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# Re-evaluation of dimethyl polysiloxane (E 900) as a food additive

EFSA Panel on Food Additives and Flavourings (FAF),
Maged Younes, Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fowler, Maria Jose Frutos Fernandez, Peter Fürst, Rainer Gürtler, Ursula Gundert-Remy, Trine Husøy, Melania Manco, Wim Mennes, Sabina Passamonti, Romina Shah, Dina Hendrika Waalkens-Berendsen, Detlef Wölfle, Matthew Wright, Polly Boon, Paul Tobback, Alessandra Giarola, Ana Maria Rincon, Alexandra Tard and Peter Moldeus

## Abstract

The Panel on Food Additives and Flavourings (FAF) provided a scientific opinion re-evaluating the safety of dimethyl polysiloxane (E 900) as a food additive. E 900 was evaluated by the Scientific Committee on Food (SCF) in 1990 and agreed with the Acceptable Daily Intake (ADI) of 1.5 mg/kg body weight (bw) per day previously established by Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974. Dimethyl polysiloxane was only absorbed to a very limited extent from the gastrointestinal tract following oral administration and the vast majority was excreted unchanged in the faeces. Corneal opacities and other effects on cornea were observed in studies in rats. These effects are considered to be caused by direct contact with the test substance in the feed and/or with the test substance in the faeces and not due to systemic exposure. The Panel considered that oral exposure of dimethyl polysiloxane did not result in any systemic adverse effects in any species and dose tested and there is no concern with respect to genotoxicity of dimethyl polysiloxane (E 900). From a 26-month toxicity study in rats, a No Observed Adverse Effect Level (NOAEL) of 1,742 and 2,055 mg dimethyl polysiloxane/kg bw per day for female and male, respectively, was identified. Using the NOAEL 1,742 mg/kg bw per day, the Panel established an ADI of 17 mg/kg bw per day for E 900 by applying an uncertainty factor of 100. Accordingly, the ADI for dimethyl polysiloxane (E 900) of 1.5 mg/kg bw per day, established by SCF in 1990, is withdrawn. The exposure estimates for the different population groups of all exposure scenarios did not exceed the ADI of 17 mg/kg bw per day for E 900. The Panel concluded that there is not a safety concern at the reported uses and use levels for dimethyl polysiloxane (E 900). The Panel also proposed a number of recommendations for the EU specifications to be amended.



**Keywords:** dimethyl polysiloxane, E 900, poly(dimethylsiloxane), polydimethylsiloxane, CAS No 9006-65-9, CAS No 63148-62-9

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**Correspondence:** fip@efsa.europa.eu

**Panel members:** Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fowler, Maria Jose Frutos Fernandez, Peter Fürst, Rainer Gürtler, Ursula Gundert-Remy, Trine Husøy, Melania Manco, Wim Mennes, Sabina Passamonti, Peter Moldeus, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfle, Matthew Wright and Maged Younes.

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## Summary

Following a request from the European Commission, the Panel on Food Additives and Flavourings (FAF) was asked to deliver a scientific opinion on the re-evaluation of dimethyl polysiloxane (E 900) as a food additive. Dimethyl polysiloxane (E 900) is authorised food additives in the European Union (EU) according to Annex II and Annex III of Regulation (EC) No 1333/2008 on food additives and specifications have been defined in the Commission Regulation (EU) No 231/2012.

In 1990, the Scientific Committee on Food (SCF) evaluated dimethyl polysiloxane and agreed with the acceptable daily intake (ADI) of 1.5 mg/kg body weight (bw) per day established previously by Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974 based on a No Observed Adverse Effect Level (NOAEL) of 150 mg/kg bw per day from a long-term toxicity rat study performed in 1959. JECFA in its latest evaluation in 2011 considered new studies and concluded that the ocular lesions were caused by local toxicity when the eyes of laboratory animals were exposed to dimethyl polysiloxane through contact with the substance in feed or faeces or through grooming of contaminated fur. The Committee re-established an ADI of 0–1.5 mg/kg bw per day and withdrew the temporary ADI of 0–0.8 mg/kg bw established in 2008.

