal	-	-	-	<0.01	-	0.09	-	<0.01	-
	RCR oral	-	-	-	<0.01	-	-	-	<0.01	-
	RCR total	-	-	-	<0.01	-	0.09	-	<0.01	-

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
33	Sun cream									
	RCR dermal	0.32	-	-	-	-	-	-	0.32	-
	RCR oral	0.10	-	-	-	-	-	-	0.10	-
	RCR total	0.42	-	-	-	-	-	-	0.42	-
34	Sun cream									
	RCR dermal	-	-	-	-	-	-	-	-	-
	RCR oral	-	-	-	-	-	-	-	-	-
	RCR total	-	-	-	-	-	-	-	-	-
35	Sun cream									
	RCR dermal	0.95	<0.01	<0.01	<0.01	-	**5.3**	-	0.95	<0.01
	RCR oral	0.30	0.02	0.02	0.08	-	-	-	0.40	0.04
	RCR total	**1.3**	0.02	0.02	0.08	-	**5.3**	-	**1.4**	0.04
46	Sun cream									
	RCR dermal	**18**	0.66	**4.4**	0.03	-	0.55	-	**23**	**5.1**
	RCR oral	**5.7**	3.9	42	0.77	-	-	-	**52**	**46**
	RCR total	**24**	**4.6**	**46**	0.80	-	-	-	**75**	**51**
28	Sun spray									
	RCR dermal	-	-	-	-	-	-	-	-	-
	RCR oral	-	-	-	-	-	-	-	-	-
	RCR total	-	-	-	-	-	-	-	-	-
29	Sun spray									
	RCR dermal	**3.9**	-	0.05	0.19	-	**1.9**	-	**4.2**	0.05

Product No.	Product type	D3*	D4*	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Drometrizole trisiloxane	Cumulated RCR * liver effect	Cumulated RCR uterus tumors (D4 + D5)
	RCR oral	1.2	-	0.47	**5.5**	-	-	-	**7.2**	0.47
	RCR total	**5.1**	-	0.52	**5.7**	-	**1.9**	-	**11**	0.52
30	Sun spray									
	RCR dermal	-	-	-	-	-	-	-	-	-
	RCR oral	-	-	-	-	-	-	-	-	-
	RCR total	-	-	-	-	-	-	-	-	-

RCR values above 1 are indicated in **bold** writing

Body cream/lotion
When adding up RCR values for dermal and oral exposure, further products with an RCR value above 1 are not identified.

For product No. 10, however, it is seen that RCR in terms of liver risk now reaches a value of 2.2, when the RCR of 0.87 for dermal and RCR of 1.4 for oral exposure are added. These values are due to the content of D3 and D6 respectively.

Sun cream/lotion
When adding up RCR values for dermal and oral exposure, further products with an RCR value above 1 are not identified.

For product No. 35, where risk was not previously estimated for D3, the addition of RCR value for oral and dermal exposure for D3 now gives a combined RCR of 1.3. When adding also the RCR for D6, a combined RCR of 1.4 is obtained for the risk of liver effects.

For product No. 46 a risk for the product is now even more clear when the dermal and oral contributions are added, and combined RCR values of 75 and 51 are now seen for liver effects and uterus tumors respectively.

For product nr. 29 it is also seen that the risk is expressed more clearly, as a combined RCR of 11 is reached when both dermal and oral RCR values for liver effects are added. The RCR values with the highest impact on this is the RCR of 5.5 for oral exposure to D6 and the RCR of 3.9 for dermal exposure to D3.

Overview
Above, RCR values above 1 for combined oral and dermal exposure to children for the following products were found (RCR for siloxanes which are not changed by adding oral and dermal RCR are not included):

Product No.	Product type	Siloxanes	RCR (oral + dermal)
10	Body cream	D3, D6	2.3 (D3+D6)
29	Sun spray	D3, D6	5.1 (D3) 5.7 (D6) 11 (D3+D5+D6)
35	Sun cream	D3	1.3 (D3)
46	Sun cream	D3, D4, D5, D6	24 (D3) 4.6 (D4) 46 (D5) 51 (D4+D5) 75 (D3+D4+D5+D6)

*Only siloxanes with an RCR>1 are indicated.

4.2.5 Risk characterisation of inhalation of spray aerosols
First step is to tind the tolerable concentrations for the various siloxane compounds in the different product types. With the above method as described in section 4.2.1 this can be calculated as indicated in TABLE 29 below.

TABLE 29 Inhalation, tolerable exposure levels for single substances and associated tolerable product concentrations.

Substance:		D3	D4	D5	D6	Dimethicone	Trisiloxane	Phenyl trimethicone
Tolerable concentration mg/m^3		0.32	1.0	5.4	0.13	-	38	-
Corresponds to inhaled tolerable amount/day:								
Tolerable conc. x 20m^3/60 kg (mg/kg bw/day):		0.11	0.03	1.8	0.04		13	
Critical effects/target organ:		liver effect	lung effects	Lungs /liver	Lungs /liver	-	liver and biliary system	-
Product category	Daily inhalation exposure with the product mg/kg bw/day	---------- Tolerable concentration in the product mg/kg ----------						
Deodorant pressure container spray	0.41	2.7x10^5	7.3x10^5	4.4x10^6	1.0x10^5	-	3.2x10^7	-
Hair spray, pressure container	4.08	2.7x10^4	7.4x10^4	4.4x10^5	9.8x10^3	-	3.2x10^6	-
Hair spray, pump spray	2.16	5.1x10^4	1.4x10^5	8.4x10^5	1.9x10^4	-	6.0x10^6	-
Hair oil/lotion, pump spray	2.40	4.6x10^4	1.3x10^5	7.5x10^5	1.7x10^4	-	5.4x10^6	-
Hair balm/conditioner, pump spray	2.39	4.6x10^4	1.3x10^5	7.5x10^5	1.7x104	-	5.4x10^6	-
Sun spray, pump spray	0.11	1.0x10^6	2.7x10^6	1.7x10^7	3.6x10^5	-	1.2x10^8	-

It should be noted that in the cases where the tolerable exposure to a substance is higher than the actual exposure to the entire product, a tolerable concentration of more than 1000 000 mg/kg is calculated, which is not possible. Nevertheless, these values may be used for calculation reasons in the risk assessment and the RCR calculations as a given content in the product, even below the tolerable exposure level, still makes up a certain contribution in terms of an RCR value, which may have impact when adding up RCR values for several substances in the product with similar toxicity.

Further, it has to be noted that risk assessment for local effects in the lung (inflammatory changes) is also performed using the dose metric mg/kg bw/day, as it is assumed that it is the daily amount of inhaled of D4, D5 and D6 and the deposited amount in the lung that determine the toxicity rather than the short term peak exposure (expressed in mg/m^3).

Below in TABLE 30, the tolerable exposure concentrations are put in relation to the measured concentrations in the products, and RCR values for the ingredients in the individual products are calculated. For the individual products, RCR values for substances with effects on the same target organ were added. Thus, RCR values for the substances D3, D5, D6 and trisiloxane are added for liver effects, and RCR values for lung effects for D4, D5 and D6 are added in order to determine the combined risk in terms of effects on liver and lungs. When adding RCR values, the value <0,01 is not included as contribution at this low level is considered to be insignificant. Values where the detection limit is indicated as ”<50” in TABLE 20 are not included in the table below but simply replaced by the notation ”-”.

TABLE 30. Risk assessment of exposure by inhalation

Product no.	Product type	D3*	D4	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Dromettrizol trisiloxane	Cumulated RCR (D4+D5+D6) lung effects	Cumulated RCR* liver effects
38	Deodorant, pressure container spray									
	Analysis conc., mg/kg	-	400	319000	1400	-	-	780		
	Tolerable conc. mg/kg	-	$7,3x10^5$	$4,4x10^6$	$1,0x10^5$	-	-	-		
	RCR	-	<0,01	0,73	0,01	-	-	-	0,74	0,74
17	Hair spray, pressure container spray									
	Analysis conc., mg/kg	-	-	-	-	-	1900	-		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-
18	Hair spray,pump spray									
	Analysis conc., mg/kg	260	210	68000	610	-	-	-		
	Tolerable conc. mg/kg	$5,1x10^4$	$1,4x10^5$	$8,4x10^5$	$1,9x10^4$	-	-	-		
	RCR	<0,01	<0,01	0,08	0,03	-	-	-	0,12	0,11
19	Hair spray,pump spray									
	Analysis conc., mg/kg	100	-	-	-	-	930	-		

Product no.	Product type	D3*	D4	D5*	D6*	Trisiloxane*	Phenyl trimethicone	Dromettrizol trisiloxane	Cumulated RCR (D4+D5+D6) lung effects	Cumulated RCR* liver effects
	Tolerable conc. mg/kg	$5,1x10^4$	-	-	-	-	-	-		
	RCR	<0,01	-	-	-	-	-	-	-	<0,01
16	Hair balm/conditioner, pump spray									
	Analysis conc., mg/kg	160	340	280000	15000	-	14000	-		
	Tolerable conc. mg/kg	$4,6x10^4$	$1,3x10^5$	$7,7x10^5$	$1,7x10^4$	-	-	-		
	RCR	<0,01	<0,01	0,38	0,88	-	-	-	**1,3**	**1,3**
20	Hair oil/lotion, pump spray									
	Analysis conc., mg/kg	15000	398000	2500	-	290	-	-		
	Tolerable conc. mg/kg	$4,6x10^4$	$1,3x10^5$	$7,7x10^5$	-	$5,4x10^6$	-	-		
	RCR	0,33	**3,1**	<0,01	-	<0,01	-	-	**3,1**	0,33
28	Sun spray, pump spray									
	Analysis conc., mg/kg	-	-	-	-	-	-	6900		
	Tolerable conc. mg/kg	-	-	-	-	-	-	-		
	RCR	-	-	-	-	-	-	-	-	-

RCR values above 1 are indicated in **bold** writing

NB. It should be noted that for D5 it has been decided to use a tolerable exposure level of 5.3 mg/m^3 for lung effects and liver effects for calculation of the tolerable concentration levels in order to be able to make an additive risk assessment of the other siloxanes with similar critical effects. If the risk assessment for D5 is made with a tolerable exposure level of 4.3 mg/m^3 based on uterus tumors and thereby corresponding lower tolerable concentrations in the products, the highest RCR value obtained would be 0,90 for spray in pressure containers, and thereby none of the products will cause unacceptable increased risk of uterus tumors (calculations for this are not included in the table).

Deodorant
One spray product deodorant (product No. 38 in pressure container) was analysed. Here an RCR value of 0.9 could be calculated for lung effects because of content of D5 (31.9 %). This RCR value is close to the limit for potential risk. However, a very conservative approach for exposure estimation has been used, as it is assumed that the entire sprayed amount is distributed in the air and thus no aerosols is deposited on the body or on room surfaces including the floor. Taking this further into account it can be concluded that no risk applies to the use of the product. The scenario is estimated to be without a risk.

Hair spray
Three hair sprayes were analysed, two pump sprays and one pressure container. The highest RCR value of 0.10 was obtained from product No. 18, which is a pump spray with 6.8% content of D5.

None of the examined hair sprays is estimated to constitute a risk in connection with inhalation.

Hair balm/conditioner
One pump spray product (product No. 16) was analysed in this category. A cumulated RCR of 1.4 for both lung effects and liver effects was obtained on the basis of the content of D5 (28% and RCR of 0.48) and D6 (1.5% and RCR of 0.88).

Especially for pump sprays, the exposure estimate is considered to be highly worst-case as it is assumed in the exposure scenario that the entire sprayed amount is distributed in the air and stays there for several minutes, and that none of the product is deposited (i.e. no deposit on the room surfaces or floor and it does not settle on hair or skin). When performing a spray test with product No. 16 it became clear that the aerosols sedimented within a few seconds, and therefore it is not considered likely that the relatively limited exceedance of the RCR value of 1 would cause a risk by inhalation.

Hair oil/lotion
One product (product No. 20) in pump spray form was analysed in this group. Here an RCR value of 3.1 was obtained due to a high content of D4 (39.8%).

Especially for pump sprays, the exposure estimate is considered to be highly worst-case as it is assumed in the exposure scenario that the entire sprayed amount is distributed in the air and stays there for several minutes, and that none of the product is deposited (i.e. no deposit on the room surfaces or floor and it does not settle on hair or skin). When performing a spray test with product No. 20 it became clear that the aerosols sedimented within a few seconds, and therefore it is not considered likely that the relatively limited exceedance of the RCR value of 1 would cause a risk by inhalation.

Sun spray
One product (product No. 28) in pump spray form was analysed in this product group. As the only siloxane, the product contained drometrizole trisiloxane (6.8%). However, no publicly available toxicity data on drometrizole trisiloxane has been found which could form a basis for a risk assessment.

Overview

Above, RCR values above 1 for inhalation exposure were found for the following products:

Product No.	Product type	Siloxanes	RCR
16	Hair balm (pump spray)	D5 + D6	1.3
20	Hair oil (pump spray)	D4	3.1

*Only siloxanes with an RCR >1 are indicated.

4.3 Discussion and conclusions on consumer risk

For the discussion and conclusion, the results of the products estimated to form a potential risk to consumers (adults or small children) are listed below in TABLE 31.

TABLE 31. Products estimated to form a potential risk for consumers (RCR >1)

No.	Product	Substance	Exposure route	RCR adults	RCR children	Assessment/comments
7	Foundation	PTM	Dermal	1.1	n.c.	Low reliability in terms of tolerable exposure level and thereby RCR for PTM
10	Body cream	D3	Dermal Oral Dermal + oral	- 	0.87 0.27 1.2	Limited exceedance of RCR=1 for D3, must be seen in relation to lack of knowledge about dermal absorption of D3.
		D6	Dermal Oral Dermal + Oral	- - -	0.04 1.1 1.14	Marginal exceeding of RCR=1 for D6. Conservative oral exposure estimate (sucking two hands every day)
		D3+D5+D6 liver effects	Oral + Dermal	-	2.3	Combined there is a 2.3 times exceedance of tolerable exposure level. **The product must be considered to constitute a risk especially to children**
16	Hair balm	D5+D6 liver effects	Inhalation	1.3	n.c.	Exposure estimation of pump spray very exaggerated. Based of visual testing of the aerosol formation from the product and the fast sedimentation the product is concluded not to constitute a risk.
20	Hair oil, pump spray	D4	Inhalation	3.1	n.c.	Exposure estimation of pump spray very exaggerated. Based of visual testing of the aerosol formation from the product and the fast sedimentation the product is concluded not to constitute a risk.
29	Sun spray	PTM	Dermal	-	1.9	Low reliability of the derivation of the tolerable exposure level for PTM. Not conclusive.
		D3	Dermal Oral Dermal + oral	-- - 	3.9 1.2 5.1	Lack of knowledge on dermal absorption of D3 which limits the reliability of the RCR value, which is however relatively high.
		D6	Dermal Oral Dermal + oral	- - -	0.19 5.5 5.7	The oral RCR value for D6 is considered to be reliable. The oral exposure estimate is conservative (sucking both hands), but even considerably lower exposure estimates would show oral RCR values above 1 for D6.
		D3+D5+D6 liver effects	Dermal + oral	-	11	**Product is estimated to constitute a risk to children**
35	Sun cream	PTM	Dermal	1.1	5.3	Low reliability of the derivation of the tolerable exposure level for PTM. Not conclusive.

		D3	Dermal Oral Oral + Dermal	- -- 	0.95 0.30 1.2	Limited exceedance of RCR value of 1 for D3, must be seen in relation to lack of knowledge about dermal absorption of D3.
46	Sun cream	D3	Dermal Oral Oral + Dermal	4.0 - -	18 5.7 24	The oral exposure estimates are conservative (sucking hands) but even considerably lower exposure estimates would result in an oral RCR value above 1.
		D4	Dermal + Oral	-	4.6	
		D5	Dermal Oral Oral + Dermal	1 - -	4.4 42 46	High reliability of dermal tolerable exposure level for D5
		D4+D5 Uterus tumors		-	51	High reliability of oral tolerable exposure values for D3, D4 and D5.
		D3+D4+D5+ D6, liver effects	Dermal + oral	-	75	**Product is estimated to form a risk, especially for children**

PTM: phenyltrimethicone. n.c. = not calculated

As it appears from the comments in the table, the calculated RCR values for phenyl trimethicone (PTM) are considered to be of very low reliability, as the estimated tolerable exposure level used for calculation of the RCR value is very uncertain. As previously mentioned, this is due to the fact that the toxicological data for phenyl trimethicone are from the mid-1960'ies, where no standards for toxicological testing existed. Furthermore, it is not known whether the quality used at that time corresponds to the qualities used in cosmetics today. The risk assessments for the products 7, 29 and 35 are therefore very uncertain, and it is not possible to make a final conclusion about risk from phenyl trimethicone.

The indentification of risk by using the products 10 og 35, based on RCR values just above 1 for dermal exposure with D3 and oral exposure for D6, is somewhat uncertain. This is due to the uncertainty for determination of the tolerable dermal exposure for D3, as data on dermal absorption are missing. Furthermore, the oral exposure estimate for D6 in body cream is very conservative, as this pertains to a child sucking cream off both hands on a daily basis. As RCR is very close to 1 for D3 and D6, it is difficult to document that the products constitute an increased risk to the consumer.

The risk assessments for use of product 46 and 29 are estimated to be considerably more robust and well founded. Both products contain several siloxanes, where RCR is considerably above 1 for children both for oral and dermal exposure. Even if there are still uncertainties about the assessment of the dermal absorption of D3, both products must be considered to constitute a risk for children.

Uncertainties and limitations

Above it was mentioned that there are various degrees of uncertainty for determination of the tolerable exposure levels for the single siloxanes depending on amount, quality and relevance of the toxicological data that are the basis for the assessment. Concerning the exposure estimates, dermal exposure is used for exposure values for the individual product types as indicated by SCCS in their guidelines for risk assessment of cosmetic products, whereas a worst case estimate is used for oral exposure to small children assuming that a child licks all cream off both hands after application. For inhalation of aerosols, an exposure model is used for precautionary reasons, where the premise is that the entire sprayed amount stays in the air and is airborne and available for inhalation for more than half an hour.

An attempt has been made to consider these uncertainties regarding derivation of the tolerable exposure levels as well as the exposure estimates in the conclusions given above.

In the risk assessment above, each product is assessed separately and it is estimated if application of one product alone can constitute a risk. When SCCS assesses the safety of cosmetic ingredients, they also include the estimates for contribution of other cosmetic products categories which may contain the same ingredient.
This method is regarded as especially relevant, when future use of a cosmtic ingredient is assessed as safety for the combined exposure from the substance is to be considered when calculating tolerable concentrations for the products.

This method was not used in this project for several reasons. First of all, the analytical results show that the content of the various siloxanes vary considerably within the different product categories, and consequently it will be difficult to make relevant scenarios with use of different types of products with realistic concentrations of the siloxanes. Secondly, in a project like this, it is very important to use a general, accepted and transparent standard approach for determination of the consumer exposure in order to strengthen the documentation when a possible risk from a product is identified.

Thirdly, it must be pointed out, that the risk assessment for the analysed products are only related to the siloxanes (D3, D4, D,5, D6, trisiloxane and partly phenyl trimethicone), for which toxicological data for assessment of a tolerable exposure level were available. Missing data thereby means that content of other detected short linear siloxane compounds and higher cyclic siloxanes (see TABLE 20) could not be included in the risk assessment.

Finally, it is considered problematic that adequate toxicological information for use in safety assessment is missing for some generally used siloxane compounds in cosmetics, e.g. phenyl trimethicone and drometrizole trisiloxane.

5. Environmental impact of siloxanes

An actual environmental risk assessment requires a mapping of the consumption of the different siloxanes, where both data on the consumption pattern of the many different products containing siloxanes – including an analysis of the market shares – and data for the content of the substances in the individual product types must be collected. This has not been possible within the frames of this project, which is the reason why it has been chosen to calculate an impact on the environment for each product type per person.

In this way the products within the same product types can be compared, and it is possible to identify the products which have the highest and lowest impact on the environment within each product type. Furthermore, there is a need to estimate whether the ongoing process with substitution of cyclic siloxanes by dimethicone in cosmetic products will lead to improvements or reductions of the impact on the environment from siloxanes.

An environmental risk assessment consists of a calculation of the ratio between the expected concentrations in the environment, Predicted Environmental Concentration (PEC) and the concentration in the environment where effects are not expected in terms of so-called Predicted No-Effect Concentrations (PNEC). PEC is here calculated after usual principles, whereas it has not been possible to find PNEC values for all siloxanes – as it will be discussed later – which is why an alternative method to quantify the environmental hazard of the substances has been used.

5.1 Exposure assessment

The predicted concentration in the environment (PEC) is calculated by the use of the program EUSES (RIVM 2007).

Inputs to the model are inherent properties of the substance, e.g. biodegradability, octanol-water distribution coefficient, logPow, vapor pressure and water solubility. Furthermore, the used amount and emission to the environment must be indicated.

For the individual product type, the daily amount used by the consumers is applied and the calculated concentrations will thereby become an environmental concentration expressed per person per product type.

Applied amounts for the environmental impact assessments is the highest measured content of each of the concerned substances in the given product type. The applied doses and substance concentrations can be seen in TABLE 32. The siloxane compound called Siloxane X has structural similarities to phenyl trimethicone. For the environmental impact assessment, it was decided to use the highest content of those substances and make the assessment using data from the siloxane with the highest content.

For assessment of release into the environment, the product types were further distributed into three groups according to their expected fate (also appears from TABLE 32):

I. The products are rinsed off directly after use

II. The product remains on the body for a longer time, whereby the volatile substances can evaporate during use and the other, non-volatile, substances can be washed off during personal washing

III. The product can come into contact with surface water during use and thereby end up directly in surface water. Altenatively, residues of the substance can we washed off during personal washing

TABLE 32. Daily product consumption per person (g) and maximum concentrations (mg/kg) in the given product category as basis for the environmental assessment.
Fate group I: The products are washed away directly after use: Fate group II: The product stays on the body for a longer time, by which the volatile substances can evaporate during use and the other, non-volatile, substances can be washed off during personal washing. Fate Group III. The product may come into contact with surface water during use and thereby end up directly in surface water. Alternatively residues of the substances are washed off during personal washing.

Product category	Daily amount g per person	Fate group	D3	D4	D5	D6	Trisiloxan	Drometrizole trisiloxan	Phenyl trimethicone	Siloxane X
Hair shampoo	18.67	I	60	-	-	10	-	40	-	-
Hair balm/conditioner	3.92	I	11 000	192 000	870 000	15 000	200 000	90	14 000	6 700
Facial day creams/lotion	1.54	II	2 600	200	90 000	55 000	800	1 100	240	-
Foundation	0.51	II	5 300	4 600	264 000	142 000	57 000	1 600	28 000	5 700
Body care creams/ lotion	7.82	II	960	60	9 700	32 000	-	80	90	-
Hair spray spray, pressure container	6.8	II	40	-	10	-	-	-	1 900	110
Hair spray spray, pump spray)	3.6	II	260	210	68 000	610	-	-	930	830
Hair oil/--lotion	4.0	II	16 000	398 000	158 000	15 000	490	50	400	410

Product category	Daily amount g per person	Fate group	D3	D4	D5	D6	Trisiloxan	Drometrizole trisiloxan	Phenyl trimethicone	Siloxane X
Deodorant/ antiperspirant Non-spray	1.50	II	5 800	5 900	910 000	990	-	10	-	-
Deodorant/ antiperspirant Spray	0.69	II	-	400	319 000	1 400	-	780	-	-
Sun cream/-lotion	18.0	III	2 900	17 000	160 000	3 200	20	3 400	740	-
Sun spray, pump spray	18.0	III	620	30	1 200	31 000	-	71 000	80	-

5.1.1 Substance properties

TABLE 33 shows physical-chemical and fate properties of some of the siloxanes.

TABLE 33. Physical-chemical and fate properties for siloxanes used for the environmental assessment. Hydrolysis data can be seen in TABLE 34. NB: not biologically degradable.

Data references: 1: ECHA reg. database; 2: EpiSuite-calculations; 3: EpiSuite database; 4: Danish QSAR-database; 5: Calculated from vapor pressure and water solubility 6: From NICNAC risk assessment report, NICNAS (2018); 7: SIDS for the substance; 8: calculated in NICNAC (2018) from the measurements for D3, D4 and D5. 9: BCF is estimated to be low, as logPow is considerably below 3. 10)Based on measured hydroxyl radical (OH) reaction rate constant from Markgraf&Wells (1997) 11) Based on measured hydroxyl radical (OH) reaction rate constant from REACH registration dossier. *): from the REACH reg. dosser of chlorodimethylsilane

Name	Molar mass	Melting point (°C)	Boiling point (°C)	Vapor pressure (Pa) at 25°C unless otherwise specified	LogPow	Bio concentation factor (BCF)	water solubilility (mg/L) at 25°C unless otherwise specified	Henry's constant (Pa·m3/mol) at 25°C unless otherwise specified	logKoc	Biodegradability	Half life in air (days)	Measured half life in air (days)
Dimethicone (Dimethyl siloxane)	Polymer	<25	344[2)]	0.001[2)]	12[2)]		1.00E-03[2)]	1.0E-05[2)]	6.1[2)]	NB[2)]	1.85[2)]	
Trisiloxane, Octamethyltrisiloxane	237	-88[1)]	153[1)]	530[1)]	6.598[1)]	27600[1)]	0.035[1)]	1.6E+06[12°C,1)]	4.34[2)]	NB[1)]	13.41[2)]	8.8[10)]
Phenyl trimethicone	373	-30[1)]	280[1)]	0.09[1)]	9.0	384-2 992, key value 2765[1)]	0.007[1)]	5.0E+03[5)]	5.67[2)]	NB[1)]	4.87[2)]	
D3 Hexamethylcyclotrisiloxane	222	64[1)]	135[1)]	671[1)]	4.4[1)]	100[7)]	1.4[2)]	1.8E+05[1)]	3.27[2)]	NB[1)]	17.88[2)]	5.7[6)]
D4 Octamethylcyclotetrasiloxane	293	18[1)]	175[1)]	132[1,6)]	6.49[1)]	14 900[1)]	0.056[1)]	1.2E+06[1)]	4.2[2)]	NB[1)]	14.1[1)]	4.5[6)]
D5 Decamethylcyclopentasiloxane	371	-38[1)]	210[1)]	23[1,6)]	8.023[1)]	16 200[1)]	0.017[1)]	3.3E+06[24.6°C1,)]	5.17[2)]	NB[1)]	10.4[1)]	4.2[6)]

Name	Molar mass	Melting point (°C)	Boiling point (°C)	Vapor pressure (Pa) at 25°C unless otherwise specified	LogPow	Bio concentation factor (BCF)	water solubiliility (mg/L) at 25°C unless otherwise specified	Henry's constant (Pa·m3/mol) at 25°C unless otherwise specified	logKoc	Biodegradability	Half life in air (days)	Measured half life in air (days)
D6 Dodecamethylcyclohexasiloxane	445	-3[1)]	245[1)]	4.7[1)]	8.87[1)]	2 860[1)]	0.0051[1)]	2.5E+06[23.6°C,1)]	5.94[2)]	NB[1)]	9[1)]	3.38[6)]
Cyclomethicone[4]	222	65[3)]	134[3)]	1 160[2)]	5.64[2)]		1.55[2)]	1.7E+05[5)]	3.27[2)]	NB[2)]	17.88[2)]	
Drometrizole trisiloxane	502	226[4)]	529[4)]	0.001[2)]	10.82[4)]	180[4)]	6.40E-07[4)]	1.0E-10[5)]	7.2[2)]	NB[2)]	0.70[2)]	
Dimethylsilanole (hydrolysis product)	76	-87[2)]	108[2)]	1730[2)]	0.6[1*)]	Low[9)]	miscible[2)]	0.13[5)]	1.5[2)]	NB[2)]	4.28[2)]	
Trimethylsilanole (hydrolysis product)	90	-11.9[1)]	98[1)]	1 900[1)]	1.19[1)]	Low[9)]	995[24°C,1)]	2.0[5)]	1.64[1,2)]	NB[1)]	4.12[2)]	11.5[11)]
Dimethylsilanediol (hydrolysis product)	92	-19[2)]	184[2)]	18.1[2)]	-0.4[2)]	Low[9)]	miscible[2)]	0.002[5)]	1.64[2)]	IB[2)]	2.23[2)]	

[4] Mix of many different cyclosiloxanes

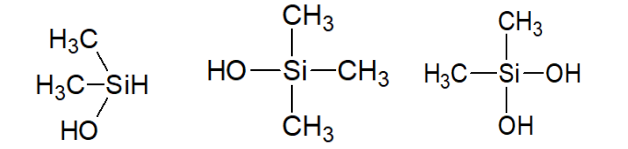
Generally, both the acyclic and the cyclic siloxanes are only very limited water soluble with a water solubility below 1-2 mg/L (see TABLE 33). Furthermore they are hydrophobic with a log-Pow above 5.

Some of the siloxanes are also very volatile from water solutions according to their high Henry's constants above 5 000 Pa·m^3/mol (see TABLE 33).

5.1.1.1 Fate in the environment

Decomposition in the environment
As it appears from TABLE 33, the siloxanes are neither lightly – nor inherently – biodegradable, but the siloxanes can be broken down to other smaller units by abiotic reactions such as hydrolysos. A precondition for these reactions is of course water.

Some of the cyclic and acyclic siloxanes are hydrolised quickly – especially at low and higher pH (data from the REACH registration dossiers for the substances) – see TABLE 34. the hydrophilic substances dimethylsilanol, trimethylsilanol and dimethylsilanediol (DMSD) are important degradation products from the hydrolysis, see for example the REACH registration dossier for D4, D5, D6.:



dimethylsilanole ***DMS*** | ***trimethylsilanole*** ***TMS*** | ***dimethylsilanediol*** ***DMSD***

Dimethylsilanol can hydrolyse into dimethylsilanediol (DMSD), which is likely to be the final hydrolysis product.

Specifically the siloxane dimethicon (polydimethylsiloxane) was tested under extreme pH conditions (pH 2-4 and 9-12) (Ducom G. et al. (2013). Here it was found, that the polymer can be hydrolised and that the decomposition products are likely to be siloxanols, i.e. siloxane compounds with one or several hydroxyls (OH)-groups as for example DMSD. The presence of hydroxyl-groups will increase the water solubility.

TABLE 34. Hydrolysis rates are indicated as half times for some of the selected siloxanes at different pH. Data for this was found in the REACH registreation dossiers.

Siloxane	pH=4	pH=5	pH=5.5	pH=7	pH=8	pH=9	Ultimate hydrolysis product
Trisiloxane		5.09 hours		329 hours		9.76 hours	DMS, DMDS
Phenyl trimethicone	>1.9 hours			>200 hours*		>2.0 hours	methyl(diphenyl)silanol and methyl(phenyl)silanediol
D3	2 min			23 min		5 min	DMS, DMDS
D4	1.8 hours			69-144 hours		0.9-1 hours	DMS, DMDS
D5	9.3 hours		351 hours	1 590 hours	214 hours	31.6 hours	DMS, DMDS
D6	42 hours			401 hours		125 hours	DMS, DMDS

In this connection, it can be emphasised, that the pH of the skin is 4-6, why some of the above siloxanes (in particular D3, and to a lesser extent phenyl trimethicone, trisiloxane and D4, and to a much lesser extent D5) are expected to be degraded partly by hydrolysis, if they stay on the skin long enough. The is relevant for instance for creams.

pH in the external environment varies of course but will in general be at pH = 7- 8. Under these conditions, hydrolysis of siloxaner will appear – but much more slowly than at lower and higher pH values. As a conservative approach, the calculations of exposure concentrations did not allow for the hydrolysis. Instead, supplementary exposure calculations were made for dimethylsilanol and trimethylsilanol to cover the hydrolysis of the substances at long-term skin contact with cosmetic products containing siloxanes – which can be relevant for the products in the fate groups II and III (cf.Table 32) , i.e. products which are not rinsed off immediately during use.

Degradation in soil

It was found that degradation of polyorganosiloxanes (including cyclic volatile methylsiloxanes) in soil is an abiotic process, which is catalysed by clay minerals (Rücker and Kümmerer, referred in NICNAS, 2018).

The fate in the environment is in general primarily examined for the cyclic siloxanes. It was found that the fate of cyclic volatile siloxanes in the soil is highly dependent on the mineralogy of the soil and the humidity levels of the soil (NICNAS, 2018). In a very disintegrated soil with a high level of clay minerals it was found that the degradation half times for D4, D5 and D6 were all less than 2 days at the same relative humidity (32%; in a closed system). The degradation products are not mentioned specifically in the reference – but they are most likely the hydrophilic substances dimethylsilanol, trimethylsilanol and dimethylsilanediol (DMSD). The degradation rate was lower in soil with a lower percentage of different clay minerals. Furthermore, the relative significance of the degradation in the soil decreases with increasing relative humidity in the soil, which is due to the increased evaporation of the volatile cyclic siloxanes at increased humidity. According to their REACH registration dossier, halflives of 5.2 days, 12.5 days and 220 days in soil are summarized for D4, D5 and D6.

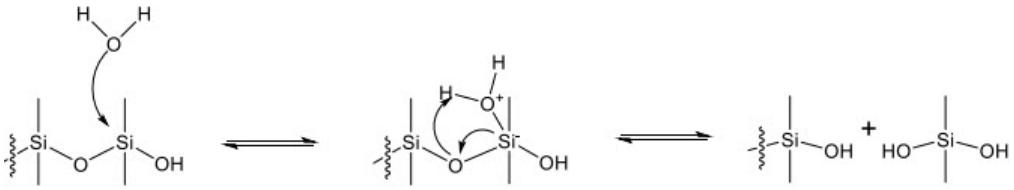
A soil degradation study is reported in REACH registration dossier for trisiloxane and a halflife of 10 days in soil is reported. The soil degradation/volatilisation study for L3 was conducted in two different soils and degradation half-lives ranging from 1.48 d at 22.5°C and 32% RH (relative humidy) to 119.5 d at 22.5°C and 100% RH were measured.The degradation products were DMSD, trimethylsilanol and 3, 3, 3, 1, 1-pentamethyldisiloxanol.

In open systems, volatilisation was the predominant process for removal of L3 from soil at 100% RH with a volatilisation half-life of <1 day, much faster than the degradation of L3 at the same moisture level in the closed system.

In loamy silt soil, the degradation half-life (closed tubes) was 0.26 d at 32% RH and at 22.5 °C. In dry soil, DMSD is the terminal degradation product for D4, D5 and D6. The initial step in the degradation process involves hydrolytic division of the siloxane ring to formation of the corresponding linear dimethylsiloxandiols, which are then hydrolysed to the common degradation product DMSD. The ring opening hydrolysis reaction is partly reversible, and when the water content in soil is increased a condensation of linear dimethylsiloxandiols may occur back to the cyclic volatile methylsiloxanes such as D3 and D4 (Xu S, referred in NICNAS, 2018). As described above, these chemicals are volatile in humid soil and will tend to evaporate to the athmosphere.

It is found that dimethicone ultimately degrades to dimethyl-silanediol (DMSD) and that this pattern is similar in a variety of soil (Lehmann et al., 1994, 1995) and not dependent on the

size of the polymer (ECETOC, 2011). Other small silanols and cyclic siloxanes are either not detected or present in only trace amounts. The environmental degradation of dimethicone in the soil environment has been tested on a laboratory scale. The degradation of dimethicone appears to happen via a two-step reaction involving an initial abiotic (i.e. non-biological) mechanism, which is - as the cyclic siloxanes - catalysed at contact with clay minerals, and a subsequent biological degradation. The pathway of hydrolysis is a stepwise reaction, where DMSD is formed and the chain length of dimethicone is shortened. So ultimately, the polymer is hydrolytically degradeded down to small linear siloxanes (L2, L3, …) This is illustrated in the below figure, (figure taken from Örn, 2019.):



Thus, the most important final degradation product which exists as a result of the abiotic degradation step is DMSD. This reaction appears fastest in dry soil (halflife in days) but has also turned out to appear in wet soil (half-life in years) and even slower in sediment (half-life in several years) (ECETOC, 2011).

DMSD was found to degrade further to yeld $^{14}CO_2$, to evaporate or incorporated in soil components (Lehmann et al., 1994, 1995). The fate of DMSD depends on the type and conditions of the soil, but it may evaporise and then become degradated in the atmosphere (probably to CO_2, water and SiO_2) or it may become very slowly biologically degradated in the soil to silica, CO_2 and water with a half time of approx. 1-3 years (Lehmann et al., 1998).

As previously mentioned, dimethicone consists of linear siloxanes with varying chain lengths and it is to be expected that the content of both low molecular and high molecular linear siloxanes varies in dimethicone. The low molecular siloxanes as opposed to the high molecular siloxanes are expected to evaporate.

Degradation in the air

TABLE 33 gives an overview of the degradation behaviour of siloxanes in air. Only siloxanes with a high Henrys constant is considered relevant with respect to the degradation rate in air. This includes trisiloxane, D3, D4, D5, D6, cyclomethicone and to a much lower degree phenyl trimethicone and trimethylsilanol.

Measurements for the small cyclic siloxanes (D3, D4, D5 and D6) show half times in the air of 3-5 days, whereas the calculated half times are somewhat higher, i.e.10-18 days. The linear siloxane, trisiloxane, shows a half-time in air of approximately 9 days, based on measured hydroxyl-reaction rate, trimethylsilanol a half-time in air of approximately 11.5 days based on based on measured hydroxyl-reaction rate. The calculated half-time in air of phenyl trimethicone is 4.9 days.

Overall, once released into air, phenyl trimethicone, D3, D4, D5, D6, cyclomethicone tend to be rapidly degraded and will only deposit on water/soil to a very low degree. Trisiloxane and trimethylsilanol has quite longer halflives in air and may therefore well deposit from air on water/soil.

No assessment has been made in terms of siloxanes evaporating during use (fate group II and III) (see section 5.1 and TABLE 32).

Comparison of the degradation rates of linear and cyclic siloxanes

Unfortunately the acyclic siloxanes are not as well examined as the cyclic in terms of their degradability. A general comparison has been made, however, between the liniar and the cyclic siloxanes (Kim et al., 2017), where the fate of the substances in the environment was examined by modelling. For this, a number of assessed substance data were included as shown in TABLE 35 – including half times in water and sediment. It shows that the acyclic siloxanes in general have about the same half times as the corresponding cyclic siloxanes with the same number of Silicium-units.

TABLE 35. Comparison of a number of properties for the short linear and cyclic siloxanes. Data are from Kim et al. (2017). The half time in water and sediment includes especially hydrolysis.
L2: hexamethyldisiloxan; L3: octamethyltrisiloxan; L4: decamethyltetrasiloxan; L5: dodecamethylpentasiloxan; D3: hexamethylcyclotrisiloxan; D4: ctamethylcyclotetrasiloxan; D5: decamethylcyclopentasiloxan; D6: dodecamethylcyclohexasiloxan

	Acyclic siloxanes		Cyclic siloxanes			
Siloxane	L3	L5	D3	D4	D5	D6
Molar mass (g/mol)	236.5	384.8	222.5	296.6	370.8	444.9
Vapor pressure (Pa at 25 °C)	535	6	671	140	33.2	6
log Pow (at 25 °C)	6.79	9.41	4.38	6.98	8.09	8.87
Water solubility (mg/L)	0.035	$7.0 \cdot 10^{-5}$	1.56	0.056	0.017	0.005
Half time in water (days at 25 °C)	13.7	41.5	0.03	3.9	70.4	401
Half time in sediment (days at 25 °C)	365	912	3	365	3 100	3 100

Distribution in the environment and possibilities for long-range-transport

An outline of the degradation and distribution in the enviroment is shown in Figure 5.1.

Siloxanes in the environment tend to distribute to the non aqueous parts of the environment. The siloxanes will primarily partition into the hydrofobic part of the environment, i.e. the soil matrix, sediment and biological material, and to the air (for the volatile siloxanes), where they slowly will degrade into SiO_2. It must be emphasised that the biodegradation of siloxanes is very slow and should be measured in years, and that the degradation rate decreases with the size of the molecule.

A monitoring study has been carred out in the Nordic countries (Nordtest, 2005), where both air, water, sludge, sediment and biota samples were analysed for the linear siloxanes hexamethyl-disiloxane (L2), octamethyltrisolixane (L3), decamethyltetrasiloxane (L4), dodecamethylpentasiloxane (L5), and the cyclic siloxanes octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodeca-methylcyclohexasiloxane (D6). In addition, hexamethylcyclotrisiloxane (D3) was analysed in biota. Siloxanes were found in all analysed media. It was concluded that there is a general pollution of siloxanes in the Nordic countries – but with great variation in concentrations. The cyclic siloxanes occurred in all media in significantly higher concentrations than the linear siloxanes.
D5 was the dominating siloxane in most samples, D4 occurred generally in the highest concentration in the air samples. The results of air measurements in urban areas indicated a regional variation, with the highest concentration in Norway and the lowest in Sweden. The air concentrations were highest inside sewage treatment plants, and elevated levels were commonly observed in other matrices surrounding STPs. No other obvious point sources were found. The concentrations were generally elevated in urban areas and in areas close to sewage treatment plants. The observed concentrations in fish liver were fairly variable. Siloxanes were mainly detected in fish liver samples from sites representing urban/diffuse sources and only a few background samples showed detectable levels. On the whole, biota data indicated that siloxanes may bioaccumulate.

The behaviour of the considered siloxanes once released to the environment will vary due to differences in their inherent properties. Distinction should be made between the volatile (trisiloxane, D3, D4, D5 and D6) and the non-volatile siloxanes (Dimethicone, phenyl trimethicone and Drometrizole trisiloxane).

Volatile siloxanes

If released to air, the volatile siloxanes (D3, D4, D5 and D6 and trisiloxane) will remain in air until they degrade. If released to sewage treatment plants (STPs) the majority (>90%) of the release will partition to sludge with a significant amount volatilizing to air from the sludge and the small amount that distributes to water will be bound to particulate and move to the sediment.
If sludge is amended to soil the volatile siloxanes (D3, D4, D5, D6, trisiloxane) quite readily will be transformed to DMSD og TMS by hydrolysis depending on the soil conditions as previous described.

Non-volatile siloxanes

The non-volatile siloxanes (dimethicone and phenyl trisiloxane) will be removed from the STP influent to the sludge. If the sludge is amended to soil, these substances can also degrade depending on soil conditions as described.

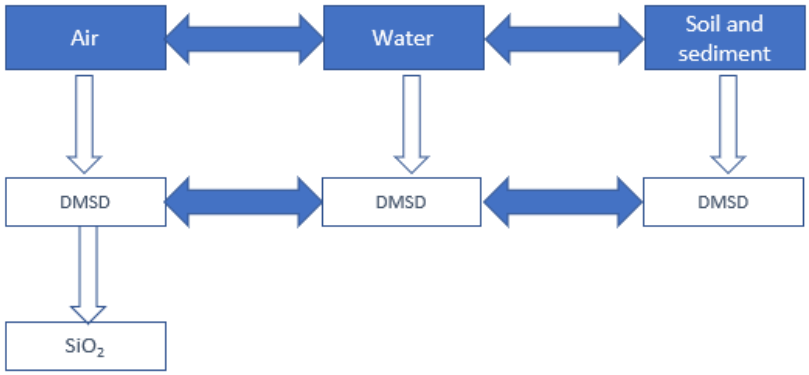


FIGURE 5.1 Degradation and distribution of siloxanes in the environment. Re-scetched from Surita & Tansel 2014.

It should be noted that the possible properties of siloxanes as a POP-substance (POP = Persistent Organic Pollutant) and potential for long-transportation (Long Range Transport Pollutant) have been discussed in literature. Several theoretical studies have been made, e.g. Xu et al. (2014), as well as several monitoring studies for instance in Svalbard (Warner et al., 2010). In general, it is not assumed that siloxanes can be transported through air to the archtic ecosystems as efficiently as for instance the PCB's or other classical POP's. Siloxanes are detected in the archtic regions, but in general the major sources of siloxanes in these environments are assumed to be local (Warer et al., 2010).

5.1.2 Calculated concentrations in the environment

The concentration in the environment at discharge to waste water is calculated, i.e. calculations were made of PEC values for the situation that residues from the products are discharged into waste water.

The hydrolysis of the siloxanes in the environment was not taken into consideration in the calculations, so the PEC values are derived are for the siloxanes themselves. However, being aware of that some of the siloxanes will be readily transformed into silanol and DMSD, calculation of PEC for the primary hydrolysis products dimethylsilanol, trimethylsilanol and DMSD was also made – assuming a full transformation of the siloxanes into these transformation products. Thus, the PECs derived for the siloxanes respectively silanols are upper estimates of their PECs.

No assessments were made of substances being released directly to surface water which can be seen by use of sun creams and sun oils, as trisiloxane, phenyl trimethicone, D3, D4, D5, D6 and Cyclomethicone are expected to evaporate very quickly from the water environment due to their high Henry's constant. However, the U-filter drometrizol trisiloxane, contained in some of the sun creams and sun oils, will hardly evaporate quickly from the water surface. The substance is only slightly water soluble (calculated water solubility less than 0.0000001 mg/L), which is why the substance is primarily found as insoluble drops in the water phase.

All the calculation results appear from Excel Appendices to the report.

The below TABLE 36 shows the calculated distribution of the substances in the waste water treatment plant. The primary removal of the siloxanes takes place via the sludge and for the cyclic siloxanes also partly via evaporation.

TABLE 36. Calculated fate in the waste water treatment plant. The table shows the distribution of the substances in the waste water treatment plant (%) according to how much evaporates, is dicharged to the water environment, ends up in the sludge or is degraded.

Siloxane	Air	Water	Sediment	Degraded
Dimethicone	0.0	8.5	91.5	0.0
Trisiloxane	44.4	3.5	52.0	0.0
Phenyl trimethicone	11.0	6.3	82.7	0.0
D3	82.0	4.5	13.6	0.0
D4	49.3	3.6	47.1	0.0
D5	22.4	4.7	73.0	0.0
D6	7.5	6.8	85.7	0.0
Cyclomethicone	82.0	4.5	13.6	0.0
Drometrizole trisiloxane	0.0	8.0	92.0	0.0
Dimethylsilanol	0.3	99.4	0.4	0.0
Trimethylsilanol	3.6	95.9	0.5	0.0

Dimethylsilanediol	0.0	99.5	0.5	0.0

The siloxanes discharged into the water from the waste water treatment plant will primarily be partitioned to the sediment. According to the calculations the part released to the air will primarily be transformed into SiO_2 via DMSD. The part of the siloxanes which ends up in the sludge is assumed to be transported to agricultural soil and tends to degrade only slowly from there – cf. the previous section.

5.2 Hazard assessment

Assessment of the hazard of siloxanes to the environment includes an assessment of the possible PBT and vPvB properties of the substances consisting of:

- Degradability. The resultat of this is an assessment of the persistence of the selected siloxanes in the environment including whether they can be characterised as P or vP substances.
- Potential for bioaccumulation. The result of this is an assessment of the identified siloxanes whether they are accumulated in biological tissue and the food chain, and an assessment of whether the identified siloxanes can be characterised as B or vB substances
- Toxicity – i.e. toxicity to primarily pelagic water organisms – but also sediment living and terrestrial organisms. The result of this is an assessment of whether the substances are T substances and - if possible – a derivation of PNEC values.

The degradation was estimated on the basis of the collected data for degradation of siloxanes in the environment, as discussed in the previous section (5.1). The potential for bioaccumulation and biomagnification is assessed based on the collected BCF-data for the siloxanes and logPow (octanol-water distribution coefficient) for the identified siloxanes. These data can be seen from TABLE 33.

The toxicity for the environment is assessed by collecting data for acute toxicity (typically reported as EC_{50}- or LC_{50} values) and chronic toxicity (typically reported as EC_{10}- or NOEC values) from the substances. Furthermore, some data for sediment living and terrestrial organisms were obtained- the collected toxicity data are shown in TABLE 37. Data are primarily found in the REACH registration dossiers. In general the substances show no acute nor chronic toxicity for water living organisms. The ECHA PBT guideline (ECHA, 2017) suggests that the toxicity can be found by calculating the effect concentration in water living organisms from test data for sediment living and terrestrial organisms via stability calculations. For this substance group it is assessed that the use of this principle will give much too low effect concentrations in the water environment, as the siloxanes bind very strongly to sediment and soil, so water living organism hardly will be exposed to siloxanes via water.