Having evaluated information submitted by interested parties on dimethyl polysiloxane and its manufacturing process, the Panel would recommend that specifications should be updated in order to better describe the material used as a food additive and ensure its safety of use:

- Include the range of the weight average molecular weight (Mw) and number average molecular weight (Mn) for dimethyl polysiloxane used as a food additive E 900.
- Include a maximum limit for cyclopolysiloxanes.
- Include a maximum limit for copper since copper-based catalysts are used in the manufacturing process.
- Setting lower limits for toxic elements (arsenic, lead, mercury).
- Revising the name of the substance to 'poly(dimethylsiloxane)'.

Dimethyl polysiloxane (various compositions and different viscosities – 10, 350 and 1,000 centistokes) was only absorbed to a very limited extent from the gastrointestinal tract following oral administration to mice, rats, monkeys and humans. The vast majority (more than 99.9%) of the orally administered dimethyl polysiloxane was excreted unchanged in the faeces.

The acute toxicity of dimethyl polysiloxane is low. There is no concern with respect to genotoxicity of dimethyl polysiloxane (E 900).

Corneal opacities and other effects on cornea observed in rats studies have been considered as caused by direct contact with the test substance in the feed, or with the test substance in the faeces and not due to systemic exposure.

The Panel considered that oral exposure of dimethyl polysiloxane did not result in any systemic adverse effects in any species and dose tested. From a 26-month toxicity study in rats (Kawabe et al., 2005) an NOAEL of 1,894 and 2,234 mg/kg bw per day for females and males, respectively, was identified. Considering that the test material contained 92% of dimethyl polysiloxane, these NOAELs correspond to 1,742 and 2,055 mg dimethyl polysiloxane/kg bw per day. The Panel noted that the test item was reported not to be used as a food additive in the EU. Nevertheless, the Panel considered it relevant for the risk assessment of the food additive E 900 because the viscosity complied with the one indicated in the EU specifications.

The Panel considered that the NOAEL of 1,742 mg/kg bw per day, the highest dose tested, could be used to derive an ADI for dimethyl polysiloxane (E 900). Using an uncertainty factor of 100, the Panel derived an ADI of 17 mg/kg bw per day for dimethyl polysiloxane (E 900). Accordingly, the ADI for dimethyl polysiloxane (E 900) of 1.5 mg/kg bw per day, established by SCF in 1990, is withdrawn.

Dietary exposure to dimethyl polysiloxane (E 900) from its use as a food additive according to Annex II of Regulation 1333/2008 was calculated according to different exposure scenarios based on maximum permitted level (MPLs) and reported use levels, as described in Section 3.4. Two food categories that may contain dimethyl polysiloxane (E 900) according to Annex III of Regulation 1333/2008 were also considered in these exposure scenarios.

The exposure estimates in the *regulatory maximum level exposure assessment scenario* reached at the mean 0.23 mg/kg bw per day and 0.51 mg/kg bw per day at the 95th percentile, both for toddlers (Table 4).

Considering that dimethyl polysiloxane (E 900) is authorised in flavoured drinks and changes the organoleptic properties of these drinks, the Panel selected the brand-loyal scenario as the most

relevant scenario for risk characterisation. In this scenario, mean exposure to dimethyl polysiloxane (E 900) from its use as a food additive ranged from 0.01 mg/kg bw per day in adults and the elderly to 0.16 mg/kg bw per day in children. The 95th percentile of exposure to dimethyl polysiloxane (E 900) ranged from 0.02 mg/kg bw per day in the elderly to 0.49 mg/kg bw per day in toddlers.

The Panel considered also the exposure estimates in the refined scenarios as overestimates of the exposure to dimethyl polysiloxane (E 900) from its use as a food additive according to Annex II of Regulation 1333/2008. This was mainly due to the inclusion of 75% of the food products labelled with dimethyl polysiloxane (E 900) in the Mintel GNPD in the refined scenarios, and the assumption that all foods belonging to the food categories included in these scenarios contained dimethyl polysiloxane (E 900) at the reported use levels.

The exposure estimates for the different population groups of all exposure scenarios did not exceed the ADI of 17 mg/kg bw per day for dimethyl polysiloxane (E 900). The Panel concluded that there is no safety concern at the reported uses and use levels for dimethyl polysiloxane (E 900).

The Panel also proposed a number of recommendations for the EU specifications to be amended.

# Table of contents

# 1. Introduction

The present opinion document deals with the re-evaluation of dimethyl polysiloxane (E 900) as a food additive.