The limited retrieved environmental toxicity data for the sediment living and terrestrial organisms suggest a comparable toxicity, where the lowest toxicity to the sediment living organisms are typically at 10-100 mg/kg dry material (NOEC) and for the terrestrial organisms at approx. 300-500 mg/kg dry material. Data was not found for all siloxanes. The polymer dimethicone is not expected to show toxicity as the substance is not bio-available. But in the long term the substance will (very slowly) be degraded into smaller siloxanes showing similar toxicity as the other smaller siloxanes. Furthermore, dimethicone contains volatile low molecular siloxanes.

All in all it is not possible to prioritise after the environmental toxicity of the selected siloxanes, as the sparse data suggest a comparable toxicity.

An assessment of possible PBT and vPvB properties of the substances are also given in TABLE 38. In general, the substances are assessed as P and vP, but the significance of this

must be presumed to be varying, as an important parameter for the substances to remain in the environment is their exposure. If – especially the smaller cyclic siloxanes – are released directly to the surface water, a quick evaporation will occur whereby the substances are expected to degrade quickly. But if the release takes place to waste water, a quick binding of the siloxanes to suspended material will probably happenand the significance of the evaporation will diminish.

The smaller siloxanes in dimethicone are volatile, whereas the polymer part of dimethicone is not volatile which is why it will primarily be in sediment (if released to water) or in soil (e.g. because of the application e of waste water sludge with residues of dimethicone on farm land). The degradation in sediment and soil will occur very slowly via abiotic processes, but in the end result in the degradation products dimethylsilanol, trimethylsilanol and dimethylsilanediol (DMSD). As previously mentioned, DMSD can be biodegraded, but this only happens very slowly. Thereby, the half life in soil for the substance is found to be in the range of years. Consequently, the degradation products must be P or vP.

TABLE 37. Toxicity for the environment from the siloxanes. Data obtained from the REACH registration dossiers of the substances

Name	PNEC	Environmental toxicity for water living organisms	Environmental toxicity for sediment living organisms	Environmental toxicity for terrestral organisms
Dimethicone (Dimethyl siloxane)	-	No data, but the polymer may contain low molecular acyclic siloxanes, which must he assessed e.g. trisiloxane.	No data, but the polymer may contain low molecular acyclic siloxanes, which must be assessed e.g. trisiloxane.	No data, but the polymer may contain low molecular acyclic siloxanes, which must he assessed e.g. trisiloxane.
Trisiloxane, Octamethyltrisiloxane	No PNEC derived for water 8.9 mg/kg dry weight (sediment, fresh) 0.89 mg/kg dry weight (sediment, marine) 0.5 mg/kg dry weight (soil) 1.7 mg/kg food (secondary poisoning)	Both acute and chronical test data for algae, crustacean and fish given in the REACH registration dossier. No toxicity for the environment indentified up to the water-solubility of the substance (neither acute nor chronic).	LC50 (Chironomus riparius, 28 days): 166 mg/kg dry weight (377 mg/kg dry weight ved 5% OC). NOEC (Chironomus riparius, 28 days): 39 mg/kg dry weight (89 mg/kg dry weight ved 5% OC) NOEC (Hyalella azteca, 28 days) >70 mg/kg dry weight ~ >95 mg/kg dry weight at 5% OC NOEC (Lumbriculus variegatus, 28 age): 1.1 mg/kg dry weight ~ 2.9 mg/kg dry weight ved 5% OC	Test not possible as the substance is not stable in soil
Phenyl trimethicone		EC50 (Pseudokirchneriella subcapitata, 72 hours) >2.2 µg/l (read-across to L4) NOEC (Daphnia magna, 21 days): 4.9 µg/l (read-across to L4) NOEC (Lepomis macrochirus, 45 days) ≥4.4 µg/l	No data	No data
D3 Hexamethylcyclotrisiloxane		EC50 (Daphnia magna, 48 hours) > water-solubility (1.6 mg/L) LC50 (Oncorhynchus mykiss, 96 hours)> water-solubility (1.6 mg/L)	No data, as the substance is quickly hydrolysed	Test not possible as the substance is not stable in soil

Name	PNEC	Environmental toxicity for water living organisms EC50(Pseudokirchnerella subcapitata, 72 hours) > water-solubility (1.6 mg/L)	Environmental toxicity for sediment living organisms	Environmental toxicity for terrestral organisms
D4 Octamethylcyclotetrasiloxane	Fresh water:1.5 µg/l Marine water: 0.15 µg/l Sediment, fresh: 3 mg/kg dry weight Sediment, marine: 0.3 mg/kg dry weight Soil: 0.54 mg/kg dry weight (equilibrium partitioning calculation) Secondary poisoning: 41 mg/kg food	Both acute and chronical test data for algae, crustacean and fish given in the REACH registration dossier. No toxicity for the environment indentified up to the water-solubility of the substance (neither acute nor chronical).	NOEC (Lumbriculus variegatus, 28 days): 13 mg/kg dry weight NOEC (Chironomus riparius, 28 days): 44 mg/kg dry weight NOEC (Hyalella aztec, 28 days): 130 mg/kg dry weight (read-across to D5)	No data
D5 Decamethylcyclopentasiloxane	Fresh water:1.2 µg/l Marine water: 0.12 µg/l Sediment, fresh: 11 mg/kg dry weight Sediment, marine: 1.1 mg/kg dry weight Soil: 2.54 mg/kg dry weight Secondary poisoning: 16 mg/kg food	Both acute and chronical test data for algae, crustacean and fish given in the REACH registration dossier. No toxicity for the environment indentified up to the water-solubility of the substance (neither acute nor chronical).	NOEC (Chironomus riparius, 28 days) 70 mg/kg dry weight NOEC (Lumbriculus variegatus, 28 days) ≥1272 mg/kg dry weight NOEC (Hyalella azteca, 28 dage) 62 mg/kg dry weight (mortality) NOEC (Hyalella azteca, 28 dage) 130 mg/kg dry weight (growth rate)	LC50 (Eisenia andrei, 28 days)>4074 mg/kg dry weight LC50 (Folsomia candida, 28 days): 813 mg/kg dry weight IC50 (Hordeum vulgare, 14 days): 209 mg/kg dry weight NOEC (Eisenia andrei, 56 days)>4074 mg/kg dry weight NOEC (Folsomia candida, 28 days): 377 mg/kg dry weight EC10 (Mikroorganism, nitrification, 28 days): >100 mg/kg dry weight
D6 Dodecamethylcyclohexasiloxane	Sediment, fresh: 13 mg/kg dry weight	Both acute and chronical test data for algae, crustacean and fish given in the REACH registration dossier. No toxicity	NOEC (Hyallela azteca, 28 dage)> 130 mg/kg dry weight (read-across to D5)	LC50 (Eisenia andrei, 28 dage)>4074 mg/kg dry weight (read-across to D5)

Name	PNEC	Environmental toxicity for water living organisms	Environmental toxicity for sediment living organisms	Environmental toxicity for terrestral organisms
	Sediment, marine: 1.3 mg/kg dry weight	for the environment indentified up to the water-solubility of the substance (neither acute nor chronical).	NOEC (Lumbriculus variegatus, 28 days)≥420 mg/kg dry weight NOEC (Chironomus riparius, 28 days)≥620 mg/kg dry weight	LC50 (Folsomia candida, 28 dage): 813 mg/kg dry weight (read-across to D5) IC50 (Hordeum vulgare, 14 dage): 209 mg/kg dry weight (read-across to D5)
Cyclomethicone	Refer to D3-D6	Refer to D3-D6	Refer to D3-D6	Refer to D3-D6
Drometrizole trisiloxane		No data	No data	No data
Dimethylsilanol (degradation product from hydrolysis)	-	EC50 (Daphnia magna, 48 hours) > 117 mg/L LC50 (Oncorhynchus mykiss, 96 hours)> 126 mg/L EC50(Pseudokirchnerella subcapitata, 72 hours) > 118 mg/L (from registration dossier for D3) ECOSAR suggests an acute toxicity above 100 mg/L.	No data. the substance has low affinity to sediment	No data. The substance has low affinity to soil
Trimethylsilanol (degradation product from hydrolysis)	-	EC50 (Daphnia magna, 48 hours) > 117 mg/L LC50 (Oncorhynchus mykiss, 96 hours): 3.0 mg/L EC50(Pseudokirchnerella subcapitata, 72 hours) > 118 mg/L QSAR models Leadscope and SciQSAR cannot be used for the substancet. ECOSAR suggests an acute toxicity above 100 mg/L.	No data. the substance has low affinity to sediment	No data. The substance has low affinity to soil

Name	PNEC	Environmental toxicity for water living organisms	Environmental toxicity for sediment living organisms	Environmental toxicity for terrestral organisms
Dimethylsilanediol (degradation product from hydrolysis)	-	No data, the QSAR models Leadscope and SciQSAR cannot be used for the substancet. ECOSAR suggests an acute toxicity above 100 mg/L.	No data. the substance has low affinity to sediment	No data. The substance has low affinity to soil

TABLE 38. Hazard assessment of siloxanes. RA: Read-across

Name	Conclusion on environmental hazard assessment	P-assessment (TABLE 33)	B-assessment	T-assessments	Toxicity data for water living organisms (if not indicated, then data are obtained from the REACH registration dossier for the substance)
Dimethicone (Dimethyl siloxane)	Not classified The polymer part of the substance is estimated as Not PBT Not vPvB concerning the low molecular acyclic siloxanes see trisiloxane	The substance is not biodegradable The substance is not volatile (low vapor pressure and low Henry's constant) The substance will probably bind to soil and sediment. The substance can be hydrolysed, but probably very slowly. End product dimethylsilanediol =>P and vP	The substance has a very high calculated logPow, but at the same time also a high molecular weight. Furthermore, the substance is only very little soluble in water Primarily due to the size of the molecule it is estimated, that the substance cannot accumulate in biological tissue. But the polymer may contain low molecular acyclic siloxanes which must be assessed as e.g. trisiloxane. =>Not B ant not vB	The substance is expected not to be toxic due to the molecule size. However, the polymer may contain low molecular acyclic siloxanes, which must be assessed as e.g. trisiloxane. =>Not T	No toxicity data found for the substance.
Trisiloxane, Octamethyltrisiloxane	H410 H413 (not harmonised) Not PBT Possibly vPvB	The substance is not biodegradable The substance is volatile in water solutions (high Henry's constant). The substance is relatively quickly decomposed in the air (a calculated half time of 0.05 days).	logPow: 6.6 BCF: 27 600 (lipid normalized), BMF 0.86 (in fish) =>Possibly B and vB. It is noted that the REACH registration dossier concludes not B and not vB.	Toxicity of the substance is not detected up to the water solubility of the substance – neither in chronic nor acute tests =>Not T	E(L)C50(mg/L): >0.0094 (Pseudokirchneriella subcapitata , 72 hr) E(L)C50(mg/L): >0.020 (Daphnia magna, 48t) E(L)C50(mg/L): >0.019 (Oncorhynchus mykiss, 96 hr) NOEC/EC10(mg/L): >0.0094 (Pseudokirchneriella subcapitata

Name	Conclusion on environmental hazard assessment	P-assessment (TABLE 33)	B-assessment	T-assessments	Toxicity data for water living organisms (if not indicated, then data are obtained from the REACH registration dossier for the substance)
		The substance can bind to soil and sediment The substance can hydrolyse in acidic and alkaline solutions. =>Possibly P and vP			, 72 hr) NOEC/EC10(mg/L): >0.015 (Daphnia magna, 21d) NOEC/EC10(mg/L): >0.027 (Oncorhynchus mykiss (early life stage test), 90d, NOEC)
Phenyl trimethicone	(H413) PBT Not vPvB PNEC: cannot be derived	The substance is not biodegradable The substance is volatile in water solutions (high Henry's constant) The substance is relatively quickly degraded in the air (has a calculated half time of 0.14 days). The substance can bind to soil and sediment The substance can hydrolyse in acidic and probably also in alkaline solutions, probably also in alkaline solutions (no data though) =>Possibly P and vP	logPow: 9 BCF: 384-2992, Key value in REACH dossier: 2765 =>Possibly B but not vB	Chronic toxicity NOEC/EC10: 0.0022-0.0049 =>T	E(L)C50(mg/L): >0.0022 (Pseudokirchneriella subcapitata, 72 hour) NOEC/EC10(mg/L): 0.0022 (Pseudokirchneriella subcapitata, 3d, NOEC) NOEC/EC10(mg/L): 0.0049 (Daphnia magna, 21d, READ-ACROSS to decamethyltetrasiloxane) NOEC/EC10(mg/L): 0.0044 (Lepomis macrochirus, 45-d, NOEC)
D3 Hexamethylcyclo-trisiloxane	Not classified Not PBT Not vPvB	The substance is not biodegradable	logPow: 4.4 BCF: 100 =>Not B not vB	The test shows no acute toxicity =>Not T	E(L)C50(mg/L): >1.6 (Pseudokirchnerella subcapitata, 96hr) E(L)C50(mg/L): >1.6 (Daphnia magna, 96hr)

Name	Conclusion on environmental hazard assessment	P-assessment (TABLE 33)	B-assessment	T-assessments	Toxicity data for water living organisms (if not indicated, then data are obtained from the REACH registration dossier for the substance)
		The substance is volatile in water solutions (high Henry's constant) The substance is relatively quickly degraded in the air (has a measured half time of 4.9 days). The substance can bind to soil and sediment The substance can hydrolyse very quickly in acidic and alkaline solutions. =>Possibly P and vP			E(L)C50(mg/L): >1.6 (Oncorhynchus mykiss, 96hr) NOEC/EC10(mg/L): 1.6 (Pseudokirchnerella subcapitata, 96hr)
D4 Octamethylcyclo-tetrasiloxane	H413 PBT vPvB	The substance is not biodegradable The substance is very volatile in water solutions (high Henry's constant) The substance is relatively quickly degraded in the air (has a calculated half time of 0.04 days). The substance can bind to soil and sediment	logPow: 6.5 BCF: 14 900 =>B and vB	No toxicity was shown of the substance up to the water solubility of the substance – neither chronical nor acute tests. The substance is however estimated to be toxic for the reproduction =>T	E(L)C50(mg/L): >0.022 (Pseudokirchneriella subcapitata, 96hr) (mg/L): >0.015 (Daphnia magna, 48hr) E(L)C50(mg/L): >0.022 (Oncorhynchus mykiss, 96hr) NOEC/EC10(mg/L): >0.022 (Pseudokirchneriella subcapitata, 96hr) NOEC/EC10(mg/L): >0.015 (Daphnia magna, 21d) NOEC/EC10(mg/L): >0.0044

Name	Conclusion on environmental hazard assessment	P-assessment (TABLE 33)	B-assessment	T-assessments	Toxicity data for water living organisms (if not indicated, then data are obtained from the REACH registration dossier for the substance)
		The substance can hydrolyse quickly in acidic and alkaline solutions. =>Possibly P and vP			(early-life stages of Oncorhynchus mykiss, 93d)
D5 Decamethylcyclo-pentasiloxane	H413 (not harmonised) Not PBT vPvB PNEC (fresh water): 1.2µg/L PNEC(sea water): 0.12µg/L PNEC(STP): 10 mg/L PNEC (fresh water sediment: 11 mg/kg dw PNEC(sea sediment: 1.1 mg/kg dw PNEC(jord): 1.27 mg/kg soil PNEC(oral): 16 mg/kg food	The substance is not biodegradable The substance is very volatile in water solutions (high Henry's constant) The substance is relatively quickly degraded in the air (has a calculated half time of 0.06 days). The substance can bind to soil and sediment The substance can hydrolyse quickly in acidic and alkaline solutions. =>Possibly P and vP	LogPow: 8.0 BCF: 16 200 =>B and vB	No toxicity was shown of the substance up to the water solubility of the substance – neither chronical nor acute tests =>Not T	E(L)C50(mg/L): >0.016 (Selenastrum capricornutum, 72hr) (mg/L): >0.0029 (Daphnia magna, 48hr) E(L)C50(mg/L): >0.016 (Oncorhynchus mykiss, 96hr) NOEC/EC10(mg/L): >0.016 (Selenastrum capricornutum, 72hr) NOEC/EC10(mg/L): >0.015 (Daphnia magna, 21d) NOEC/EC10(mg/L): >0.0144 (early-life stages of Oncorhynchus mykiss, 90d)
D6 Dodecamethylcyclohexasiloxane	H413 (not harmonised) Not PBT Not vPvB	The substance is not biodegradable	logPow: 8.9 BCF: 2 860 =>B not vB	No toxicity was shown of the substance up to the water solubility of the substance – neither chronical nor acute tests	E(L)C50(mg/L): >0.002 (Pseudokirchnerella subcapitata, 72 hr) >0.020 (Daphnia magna, 48t)(mg/L):

Name	Conclusion on environmental hazard assessment	P-assessment (TABLE 33)	B-assessment	T-assessments	Toxicity data for water living organisms (if not indicated, then data are obtained from the REACH registration dossier for the substance)
		The substance is very volatile in water solutions (high Henry's constant) The substance is relatively quickly degraded in the air (has a measured half time of 3.4 days). The substance can bind to soil and sediment The substance can hydrolyse quickly in acidic and alkaline solutions. =>Possibly P and vP		=>Not T	E(L)C50(mg/L): NOEC/EC10(mg/L): >0.002 (Pseudokirchnerella subcapitata, 72 hr) NOEC/EC10(mg/L): >0.0046 (Daphnia magna, 21d) NOEC/EC10(mg/L): >0.0144 (Oncorhynchus mykiss, 90 d, READ-ACROSS)
Cyclomethicone	H413 (not harmonised) PBT, if content of D4≥3% Not PBT, if content of D4<3% Possibly vPvB	The substance is not biodegradable The substance is very volatile in water solutions (high Henry's constanct) The substance will degrade relatively quickly in the air in the range of 4-6 days The substance can bind to soil and sediment The substance can hydrolyse in acidic and alkaline solutions	LogPow: 5.64 =>can be B and vB	The substance contains D4. If the content of D4 is above 3%, then the substance must be characterised as toxic for the reproduction =>T (if content of D4 ≥3%) =>Not T (if content of D4 <3%)	Mixture of a number of cyclic siloxanes. Assessed on the basis of D3, D4, D5, D6

Name	Conclusion on environmental hazard assessment	P-assessment (TABLE 33) =>Possibly P and vP	B-assessment	T-assessments	Toxicity data for water living organisms (if not indicated, then data are obtained from the REACH registration dossier for the substance)
Drometrizole trisiloxane	Not PBT Not vPvB	The substance is not biodegradable The substance is not volatile Will probably hydrolise to a limited extent The substance can bind to soil and sediment =>Possibly P and vP	logPow: >10 Calculated BCF: 180 =>Not B and not vB	Cannot be assessed	No data
Dimethylsilanol (hydrolysis product)	Not PBT or vPvB	Converted abioticallly to DMSD	Not bioaccumulative =>Not B and not vB	Only few data. No indication that the substance is toxic for the environment =>hardly T	
Trimethylsilanol (hydrolysis product)	Not PBT or vPvB	Converted abioticallly to DMSD	Not bioaccumulative =>Not B and not vB	No indication that the substance is toxic for the environment =>hardly T	
Dimethylsilanediol (hydrolysis product) DMSD	Not PBT or vPvB	The substance is probably very heavily degradable (see text of the report) =>P or vP	Not bioaccumulative =>Not B and not vB	No indication that the substance is toxic for the environment =>hardly T	

5.3 Impact on the environment

Usually, both calculated environmental concentrations, PEC and derived PNEC values are included in a risk characterisation. Unfortunately, not all the considered siloxanes have derived PNEC values which means that a mutual sorting of the products on the basis of the PEC:PNEC proportions does not make sense.

The substances are therefore given an environmental hazard score according to their PBT/vPvB characterisation:
1: PBT and vPvB
2: vPvB or PBT
3: Neither PBT or vPvB

The siloxanes in the products are hereafter given a environmental impact score which is calculated as the ratio between PEC in the various environments (water, sediment, soil), (section 5.1) and the hazard score. The lower the environmental score, the lower the environmental impact. The PECs are derived using the environmental properties as shown in TABLE 33 and the assumed concentration in the products and daily consumption as presented in TABLE 32.

These environmental impact scores appear from the enclosed Excel sheet.

Subsequently, the following prioritisation was made:

- Within each product type, a sorting according to hazard for the environment was made so substances with the lowest risk score are at the bottom. A sorting according to both water phase, sediment and soil was made, since the substances do not behave uniformly in the environment. The result of this prioritization can be seen in APPENDIX 4.
- Within the product type facial cream/lotion, the products with D5, D6 and D3 appear to be the most hazardous for the environment for the water phase – and the products with drometrizole-trisiloxanes are the least hazardous for the environment. For sediment and soil the sequence is slightly different, where for instance drometrizole trisiloxane is the most hazardous for the environment in terms of soil and D4 the least hazardous for the environment. This is a reflection of which environmental compartment the siloxanes tend to partition to.
- A genereal sorting was made, where the combinations of product type and substance giving the highest risk score is listed on the top. Again, a sorting according to both the water phase, the sediment phase and the soil phase was made, as the substances do not act in the same way in the environment. The results are shown in APPENDIX 4. Detailed calculations appear from Appendices.

Top 10 of the product types posing the apparent highest impact to the environment for the water phase - if they contain siloxanes in levels corresponding to the levels measured in this project:

- Hair conditioner / conditioner with D5
- Flaxseed oil /lotion with D4
- Sun creme/lotion with D5
- Hair conditioner / conditioner with D4
- Deodorant / antiperspirant, non-spray with D5
- Hair conditioner / conditioner with Trisiloxane,
- Flaxseed oil /lotion with D5
- Sun creme/lotion with D4

- Sun creme spray, pump spray with D6
- Hairspray, spray, pump spray with D5

Top 10 of the siloxane product types appearing to show the highest impact on the sediment compartment:

- Sun creme spray, pump spray with Drometrizole trisiloxane
- Hair conditioner / conditioner with D5
- Sun creme/lotion with D5
- Sun creme spray, pump spray with D6
- Deodorant / antiperspirant, non-spray with D5
- Body care creams / lotions with D6
- Flaxseed oil /lotion with D5
- Sun creme/lotion with Drometrizole trisiloxane
- Flaxseed oil /lotion with D4
- Facial day cream /-lotion with D6

Top 10 of the product types posing the apparently highest impact on the environment for the soil phase when containing siloxanes:

- Sun creme spray, pump spray with Drometrizole trisiloxane
- Sun creme/lotion with Drometrizole trisiloxane
- Hair conditioner / conditioner with Phenyl trimethicone
- Facial day cream /-lotion with Drometrizole trisiloxane
- Foundation with Drometrizole trisiloxane
- Hair shampoo with Drometrizole trisiloxane
- Foundation with Phenyl trimethicone
- Body care creams / lotions with Drometrizole trisiloxane
- Deodorant / antiperspirant, spray with Drometrizole trisiloxane
- Hairspray, spray, pressure vessel with Phenyl trimethicone

To analyse the relative importance of the various environmental compartments, it may be useful to look on how the siloxanes partition in the environment. FIGURE 5.2 shows the predicted distribution of the siloxanes at steady-state (predicted from the SimpleBox part of EUSES) both if the discharges takes place directly into water (I) or if the discharge takes place to waste water to be treated into waste water treatment plant. From the figure, it is obvious that -except for the degradation products from the hydrolysis – that the main environmental compartments for the siloxanes are air (for the volatile siloxanes) and sediment and soil (for the remaining siloxanes). Thus, the water phase is of relatively lower importance -except for the degradation products from the hydrolysis. Therefore, for a prioritization of the products then it may be most relevant to prioritize according to their relative impact on the soil and the sediment compartments. To be noted also is, that the volatile siloxanes are not on any of the top-10 lists, which is not surprising, as these siloxanes mainly partition to the air phase (FIGURE 5.2).

To be noted is that the content of D3 in the products is only determinded semi-quantitatively, so the reported concentrations in the products of D3 are determined with a larger uncertainty than the quantitatively determined concentrations. This uncertainty will cause a larger uncer-

tainty in the calculated PECs for D3 compared to the PECs calculated from quantitatively determined concentrations in the products. However, this is most likely of minor importance in a prioritization of the products, as D3 mainly will be distributed into air, where it will be rapidly degraded (see FIGURE 5.1).

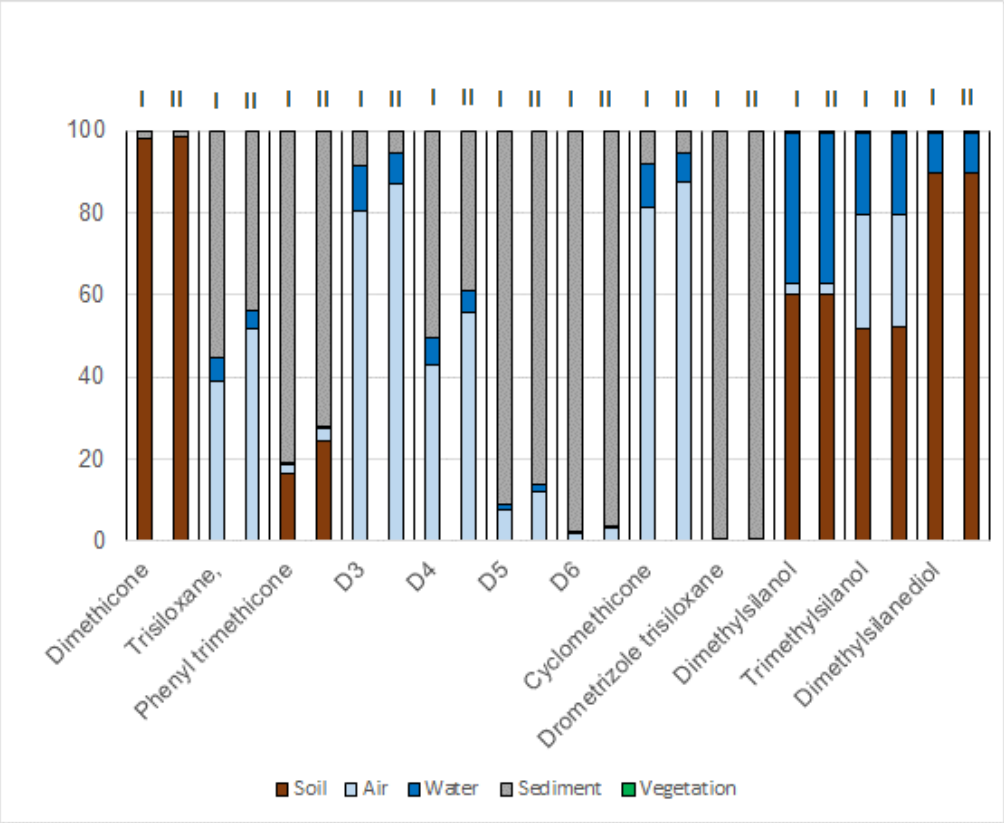


FIGURE 5.2 Predicted distribution of the siloxanes at steady-state (predicted from the SimpleBox part of EUSES). I: if released directly into water; II: if released via waste water to be handled in waste water treatment plants.

5.4 Discussion and conclusions on the impact on the environment

In connection with the environmental assessment, a hazard assessment was made for the selected siloxanes. D4 was estimated to have both PBT and vPvB properties. Cyclomethicone with a content of D4 above 3% is assessed as a PBT substance and as a non PBT substance if the content of DH is below 3%. D5, trisiloxane and cyclomethicone were estimated to have vPvB properties, whereas phenyl trimethicone was assessed as a PBT substance. The substances D3, D6, dimethicone and drometrizole trisiloxane were characterised as neither PBT nor vPvB.

Abiotic degradation (hydrolysis) is an important primary degradation route for siloxanes. The most important degradation products from the abiotic degradation processes are identified as dimethylsilanol, trimethylsilanol and dimethylsilanediol (DMSD). Dimethylsilanol can be hydrolysed to dimethylsilanediol, which is probably the final hydroysis product. DMSD can be biologically degraded, but this is a very slow reaction with half life in soil in the range of years. The degradation of DMSD in the air is substantially quicker. The final degradation product – apart from water and CO_2 – is SiO_2. The degradation products must therefore be characterized as P or vP.

All siloxanes are thus considered recalcitrant. Furthermore, as the degradation is a stepwise process, the total degradation time will increase with the molecular size. This means that polymer dimethicone must be expected to remain in the environment for considerably longer time than the cyclic and acyclic smaller siloxanes.

On the basis af the limited toxicity data to benthic and terrestrial organisms, it is not possible to prioritize the siloxanes with respect to their inherent toxicity to benthic and terrestrial organisms. The polymer dimethicone is however not toxic, as the substance is not bioavailable. In this connection, it must be mentioned that the polymer itself may contain low molecular siloxanes in a lower concentration, and that a small fraction of the dimethiocone eventually (and very slowly) will degrade into smaller siloxanes with similar toxicity as for the other siloxanes.

All in all it is not possible to make a priority on the basis of the environmental toxicity of the selected siloxanes, as the sparse data suggest a comparable toxicity.

Taking into account how the various siloxanes partition in the environment, the water phase is of relatively lower importance. It may be most relevant to prioritize according to the relative impact on the soil and the sediment compartments. Primarily products with rometrizone trisiloxane and phenyl trimethiocone showed the relatively highest impact on the soil compartment, whereas primarily products with D5 and D6 showed the relatively highest impact on the sediment compartment.

On the basis of, among other things, the results obtained in this report it seems that there is an ongoing process of substituting cyclic siloxanes with for instance dimethicone in cosmetic products. As a rule, dimethicone is not as toxic and bioaccumulative as the other smaller siloxanes, but eventually a small fraction of the substance will degrade into smaller units which will show similar toxicity and potential for bioaccumulation and overall, it will persist in the environment for a longer time than the smaller siloxanes.

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Appendix 1. Mapping

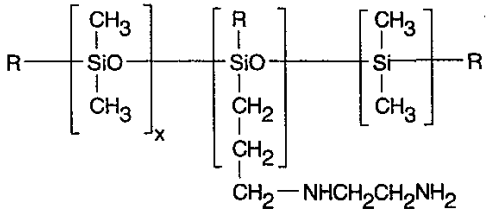
Overall for the entire Appendix 1, the following methods were used to prioritise the single product types for each selected substance: When prioritising products for selection, emphasis was put on the number of products and number of scannings for the product type. For exposure reasons the highest importance was put on leave-on products in relation to the risk to the consumer compared to wash-off products, which will rather cause exposure to the environment. Whether the product is used on a daily basis is also assessed. Furthermore, focus was also to include products with oral and/or inhalation exposure in addition to dermal exposure. In connection with the target groups, exposure to children was alos prioritised. High siloxane concentration in the product was also a trigger for is prioritization.

For each product type an overall prority score was given considering all these aspects together:
+++ High priority; ++ priority; + low priority; - no priority /prioritizing not possible.

Appendix 1.1 Mapping of Amodimethicone

Description:

CIR (2003):



Amodimethicone

where R represents OH or CH3

Amodimethicone is a silicone polymer with amine groups attached into the chemical structure.

The function is as hair conditioning agent.

Costmetic Ingredient Review*:*

CIR (2003). 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.

CosIng (2019):

CAS 71750-80-6. Antistatic, hair conditioning agent

http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

Making Cosmetics: *(https://www.makingcosmetics.com/About-Us_ep_4-1.html*):

Amodimeticone CAS 68554-54-2; 24938-91-5; 112-02-7.

Water soluble emulsion. hair conditioner agent giving softness and gloss. Giving silky feeling in creams. Used in hair and skin conditioner products e.g. shampoo, creams and lotions. Typical concentration 1-15 %

https://www.makingcosmetics.com/Amodimethicone_p_975.html

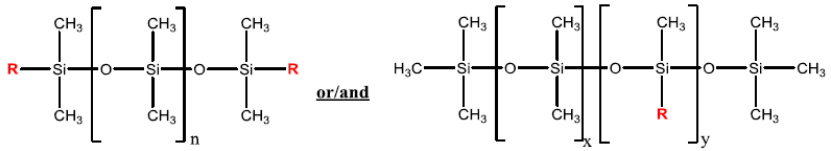
Amodimethicone	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	Daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003)	Priority / Commens
Product types	Total 10						1-15 %**	
Facial care – day cream/lotion	1	233	+	+	D	W/M	-	-
Facial care - Mask	2	324	+/-	-	D	W	-	-
Hair care - Balm / conditioner / treatment / mask	182	66 505	-	+	D	W/M/C	0.7-3 %	+++ most products/ consumer interest, limited exposure to the consumer, but exposure to the environment
Hair care - Hair colour	23	3 858	-	-	D	W/M	2 %	++
Hair care – Hair spray / hair spray/ heat spray	14	4 949	+	+	D/I	W	-	+++ Inhalation and leave-on
Hair care – Hair oil / cream/ lotion / serum	28	6 202	+	-	D	W	-	+

Amodimethicone	**Number of products in Kemiluppen** **(>50)***	**Number of scannings in Kemiluppen** **(>5 000)***	**Leave-on** **+/-**	**Daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **(CIR 2003)**	**Priority / Commens**
Hair care - hair mousse	12	5 464	+	+	D	W/M	-	+++
Hair care -hair shampoo	86	49 850	-	+	D	W/M/C	-	+++ Second largest product category (+ children)
Cosmetics - Primer / fixer	1	420	+	+	D	W	-	-
Soap and hygiene Body shampoo / body gel / foam bath	1	12	-	+	D	W/M/C	-	-
Products total	350							Highest priority: 4 different types of hair care products

*Marked in bold writing ** Making Cosmetics, web-site

Appendix 1.2 Mapping of Cetyl PEG/ppg-10/1 dimethicone

Description
CIR (2015):



Cetyl PEG/PPG-10/1 dimethicone indicated to have an average molecule weight >1000 Da; less than 5.5% of the substance has a molecule weight <500 g/mol and 9.0% <1000 g/mol. Water Sol. 8 mg/L
Safe as a cosmetic ingredient; max. use conc. 80 %

CIR (2015).Safety Assessment of Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients as Used in Cosmetics. Cosmetic Ingredient Review.January 2015. https://www.cir-safety.org/sites/default/files/ROPSIL_092014%20_Tent.pdf

CosIng (2019):
Cetyl peg/ppg-10/1 dimethicone is a copolymer of cetyldimethicone and a alkoxylated derivate of dimethicone consisting in average of 10 mol ethylenoxyde and 1 mol propyl-enoxyde. Function: emulsifier, surfactant, skin conditioning agent.
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

Making Cosmetics: (https://www.makingcosmetics.com/About-Us_ep_4-1.html)**:** not included

SpecialChem:
https://cosmetics.specialchem.com/inci/
The substance is recommended for use as emulsification and dispersion agent. Lead to good adhesure to the skin. In foundation (both as fluid and powder) and in BB cream.

Cetyl peg/ppg-10/1 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2015)	Priority/ Comments
Product types	23						0.034-15%**	
Facial care – BB/CC cream	8	5 923	+	+	D	W	0.034-15%	+++ High exposure
Facial care – day cream/lotion	4	650	+	+	D	W/M	0.034-15%	-
Facial care – Lip balm	5	1 719	+	+	D/O	W/M/C	0.034-15%	++ Oral, children, but few products
Facial care – Eye cream / -serum / -gel	1	1 216	+	+	D	W	0.53-15%	-
Hair care - Balsam / conditioner / kur / maske	3	3 708	-	+/-	D	W/M	0.034-15%	-
Hair care – Hair oil / creme/ lotion / serum	1	300	+	+/-	D	W/M	0.034-15%	-

Cetyl peg/ppg-10/1 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2015)	Priority/ Comments
Hair care – dry shampoo	1	175	+	-	D/I	W/M	0.4%	-
Cosmetic – Blush / highlighter	2	288	+	+	D	W	0.034-15%	-
Cosmetic - Con-cealer / corrector	20	20 501	+	+	D	W	0.034-15%	+ small amount used
Cosmetic - Founda-tion	59	27 700	+	+	D	W	0.034-15%	+++ Many products, consumer intereest
Cosmetic – Lipstick / lipgloss / lip pencil	2	507	+	+	D/O	W	0.034-15 %	-
Cosmetic - Mascara / lashes	2	585	+	+	D	W	0.53-15%	-

Cetyl peg/ppg-10/1 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2015)	Priority/ Comments
Cosmetic – Nail polish / nail care	2	694	+	+	D	W	0.02%	-
Cosmetic - Primer / fixer	7	2 859	+	+	D	W	0.034-15%	+
Cosmetic - Powder	1	807	+	+	D	W	0.034-15%	-
Cosmetic – Eye shadow	8	665	+	+	D	W	0.53-15%	+
Body care - Cream / lotion / balm	11	2 953	+	+	D	W/M/C	0.034-15%	+++ Also children
Body care – hand care	2	484	+	+	D	W/M	0.034-15%	-
Body care – oint-ment / gel	1	1 689	+	-	D	W/M/C	0.034-15%	-
Sun care - Face	3	866	+	+	D	W/M/C	0.034-15%	-

Cetyl peg/ppg-10/1 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2015)	Priority/ Comments
Sun care – Sun cream / - lotion / - gel	2	1 075	+	+	D	W/M/C	0.034-15%	-
Soap and hygiene - Deodorant	2	282	+	+	D	W/M	0.7-2%	-
Soap and hygiene – intimate care	1	150	-	+	D	W/M	0.5-3.5%	-
total products	148							Highest priority creams

Appendix 1.3 Mapping of Cyclomethicone

Description

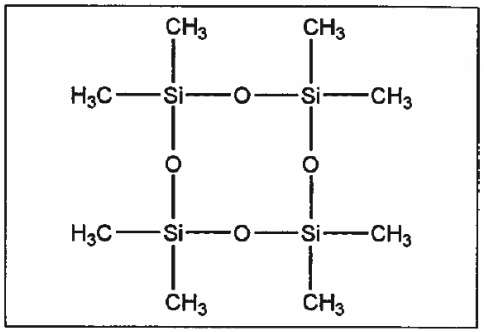


Figure 2. Structure of tetramer (n = 4).[3]

CIR (2011):
Cyclomethicone (CAS 69430-24-6) is a mixture of cyclic dimethylpolysiloxane substances with 3 to 6 siloxane units (the tetramer D4 is shown in the figure above). The substance is a colourless, odourless, not greasing silicone fluid with low viscosity with relatively high vapour pressure making the fluid evaporate relatively quickly.
Function: hair- and skin conditioning agent, softener and solvent. Typically used in personal care agents, antiperspirants, skin creams and shampoo. Certain roll-on antiperspirants may contain up to 60 %.

CIR (2011). Safety assessment of cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane. Int J Toxicol. 2011 Dec;30(6 Suppl):149S-227S. doi: 10.1177/1091581811428184

CosIng (2019): Cyclomethicone (CAS: 69430-24-6 / 556-67-2 / 541-02-6 / 540-97-6) is a mixture of low molecular volatile cyclic siloxanes, mainly containing octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in varying amounts.
Function: antistatic, softener, hair conditioning, moisturising, solvent, viscosity agent
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

Making Cosmetics (https://www.makingcosmetics.com/About-Us_ep_4-1.html):
Cyclomethicone: Typical concentration 1-40 %
https://www.makingcosmetics.com/Cyclomethicone_p_1052.html

ECHA (2019). Indicates that the highest tonnage level of (cyclomethicone (CAS 69430-24-6) is used for deodorants/antiperspirants.

ECHA (2019. ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION
SUBSTANCE NAME(S): Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6).

Cyclomethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>500)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2011) Table 3	Priority Comments
Product types	28							
Facial care – Cleansing / makeup remover / wash	2	1 008	-	+	D	W/M	-	-
facial care – day cream/lotion	23	13 236	+	+	D	W/M	1-82	+++ daily use, potential high conc in the product
facial care – Night cream	5	854	+	+	D	W/M	9-89	++
facial care – Se-rum	3	991	+	+	D	W/M	0.2-83	++ only few products
facial care – Eye cream / - serum / - gel	3	2 928	+	+	D	W	2-57	-
facial care – Eye makeup remover	1	1 036	-	+	D	W	2-85	-

Cyclomethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>500)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2011) Table 3	Priority Comments
Baby care -baby lotion/-cream	1	395	+	+	D/O	C	-	+++ Only one product, but for children and high exposure
Hair care – Balm / conditioner / treatment / mask	14	5 184	-	+	D	W/M	0.3-81	++ exposure to the environ-ment
Hair care -hair colour	2	167	+	-	D	W/M	2	-
Hair care – hair spray / hair spray/ heat spray	3	552	+	+/-	D	W	0.2-11	-
Hair care – Hair oil / cream/ lotion / serum	25	20 477	+	+/-	D	W/M	0.2-80	+++ many products, consumer interest
Hair care -dry shampoo	1	175	+	-	D/I	W/M	0.1	-
Hair care – wax / mud / clay / paste / gum	2	8 315	+	+/-	D	W/M	0.2-80	-

Cyclomethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>500)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2011) Table 3	Priority Comments
Cosmetics – Blush / highlighter	1	74	+	+	D	W	5-42	-
Cosmetics – Foundation	3	642	+	+	D	W	2-50	-
Cosmetics – Mas-cara/ lashes	1	258	+	+	D	W	2-15	-
Cosmetics – Nail spray/ nail care	1	21	+	+/-	D	W	-	-
Cosmetics – Pri-mer/ fixer	1	196	+	+	D	W	-	-
Cosmetics – eye shadow	2	915	+	+	D	W	0.06-46	-
Body care – Cream / lotion / balm	4	1 622	+	+	D	W/M	0.3-30	-
Body care – foot care	2	218	+	-	D	W/M	8-22	-
Body care – hand care	2	547	+	+/-	D	W/M	0.3-30	-

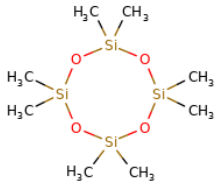
Cyclomethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>500)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2011) Table 3	Priority Comments
Body care – oil	4	2 466	+	+/-	D	W/M	8-22	-
Sun care – face	2	118	+	+	D	W/M	21-44	-
Sun care – Sun cream / - lotion / - gel	1	486	+	+	D (O)	W/M/(C)	21-44	++ children
Sun care – Sun spray	3	3 378	+	+	D/I	W/M/C	-	-
Soap and hygiene – Body shampoo / body gel / foam bath	1	12	+	+	D	W/M/C	80	-
Soap and hygiene -Deodorant	71	74 238	+	+	D	W/M	5-56	+++ +++ Many products, potential high conc., inhalation of spray, high exposure to the environment

Cyclomethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>500)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2011) Table 3	Priority Comments
Total products	184							Highest priority creams and hair care products

Appendix 1.4 Mapping of D4 – Cyclotetrasiloxane

Description

CIR (2011):



Cyclomethicone (CAS 556-67-2) with the chemical name Octamethylcyclotetrasiloxane has the following functions: antistatic, emollient, humectant, solvent, viscosity controlling and hair conditioning in cosmetic products. Depending on the product type, the concentration of D4 in formulations varies between 0.1 and 54%. It is common to use a blend of cyclosiloxanes D4, D5 and D6 in cosmetic products. Thus, products containing D4 may also contain D5 and D6. Cyclosiloxane blends containing D4, D5 and D6 are used in the formulation of various types of hair care and skin care products as well as in antiperspirants/deodorants.

CIR (2011). Safety assessment of cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane. Int J Toxicol. 2011 Dec;30(6 Suppl):149S-227S. doi: 10.1177/1091581811428184.

CosIng (2019):
Function: emollient, hair conditioning, skin conditioning, solvent : *http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced*

SpecialChem: On 10th January 2018, Commission Regulation (EU) 2018/35 was added, specifically restricting the input of **octamethylcyclotetrasiloxane** (D4) and **decamethylcyclopentasiloxane** (D5) to less than 0.1% in wash-off cosmetic products. This restriction will come into effect by 31st January 2020, after which time all products being sold in the EU market must comply. *https://cosmetics.specialchem.com/tech-library/article/restriction-of-d4-and-d5-in-personal-care-products*

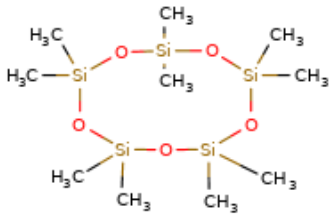
ECHA (2019)
ECHA (2019. ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION. SUBSTANCE NAME(S): Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6

D4 Cyclotetrasiloxane	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) Table 3	Priority/ Comments
Product types	5							
Facial care – Day cream / lotion	1	13	+	+	D	W/M	0.04-10	-
Hair care - Balm / conditioner / treatment / mask	6	133	-	+/-	D	W/M	0.0007-2	++ exposure to the environment
Hair care – Hair spray / hair spray/ heat spray	1	1	+	+/-	D/I	W	-	-
Hair care – Hair oil / cream/ lotion / serum	12	3 054	+	+/-	D	W/M	0.2-2	+++ Most products
Cosmetics - Foundation	3	482	+	+	D	W	-	-
total products	23							Only few products, highest priority, hair products

Appendix 1.5 Mapping of D5 – Cyclopentasiloxane

Description

CIR (2011):
Chemical name is Decamethylcyclopentasiloxane



D5 can be used instead of D4 in cosmetic/personal care formulations. However, due to the differences in physical properties and in the sensory characteristics, the level of D5 in most cases needs to be adjusted in order to maintain comparable functional properties of the formulation. Some formulations can use a combination of D4/D5 but the combined level generally will not exceed the level that would be used if just one of the materials was used. In practice, however, manufacturers use D4 or D5 rather than blends.
D5 is noted to have an average molecular weight of 371 Da. Water sol. 17 ppb

CIR (2011). Safety assessment of cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane. Int J Toxicol. 2011 Dec;30(6 Suppl):149S-227S. doi: 10.1177/1091581811428184.

CosIng (2019):
Function: emollient, hair conditioning, skin conditioning, solvent
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

SpecialChem:
Cyclopentasiloxane (CAS 541-02-6) is a silicone compound with the formula [(CH3)2SiO]5. It is a colorless, odorless liquid that has a low viscosity. It gives a silky and slippery feel when applied to skin and hair. It is mainly used in antiperspirants, sun-block creams, hair conditioners and skin care products.
On 10th January 2018, Commission Regulation (EU) 2018/35 was added, specifically restricting the input of **octamethylcyclotetrasiloxane** (D4) and **decamethylcyclopenta-siloxane** (D5) to less than 0.1% in wash-off cosmetic products. This restriction will come into effect by 31st January 2020, after which time all products being sold in the EU market must comply.
https://cosmetics.specialchem.com/inci/cyclopentasiloxane

ECHA (2019). Indicate contents in skin care products (max 90%) male-up and mak-up removing products (max. 90%), deodorants and antiperspirants (max 60%), hair care leave-on products (max 95%) and others (max 75%). Indicate that the highest tonnage level is used for deodorants/antiperspirants.

ECHA (2019). ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION
SUBSTANCE NAME(S): Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6).