## 1.1. Background and Terms of Reference as provided by the European Commission

### 1.1.1. Background

Regulation (EC) No 1333/2008[1] of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010.[2] This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU[3] of 2001. The report "Food additives in Europe 2000[4] "submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References are replaced by those below

### 1.1.2. Terms of Reference

The Commission asks the European Food Safety Authority to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

## 1.2. Information on existing authorisations and evaluations

Dimethyl polysiloxane is authorised as a food additive in the EU in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives and its specifications are defined in the Commission Regulation (EU) No 231/2012.[5]

Dimethyl polysiloxane was first evaluated by JECFA in 1969 and again in 1974 when an acceptable daily intake (ADI) of 0–1.5 mg/kg bw was derived, based on an NOAEL of 150 mg/kg bw per day from a long-term toxicity rat study performed in 1959 (JECFA, 1974, 1975).

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008.
[2] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.
[3] COM(2001) 542 final.
[4] Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.
[5] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012.

In 1979, JECFA specified that the previously established ADI of 0–1.5 mg/kg bw applied only to compounds with 200–300 subunits and not to compounds with a relative molecular mass in the range of 200 to 300 as previously stated. The average molecular mass was also corrected to be in the range of 15,000 to 22,000. The viscosity was specified to be in the range of 100 to 1,500 centistokes (JECFA, 1980). No toxicological monograph was prepared.

In 1990, the JECFA specifications were revised to include material with a range of 90–410 subunits and an average molecular mass of 6,800–30,000, but no toxicological evaluation was performed (JECFA, 1991).

In 2008, the substance was again on the agenda of JECFA and the ADI of 0–1.5 mg/kg bw previously established was withdrawn and an additional safety factor of 2 was included to establish a temporary ADI of 0–0.8 mg/kg bw because of effects on the cornea of test animals in new studies evaluated by the Committee. An addendum to the toxicological monograph was prepared (JECFA, 2009).

In 2011, JECFA considered new studies and concluded that the ocular lesions were caused by local toxicity when the eyes of laboratory animals were exposed to dimethyl polysiloxane through contact with the substance in feed or faeces or through grooming of contaminated fur. The Committee therefore re-established an ADI of 0–1.5 mg/kg bw per day (JECFA, 2011a). No monograph was prepared.

In 1990, the SCF evaluated dimethyl polysiloxane and agreed with the ADI of 1.5 mg/kg bw per day established by JECFA in 1974 (SCF, 1991).

ANSES has published a series of opinions on the use, as processing aids, of various anti-foaming agents, including dimethyl polysiloxane (ANSES, 2017a,b,c). ANSES emphasised that the database was extremely limited quantitatively and qualitatively. Due to low use levels as processing aid, exposure levels were determined to be low (from 0.2 to 22% percent of the ADI of 1.5 mg/kg bw per day), and ANSES concluded there was no safety concern.

In the EU, dimethyl polysiloxane (substance number: 575, reference number: 76721, CAS Registry Number: 63148-62-9, molecular weight: > 6,800 Da, viscosity: not less than 100 centistokes at 25°C) is furthermore permitted for plastics in contact with food according to Commission Regulation (EU) 10/2011.[6] A specific migration limit is not defined.

Furthermore, dimethyl polysiloxane (dimethicone, CAS No 63148-62-9, 9006-65-9 or 9016-00-6) is permitted as an antifoaming agent, as an emollient, for use in skin conditioning and for skin protection, in cosmetic products (European Commission database-CosIng.[7])

## 2. Data and methodologies

### Data

The FAF Panel was not provided with a newly submitted dossier. EFSA launched public calls for data[8,9] to collect information from interested parties.

The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature up to March 2020. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based, however not always these were available to the Panel.

Food consumption data used to estimate the dietary exposure to dimethyl polysiloxane (E 900) were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database[10]).

The Mintel Global New Products Database (GNPD) was used to verify the use of dimethyl polysiloxane (E 900) in food and beverage products and food supplements within the EU's food market. The Mintel GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

[6] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1–89.
[7] Available online: http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple
[8] Call for scientific data on miscellaneous food additives permitted in the EU and belonging to several functional classes. Published: 15 June 2012. Available from: https://www.efsa.europa.eu/sites/default/files/consultation/120215.pdf
[9] Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 5). Available from: https://www.efsa.europa.eu/sites/default/files/consultation/160524.pdf
[10] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

## Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

The FAF Panel assessed the safety of dimethyl polysiloxane (E 900) as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance documents: Guidance on submission for food additive evaluations by the SCF (2001) and taking into consideration the Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012).