D5 Cyclopentasiloxane	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>10 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority/ Comments
Product types	47							
facial care – cleansing / makeup remover / wash	14	7 815	-	+	D	W	3-59 10-90	+
facial care – BB/CC cream	21	14 550	+	+	D	W	1-61 5-90	+++
facial care – Lip balm	5	2 668	+	+/-	D/O	W/M/C	7-74 5-75	+
facial care – day cream/lotion	69	32 621	+	+	D	W/M/C	1-61 5-90	+++ Many products, consumer interest, potential high conc
facial care – Mask	8	1 448	-	-	D	W/M	5-6 5-90	+
facial care – Micellar water	4	528	-	+	D	W/M	3-59	-

D5 Cyclopentasiloxane	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>10 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority/ Comments
facial care – Night cream	4	787	+	+	D	W	0.4-22 5-90	-
facial care – facial oil	1	41	+	+	D	W	3-59 5-90	-
facial care – cleaning tissue	1	839	-	+	D	W/M	3-59	-
facial care – Scrub / peeling	1	5 327	-	-	D	W/M	unknown	-
facial care – Serum	10	8 974	+	-	D	W/M	3-59	++
facial care – Skin tonic / toner / mist	2	373	+	+	D/I	W/M	3-59	-

D5 Cyclopentasiloxane	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>10 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority/ Comments
facial care – Eye cream / - serum / - gel	8	1 422	+	+	D	W	1-61	+
facial care – Eye makeup remover	8	7 624	-	+	D	W	32-59 10-90	+
Shaving and hair re-moval – Aftershave product	1	89	-	-	D	M	2-21	-
Hair care – Balsam / conditioner / kur / maske	73	19 334	-	+/-	D	W/M	0.009-89	+++ Exposure to the environment, many products
Hair care – Gel	1	65	+	+/-	D	W/M	13-93 20-95	-
Hair care – Hair spray / hair spray/ heat spray	17	2 354	+	+	D/I	W	0.2-36	++

D5 Cyclopentasiloxane	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>10 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority/ Comments
Hair care – Hair mousse	1	296	+	+	D	W/M	1 20-95	-
Hair care – hair oil / cream/ lotion / serum	94	31 070	+	+/-	D	W/M	0.8-91 20-95	+++ many products, potential high conc. in product
Hair care – Shampoo	5	2 250	-	+/-	D	W/M/C	0.02 (0.002 colour-ing)	+
Hair care – dry sham-poo	3	2 124	+	-	D	W/M	0.02	-
Hair care – Wax / mud / clay / paste / gum	9	15 638	+	+	D	W/M	13-93 20-95	+
Cosmetic – Blush / highlighter	4	432	+	+	D	W	4-75	-

D5 Cyclopentasiloxane	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>10 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority/ Comments
Cosmetic – brows	3	3 205	+	+	D	W	22	-
Cosmetic – Concealer / corrector	34	24 850	+	+	D	W	0.7-81	+
Cosmetic – Founda-tion	103	36 562	+	+	D	W	17-83 10-90	+++ Many products, potential high conc, daily use
Cosmetic – Lipstick / lipgloss / lip pencil	9	4 740	+	+	D/O	W	9-48	++ Oral exposure
Cosmetic – Mascara / lashes	19	3 919	+	+	D	W	0.06-33	+
Cosmetic – Nail spray / nail care	1	55	+	+/-	D	W	0.009	-

D5 Cyclopentasiloxane	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>10 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority/ Comments
Cosmetic – Primer / fixer	38	13 373	+	+	D	W	26	+
Cosmetic – Powder	4	942	+	+	D	W	0.0001-30	-
Cosmetic – eye pencil / eyeliner	6	2 776	+	+	D	W	13-51	+
Cosmetic – eye shaddow	2	915	+	+	D	W	3-72	-
Body care – Cream / lotion / balm	98	38 374	+	+	D	W/M/C	0.3-88	+++, high exposure
Body care – Folt care	5	1 388	+/-	-	D	W/M	12	+
Body care – hand care	22	6 246	+	+	D	W/M	0.3-88	++
Body care – Oil	7	3 005	+	+	D	W/M	3-59	++

D5 Cyclopentasiloxane	Number of products in Kemiluppen (>50)*	Number of scannings in Kemiluppen (>10 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority/ Comments
Body care – ointment / gel	1	252	+	+/-	D	W/M/C	3-93	-
Sun care – Aftersun	4	372	+	+	D	W/M/C	0.1-49	-
Sun care – face	2	230	+	+	D	W/M	0.1-49	-
Sun care – Self tan-ning	6	6 400	+	-	D	W/M	1-24	+
Sun care – Sun cream / - lotion / - gel	14	6 232	+	+	D	W/M/C	0.1-49	+++ High exposure, potential high conc, children
Sun care – Sun oil	1	1 193	+	+	D	W/M	0.1-49	-
Sun care – Sun spray	5	1 910	+	+	D	W/M/C	2	++
Soap and hygiene – Body shampoo / bodygel / foam bath	2	52	-	+	D	W/M/C	-	-

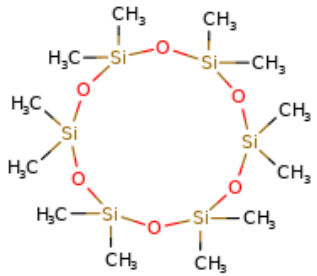
D5 Cyclopentasiloxane	**Number of products in Kemiluppen** **(>50)***	**Number of scannings in Kemiluppen** **(>10 000)***	**Leave-on** **+/-**	**daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **(CIR 2011)** **ECHA 2019**	**Priority/ Comments**
Soap and hygiene – Deodorant	101	74 290	+	+	D/I	W/M	0.4-19 10-60	+++ many products, potential high conc., inhalation of spray, high exposure to the environment
Total products	854							Highest priority creams and hair care products

*Marked in bold writing

Appendix 1.6 Mapping of D6 – Cyclohexasiloxane

Description

CIR (2011):
Chemical name is Dodecamethylcyclohexasiloxane (D6)



CIR (2011). Safety assessment of cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane. Int J Toxicol. 2011 Dec;30(6 Suppl):149S-227S. doi: 10.1177/1091581811428184

CosIng (2019):
Function: emollient, hair conditioning, skin conditioning, solvent
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

ECHA (2019):
Indicate content in skin care products (max 18%), make up nad make up removers (max 18%), deodorant and antiperspirants (max 18%), hair care leave-on products (max 18%), wash-offf products (max 18%), wipes (max 8%) and others (max 50 %)
ECHA (2019. ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION
SUBSTANCE NAME(S): Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6).

D6 Cyclohexasiloxane	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority Comments
Product types	32							
Facial care - cleansing / makeup remover / wash	2	235	-	+	D	W/M	0.003-2 max 18	-
Facial care – BB/CC cream	12	9 222	+	+	D	W/M	0.03-22 max 18	++
Facial care – day cream /lotion	41	22 626	+	+	D	W/M	0.03-22 max 18	+++ Many products, consumer interest
Facial care - Mask	7	1 827	-	-	D	W/M	2 max 18	+
Facial care – Night cream	2	657	+	+	D	W	0.005-12 max 18	-
Facial care - Scrub / peeling	1	75	-	-	D	W/M	0.003-2	-
Facial care - Serum	3	1 067	+	+/-	D	W/M	0.03-22	-

D6 Cyclohexasiloxane	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority Comments
Facial care – eye cream / - serum / - gel	3	338	+	+	D	W	15-24	-
Facial care – Eye-makeup remover	2	2 079	-	+	D	W	8-27 max 18	-
Shaving and hair removal - Aftershave product	1	46	+	+	D	M	0.03-11	-
Hair care - Balm / conditioner / treatment / mask	1	2	-	+/-	D	W/M	0.8-1	-
Hair care – Hair spray / hair spray/ heat spray	2	118	+	+/-	D/I	W	6	-
Hair care – Hair oil / cream/ lotion / serum	11	4 771	+	+/-	D	W/M	0.3-30 max 18	+
Hair care – dry shampoo	2	2 066	+	-	D/I	W/M	0.9-4	-

D6 Cyclohexasiloxane	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority Comments
Cosmetic - Brows	1	786	+	+	D	W	0.04	-
Cosmetic - Concealer / corrector	12	3 983	+	+	D	W	2-12	+
Cosmetic - Founda-tion	40	23 013	+	+	D	W	0.2-48 max 18	+++ Many products, con-sumer interest
Cosmetic - Lipstick / lipgloss / lip pencil	1	581	+	+	D/O	W	0.02-8	-
Cosmetic - Mascara / lashes	8	1 258	+	+	D	W	0.08-8	+
Cosmetic - Primer / fixer	13	4 354	+	+	D	W	0.4	+
Cosmetic – Eye pencil / eyeliner	1	1 421	+	+	D	W	0.08-8	-

D6 Cyclohexasiloxane	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2011) ECHA 2019	Priority Comments
Cosmetic – eye shadow	3	1 009	+	+	D	W	0.02-12	-
Body care - Cream / lotion / balm	33	11 832	+	+	D	W/M/C	0.003-2	+++ High exposure, children
Body care – Foot care	1	712	+	-	D	W/M	0.9-7	-
Body care – Hand care	5	858	+	+/-	D	W/M	0.03-15	+
Sun care - Aftersun	5	337	+	+	D	W/M/C	0.03-4	++
Sun care - face	1	133	+	+	D	W/M	0.03-4	-
Sun care – Self tanning	2	860	+	-	D	W/M	0.0008-7	-
Sun care – Sun cream / - lotion / - gel	9	6 555	+	+	D	W/M/C	0.03-4	+++ High exposure, children
Sun care – Sun spray	12	6 599	+	+	D	W/M/C	0.6	+++

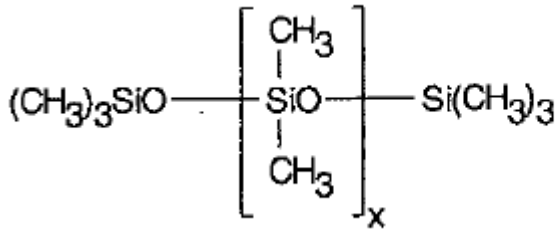
D6 Cyclohexasiloxane	**Number of products in Kemiluppen** **(>10)***	**Number of scannings in Kemiluppen** **(>5 000)***	**Leave-on** **+/-**	**daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **(CIR 2011)** **ECHA 2019**	**Priority Comments**
								High exposure, children
Soap and hygiene – Body shampoo / body gel / foam bath	1	40	-	+	D	W/M/C	-	-
Soap and hygiene - Deodorant	4	490	+	+	D/I	W/M	0.4-19 max 18	-
Total products	242							Highest priority creams and sun care products

*Marked in **bold** writing

Appendix 1.7 Mapping of dimethicone

Description:

CIR (2003)



Dimethicone

Dimethicone (CAS 9006-65-9, 63148-62-9; 9016-00-6) is a mixture of completely methylated chains of linear siloxane polymers with trimetylsoloxy groups in the ends of the chains. Dimethicone is a white almost odorfree fluid.
Function in cosmetic products: antifoam agent; skin conditioning agent, softener.

CIR (2003). 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.

Cosing (2019)
Dimethicone (CAS 9006-65-9, 63148-62-9; 9016-00-6). Functions: antifoam, softener, skin protection, skin conditioner.

Specifically in order to limit the number of +++ priorities in below table, it was also taken into consideration in the final priority, the quantity of use per use as a high use volume of the product type will underline the prioritisation.

Dimethicone	Number of products in Kemiluppen (>100)*	Number of scannings in Kemiluppen (>25 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)	Prioritising/ Commenting
Product types	Ialt 56							
Facial care - cleansing / makeup remover	22	16 546	-	+	D	W	4%	-
Facial care - BB/CC cream	32	37 488	+	+	D	W	0.0001%- 10%	++
Facial care – Day cream / lotion	364	204 719	+	+	D	W/M	0.0001%- 10%	+++ Can be used in combination with night cream
Facial care – lip balm	13	13 898	+	+	D/O	W/M/C	0.6-20% (for lip-stick)	+++ Oral/ children
Facial care - Mask	31	19 043	+/-	-	D	W	2%	-
Facial care – Night cream	43	17 306	+	+	D	W	1-2%	+++ Can be used in combination with day cream
Facial care – oil for face	1	165	+	+	D	W	-	-
Facial care – cleansing tissues	8	4 155	-	+	D	W	-	+

Dimethicone	Number of products in Kemiluppen (>100)*	Number of scannings in Kemiluppen (>25 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)	Prioritising/ Commenting
Facial care - Scrub / peeling	6	7 784	-	-	D	W	-	+
Facial care - Serum	28	11 734	+	+	D	W	0.0001%- 10%	+
Facial care – Skin tonic / toner / mist	5	3 911	+	+	D	W	0.0001%- 10%	+ Few products
Facial care – eye cream / - serum / - gel	42	26 609	+	+	D	W	0.5-1%	+ small amount per time
Facial care – Eye-makeup remover	3	4 983	-	+	D	W	4%	-
Baby care - Baby-lotion / - cream	5	1 468	+	+	D	C	2%	++ large amount per time / children Few products
Baby care – Baby wet wipes	1	98	-	+	D	C	2%	-
Shaving and hair removal (men)	10	4 490	-	+	D	M	0.5-3%	-

Dimethicone	Number of products in Kemiluppen (>100)*	Number of scannings in Kemiluppen (>25 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)	Prioritising/ Commenting
Shaving and hair removal (women)	6	3 350	-	-	D	W	0.5-3%	-
Various giftboxes and other	6	3 021					-	not possible to assess
Hair care - Balm / conditioner / treatment / mask	172	48 881	-	+	D	W/M	0.2-10%	++ Wash-off
Hair care - gel	2	582	+	+	D	W/M	10-80% (various hair products)	-
Hair care -hair colour	19	2 679	-	-	D	W/M	0.5%	-
Hair care – Hair spray / hair spray/ heat spray	18	2 036	+	+	D/I	W	0.2 – 0.6%	+ Low conc.
Hair care – Hair oil / cream/ lotion / serum	71	41 858	+	-	D	W	10-80% (div hair preparations)	+

Dimethicone	Number of products in Kemiluppen (>100)*	Number of scannings in Kemiluppen (>25 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)	Prioritising/ Commenting
Hair care -hair powder	1	138	+	+	D	W	-	-
Hair care -hair shampoo	154	76 597	-	+	D	W/K/C	0.08-4%	++ Also children
Hair care -dry shampoo	4	233	+	+	D	M/W	-	-
Hair care - wax / mud / clay / paste / gum	29	6 773	+	+	D	M/W	10-80% (div hair preparations)	+++
Cosmetic - Blush / highlighter	62	26 225	+	+	D	W	3-23%	+ small amount per time
Cosmetic - Brows	14	7 720	+	+	D	W	13%	- small amount per time
Cosmetic - Con-cealer / corrector	34	33 226	+	+	D	W	-	- small amount per time
Cosmetic – Foun-dation	121	78 693	+	+	D	W	1-16%	++

Dimethicone	Number of products in Kemiluppen (>100)*	Number of scannings in Kemiluppen (>25 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)	Prioritising/ Commenting
Cosmetic - Lip-stick / lipgloss / lip pencil	18	11 054	+	+	D/O	W	0.6-20%	++ Oral exposure few products
Cosmetic - Mas-cara / lashes	28	55 852	+	+	D	W	0.3-4%	small amount per time
Cosmetic – Nail spray / nail care	36	13 308	+	+	D	W	0.001-3%	-
Cosmetic – Nail spray remover	1	632	-	+	D	W	-	-
Cosmetic - Primer / fixer	43	20 338	+	+	D	W	24%	+++ very high conc.
Cosmetic - Pow-der	89	63 836	+	+	D	W	0.3-30%	++ small amount per time
Cosmetic – eye pencil / eyeliner	1	2	+	+	D	W	1-13 %	-
Cosmetic – eye shadow	81	47 917	+	+	D	W	1-10%	small amount per time

Dimethicone	Number of products in Kemiluppen (>100)*	Number of scannings in Kemiluppen (>25 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)	Prioritising/ Commenting
Body care - Cream / lotion / balm	322	199 163	+	+	D	M/W/C	0.5-10%	+++ Children / large amount per time
Body care – Foot care	26	8 532	+/-	-	D	W	-	+
Body care – Hand care/cream	130	85 749	+	+	D	M/W	0.5-10%	++
Body care - Oil	6	6 230	+	+	D	M/W/C	0.5-10%	++ Children / large amount per time, few products
Body care - onit-ment / gel	13	7 296	+	+	D	M/W/C	0.5-10%	++ Children / large amount per time, few products
Body care - Scrup	1	161	-	-	D	W	-	-
Sun care - After-sun	23	9 733	+	+	D	M/W/C	1-15%	++ Children / large amount per time, few products
Sun care - face	18	6 943	+	+	D	M/W/C	1-15%	++ Children / large amount per time, few products

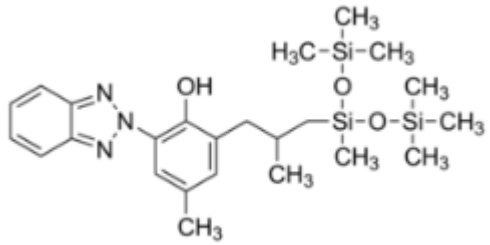
Dimethicone	Number of products in Kemiluppen (>100)*	Number of scannings in Kemiluppen (>25 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)	Prioritising/ Commenting
Sun care – Self tanning	17	12 008	+	+	D	M/W	1-15%	++ large amount per time, few products
Sun care – Sun cream / - lotion / - gel	105	65 235	+	+	D	M/W/C	1-15%	+++ Children / large amount per time
Sun care – Sun spray	12	5 224	+	+	D/I	M/W/C	1-15%	+++ Children/ large amount per time,/ inhalation
Sun care – Sun stick	3	2 117	+	+	D/O	M/W/C	1-15%	++ Children/ oral exposure
Soap and hygiene – Body shampoo / body gel / foam bath	2	75	-	+	D	M/W/C	0.08-4%	-
Soap and hygiene - Deodorant	154	173 842	+	+	D	M/W	0.5-23%	++
Soap and hygiene – Intimate care	2	855	+	+	D	M/W	-	-

Dimethicone	**Number of products in Kemiluppen** **(>100)***	**Number of scannings in Kemiluppen** **(>25 000)***	**Leave-on** **+/-**	**daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **(CIR 2003)** **(>5%)**	**Prioritising/ Commenting**
Soap and hygiene - Toothpaste	2	1 330	-	+	D/O	M/W/C	-	-
Soap and hygiene – wet wipes	1	216	-	+	D	M/W/C	-	-
Total products	2 458							Highest priority creams, hair care prodcuts and sun care products

*Marked in **bold** writing

Appendix 1.8 Mapping of drometerizole trisiloxane

Description



CIR:
Drometrizole trisiloxane is not included in the CIR database.

CosIng (2019):
Drometrizole trisiloxane (CAS: 155633-54-8).
Funcion: UV-absorber; UV-filter
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

Making Cosmetics (https://www.makingcosmetics.com/About-Us_ep_4-1.html):
Drometrizole trisiloxane is not included.

SpecialChem:
Drometrizole trisiloxane is not included.
https://cosmetics.specialchem.com/inci/

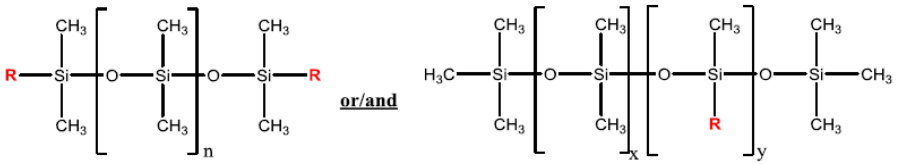
Drometrizol trisoloxan	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003) (>5%)*	Priority/ Comments
Product types	8						Max. Conc. 15%	
facial care - BB/CC cream	3	3 630	+	+	D	W	< 15%	-
facial care – day cream/lotion	7	5 084	+	+	D	M/W	< 15%	++
Cosmetic – Nail spray remover	1	211	-	+	D	W	< 15%	-
Sun care - face	6	3 583	+	+	D	M/W/C	< 15%	++
Sun care – Sun cream / - lotion / - gel	43	32 993	+	+	D	M/W/C	< 15%	+++ Large exposure, children
Sun care – Sun oil	3	999	+	+	D	M/W/C	< 15%	-

Drometrizol trisoloxan	**Number of products in Kemiluppen** **(>10)***	**Number of scannings in Kemiluppen** **(>5 000)***	**Leave-on** **+/-**	**daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **(CIR 2003)** **(>5%)***	**Priority/ Comments**
Sun care – Sun spray	18	11 974	+	+	D/I	M/W/C	< 15%	+++ Large exposure, children
Sun care – Sun stick	4	3 974	+	+	D/O	M/W/C	< 15%	-
total products	85							Highest priority, sun care products

*Marked with **bold** writing

Appendix 1.9 Mapping of PEG-10 dimethicone

Description



CIR (2015):

PEG-10 dimethicone is described as having an average molecule weight >1000 g/mol. Water Sol.

Safe as cosmetic ingredients in the present practices of use and concentration.; max. use conc. 10 %.

CIR (2015).Safety Assessment of Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients as Used in Cosmetics. Cosmetic Ingredient Review.January 2015. https://www.cir-safety.org/sites/default/files/ROPSIL_092014%20_Tent.pdf

CosIng (2019):

Sillcones and siloxanes, dimethyl, hydropoly(oxy-1,2-ethanediyl methyl, trimethylsilyl terminated (10 mol EO average molar ratio)

Function: Hair conditioning, skin conditioning

http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

Making Cosmetics (https://www.makingcosmetics.com/About-Us_ep_4-1.html):

Not registered

SpecialChem:

PEG-10 Dimethicone is a polyethylene glycol derivative of dimethicone. It functions as a hair and skin conditioning agent.

https://cosmetics.specialchem.com/inci/

PEG-10 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2015) Table 4	Priority/ Comments
Product types	14							
Facial care – BB/CC cream	12	25 436	+	+	D	W/M	0.013-5.3	+++
Facial care – day ceream/lotion	13	3 500	+	+	D	W/M	0.013-5.3	+++
Facial care – Night cream	1	530	+	+	D	W/M	0.013-5.3	-
Facial care - Serum	5	1 909	+	+	D	W/M	0.013-5.3	+
Facial care – Eye cream / -serum / -gel	4	391	+	+	D	W	0.38-4.2	-
Hair care - Balm / conditioner / treat-ment / mask	2	561	-	+	D	W/M	0.1-6	-

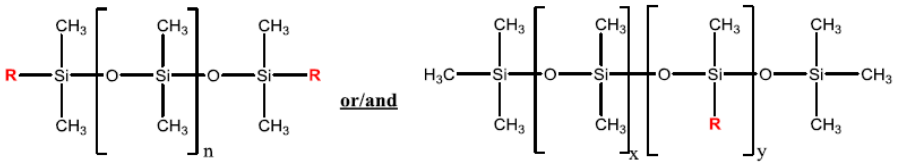
PEG-10 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2015) Table 4	Priority/ Comments
Hair care - Hair oil /cream / lotion / serum	1	319	+	+/-	D	W/M	0.013-5.3	-
Hair care - Shampoo	1	63	-	+/-	D	W/M/C	0.1-6	-
Cosmetic – Blush / highlighter	1	24	+	+	D	W	0.013-5.3	-
Cosmetic - Concealer / corrector	18	15 416	+	+	D	W	0.013-5.3	+ minor exposure
Cosmetic - Foundation	76	40 470	+	+	D	W	0.013-5.3	+++ many products, consumer interest
Cosmetic - Primer / fixer	6	2 365	+	+	D	W	0.013-5.3	+
Body care – Hand care	1	443	+	+	D	W/M	0.013-5.3	-

PEG-10 dimethicone	**Number of products in Kemiluppen** **(>10)***	**Number of scannings in Kemiluppen** **(>5 000)***	**Leave-on** **+/-**	**daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **(CIR 2015)** **Table 4**	**Priority/ Comments**
Sun care - face	1	97	+	+	D	W/M	0.013-5.3	-
Total products	142							Highest priority creams

*Marked with **bold** writing

Appendix 1.10 Mapping of PEG-12 dimethicone

Description



CIR (2015):

PEG-12 dimethicone is describes as having an average of molecule weight of 500-1000 ~3000 g/mol. Fully water sol.

Safe as cosmetic ingredients in the present practices of use and concentration.; max. use conc. 10 %

CIR (2015).Safety Assessment of Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients as Used in Cosmetics. Cosmetic Ingredient Review.January 2015. *https://www.cir-safety.org/sites/default/files/ROPSIL_092014%20_Tent.pdf*

CosIng (2019):

Silicones and siloxanes, dimethyl, hydropoly(oxy-1,2-ethanediyl methyl, trimethylsilyl terminated (12 mol EO average molar ratio)

Funktion: Hair conditioning, skin conditioning

http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

SpecialChem:

Used for skin care, hair care and shower gels. Acts as an emollient and a conditioning agent. Posesses detackifying and good solubility properties. Offers characteristics such as soft silky feel, no build up and improved wet and dry combing.

https://cosmetics.specialchem.com/inci/

PEG-12 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003)	Priority/ Comments
Product types	25							
Facial care - cleansing / makeup remover	1	25	-	+	D	W	0.1-5	-
Facial care – BB/CC cream	2	2 605	+	+	D	W	0.0016-6.5	-
Facial care – Day cream / lotion	8	6 164	+	+	D	W/M/C	0.0016-6.5	+
Facial care - Mask	3	422	-	-	D	W/M	0.1-5	-
Facial care – cleansing tissues	1	1 521	-	+	D	W/M	0.1-5	-
Facial care - Scrub / peeling	2	1 082	-	-	D	W/M	0.1-5	-

PEG-12 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003)	Priority/ Comments
Facial care - Serum	4	2 488	+	-	D	W/M	0.0016-6.5	-
Facial care – Skin tonic / toner / mist	3	2 620	+	+	D/I	W/M	0.0016-6.5	-
Facial care – Eye-makeup remover	1	127	-	+	D	W	0.0016-2	-
Baby care - Babyshampoo	1	146	-	-	D	C	4	-
Hair care - Balm / con-ditioner / treatment / mask	7	911	-	+/-	D	W/M	0.1-5	+
Hair care - gel	2	823	+	+/-	D	W/M	0.0016-6.5	-

PEG-12 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003)	Priority/ Comments
Hair care -hair colour	5	1 169	+	-	D	W/M	0.1-1	+
Hair care – Hair spray / hair spray/ heat spray	52	14 402	+	+	D/I	W	0.0016-6.5	+++ Many products
Hair care -hair powder	11	2 332	+	+	D	W/M	0.0016-6.5	+
Hair care – Hair oil / cream/ lotion / serum	8	1 502	+	+/-	D	W/M	0.0016-6.5	+
Hair care -hair sham-poo	28	3 708	-	+/-	D	W/M/C	0.0016-6.5	+++ Exposure to the environment
Hair care - wax / mud / clay / paste / gum	3	347	+	+	D	W/M	0.0016-6.5	-

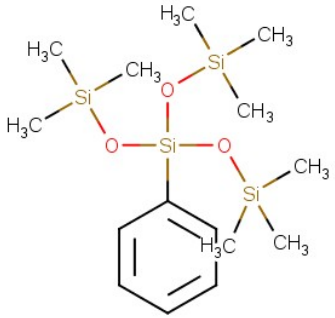
PEG-12 dimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003)	Priority/ Comments
Cosmetic – Nail spray / nail care	3	538	+	+/-	D	W	0.24	-
Body care - cream / lotion / balm	1	34	+	+	D	W/M/C	0.0016-6.5	-
Body care – food care	1	330	+	-	D	W/M	0.0016-6.5	-
Sun care – Selt tanner	2	630	+	-	D	W/M	0.0016-6.5	-
Sun care – Sun creame / - lotion / - gel	3	458	+	+	D	W/M/C	0.0016-6.5	-
Soap and hygiene - Deodorant	5	8 332	+	+	D	W/M	0.5-2.5 0.1 (aerosol)	+
Soap and hygiene – Hand desinfection	2	194	-	+	D	W/M	0.1-5	-
Total products	159							Highest priority hair care products

*Markeres med fed skrifttype

Appendix 1.11 Mapping of Phenyl trimethicone

Description

CIR (1986 and 2006)



CIR (1986). Final report on the safety assessment of phenyl trimethicone: J Am Coll Toxicol, 5 (5), 353 – 371.
CIR (2006). Annual review of cosmetic ingredient safety asessments – 2004/2005. Int J Toxicol 25(supl 2), 54-56.

CosIng (2019):
Phenyl trimethicone (CAS 2116-84-9). Function: anti foam agent, surfactant, hair and skin conditioning agent.
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

SpecialChem:
Silicone-based. Phenyl Trimethicone is used in cosmetics and beauty products functioning as an anti-foaming agent, hair conditioning agent and skin-conditioning agent. It improves texture of hair that has been damaged by chemical treatment.
https://cosmetics.specialchem.com/inci/.

Phenyl trimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2006) Table 17	Priority/ Comments
Product types	28							
Facial care - Cleansing / makeup remover / wash	4	6 341	-	+	D	W/M	2-4	-
Facial care – BB/CC cream	9	4 747	+	+	D	W/M	4-6	+
Facial care – day cream/lotion	13	3 822	+	+	D	W/M	4-6	++
Facial care - Lipbalm	1	81	+	+	D/O	W/M/C	0.08-36	-
Facial care - Mask	3	743	-	+/-	D	W/M	-	-
Facial care – Night cream	1	391	+	+	D	W/M	2	-

Phenyl trimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2006) Table 17	Priority/ Comments
Facial care - Serum	2	559	+	+/-	D	W/M	2	-
Facial care – eye cream / - serum / - gel	4	2 976	+	+/-	D	W/M	0.008-1	-
Hair care - Balm / conditioner / treatment / mask	19	5 403	-	+/-	D	W/M	0.3-2	++
Hair care – Hair spray / hair spray/ heat spray	17	3 171	+	+/-	D/I	W	-	++
Hair care – Hair oil/ cream/ lotion / serum	25	10 990	+	+/-	D	W/M	5-11	+++ Many products, consumer interest
Hair care – hair powder	1	683	+	-	D/I	W/M	5-11	-

Phenyl trimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2006) Table 17	Priority/ Comments
Hair care – Dry shampoo	2	234	+	-	D/I	W/M	5-11	-
Hair care - wax / mud / clay / paste / gum	6	1 436	+	+/-	D	W/M	5-11	+
Cosmetic - Blush / highlighter	10	3 365	+	+	D	W	2-15	+
Cosmetic - Brows	1	2 391	+	+	D	W	0.0075-22	-
Cosmetic - Con-cealer / corrector	13	9 164	+	+	D	W	2-15	+
Cosmetic - Founda-tion	31	16 430	+	+	D	W	2-22	+++ Many products, potential high conc, daily use

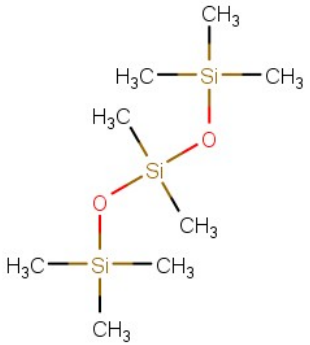
Phenyl trimethicone	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. CIR (2006) Table 17	Priority/ Comments
Cosmetic - Lipstick / lipgloss / lip pencil	5	4 121	+	+	D/O	W	0.08-36	-
Cosmetic - Primer / fixer	6	1 928	+	+	D	W	2-22	-
Cosmetic - Powder	25	25 712	+	+	D/I	W	0.1-18	++
Cosmetic – eye shadow	6	5 181	+	+	D	W	4-13	
Body care - Cream / lotion / balm	4	7 538	+	+	D	W/M/C	2-4	-
Body care – Foot care	1	190	+	-	D	W/M	2	-
Body care - Oil	1	215	+	+/-	D	W/M	2	-

Phenyl trimethicone	**Number of products in Kemiluppen** **(>10)***	**Number of scannings in Kemiluppen** **(>5 000)***	**Leave-on** **+/-**	**daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **CIR (2006) Table 17**	**Priority/ Comments**
Sun care – Sun cream / - lotion / - gel	1	96	+	+	D	W/M/C	0.5-9	-
Sun care – Sun spray	2	1 303	+	+	D/I	W/M/C	0.5-9	-
Soap and hygiene – Body shampoo / body gel / foam bath	1	12	-	+	D	W/M/C	-	-
Total products	214							Highest priority hair care products and cosmetics in the form of foundation

*Marked with **bold** writing

Appendix 1.12 Mapping of trisiloxane

Description



CIR: Trisioxae is not included in the CIR database.

CosIng (2019):
Trisiloxane (octamehyltrisiloxane) (CAS: 203-497-4).
Function: antifoam agent, skin conditioning agent.
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.advanced

Making Cosmetics (https://www.makingcosmetics.com/About-Us_ep_4-1.html):
Trisiloxane not included omfattet.

SpecialChem:
Trisiloxane (octamehyltrisoloxane) (CAS: 203-497-4).
Function: antifoam agent, skin conditioning agent.
https://cosmetis.specialchem.com/inci/trisiloxane

Trisiloxane	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003)	Priority/ Comments
Product types	15						-	
Facial care - cleansing / makeup remover / wash	3	5 289	-	+	D	W	-	-
Facial care – day cream/lotion	12	8 413	+	+	D	M/W/C	-	+++ Most products
Facial care – Night cream	1	587	+	+	D	W	-	+
Facial care – cleansing tissues	2	1 293	-	+	D	W	-	+
Hair care - Balm / conditioner / treatment / mask	1	89	+	+	D	M/W	-	+
Hair care – Hair spray / hair spray/ heat spray	3	386	+	+	D/I	W	-	+

Trisiloxane	Number of products in Kemiluppen (>10)*	Number of scannings in Kemiluppen (>5 000)*	Leave-on +/-	daily use +/-	Exposure Dermal Inhalation Oral	Primary target group(s) Women = W Men = M Children <3 years = C	Conc. (CIR 2003)	Priority/ Comments
Hair care – hair oil / cream/ lotion / serum	4	1 551	+	-	D	W	-	+
Cosmetic - Con-cealer / corrector	1	2 200	+	+	D	W	-	+
Cosmetic - Foun-dation	4	1 257	+	+	D	W	-	+
Cosmetic - Mas-cara / lashes	1	1 235	+	+	D	W	-	+
Cosmetic - Primer / fixer	1	2	+	+	D	W	-	+
Body care - Cream / lotion / balm	1	822	+	+	D	M/W/C	-	+
Sun care – Self tanning	1	432	+	+	D	M/W	-	+

Trisiloxane	**Number of products in Kemiluppen** **(>10)***	**Number of scannings in Kemiluppen** **(>5 000)***	**Leave-on** **+/-**	**daily use** **+/-**	**Exposure** **Dermal** **Inhalation** **Oral**	**Primary target group(s)** **Women = W** **Men = M** **Children <3 years = C**	**Conc.** **(CIR 2003)**	**Priority/ Comments**
Sun care – Sun cream / - lotion / - gel	3	1 351	+	+	D	M/W/C	-	+
Sun care – Sun spray	1	821	+	+	D	M/W/C	-	+
Total products	39							Highest priority creams

*Marked in **bold** writing

Appendix 2. Outline of analysis results

Analysis results (mg/kg) for content of siloxanes and siloxane compounds in cosmetic products (10.000 mg/kg = 1%). [1)] Content is determined quantititatively; [2)] Content is determined semi-quantititatively; Det. lim. = detection limit; – Means content is below the detection limit; * Means the detection limit of each single siloxane.

Product No.	D4[1)]		D5[1)]		D6[1)]		Trisiloxane[1)]		Drometrizole trisiloxane[1)]		Phenyl trimethicone[1)]		Siloxane X[2)]		D3[2)]		Sum of cyclic siloxanes[2)]		Sum of linear siloxanes[2)]	
Det. lim.	50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		5 mg/kg		50 mg/kg		5 mg/kg*		5 mg/kg*	
Unit	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD
1	-	-	490	0.4	28 000	8.0	-	-	650	0.3	140	5.9	-	-	810	4.3	80	4.7	2 600	2.2
2	-	-	90 000	14	55 000	6.7	-	-	1 100	7.8	240	0.3	-	-	2 600	4.7	110	25	4 500	10
3	200	21	70	25	-	-	800	1.6	210	31	130	19	-	-	130	4.5	-	-	2 600	13
36	260	38	369000	8.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	5 900	18	910000	15	990	26	-	-	-	-	-	-	-	-	5 800	18	-	-	-	-
38	400	15	319000	2.0	1 400	20	-	-	780	12	-	-	-	-	-	-	-	-	-	-
5	3 300	6.8	262000	8.5	12 000	5.4	-	-	80	11	890	1.5	1 000	2.4	1 900	8.7	330	4.0	410	15
6	410	15	14 000	23	142000	7.3	-	-	-	-	-	-	-	-	5 300	1.4	370	1.7	90	17
7	-	-	70	3.0	100	0.6	-	-	1 600	0.8	28 000	6.1	5 700	0.4	1 200	0.03	240	3.7	8 800	1.6

Product No.	D4[1)]		D5[1)]		D6[1)]		Trisiloxane[1)]		Drometrizole trisiloxane[1)]		Phenyl trimethicone[1)]		Siloxane X[2)]		D3[2)]		Sum of cyclic siloxanes[2)]		Sum of linear siloxanes[2)]	
Det. lim.	50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		5 mg/kg		50 mg/kg		5 mg/kg*		5 mg/kg*	
Unit	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD
40	4 600	1.0	264000	1.2	13 000	12	57 000	5.6	650	2.0	1 900	4.3	-	-	1 700	10	290	0.9	16 000	0.9
12	2 800	9.8	870000	4.7	7 900	10	-	-	80	3.1	-	-	-	-	500	4.1	1 100	1.1	-	-
13	580	4.7	857000	3.4	11 000	6.3	-	-	70	10	3 500	16	3 200	6.7	2 000	7.5	640	5.0	90	4.5
15	260	3.1	66 000	18	900	3.5	90	5.8	90	5.8	470	0.6	600	2.9	470	11	-	-	2 800	0.5
16	340	6.1	280000	0.8	15 000	23	-	-	-	-	14 000	3.1	6 700	7.9	160	12	-	-	-	-
42	192000	1.8	232000	9.5	6 600	19	-	-	-	-	-	-	-	-	11 000	14	960	2.3	240	0.2
43	20 000	2.2	298000	8.7	5 300	4.3	200000	2.0	70	2.5	180	0.3	-	-	5 000	11	1 200	0.4	30	20
17	-	-	-	-	-	-	-	-	-	-	1 900	8.3	110	17	-	-	-	-	-	-
18	210	3.8	68 000	5.2	610	2.4	-	-	-	-	-	-	20	1.1	260	3.5	-	-	-	-
19	-	-	-	-	-	-	-	-	-	-	930	3.7	830	5.4	100	15	-	-	-	-
20	398000	28	2 500	12	-	-	290	12.7	-	-	-	-	-	-	15 000	2.7	-	-	-	-
21	238000	2.6	150000	3.8	10 000	1.9	490	0.5	-	-	-	-	-	-	16 000	1.6	1 000	3.0	-	-
22	450	9.5	1105000	6.9	17 000	12	-	-	100	55	-	-	-	-	470	4.6	1 200	0.2	80	4.9
23	50	0.1	158000	2.0	-	-	130	2.7	-	-	400	3.0	410	25	280	3.7	-	-	1 600	2.1
44	-	-	360	8.4	530	14	200	18.9	-	-	-	-	10	17	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Product No.	D4[1)]		D5[1)]		D6[1)]		Trisiloxane[1)]		Drometrizole trisiloxane[1)]		Phenyl trimethicone[1)]		Siloxane X[2)]		D3[2)]		Sum of cyclic siloxanes[2)]		Sum of linear siloxanes[2)]	
Det. lim.	50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		50 mg/kg		5 mg/kg		50 mg/kg		5 mg/kg*		5 mg/kg*	
Unit	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD	mg/kg	%RSD
24	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	40	3.6	-	-
26	-	-	-	-	-	-	-	-	-	-	-	-	-	-	60	45	140	7.6	-	-
8	-	-	9 700	10	230	23	-	-	-	-	-	-	-	-	100	9.2	-	-	-	-
9	-	-	1 700	2.7	120	2.7	-	-	-	-	-	-	-	-	50	0.3	-	-	-	-
10	60	13	570	10	32 000	2.7	-	-	-	-	-	-	-	-	960	20	-	-	-	-
11	-	-	350	4.0	15 000	9.2	-	-	-	-	-	-	-	-	70	6.5	-	-	-	-
41	-	-	-	-	120	48	-	-	80	28	90	20	-	-	-	-	-	-	1 400	31
33	-	-	-	-	-	-	-	-	980	1.3	-	-	-	-	50	10	-	-	-	-
34	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	100	5.0	80	1.6	340	11	-	-	3 400	7.4	740	10	-	-	150	13	-	-	25 000	3.1
46	17 000	4.5	160000	14	3 200	16	-	-	1 100	2.5	80	0.5	-	-	2 900	18	170	3.4	26 000	3.4
28	-	-	-	-	-	-	-	-	6 900	17	-	-	-	-	-	-	-	-	-	-
29	-	-	1 800	5	23 000	5	-	-	24 000	14	270	6	-	-	620	30	-	-	2 500	16
30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Appendix 3. Toxicological hazard assessment

For the selected silicone compounds, a hazard assessment was made based on literature search and the most recent expert assessments of the substances.

In the hazard assessment of a substance, the critical effects of the substance are identified and the corresponding NOAEL is pointed out to form the basis for derivation of the the tolerable exposure level:

Tolerable exposure level = NOAEL/ reference MoS (Margin of Safety)

where reference MoS according to SCCS (2018) is the product of several uncertainly factors. The uncertainty factors considers e.g. extrapolation from animal experimental data to the human situation; accounts for differeces between humansh and also includes considerations regarding relevance and quality of the test data. Typically a MoS value of 100 reference is used, if extrapolation is made from a NOAEL from a 90-day animal test to a safe human exposure level.

Dimethicone

The American expert group ”Cosmetic Ingredient Review Expert Panel” in 2003 made a toxicological assessment of the silicone polymer dimethicone (CIR 2003) which recently has been updated (CIR 2020). Also, ECETOC (2011) has made a very thorough description of the toxicity of linear polydimethylsiloxanes. Data from these assessment arethe basis for the toxicological description below. Both experimental animal data and human data indicate that dimethicone is not absorbed after oral intake, which is considered to be a follow of the very high molecular mass of the polymer. In cases with a high content of low molecular pylymers (approx. 10%, molecule weight not indicated), an oral absorption of approx. 3.5% was found in humans. In terms of skin absorption, human tests with dimethicone have shown, that the substance is not absorbed.

Dimethicone has no or very low acute toxic potential after oral and dermal exposure, whereas inhalation of aerosols in guinea pigs lead to lethal effects at an aerosol concentration of 2.12 mg/L, probably as a result of oedema and bleedings in the lungs. Data from the inhalation test is from 1953, and not further information abouth the quality of the used dimethicone solution is available.

In rabbits, dimethicone was seen to cause slight skin irritation. However, testing with humans using 24 hours of occlusive exposure to the arm did not result in irritative effects. In several skin sensitization tests in guinea pigs, no skin sensitization from dimethicone was seen. Several tests on eye irritation was reported, where especially older tests showed that dimethicone (quality not further defined) were able to cause eye irritation. More recent tests do show mild or no eye irritation (CIR 2003).

In a combined chronic and oncogenicity study uising oral exposure to rats increased incidence of ocular opacities were observed at dose levs of 300 and 1000 mg/kg bw/day. These effects were considered related to local irritation of the test substance, No systemic effects

were observed and 1000 mg/kg bw/day was identified as a NOAEL. (ECETOC 2011, CIR 2020, JECFA 2009).

In a test with pregnant rabbits from 1994, dimethicone was dosed with via the diet to rabbits from day 6 to day 19 during the gestation period. The concentration of dimethicone in the diet was 0.5%, 1% and 2.5%. Neither maternal toxic effects nor effect in the offspring were seen (CIR 2003).

Other older reproductive toxicity testing were described in CIR (2003). However, the tests are regarded as neither conclusive nor suitable for further assessment due to very different qualities of dimethicone (e.g. dimethicone mixed with motor oil etc.), or because of very unprecise reporting of the results.

CIR (2003) and CIR (2020) from a number of *in vitro* mutagenic tests with bacteria and mammalian cells found that dimethicone did not show any genotoxic potential.

Neither ECETOC (2011) nor CIR (2020) developed a tolerable exposure level for dimethicione. In relation to oral exposure from food JECFA (2009) concluded a temporary acceptable daily intake of 0-0.8 mg/kg bw/day, however, the toxicological rationale for this value was not further specified.

Overall assessment
Dimethicone has a very low potential for acute toxicity at oral and dermal exposure. For inhalation of aerosols, some data indicate concern for high acute toxicity.
At local skin and eye contact, the most recent animal tests indicate no to mild grades of irritation, whereas skin irritation was not seen in tests with humans. In tets for skin sensitising tests, dimethicone failed to induce skin sensitization.
Dimethicone is considered not to be mutagenic or carcinogenic, and data do not suggest concern for reproductive toxicity, although the data base is limited for this end-point.

Calculation of tolerable exposure level
As the underlying basis is a NOAEL value of 1000 mg/kg bw/day in rats, the oral tolerable exposure levels is estimated as:

Tolerale exposure level (oral) = 1000 mg/kg bw/day / 10 x 10
Tolerale exposure level (oral) = 10 mg/kg bw/day.

as an uncertainty factor 10 is used to extrapolate from mice to humans and a factor 10 is used to consider differences in human susceptibility.

Data show, that dimethicone is not absorbed through the skin, thus, it is not relevant to calculate a tolerable exposure level for skin contact.
.
Reliability: It is estimated that the reliabitity of the value for the oral tolerable dose level is high based on the description of the chronic toxicity test that was conducted in 2003.

References

CIR (2003). 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 eth-

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CIR (2020). Safety Assessment of Dimethicone, Methicone, and Substituted-Methicone Polymers, as Used in Cosmetics. Tentative Amended Report for Public Comment.

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D3 (hexamethylcyclotrisiloxane)

This substance has neither be assessed by SCCS nor CIR. However, the substance is REACH registered on Annex X level and thus, data from the REACH registration is used for the hazard assessment of the substance.
Toxnet search did not lead to supplementary relevant data.

The following relevant studies are from the REACH registration (november 2019).

According to an OECD 111 hydrolysis test substance has a hydrolysis half life of 23 min at pH 7 and at 25° C, and of 2 min at pH 4 and of 5 min at pH 9. The hydrolysis is reported to cause formation of hexamethyltrisiloxanediol (3663-50-1) and dimethylsilanediol (DMSD, CAS 1066-42-8).

There are no tests concerning acute toxicity effects of D3, but for the hydrolysis product dimethylsilanediol an oral LD50 in rats of > 2000 mg/kg bw is given.

Skin and eye irritation testing made before OECD's test guidelines showed light and no irritation respectively, and in an OECD guinea pig maximisation test no potential for skin sensitization was observed.

In an oral 14 days test with rats using exposure levels from 25 to 1600 mg/kg bw/day, dosis related increased liver weight was observed and a NOAEL of 25 mg/kg bw/day was set on the basis of increased liver weight in male rats at higher dose levels.
In an oral 28 days test, where rats were dosed with 1500 mg/kg bw/day increased liver weight was found. It is, however, indicated in the REACH registration that this effect was considered as an adaptive and non-hazardous effect.

In a 28 days inhalation test (from 1992, OECD 412) with rats exposed to 0, 0.084, 0.945, 9.041 mg/l 6 hours a day, 4 lethal outcomes were seen at the highest exposure level (out of 30 exposed animals) probably as a result of local effects and oedema in the lungs. At the two highest exposure levels histopatological signs from irritation of the tissue in the upper respiratory passages was seen, and at the highest exposure level also effects in the pulmonary tissue was observed. On this basis, a NOAEC of 84 mg/m^3 was determined for local effects in the respiratory system. NOAEC for systemic effects was determined at 945 mg/m^3 in relation to effects on liver and kidneys in the dead animals at the highest exposure level.

In a 90 days inhalation test (from 2001, OECD 413) rats were exposed to 0, 15, 150, 600, 2500 ppm D3, 6 hours/day, 5 days a week. Increased liver weight was observed in all exposure groups. In male rats at all exposure levels histopatological changes (centrilobular hypertrofy) were seen with male rats for all dosage groups. This was also observed in female rats at 150 and dose levels above. These effects were considered as an adaptive non-adverse response, as the effects were reversible after an exposure free period of 28 days. NOAEC was determined to 150 ppm (corresponding to 1365 mg/m^3) on the basis of impact on the body weight in males at higher dosage levels.

As D3 after repeated exposure results in induction of the liver, increased liver weight and histopatological changes is in the context of this project, however, considered as an adverse effect even though the effects after exposure free period was found to be reversible. Thus, a LOAEC of 15 ppm (corresponding to 136 mg/m^3) can be set for these effects.

In a reproduction screening test with repeated exposure (from 2002, OECD 422) rats were exposed at 100, 500 and 2500 ppm D3, 6 hours per day. At the highest exposure level, increased liver and kidney weight was seen in male rats and further a 30% reduction in the organ weight of the seminal vesicle was observed.
At histopatology, atrophy of the the seminal vesicle was seen. Furthermore, hazardous effects were seen with male rats in the kidneys due to local protein congestion in the tissue at the two highest exposure levels. NOAEC was determined to 100 ppm corresponding to 900 mg/m^3.

It should be noted, that it was not reported in the study summaries whether local respiratory effects could be seen in the two last inhalation tests.

In *in vitro* tests with bacteria and mammalian cells (OECD 471, 473 and 476) no signs of mutagenic/ cytogenec effects were found.

In a reproduction screening test with repeated dosage (from 2002, OECD 422) rats were exposed to 100, 500 and 2500 ppm D3 6 hours per day. At highest exposure level, decreased number of implantations and reduced litter size were seen, and NOAEC in terms of reproductive toxicity was determined to 500 ppm (4500 mg/m^3).

On the basis of the above data from the REACH registration of D3, an oral NOAEL of 25 mg/kg bw/day in relation to liver effects from a 14 day study and a LOAEC of 136 mg/m^3 also in relation to liver effects can be set.