When in animal studies, the test substance was administered in the feed or in drinking water, but doses were not explicitly reported by the authors as mg/kg bw per day based on actual feed or water consumption, the daily intake is calculated by the Panel using the relevant default values. In case of rodents, the values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012) are applied. In the case of other animal species, the default values by JECFA (2000) are used. In these cases, the dose was expressed as 'equivalent to mg/kg bw per day'.

Dietary exposure to dimethyl polysiloxane (E 900) from its use as a food additive was estimated combining the food consumption data available within the EFSA Comprehensive Database with the maximum permitted levels (MPLs) and reported use levels submitted to EFSA following a call for data. The exposure was estimated according to different exposure scenarios. Uncertainties in the exposure assessment were identified and discussed.

# 3. Assessment

## 3.1. Technical data

### 3.1.1. Identity of the substance

According to Commission Regulation (EU) 231/2012, dimethyl polysiloxane (E 900) is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(CH_3)_2SiO$ and stabilised with trimethylsiloxy end-blocking units of the formula $(CH_3)_3SiO$. Its chemical formula is $(CH_3)_3$-Si-[O-Si$(CH_3)_2$]n-O-Si$(CH_3)_3$. The chemical name reported is 'siloxanes and silicone, dimethyl' and as synonyms: polydimethyl siloxane; PDMS; silicone fluid; silicone oil; dimethyl silicone.

According to JECFA specifications for polymethylsiloxane (2011b), the molecular weights of the linear polymers range from approximately 6,800–30,000 Da, its chemical name is α-(trimethylsilyl)-ω-methylpoly(oxy(dimethylsilylene)) and its CAS Registry Number is 9006-65-9.

According to industry (Documentation provided to EFSA No 5), the CAS No 63148-62-9 is commonly used for dimethyl polysiloxane and it is preferable to CAS No 9006-65-9 which is used for dimethicone. Both CAS numbers represent the same substance; from the ECHA inventory, the name 'dimethicone' has both CAS numbers. This is also the case in the European Commission database for cosmetic ingredients. For CAS No 63148-62-9, the EC No is 613-156-5.

The structural formula of dimethyl polysiloxane is given in Figure 1.

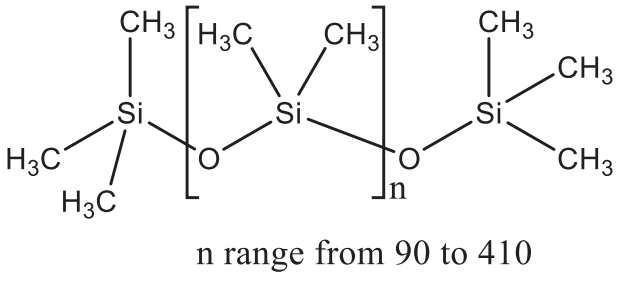



**Figure 1:** Structural formula of dimethyl polysiloxane (JECFA, 2011b)

The Panel noted that the name 'dimethyl polysiloxane' is not precise for the material and 'poly (dimethylsiloxane)' would be a more accurate name.

According to industry (Documentation provided to EFSA No.5), monodisperse dimethyl polysiloxane nanoparticles are not used as a food additive E 900.

### 3.1.2. Specifications

Specifications have been defined in Commission Regulation (EU) No 231/2012 and by JECFA (2011b) (see Table 1).

**Table 1:** Specifications established for dimethyl polysiloxane (E 900) according to Commission Regulation (EU) No 231/2012 and for polydimethylsiloxane (INS 900a) according to JECFA (JECFA, 2011b)