Calculation of tolerable exposure levels
From a NOAEL of 25 mg/kg bw/day, a tolerable exposure level for oral exposure can be calculated:

Tolerable exposure (oral) = 25 mg/kg bw/day / 10 x 10 x 6
Tolerable exposure (oral) = 0.04 mg/kg bw/day.

An uncertainty factor of 10 is used for extrapolation from rats to humans and furthermore a factor 10 to allow for differences in human susceptibility. A factor 6 is further used for extrapolation from short time exposure (14 days) to 90-day exposure.

From a LOAEC of 136 mg/m^3 a tolerable exposure level for inhalation can be calculated. The LOAEC should first be converted from exposure 6 hours per day 5 days per week to a 24 hours continuous exposure:

LOAEC (continuous) = 136 mg/m^3 x 6 h/24 h x 5 days/7 days = 24 mg/m^3

From this value, a tolerable exposure level can be calculated:

Tolerable exposure (inh) = *24* mg/m^3 / 2.5 x 10 x 3 = 0.32 mg/m^3

An uncertainty factor of 2.5 is used for extrapolation from rats to humans in connection with inhalation exposure and a factor of 10 is used to allow for differences in human susceptibility: A further factor of 3 is used for the extrapolation from a LOAEC value.

There are no specific data to illustrate absorption of D3 at skin contact. As the target organ for toxicity is the liver, it is considered more relevant to extrapolate from inhalation data to dermal exposure, because no first-pass effect in the liver can occur as from oral exposure.

Also there are no data concerning absorption by inhalation,but it is estimated that absorption will be significantly lower for dermal absorption. However, because of lack of data it is not considered justifiable to adjust for a lower dermal absorption with more than a factor 2.

As a first step in the calculation, the tolerable exposure level at inhalation is converted from mg/m^3 to mg/kg bw/day:

Tolerable exposure (inh, mg/kg bw/day) = Tolerabelt eksponering (inh)) x 20 m^3/ 60 x kg

Tolerable exposure (inh, mg/kg bw/day) = 0.32 mg/m^3 x 20 m^3/ 60 kg bw = 0.11 mg/kg bw/day

When converting to tolerable dermal exposure, consideration is taken for a factor 2 lower absorption.

Tolerable exposure (dermal) = 0.11 mg/kg bw/day x 2 = 0.22 mg/kg bw/day

Reliability: Data which are the basis for the calculations of tolerable exposure levels for oral exposure and inhalation are more recent OECD tests, and the calculated values must therefore be considered as reliable. The value for dermal exposure is based on an estimated absorption through the skin and here data on skin absorption would increase the reliability of the value. The used value for dermal absorption is estimated to be conservative.

References
REACH-registration of "Hexamethylcyclotrisiloxane": *https://echa.europa.eu/registration-dossier/-/registered-dossier/14554*

D4 (octamethylcyclotetrasiloxane)

On the basis of literature search in Toxnet and checking of data in the REACH registration for D4, it can be seen that no further data has been provided since the SCCS assessment from 2010.. In Toxnet, more recent literature from 2017 is indicated, but the publications mainly include tests which are already included in the SCCS (2010) assessment as non-published laboratory data.

D4 is a well tested substance in terms of toxicology and fulfils the data requirements in REACH for highest tonnage level (above 1 000 tons per year).The substance has also been evaluated by CeHoS (Danish Centre on Endocrine Disrupters) and is consideret to be an endocrine disruptor (CeHoS 2018).

EU´s expert group for consumer safety, SCCS, published in 2010 an assessment of the toxicological data available for cyclomethicone, which primarily includes data for D4 and D5.

The most significant conclusions from SCCS (2010) are indicated below.

SCCS (2010) estimated a dermal absorption of 0.5% for D4 based on *in vitro* and *in vivo* studies concering dermal absorption. From data from inhalation tests, the absorption by inhalation was determined to 5% for rats and 12 % for humans. Approx. 80% of the absorbed dose is eliminated via exhaled air. D4 is lipid soluble and would preferentially deposit in fat and highly lipophilic tissues.
SCCS (2010) used an oral absorption of 52% in connection with assessment of a MoS value from an oral study. This is in accordance with CIR (2011) which from an oral absorption test in rats dosed with radioactively marked D4 found at oral absorption of D4 up to 52%.

Low acute toxicity was seen after oral exposure and thus, rats survived a dose of 5.0 ml / kg bw. Correspondingly, a dermal dose of 10 g /kg bw did not lead to any fatal outcome in rabbits. By inhalation of D4 in rats, an LC value of 36 mg/L was found, i.e. a very low acute toxic potential by inhalation.

At skin and eye contact in animal testing studies, Only slight grades of irritation were seen from in experimental animal testing for skin and eye irritation, and a GPMT test indicated no concern for skin sensitization.

Based on negative *in vitro* data for mutagenic/genotoxic effects in bakteria and mammalian cells as well as *in vivo* tests, D4 is not considered as having any genotoxic potential.

In an 90 day inhalation tests with rats exposed to 0, 35, 122, 488 or 898 ppm (0.42, 1.48, 5.91 and 10.87 mg/l) 6 hours per day 5 days per week, increased incidences of ovarian atrophy were observed in the ovaries at highest exposure level with female rats. From the study a NOEC of 35 ppm was observed for increased liver weight and a LOAEC of 35 ppm for adverse effects in the lungs.

In a one-generation inhalation study in rats, a reduced number of yellow bodies and increased liver and kidney weight at 35 ppm were found, but the effects were not considered as adverse and a NOAEC of 300 ppm was determined. At 700 ppm, reduced number of implantations and foetuses as well as increased pre- and post implantation loss were observed. On the basis of SCCS (2010) determined a NOAEC 300 ppm for reproductive toxicity..

In a carcinogenicity study with D4 in rats, inhalation at highest exposure level of 700 ppm (8474 mg/m3) caused increased incidence of tumors in the uterus. Furthermore, the exposure resulted in significantly increased kidney and liver weight. None of these effects were seen at 150 ppm (1 816 mg/m^3) that is considered as a NOAEC. As D4 is not a genotoxic substance, SCCS found that the induction of tumors is subject to a threshold value. The mode of action and the relevance to humans has not been clarified, but D4's efffect as a dopamine agonist in rats is estimated to be a possible factor.

As basis for risk assessment of D4, SCCS (2010) determined the following values:

NOAEC for systemic effects: 150 ppm (1816 mg/m^3) in relation to tumors in the uterus, and effects on kidneys and liver, based on the data from the carcinogenic study.

Considering 5% absorption rate by inhalation, SCCS (2010) converted this exposure level to a daily systemic dosage of 17.8 mg/kg bw/day in rats.

SCCS (2010) did not consider the local inflammation effects in the lungs to be relevant in connection with use of D4 in cosmetics.

The Danish EPA (2014) has evaluated the same data and in connection with derivation of a health based air quality criterion for D4 a LOAEC of 35 ppm in relation to inflammatory responses in the lungs was concluded.

Calculation of tolerable exposure levels
For inhalation, the starting point is a LOAEC value of 35 ppm (420 mg/ m^3) from a 90-day inhalation test on the basis of infallmation in the lungs. This value can be converted to 24 hours of continuous exposure:

LOAEC (continuous) = 420 mg/m^3 x 6h/24 h x 5 days/7 days = 75 mg/m^3

from this value, at tolerable exposure level can be calculated:

Tolerable exposure level = 75 mg/m^3 / 2.5 x 10 x 3 = 1.0 mg/m^3

An uncertainty factor of 2.5 is used to extrapolate from rats to humans in connection with inhalation exposure, another factor 10 is used to allow for differences in human susceptibility. Further a factor of 3 is used because of extrapolation from LOAEC level.

From a systemic NOAEL of 17.8 mg/kg bw/day (as calculated by SCCS (2010) from a NOAEC of 1816 mg/m^3) the tolerable exposure level for systemic effects can be calculated:

Tolerable exposure level (internal) = 17.8 mg/kg bw/day / 10 x 10
Tolerable exposure level (internal) = 0.178 mg/kg bw/day.

An uncertainty factor of 10 is used for extrapolation from rats to humans and furthermore a factor 10 to allow for differences in human susceptibility.

This value corresponds internal absorbed dose of the substance. As the oral absorption of D4 is estimated to be up to 52%, the oral tolerable value can be calculated:

Tolerable exposure level (oral) = 0.178 mg/kg bw/day x 100%/ 52%
Tolerable exposure level (oral) = 0.34 mg/ kg bw/day

As the dermal absorption of D4 is estimated to be 0.5%, the dermal tolerable value can be calculated:

Tolerable exposure level (dermal) = 0.178 mg/kg bw/day x 100%/ 0.5%
Tolerable exposure level (dermal) = 35.6 mg/ kg bw/day

Reliability: The above tolerable exposure levels are calculated on the basis of a relatively recent expert assessment by SCCS (2010) and Danish EPA (2014) and the values are therefore regarded as realiable.

References
SCCS (2010). Opinion on Cyclomethicone. Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, D4) and Decamethylcyclopentasiloxane (Cyclopentasiloxane, D5). SCCS/1241/10.

Danish EPA (2014). Siloxanes (D3, D4, D5, D6, HMDS). Evaluation of health hazards and proposal of a health-based quality criterion for ambient air Environmental Project No. 1531. Danish Environmental Protection Agency.

D5 (decamethylcyclopentasiloxane)

D5 is a toxicologically well tested substance on many end-points except regarding reproductive toxicity. In connection with substance evaluation under the REACH legislation registration it was been requested to perform prenatal developmental toxicity testing by inhalation in two animal (/before March 2020) in order to fullfil the REACH data requirements at highest tonnage level (i.e. above 1 000 tons per year).

EU´s expert group for consumer safety, SCCS has in 2016 published a toxicological assessment of D5.

From a literature search in Toxnet and reveiw of data in the REACH registration for D5 it can be seen that no significant new data since the SCCS assessment in 2016 is available. Thus, the hazard assessment below is based on data and conclusions from SCCS (2016).

SCCS (2016) estimated the dermal absorption to 0.06% based on *in vitro* tests with human skin and *in vivo* tests with human volunteers. Furthermore, the human absorption by inhalation is estimated to be in the interval 3-10% (2.3% in rats). The oral absorption in rats was estimated to approx. 10%.

In experimental animal testing, D5 showed low acute toxic potential. However, the substance is considered to cause slight degree of irritation in conncection with exposure to skin and eyes.

D5 is not found to to be skin sensitizing based on *in vivo* tests (Local lymph node assay and Guinea Pig Maximisation Tests).

Furthermore, D5 did not result in mutagenic/ genotoxicological effects in well performed *in vitro* and *in vivo* tests.

From a 90 day study using oral exposure to rats, SCCS (2016) determined an oral NOAEL value of 100 mg/kg bw/day based on increased liver weight at higher dose levels. In a 90 days inhalation test, where rats were exposed 6 hours per day 5 days per week to 0; 28.6; 49.2; 87.7 eller 233 ppm of D5, a NOAEC of 49.2 ppm (744 mg/m3) was found based on effects in lungs and nasal mucous membranes. In female rats, effects in the ovaries and the uterus was found at the highest exposure level of 233 ppm (3536 mg/m^3).
Enlarged liver was found in female rats at 49.2 ppm and above and at 233 ppm in male rats. As no histopatological changes in the liver was observed, the SCCS (2016) did not consider these effects as adverse. In connection with the risk assessment in this project, the effects on the liver are, however, based on a precautionary approach considered to be a relevant finding for risk assessment (especially as also other siloxane compounds impact the liver). Thus, LOEC of 49.2 ppm is used as a NOAEC for liver impact.

Both a one-generation and a two-generation reproduction study have been performed in rats. From these studies, the SCCS determined a NOAEC value of 160 ppm (2428 mg/m^3 – the highest exposure level tested) for impact on both fertility and foetal development. SCCS (2016) did however note, that exposure at 160 ppm caused increased anogenital distance to the newborn males, but doubted these findings as they could not be supported by relevant data concerning hormonal effects.

In a carcinogenic study with rats, inhalation at highest exposure level of D5 of 160 ppm caused increased incidence of cancer in the uterus, whereas this was not seen at 40 ppm (607 mg/m^3) that was determined as a NOAEC. SCCS (2016) found that the mode of action behind these findings could not be clarified, but it was considered unlikely, that the effects were related to hormonal effects, as studies have shown, that D5 does not have direct oestrogen , anti- oestrogen, androgen, anti-androgen or progesterone activity. SCCS (2016) found indications that D5 can act as a dopamine agonist, which may be significant for development of cancer in the uterus.

In any case, the carcinogenic effect of D5 is considered to be subject to a threshold, as D5 is not considered to be genotoxic.

SCCS (2016) determined the following relevant values for hazard charaterisation and risk assessment:

NOAEC for local effects in the lungs: 49 ppm (744 mg/m^3)
NOAEC for systemic effects, cancer in the uterus: 40 ppm (607 mg/m^3). This value is converted by SCCS (2016) to a systemically absorbed dose of 3 mg/kg bw/day in rats.

Calculation of tolerable exposure levels
In connection with inhalation and local adverse effects in the lungs and enlarged liver, the starting poing is a NOAEC of 744 mg/m^3 from exposure during 6 hours/ day, 5 days/ wek. This value can be converted to 24 hours continuous exposure:

NOAEC (continuous) = 744 mg/m^3 x 6h/24 h x 5 days/7 days = 133 mg/m^3

From this value, a tolerable exposure levels can be calculated:

tolerable exposure levels (inh, local) = 133 mg/m^3 / 2.5 x 10 = 5.3 mg/m^3

as an uncertainty factor of 2.5 is used for extrapolation from rats to humans for inhalation exposure and a factor 10 is used to consider differences in human susceptibility.

In connection with inhalation and systemic damaging effects (tumors in uterus) the starting point is a NOAEC of 607 mg/m^3 from exposure during 6 hours/ day, 5 days/ wek. This value can be converted to 24 hours continuous exposure:

NOAEC (continuous) = 607 mg/m^3 x 6t/24 h x 5 days/7 days = 108 mg/m^3

From this value a tolerable exposure levels can be calculated:

tolerable exposure levels (inh, systemic) = 108 mg/m^3 / 2.5 x 10 = 4.3 mg/m^3

as an uncertainty factor of 2.5 is used for extrapolation from rats to humans for inhalation exposure and a factor 10 is used to consider differences in human susceptibility.

From a systemic NOAEL of 3 mg/kg bw/day as calculated by SCCS (2016) the tolerable exposure level for systemic effects can be calculated:

tolerable exposure levels (internal) = 3 mg/kg bw/day / 10 x 10
tolerable exposure levels (internal) = 0.03 mg/kg bw/day.

This value corresponds to an internal, absorbed dose of the substance. As the oral absorption of D5 is estimated to 10% in rats as well as in humans by SCCS (2016), the oral tolerable value can be calculated:

tolerable exposure levels (oral) = 0.03 mg/kg bw/day x 100%/ 10%
tolerable exposure levels (oral) = 0.30 mg/kg bw/day

as the dermal absorption of D5 is estimated to be 0.06% the dermal tolerable value can be calculated:

tolerable exposure levels (dermal) = 0.03 mg/kg bw/day x 100%/ 0.06%
tolerable exposure levels (dermal) = 50 mg/ kg bw/day

Reliability: The above tolerable exposure levels are calculated on the basis of a recent expert assessment made by SCCS (2016), and the values are therefore considered to be reliable estimates.

References

SCCS (2010). Opinion on Cyclomethicone. Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, D4) and Decamethylcyclopentasiloxane (Cyclopentasiloxane, D5). SCCS/1241/10

SCCS (2016). Opinion on decamethylcyclopentasiloxane (cyclopentasiloxane, D5) in cosmetic products. SCCS/1549/15. Final version of 29 July 2016.

D6 (dodecamethylcyclohexasiloxane)

In connection with literature search, toxicological data were found in PubChem (2019), in CIR (2011) as well as in EH Canada (2008). It is however found that the toxicological data indicated in the REACH registration of he substance (updated June 2019) forms the best basis for an assessment of the substance.

D6 is a well tested substance with regard to toxicology except for the end-point reproductive toxicity. In connection substance evaluation of the REACH registration an oral one-generation test in rats is requested to be performed before Juni 2021 in order to fullfil the REACH data requirements at highest tonnage level (i.e. above 1 000 tons per year).

Data on D6 is extracted from of the REACH registration of the substance, which is updated in July 2019.

Based on an oral test with radioactively marked D6 in rats, the oral absorption of D6 is estimeated to be 15%.
From an *in vitro* study with human skin, the absorption over skin is estimated to be 0.03%

Oral and dermal LD50 in rats was found to be more than 2000 mg/kg bw. There are no available data concerning acute toxicity and inhalation.

As for skin and eye irritation, tests with rabbits did not show irritation after skin exposure whereas slight eye irritation appeared in the first 24 hours after the exposure.

From skin sensitizing tests (GPMT-test) D6 is not considered to have any skin sensitizing potential.

From a 90 days inhalation study from 2013 inh rats exposed 6 hours/ day to 18.2; 182 and 546 mg/m^3, the NOAEC was concluded to 18.2 mg/m^3, as a result of adverse effets in nasal mucous membrane and slight effects in lungs and liver at higher exposure levels.

From 28 days of repeated oral exposure in rats to 100, 330 and 1000 mg D6 /kg bw/day, a NOAEL value of 1000 mg/kg bw/day was concluded. In the study significantly increased fatty deposits in the liver at all dose levels was seen, but this effect was not considered to be adverse. Furthermore, enlarged cells were seen in the thyroid gland at all dose levels but this was considered to be an adaptive reaction to stimulation of the liver and increased degradation of thyroid hormones.

D6 showed no mutagenic properties *in vitro* in bacteria and mammalian cells, and was also without effect i an *in vivo* micronucleus test in mice.

No cancer study for D6 is available.

The REACH registration includes an OECD screening study for reproductive effects in rats. f. In the study were given oral doses of 100, 330 and 1000 mg D6 /kg bw/day and a NOAEL value at the highest dose level of 1000 mg/kg bw/day was concluded. A decease (however, not statisstically significant) of the pregnancy rate was seen at the highest dose level.

In two prenatal developmental toxicity studies in rats and rabbits, respectively, a NOAEL for maternal toxicity and for adverse effects in offsprings was determined to the highest dose level of 1000 mg/kg/day for both species. In rats, statistically significantly increased maternal liver weight was observed, but as histopathological changes could not be found, the effect was not considered as adverse.

Thus, in the REACH registration, a NOAEL of 1000 mg/kg bw/day was used as the starting point for a hazard characterization, as the observed effects on liver and thyroid gland from 100 mg/kg bw/day and higher was not considered as adverse.

In an assessment of D6 made by the Canadian environment and health authorities, these effects were however considered as critical effects for a risk assessment of the substance, and a LOEL of 100 mg/kg/ day was concluded (EH Canada 2008).

Assessment
For risk assessment in this report, the following starting points are used:

LOEL in terms of effects on the thyroid gland and fatty deposits in the liver for repeated oral exposure in 28 days: 100 mg/kg bw/day

NOAEC in terms of adverse local effects in the lungs and effects in the liver for repeated inhalatiomn exposure, 90 days: 18.2 mg/m3

Calculation of tolerable exposure levels
In connection with inhalation and local adverse effect in the lungs, the starting point is a NOAEC of 18.2 mg/m^3 for exposure 6 hours/ day, 5 days/ week. This value can be converted to 24 hours continuous exposure:

$$\text{NOAEC (continuous)} = 18.2 \text{ mg/m}^3 \times 6 \text{ h}/24 \text{ h} \times 5 \text{ days}/7 \text{ days} = 3.3 \text{ mg/m}^3$$

From this value, a tolerable exposure level can be calculated:

tolerable exposure level (inh, local and systemic effects) = 3.3 mg/m^3 / 2.5 x 10

tolerable exposure level (inh, local and systemic effects) = 0.13 mg/m^3

An uncertainty factor of 2.5 is used to extrapolate from rats to humans by inhalation and furthermore a factor 10 is used to consider differences in human susceptibility.

In connection with oral exposure and adverse effects in the thyroid gland, the following tolerable exposure levels can be calculated from a LOAEL of 100 mg/kg bw/day:

tolerable exposure level (oral) = 100 mg/kg bw/day / 10 x 10 x 3
tolerable exposure level (oral) = 0.33 mg/ kg bw/day

An uncertainty factor of 2.5 is used to extrapolate from rats to humans by inhalation and furthermore a factor 10 is used to consider differences in human susceptibility. Furthermore, a factor 3 is used to extrapolate from short term exposure (28 days) with the test animals.

When converting to at tolerable exposure level at dermal exposure, different route-specific absorption rates has to be accounted for. In rats, 15% absorption for oral exposure was found, whereas a dermal absorption of 0.03% was found from an *in vitro* test with human skin.

tolerable exposure level (dermal) = 0.33 mg/kg bw/day *x 15%/ 0.03%*
tolerable exposure level (dermal) = 165 mg/ kg bw/day

Reliability: The tests, which are the basis for the calculation of the tolerable exposure levels, are from 2005 and 2013 and are indicated with a Klimishscore of 1 in the REACH registration and the data including the estimiated tolerable exposure levels are considered as reliable.
It has however to be noted that the REACH registrant considered the observed effects on liver and thyroid gland as non-adverse, adaptive effects, whereas in this assessment they are considered to be potential adverse. More in-depth interpretation of the studies would however, require access to background reports of the studies.

References

CIR (2011). Safety assessment of cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane. Int J Toxicol. 2011 Dec;30(6 Suppl):149S-227S. doi: 10.1177/1091581811428184.

EH Canada (2008). Screening Assessment for the Challenge Dodecamethylcyclohexasiloxane, 1-78. Environment Canada, Health Canada, November 2008. https://www.ec.gc.ca/ese-ees/FC0D11E7-DB34-41AA-B1B3-E66EFD8813F1/batch2_540-97-6_en.pdf

REACH-registrering af "Dodecamethylcyclohexasiloxane". https://echa.europa.eu/registration-dossier/-/registered-dossier/15811

Phenyl trimethicone

No more recent data and no REACH registration data are available for the silicone polymer phenyl trimethicone. US EPA's comptox database indicates, that there are no toxicological data on the substance. The assessment can therefore only based on the safety assessment made by Cosmetic Ingredient Review Expert Panel from 1986 (CIR 1986), who made an assessment of the substance mainly based on a number of unpublished data.

Data in this assessment are of older date, and in general the data can be considered to be rather insufficient compared to today´s standards of testing.

Phenyl trimethicone was assesssed for skin absorption in a test with test subjects that were dosed with phenyl trimethicone applied in doses of 50 mg/kg bw/day on the back for a period of 10 days. Blood and urine samples were taken through the entire period, but in no samples increased silicium content was seen, which signals very low absorption of the polymer.

Phenyl trimethicone has a low acute toxicity as oral LD50 in rats is above 10.2 g/kg bw and dermal LD50 in rabbits is above 2.0 g /kg bw.

In skin irritation tests, 24 hours of exposure to 0.5 ml phenyl trimethicone on intact and damaged rabbit skin showed only minor irritation (a score of 0.7 on a scale up to 8).
In an equivalent eye irritation test in rabbits, only minor eye irritation was observed within the first 24 hours which then disappeared completely within the subsequent 24 hours.

The substance showed no skin sensitizing effects in a GPMT test.

In 50 voluntary subjects 9 dosings of 24 hours occlusive patch test with 100% phenyl trimethicone neither signs of skin irritation nor skin sensitization was observed.

In a 28 days study with repeated skin exposure in rabbits using a dose level of 200 mg/kg bw/day phenyl trimethicone in 28 days, no adverse effects was observed.

In terms of mutagenicity, only testing in bacteria has been reported (Ames test) where phenyl trimethicone did not show any mutagenic potential.

In teratogenic studies in rats and rabbits, no deformities or impact on viable offsprings were seen at exposure levels up to 500 mg/kg bw/day. However, in one study in rabbits increased resorption rates and reduced number of viable offspring was observed at a dose level of 200 mg/kg bw/day. It should be noted, that the studies were performed in 1966 and 1967 and that data have been reported with very few details by CIR (1986).

Based on the above data, a dosage of 200 mg/kg bw/day for repeated dermal exposure is to be considered as a LOAEL, as increased number of resorptions and reduced number of viable offsprings were seen at this exposure level.

Calculation of tolerable exposure levels
On the basis of a LOAEL oft 200 mg/kg bw/day for developmental effets a tolerable exposure leves for dermal exposure can be calculated:

tolerable exposure level (dermal) = 200 mg/kg bw/day */ 10 x 10 x 10*
tolerable exposure level (dermal) = 0.2 mg/ kg bw/day

An uncertainty factor of 10 is used to extrapolate from rabbits to humans and a factor 10 to account for differences in human susceptibility. Furthermore, a factor 10 is used to extrapolate from a developmental effect level to a no-effect level.