| | **Commission Regulation 231/2012** | **JECFA (2011b)** |
|---|---|---|
| **Definition** | Dimethyl polysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(CH_3)_2SiO$ and stabilised with trimethylsiloxy end-blocking units of the formula $(CH_3)_3SiO$ | Polydimethylsiloxane consists of fully methylated linear siloxane polymers containing repeating units of the formula $[(CH_3)_2SiO]$ with trimethylsiloxy end-blocking units of the formula $(CH_3)_3SiO$-. The additive is produced by hydrolysis of a mixture of dimethyldichlorosilane and a small quantity of trimethylchlorosilane. The average molecular weights of the linear polymers range from approximately 6,800 to 30,000 |
| Assay | Content of total silicon not less than 37.3% and not more than 38.5% | Silicon content not less than 37.3% and not more than 38.5% of the total |
| **Description** | Clear, colourless, viscous liquid | Clear, colourless, viscous liquid. |
| **Identification** | | |
| Specific gravity (25°C/25°C) | Between 0.964 and 0.977 | 0.964–0.977 |
| Refractive index | $[n]_D^{25}$ between 1.400 and 1.405 | $n^{25}_D$ : 1.400–1.405 |
| Infrared absorption spectrum | The infrared absorption spectrum of a liquid film of the sample between two sodium chloride plates exhibits relative maxima at the same wavelengths as those of a similar preparation of dimethyl polysiloxane Reference Standard | The infrared absorption spectrum of a liquid film of the sample between two sodium chloride plates exhibits relative maxima at the same wavelengths as those of a similar preparation of USP dimethyl polysiloxane Reference Standard |
| Solubility | – | Insoluble in water and in ethanol; soluble in most aliphatic and aromatic hydrocarbon solvents |
| **Purity** | | |
| Loss on drying | Not more than 0.5% (150 °C, 4 h) | Not more than 0.5% (150 °C, 4 h) |
| Viscosity | Not less than 1.00 $10^{-4}$ $m^2s^{-1}$ at 25 °C [equivalent to 100 centistokes] | 100 – 1,500 centistokes at 25 °C |
| Arsenic | Not more than 3 mg/kg | – |
| Lead | Not more than 1 mg/kg | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg | – |

The Panel noted that, according to the EU specifications for dimethyl polysiloxane (E 900), impurities of the toxic elements arsenic, lead and mercury are accepted up to concentrations of 3, 1 and 1 mg/kg, respectively. Contamination at those levels could have a significant impact on the exposure, which are already close to the health-based guidance values or benchmark doses (lower confidence limits) established by EFSA (EFSA CONTAM Panel, 2009, 2010, 2012a,b, 2014).

Analytical certificates/specifications for commercial products of dimethyl polysiloxane manufactured by three companies were submitted by the interested parties (Documentation provided to EFSA No. 6). Company A provided data for two formulations having a viscosity of either 350 or 1000 cst. In all cases, the data from three batches from these formulations met the current EU specifications for dimethyl polysiloxane (E 900). Results on arsenic, lead and mercury were all reported as not detected with limits of detection (LOD) being 0.5, 0.5 and 0.3 mg/kg, respectively. Company B provided data on colour, transparency, odour, viscosity and refractive index for four lots with viscosity of 100 cst, which all fulfil the EU requirements. According to the data provider, these criteria are determined for each lot. Other parameters are termed 'guaranteed values', such as maximum limits for arsenic of 2 mg/kg and

for 'heavy metal' of 20 mg/kg, without further specification. Company C provided certificates on two commercial products with 350 and 1000 cst, respectively. Data on basic parameters meet the current EU specifications. No results on toxic elements were provided. The Panel noted that, based on the analytical data provided by Company A, lowering of the EU specifications for toxic elements is possible.

The Panel noted that, in the JECFA specifications (2011b), a range of 6,800–30,000 for the average molecular weight is defined for dimethyl polysiloxane used as a food additive, while a limit is not included in the EU specifications. In addition, a maximum limit of 1,500 centistokes (25°C) for the viscosity is also specified in the JECFA specifications. Information on weight average molecular weight (Mw) of approximately 20,000 and 33,000 and number average molecular weight (Mn) of approximately 11,000 and 16,000 for dimethyl polysiloxane with 350 and 1000 cst, respectively, have been provided (Documentation provided to EFSA No 6).

The Panel noted that cyclopolysiloxanes can be formed during the manufacturing process. Although they are volatile, they could contaminate the final product. Several publications have reported that some of the cyclopolysiloxanes may have toxic effects including endocrine-disrupting activity (Helms et al., 2018; Helms et al., 2019), associated with oestrogenic effects *in vitro* and *in vivo* (Quinn et al., 2007), and increase endometrial hyperplasia and uterine adenocarcinomas in rats (Jean et al., 2016, 2017b; Jean and Plotzke, 2017a). The Panel considered that cyclopolysiloxanes should not be present in the food additive dimethyl polysiloxane E 900.

### 3.1.3. Manufacturing process

According to information provided by industry (CEFIC-CES, 2012, Dow-Corning-Corporation, 2005, Documentation provided to EFSA No 5), the starting material for the manufacturing of dimethyl polysiloxanes is pure silicon obtained from quartz sand after heating under high temperature.

In a following step, the silicon powder is reacted with methyl chloride ($CH_3Cl$) at high temperature (200°C–300°C) and under high pressure (100–500 kPa). The reaction is catalysed by a copper-based catalyst and generates different methyl chlorosilanes.

It was stated that the copper catalyst is a volatile compound (Dow-Corning-Corporation, 2005, Documentation provided to EFSA No. 25). However, in the absence of information on the nature of this catalyst, the Panel considered that a limit for copper should be included in the EU specifications.

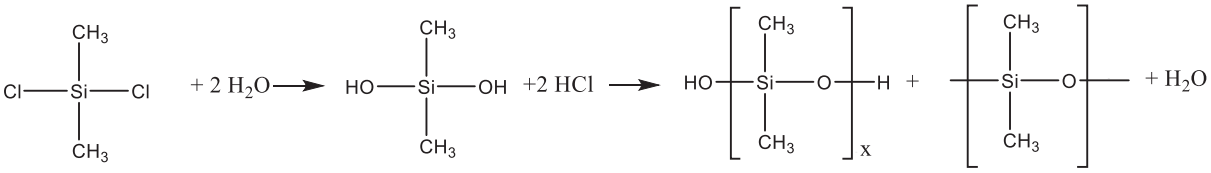
The general reaction scheme is as follows:

$$xSi + yCH_3Cl \rightarrow \text{methyl chlorosilanes}$$

In the resulted mixture of chlorosilanes, dimethyldichlorosilane [$(CH_3)_2SiCl_2$] is present with the highest mass fraction. Pure dimethyldichlorosilane is separated from the mixture of chlorosilanes by distillation.

Dimethyldichlorosilane is hydrolysed, giving rise to a mixture of cyclic dimethyl polysiloxanes (with 3–6 repeating SiO units) and linear chains (with 30–50 repeating SiO units). This mixture separates from the aqueous acid phase, the ratio between the cyclic and linear oligomers depending on the hydrolysis conditions (concentrations, pH, solvents).

The general reaction scheme is as follows:

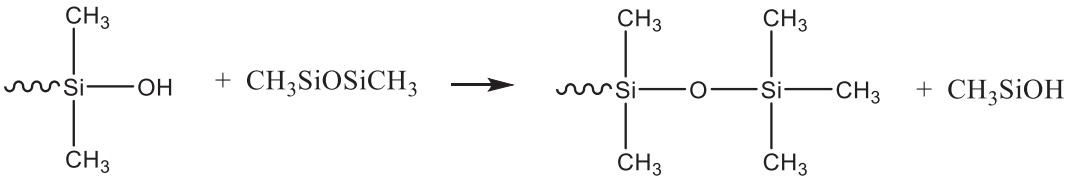



Linear dimethyl polysiloxane  Cyclic dimethyl polysiloxane

Linear chains are polymerised under acidic catalysis until the desired viscosity is obtained.

In the case of the cyclic starting material, the rings open under acid catalysis and the resulting linear chains polymerise, under controlled conditions, to the desired viscosity. The catalyst and the low molecular weight species are removed by distillation at high temperature and under low pressure (< 1 mbar). The removal of traces of catalyst is an important step in the manufacturing of dimethyl polysiloxane (Dow-Corning-Corporation, 2005, Documentation provided to EFSA No 25).

Finally, a process called 'end blocking' is used to control chain length, molecular weight and viscosity.




The silicone fluid with the desired viscosity is filtered to remove impurities.

No analytical data demonstrating the absence of starting materials or intermediate products (e.g. dimethyldichlorosilane/dimethylsilanediol/$CH_3SiOSiCH_3$/$CH_3SiOH$) in the final product was available, but according to the information available on the production process, the Panel considered that they are not expected to be present.