It should be noted, that derivation of this tolerable exposure level is subject to very high uncertainty as a result of data deriving from unpublished reports from 1966/67.

Reliability: The reliability of the calculated tolerable exposure levels is considered to be very limited, as the background data are very old from 1966/67, i.e. the studies were performed under conditions very far from today´s standard. Furthermore, it is uncertain whether the quality of phenyl trimethicone used in these old studies correspond to the qualities used today in cos-

metics. Due to lack of knowledge about the absorption of the substance over the various exposure routes, it is not considered possible to convert the tolerable dermal dose level to tolerable oral dose levels and tolerable inhalation dose levels.

References

CIR (1986). Final Report on the Safety Assessment of Phenyl Trimethicone. CIR Expert Panel. JOURNAL OF THE AMERICAN COLLEGE OF TOXICOLOGY 5 (5), 353-371.

CIR (2006). Annual review of cosmetic ingredient safety asessments – 2004/2005. Int J Toxicol 25(supl 2), 54-56.

Trisiloxane (octamethyltrisiloxane)

The substance was neither assessed by SCCS or CIR, and no data were found at a Toxnet or Pubchem searc. The substance is however REACH registered at Annex IX level, and data extracted from the REACH registration (visited November 2019) is used for hazard assessment of the substance.

In connection with ECHA´s substance evaluation of the substance a prenatal developmental toxicity study, ecotox tests with earthworms, plants and micro organisms in soil have been frequested in order to fulfil the REACH data-requirements.

According to the REACH registration, there are no available specific data for determination of the absorption of the substance by oral, dermal or inhalation exposure, but for decamethyltetrasiloxane, which has one siloxane group more included in the molecule, a dermal absorption of 0.03% is assumed from an *in vitro* test with human skin.

According to the REACH registration, trisiloxane has a low acute toxicity, as oral and dermal LD50 is above the tested dosage level of 2 000 mg/kg bw. LC50 is above 22.6 mg/L.

From a skin irritation test with D6 and by making read-across to eye irritation data for D5, it is concluded, that trisiloxane has no potential for skin or eye irritation properties.

In a Guinea Pig Maximisation test, trisiloxane showed no potential for skin sensitisation.

In a 28 days oral study in rats (OECD 407 test from 2010) using dose levels of 0, 5, 25, 250 and 1000 mg/kg bw/day male rats were observed as most susceptible towards adverse effects fromthe exposure. Effects on blood, increased absolute and relative liver weight, dark/brown discolouration of the liver, chronic inflammation and increased cell division in the biliary system were observed and based of these findings, a NOAEL of 25 mg/kg bw/day was concluded.

Corresponding findings were observed in an OECD 413 90-days inhalation test from 2009, where rats were exposed to trisiloxane in vapour form 6 hours/ day at 0, 95, 400 and 3200 ppm. The effects were seen at highest exposure level and was more significant in male rats. A NOAEC of 400 ppm (3 869 mg/m^3) was concluded from the study.

Mutagenic and cytogenic *in vitro* test (OECD 471 and OECD 473) with bacteria and mammalian cells showed genotoxic potential for trisiloxane in connenction with the mammalian cells. When considering the negative tests from other *in vitro* and *in vivo* data from the read-across substances hexamethyldisiloxane and decamethyltetrasiloxane this indicate though, that trisiloxane most likely have no genotoxic potential.

In an OECD 422 reproduction screening study in rats inhalation of up to 3200 ppm did not affect any reproductive parameters.

In an oral OECD 414 prenatal developmentsl toxicity study pregnant female rats were dosed up to a dose level of 750 mg/kg bw/day. No effects on the offspring were noted, however, increased maternal liver weight and presence of chronic inflammation in the liver was observed at 750 mg/kg bw/day but not at 250 mg/kg bw/day.

Based on the above data, an oral NOAEL of 25 mg/kg bw/day can be determined and a NOAEC of 3869 mg/m^3 for inhalation based on effects in the liver and biliary system at higher exposure levels.

Calculation of tolerable exposure levels
On the basis of an oral NOAEL of 25 mg/kg bw/day in terms of effects on liver and biliary system, a tolerable oral exposure level can be calculated:

tolerable exposure level (oral) = 25 mg/kg bw/day / 10 x 10 x 3
tolerable exposure level (oral) = 0.083 mg/ kg bw/day

An uncertainty factor of 10 iss used to extrapolate from rats to humans and also a factor 10 to account for differences in human susceptibility. Furthermore, a factor 3 is used to extrapolate from a 28 days study to 90 days exposure.

Based on a NOAEC of 3869 mg/m^3 in terms of effects to the liver and biliary system, a tolerable exposure level can be calculated for inhalation:

As the NOAEC value is based on inhalation 6 hours per day in 90 days, the value can be converted to 24 hours continuous exposure:

NOAEC (continuous) = 3869 mg/m^3 x 6h/24 h = 967 mg/m^3

from this value a tolerable exposure level can be calculated:

tolerable exposure level (inh) = *967* mg/m^3 / 2.5 x 10
tolerable exposure level (inh) = 38 mg/m^3

An uncertainty factor of 2.5 was used to extrapolate from rats to humans in connection with inhalation and furthermore a factor 10 to allow for differences in human susceptibility.

In the REACH registration it was estimated, that the substance at dermal exposure is absorbed 100 times less than by inhalation in connection with calculation of a tolerable exposure (DNEL value) for dermal contact. From experimental data for D4 and D5, corresponding differences were seen between absorption by inhalaton and at skin contact (approx. a factor 10 for D4 and approx. a factor 50-100 for D5, see above). At the same time, the substance decamethyltetrasiloxane, which is structurally very similar to trisiloxane, but which due to a larger molecule size must be considered to have lower skin penetration than trisiloxane, was found to have a dermal absorption of 0.03%. In case it is assumed, that trisiloxane has approx. 10 times more skin penetration than decamethyltetrasiloxane (corresponding to approx. 0.3%) and assuming that the substance is not absorbed less at inhalation than D4 which is absorbed by 5%, a difference of absorption for the two exposure routes of at least a factor 10 could be estimated.
For cautious reasons, a factor 10 is consequently used rather than the somewhat larger factor estimated in connection with the REACH registration.

First step to calculate tolerable exposure at dermal exposure is to convert dose to mg/kg bw/day

Tolerable exposure (inh, mg/kg bw/day) = Tolerable exposure (inh) x 20 m^3/ 60 x kg

Tolerable exposure (inh, mg/kg bw/day) = 38 mg/m^3 x 20 m^3/ 60 x kg = 13 mg/kg bw/day

When converting to tolerable dermal exposure, a significantly lower absorption is allowed for.

Tolerable exposure (dermal) = 13 mg/kg bw/day x 10 = 130 mg/kg bw/day

Reliability: the background data for calculation of the tolerable exposure levels are from more recent OECD guideline tests, and therefore the calculated levels for inhalation and dermal exposure are considered as reliable. Some uncertainly pertains to the value for dermal exposure, no specific data for skin absorption are available, which is why it is estimated to be 1/10 of the absorption at inhalation.

References

REACH registration of ” Octamethyltrisiloxane”. https://echa.europa.eu/substance-information/-/substanceinfo/100.003.181

Drometrizol trisiloxane

There are no toxicological data from *SCCS, CIR, Toxline, Pubchem* or from US EPA’s comptox database on drometrizol trisiloxane. The substance is furthermore not REACH registered. In 2015 the Danish Environmental Protection Agency made an assessment of a number of cosmetic sun filters, and here it was also found, that there were no available toxicological data for the substance (Danish EPA 2015).

On this basis, there is consequently no possibility to make neither hazard assessment nor risk assessment for the substance, which according to the cosmetics legislation is an approved UV-filter.

References

Danish EPA (2015. Survey and health assessment of UV filters Survey of chemical substances in consumer products No. 142, 2015.

Appendix 4. Environmental sorting of products and substances

A general sorting has been made, where the combinations of product type and substance giving the highest risk score can be found at the top. Again a sorting was made according to the water phase, the sediment phase and the soil phase, as the substances do not act exactly the same way in the environment. These are shown in below tables.

Sorting according to the environmental impact score in the water phase for the combinations of product type and siloxane

Product type	Siloxane Environmental risk score in the water phase ↓
Hair conditioner / conditioner	D5
Flaxseed oil /lotion	D4
Sun creme/lotion	D5
Hair conditioner / conditioner	D4
Deodorant / antiperspirant, non-spray	D5
Hair conditioner / conditioner	Trisiloxane,
Flaxseed oil /lotion	D5
Sun creme/lotion	D4
Sun creme spray, pump spray	D6
Hairspray, spray, pump spray	D5
Deodorant / antiperspirant, spray	D5
Facial day cream /-lotion	D5
Foundation	D5
Body care creams / lotions	D6
Body care creams / lotions	D5
Sun creme spray, pump spray	Drometrizole trisiloxane
Hair conditioner / conditioner	Phenyl trimethicone
Flaxseed oil /lotion	D3
Facial day cream /-lotion	D6
Sun creme/lotion	D3
Foundation	D6
Hair conditioner / conditioner	D3
Flaxseed oil /lotion	D6
Hair conditioner / conditioner	D6
Sun creme/lotion	D6
Foundation	Trisiloxane,
Sun creme spray, pump spray	D5
Deodorant / antiperspirant, non-spray	D4
Foundation	Phenyl trimethicone
Hairspray, spray, pressure vessel	Phenyl trimethicone
Sun creme spray, pump spray	D3
Sun creme/lotion	Phenyl trimethicone
Deodorant / antiperspirant, non-spray	D3
Body care creams / lotions	D3
Foundation	D4
Hairspray, spray, pump spray	Phenyl trimethicone
Sun creme/lotion	Drometrizole trisiloxane

Product type	Siloxane Environmental risk score in the water phase ↓
Facial day cream /-lotion	D3
Foundation	D3
Flaxseed oil /lotion	Phenyl trimethicone
Flaxseed oil /lotion	Trisiloxane,
Hairspray, spray, pump spray	D4
Hairspray, spray, pump spray	D6
Facial day cream /-lotion	Trisiloxane,
Sun creme spray, pump spray	D4
Sun creme spray, pump spray	Phenyl trimethicone
Hair shampoo	D3
Body care creams / lotions	D4
Deodorant / antiperspirant, non-spray	D6
Hairspray, spray, pump spray	D3
Facial day cream /-lotion	D4
Deodorant / antiperspirant, spray	D4
Deodorant / antiperspirant, spray	D6
Body care creams / lotions	Phenyl trimethicone
Sun creme/lotion	Trisiloxane,
Facial day cream /-lotion	Phenyl trimethicone
Hairspray, spray, pressure vessel	D3
Facial day cream /-lotion	Drometrizole trisiloxane
Hair shampoo	D6
Hairspray, spray, pressure vessel	D5
Foundation	Drometrizole trisiloxane
Hair shampoo	Drometrizole trisiloxane
Body care creams / lotions	Drometrizole trisiloxane
Deodorant / antiperspirant, spray	Drometrizole trisiloxane
Hair conditioner / conditioner	Drometrizole trisiloxane
Flaxseed oil /lotion	Drometrizole trisiloxane
Deodorant / antiperspirant, non-spray	Drometrizole trisiloxane

Sorting according to the environmental impact score in the sediment phase for the combinations of product type and siloxane

Product type	Siloxane Environmental risk score in the sediment phase ↓
Sun creme spray, pump spray	Drometrizole trisiloxane
Hair conditioner / conditioner	D5
Sun creme/lotion	D5
Sun creme spray, pump spray	D6
Deodorant / antiperspirant, non-spray	D5
Body care creams / lotions	D6
Flaxseed oil /lotion	D5
Sun creme/lotion	Drometrizole trisiloxane
Flaxseed oil /lotion	D4
Facial day cream /-lotion	D6
Hairspray, spray, pump spray	D5
Deodorant / antiperspirant, spray	D5
Foundation	D6
Flaxseed oil /lotion	D6
Hair conditioner / conditioner	D6
Sun creme/lotion	D6
Hair conditioner / conditioner	Phenyl trimethicone
Hair conditioner / conditioner	D4
Facial day cream /-lotion	D5
Foundation	D5
Hair conditioner / conditioner	Trisiloxane,
Body care creams / lotions	D5
Sun creme/lotion	D4
Foundation	Phenyl trimethicone
Hairspray, spray, pressure vessel	Phenyl trimethicone
Sun creme/lotion	Phenyl trimethicone
Sun creme spray, pump spray	D5
Hairspray, spray, pump spray	Phenyl trimethicone
Facial day cream /-lotion	Drometrizole trisiloxane
Flaxseed oil /lotion	Phenyl trimethicone
Hairspray, spray, pump spray	D6
Foundation	Drometrizole trisiloxane
Hair shampoo	Drometrizole trisiloxane
Deodorant / antiperspirant, non-spray	D6
Foundation	Trisiloxane,
Body care creams / lotions	Drometrizole trisiloxane
Deodorant / antiperspirant, spray	Drometrizole trisiloxane
Sun creme spray, pump spray	Phenyl trimethicone
Deodorant / antiperspirant, spray	D6
Hair conditioner / conditioner	Drometrizole trisiloxane
Deodorant / antiperspirant, non-spray	D4
Body care creams / lotions	Phenyl trimethicone
Flaxseed oil /lotion	Drometrizole trisiloxane
Facial day cream /-lotion	Phenyl trimethicone
Flaxseed oil /lotion	D3
Hair shampoo	D6
Sun creme/lotion	D3
Foundation	D4
Hair conditioner / conditioner	D3
Flaxseed oil /lotion	Trisiloxane,
Facial day cream /-lotion	Trisiloxane,
Hairspray, spray, pump spray	D4
Sun creme spray, pump spray	D3

Product type	Siloxane Environmental risk score in the sediment phase ↓
Sun creme spray, pump spray	D4
Body care creams / lotions	D4
Deodorant / antiperspirant, non-spray	Drometrizole trisiloxane
Deodorant / antiperspirant, non-spray	D3
Body care creams / lotions	D3
Hairspray, spray, pressure vessel	D5
Facial day cream /-lotion	D4
Deodorant / antiperspirant, spray	D4
Sun creme/lotion	Trisiloxane,
Facial day cream /-lotion	D3
Foundation	D3
Hair shampoo	D3
Hairspray, spray, pump spray	D3
Hairspray, spray, pressure vessel	D3

Sorting according to the environmental impact score in the soil phase for the combinations of product type and siloxane

Produkttype	Siloxane Environmental risk score in the soil phase ↓
Sun creme spray, pump spray	Drometrizole trisiloxane
Sun creme/lotion	Drometrizole trisiloxane
Hair conditioner / conditioner	Phenyl trimethicone
Facial day cream /-lotion	Drometrizole trisiloxane
Foundation	Drometrizole trisiloxane
Hair shampoo	Drometrizole trisiloxane
Foundation	Phenyl trimethicone
Body care creams / lotions	Drometrizole trisiloxane
Deodorant / antiperspirant, spray	Drometrizole trisiloxane
Hairspray, spray, pressure vessel	Phenyl trimethicone
Sun creme/lotion	Phenyl trimethicone
Hair conditioner / conditioner	Drometrizole trisiloxane
Hairspray, spray, pump spray	Phenyl trimethicone
Flaxseed oil /lotion	Drometrizole trisiloxane
Flaxseed oil /lotion	Phenyl trimethicone
Hair conditioner / conditioner	D5
Sun creme spray, pump spray	D6
Sun creme/lotion	D5
Sun creme spray, pump spray	Phenyl trimethicone
Body care creams / lotions	D6
Deodorant / antiperspirant, non-spray	D5
Body care creams / lotions	Phenyl trimethicone
Flaxseed oil /lotion	D4
Flaxseed oil /lotion	D5

Produkttype	Siloxane Environmental risk score in the soil phase ↓
Deodorant / antiperspirant, non-spray	Drometrizole trisiloxane
Facial day cream /-lotion	D6
Facial day cream /-lotion	Phenyl trimethicone
Foundation	D6
Flaxseed oil /lotion	D6
Hair conditioner / conditioner	D6
Sun creme/lotion	D6
Hair conditioner / conditioner	D4
Hairspray, spray, pump spray	D5
Deodorant / antiperspirant, spray	D5
Hair conditioner / conditioner	Trisiloxane,
Facial day cream /-lotion	D5
Sun creme/lotion	D4
Foundation	D5
Body care creams / lotions	D5
Sun creme spray, pump spray	D5
Hairspray, spray, pump spray	D6
Deodorant / antiperspirant, non-spray	D6
Foundation	Trisiloxane,
Deodorant / antiperspirant, spray	D6
Deodorant / antiperspirant, non-spray	D4
Flaxseed oil /lotion	D3
Sun creme/lotion	D3
Hair conditioner / conditioner	D3
Hair shampoo	D6
Foundation	D4
Flaxseed oil /lotion	Trisiloxane,
Sun creme spray, pump spray	D3
Hairspray, spray, pump spray	D4
Facial day cream /-lotion	Trisiloxane,
Deodorant / antiperspirant, non-spray	D3
Body care creams / lotions	D3
Sun creme spray, pump spray	D4
Body care creams / lotions	D4
Facial day cream /-lotion	D3
Facial day cream /-lotion	D4
Deodorant / antiperspirant, spray	D4
Foundation	D3
Sun creme/lotion	Trisiloxane,
Hairspray, spray, pressure vessel	D5
Hair shampoo	D3
Hairspray, spray, pump spray	D3

Produkttype	Siloxane Environmental risk score in the soil phase ↓
Hairspray, spray, pressure vessel	D3
Sun creme spray, pump spray	Drometrizole trisiloxane
Sun creme/lotion	Drometrizole trisiloxane
Hair conditioner / conditioner	Phenyl trimethicone
Facial day cream /-lotion	Drometrizole trisiloxane
Foundation	Drometrizole trisiloxane
Hair shampoo	Drometrizole trisiloxane
Foundation	Phenyl trimethicone
Body care creams / lotions	Drometrizole trisiloxane
Deodorant / antiperspirant, spray	Drometrizole trisiloxane
Hairspray, spray, pressure vessel	Phenyl trimethicone

Sorting according to product type. The higher a substance is on the list the higher impact on the environment from the substance.

Product type	**Water**	**Sediment**	**Soil**
Body care creams / lotions	D6 D5 D3 D4 Phenyl trimethicone Drometrizole trisiloxane	D6 D5 Drometrizole trisiloxane Phenyl trimethicone D4 D3	Drometrizole trisiloxane D6 Phenyl trimethicone D5 D3 D4
Deodorant / antiperspirant, non-spray	D5 D4 D3 D6 Drometrizole trisiloxane	D5 D6 D4 Drometrizole trisiloxane D3	D5 Drometrizole trisiloxane D6 D4 D3
Deodorant / antiperspirant, spray	D5 D4 D6 Drometrizole trisiloxane	D5 Drometrizole trisiloxane D6 D4	Drometrizole trisiloxane D5 D6 D4
Facial day cream /-lotion	D5 D6 D3 Trisiloxane, D4 Phenyl trimethicone	D6 D5 Drometrizole trisiloxane Phenyl trimethicone Trisiloxane, D4	Drometrizole trisiloxane D6 Phenyl trimethicone D5 Trisiloxane, D3

	Drometrizole trisiloxane	D3	D4
Flaxseed oil /lotion	D4 D5 D3 D6 Phenyl trimethicone Trisiloxane, Drometrizole trisiloxane	D5 D4 D6 Phenyl trimethicone Drometrizole trisiloxane D3 Trisiloxane,	Drometrizole trisiloxane Phenyl trimethicone D4 D5 D6 D3 Trisiloxane,
Foundation	D5 D6 Trisiloxane, Phenyl trimethicone D4 D3 Drometrizole trisiloxane	D6 D5 Phenyl trimethicone Drometrizole trisiloxane Trisiloxane, D4 D3	Drometrizole trisiloxane Phenyl trimethicone D6 D5 Trisiloxane, D4 D3
Hair conditioner / conditioner	D5 D4 Trisiloxane, Phenyl trimethicone D3 D6 Drometrizole trisiloxane	D5 D6 Phenyl trimethicone D4 Trisiloxane, Drometrizole trisiloxane D3	Phenyl trimethicone Drometrizole trisiloxane D5 D6 D4 Trisiloxane, D3
Hair shampoo	D3 D6 Drometrizole trisiloxane	Drometrizole trisiloxane D6 D3	Drometrizole trisiloxane D6 D3
Hairspray, spray, pressure vessel	Phenyl trimethicone D3 D5	Phenyl trimethicone D5 D3	Phenyl trimethicone D5 D3
Hairspray, spray, pump spray	D5 Phenyl trimethicone D4 D6 D3	D5 Phenyl trimethicone D6 D4 D3	Phenyl trimethicone D5 D6 D4 D3
Sun creme spray, pump spray	D6 Drometrizole trisiloxane D5 D3 D4	Drometrizole trisiloxane D6 D5 Phenyl trimethicone D3	Drometrizole trisiloxane D6 Phenyl trimethicone D5 D3

	Phenyl trimethicone	D4	D4
Sun creme/lotion	D5 D4 D3 D6 Phenyl trimethicone Drometrizole trisiloxane Trisiloxane,	D5 Drometrizole trisiloxane D6 D4 Phenyl trimethicone D3 Trisiloxane,	Drometrizole trisiloxane Phenyl trimethicone D5 D6 D4 D3 Trisiloxane,

Survey and risk assessment of siloxanes in cosmetic products

Engelsk resume

The aim of the project was to build knowledge about the use of siloxanes in cosmetic products and investigate whether the use of cosmetic products that contain siloxanes can pose a risk to the environment and to human health.

In the project, more than 80 different siloxane compounds were identified on the ingredient lists of various cosmetic products. Among these, the small cyclic siloxanes are considered to be particularly problematic, and the project shows that many companies are already on their way to replacing these substances in the products they sell. The linear siloxane compound dimethicone, or variants thereof, is often used as a substitute. Although dimethicone appears to be less problematic to human health, the substance still raises concerns for the environment because dimethicone decomposes to smaller substances that exhibit similar toxicity and potential for biodegradation.

40 different products with declared content of siloxanes were selected for chemical analysis. The results indicate that in most products there are low concentrations of non-declared siloxanes including the cyclic siloxanes. These were also found as residues in dimethicone, probably because cyclic siloxanes are used in the production.

For seven of the selected products, a risk for children could be calculated, and a risk for adults could be calculated for three out of the seven products. Many of the calculations are however associated with great uncertainty either because only very old data is available, or because the applied exposure scenarios are considered unrealistic for the specific product.

Dansk Resume

Formålet med projektet var at opbygge viden om brugen af siloxaner i kosmetiske produkter og undersøge om anvendelse af kosmetiske produkter, der indeholder siloxaner, kan udgøre en risiko for miljø og sundhed.

I projektet blev der identificeret over 80 forskellige siloxanforbindelser, der anvendes som ingredienser til kosmetik og plejeprodukter. Heriblandt anses de små ringsluttede siloxaner (cykliske siloxaner) for særligt problematiske, og projektet viser, at mange virksomheder allerede er godt i gang med at udskifte disse stoffer i de produkter, de sælger. Den lineære siloxanforbindelse dimethicone, eller afarter heraf, anvendes ofte som erstatning, men selv om dimethicone ser ud til at være mindre problematisk for menneskers sundhed, giver stoffet alligevel anledning til bekymring for miljøet, fordi dimethicone nedbrydes til mindre enheder, der udviser lignende toksisitet og potentiale for bioarmumulering.

Der blev udvalgt 40 forskellige produkter med deklareret indhold af siloxaner til kemisk analyse. Resultaterne indikerer, at der i de fleste produkter findes lave koncentrationer af ikke deklarerede siloxaner - herunder de ringsluttede. De cykliske siloxaner blev også fundet som rester i dimethicone, sandsynligvis fordi cykliske siloxaner benyttes til fremstilling heraf.

For syv af de udvalgte produkter kunne der beregnes en risiko for børn, mens der for tre af disse produkter også kunne beregnes en risiko for voksne. Mange af beregningerne er dog behæftet med stor usikkerhed. enten fordi der kun er meget gammel data tilgængeligt, eller fordi de opstillede eksponeringsscenarier ikke anses for realistiske for det specifikke produkt.

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