### 3.1.4. Methods of analysis in food

Flame atomic absorption spectrometry has been used for the determination of dimethyl polysiloxane in fats and oils (Doeden et al., 1980; McCamey et al., 1986) and for estimation of the amount of dimethyl polysiloxane taken up by food fried in a dimethyl polysiloxane-containing oil (Freeman et al., 1973).

Solvent extraction combined with flame atomic absorption spectroscopy was used for the determination of dimethyl polysiloxane in fruit juices and beer (Kacprzak, 1982; Parker, 1990; Gooch, 1993).

Infrared absorption spectroscopy was used to determine, after extraction, dimethyl polysiloxane in pineapple and in vegetables processed with silicone antifoams (e.g. bread, waffles, hydrolysed vegetable protein and frozen vegetables) (Horner et al., 1960).

$^1$H-nuclear magnetic resonance has been used for the determination of dimethyl polysiloxane in wine and edible oils (Mojsiewicz-Pienkowska et al., 2003).

Size exclusion chromatography with evaporative light scattering detection was described and tested experimentally to separate and determine molecular weights of linear dimethyl polysiloxanes (Mojsiewicz-Pienkowska, 2008).

An overview of the fractionation methods for various silicones (including dimethyl polysiloxane) are described by Mojsiewicz-Pienkowska and Lukasiak (2003). In addition, a review of the determination of silicones in biological matrices is provided by Čavić-Vlasak et al. (1996).

### 3.1.5. Stability of the substance, and reaction and fate in food

The following information was provided by the interested parties (Documentation provide to EFSA, 2010), dimethyl polysiloxane's molecular backbone structure consists of alternating silicon and oxygen atoms and breaking the Si-O-bonds requires comparatively high activation energy (Andriot et al. 2007; Kendrick et al. 1989). The ECETOC monograph (2011; 2$^{nd}$ edition) states that dimethyl polysiloxanes are chemically stable substances showing a remarkable resistance to thermal and oxidative degradation and radiation. Dry heat of 150°C is considered to have little effect in that only traces of formaldehyde can be detected from reaction of oxygen with the methyl groups. Wet heat (steam) at 120°C or higher causes depolymerisation. Strong acids or bases attack the Si-O-Si bonds. Siloxane structures of varying molecular sizes are formed, traces of the catalyst may also induce this depolymerisation reaction (see also Kucera and Lanikova, 1961). The removal of traces of catalyst is an important step in the manufacturing of dimethyl polysiloxane (Dow-Corning-Corporation, 2005, Documentation provided to EFSA No 25). Depolymerisation of dimethyl polysiloxane is observed at high temperatures: the molecular chains are stable up to at least 300–450°C, complete pyrolysis is observed at temperatures of at least 500°C (Kendrick et al. 1989). Freeman et al. (1973) investigated the effects of frying potatoes chips in oil containing 2 mg/kg silicone or more. They observed a reduction of the dimethyl polysiloxane concentration in the oil; the dimethyl polysiloxane was absorbed by the potato chips. Totani et al. (2018) investigated the protective effect of dimethyl polysiloxane on canola oil during deep frying of potatoes at 180°C, for 6 h continuously or with 10-, 20-, or 30-min intervals between frying sessions. The total polar compounds content (TPC) of the oil was used as indicator value for oil stability. A superior protective effect of PDMS on the frying oil was observed regardless of the deep-frying pattern employed.

In conclusion, the data on the chemical properties and stability of dimethyl polysiloxane indicated that the food additive will be stable in foods at the typical acidic and alkaline conditions present in food. Though dimethyl polysiloxane as such may depolymerise at temperatures above approximately 300°C, such reactions have not been observed and are not expected when frying foods in oils that contain dimethyl polysiloxane.

## 3.2. Authorised uses and use levels

Maximum levels of dimethyl polysiloxane (E 900) in foods have been defined in Annex II to Regulation (EC) No 1333/2008[11] on food additives, as amended. In this document, these levels are named MPLs.

Currently, dimethyl polysiloxane (E 900) is an authorised food additive, used as an antifoaming agent in foods, in the EU with MPLs ranging from 10 to 100 mg/kg in 14 food categories as set by Annex II to Regulation (EC) No 1333/2008 (Table 2).

**Table 2:** MPLs of dimethyl polysiloxane (E 900) in food categories according to the Annex II to Regulation (EC) No 1333/2008

| Food category number | Food category name | E-number/ Group | Restrictions/ exception | MPL (mg/L or mg/kg as appropriate) |
|---|---|---|---|---|
| 02.1 | Fats and oils essentially free from water (excluding anhydrous milk fat) | E 900 | only oils and fats for frying | 10 |
| 02.2.2 | Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions | E 900 | only oils and fats for frying | 10 |
| 04.2.3 | Canned or bottled fruit and vegetables | E 900 | | 10 |
| 04.2.5.2 | Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC | E 900 | | 10 |
| 04.2.5.3 | Other similar fruit or vegetable spreads | E 900 | | 10 |
| 05.2 | Other confectionery including breath freshening microsweets | E 900 | | 10 |
| 05.3 | Chewing gum | E 900 | | 100 |
| 05.4 | Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | E 900 | | 10 |
| 06.6 | Batters | E 900 | | 10 |
| 12.5 | Soups and broths | E 900 | | 10 |
| 14.1.2 | Fruit juices as defined by Directive 2001/112/EC and vegetable juices | E 900 | only pineapple juice and *Sød.saft* and *sødet.saft* | 10 |
| 14.1.4 | Flavoured drinks | E 900 | | 10 |
| 14.2.3 | Cider and perry | E 900 | excluding *cidre bouché* | 10 |
| 17.1 | Food supplements supplied in a solid form, excluding food supplements for infants and young children | E 900 | only food supplements in effervescent tablet form | 10[(a)] |

MPL: maximum permitted level.
(a): Maximum level applies to the dissolved food supplement ready for consumption when diluted with 200 ml of water.

According to Annex III, Part 1 of Regulation (EC) No 1333/2008, dimethyl polysiloxane (E 900) is also authorised as a carrier in glazing agents for fruit at quantum satis (*QS*).

According to Annex III, Part 2 of Regulation (EC) No 1333/2008, dimethyl polysiloxane (E 900) is also authorised as a food additive in colour preparations of E 160a carotenes, E 160b annatto, bixin,

[11] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16.

norbixin, E 160c Paprika extract, capsanthin, capsorubin, E 160d lycopene and E 160e beta-apo-8′-carotenal with a maximum level of 200 mg/kg in the preparation and 0.2 mg/L in the final food.

According to Annex III, Part 4 of Regulation (EC) No 1333/2008, dimethyl polysiloxane (E 900) is also authorised as a food additive in all food flavourings at a maximum level of 10 mg/kg in flavourings.

In addition, according to Annex III, Part 5, Section A, of Regulation (EC) No 1333/2008, dimethyl polysiloxane (E 900) is also authorised as a food additive in preparations of beta-carotene and lycopene with a maximum level of 200 mg/kg in the preparation and 0.2 mg/L in the final food.

## 3.3. Exposure data

### 3.3.1. Reported use levels or data on analytical levels of dimethyl polysiloxane (E 900)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call[12] for occurrence data (usage level and/or analytical data) on dimethyl polysiloxane (E 900). In response to this public call, industry provided updated information on the use levels of dimethyl polysiloxane (E 900) in foods to EFSA. No analytical data on the concentration of dimethyl polysiloxane (E 900) in foods were provided by the Member States.

**Summarised data on reported use levels in foods provided by industry**

Industry provided EFSA with 28 use levels of dimethyl polysiloxane (E 900) in foods for three out of the 14 food categories (FCs) in which dimethyl polysiloxane (E 900) is authorised. Most of these use levels were for the use of dimethyl polysiloxane (E 900) in FC 02.1 Fats and oils essentially free from water (excluding anhydrous milkfat (n = 10) and FC 14.1.4 Flavoured drinks (n = 11).

In addition, four use levels of dimethyl polysiloxane (E 900) were provided for two food categories in which dimethyl polysiloxane (E 900) is not authorised to be added directly, but due to Annex III authorisation (present due to carry-over): FC 04.1.1 Entire fresh fruit and vegetables (n = 1) and FC 08.2 Meat preparations as defined by Regulation (EC) No 853/2004 (n = 3). These levels were included in the analysis.

The use levels of dimethyl polysiloxane (E 900) in foods were provided by Spanish Association of Postharvest Services and Processes (AGRUPOST), Food Drink Europe (FDE), the European Margarine Association (IMACE) and FEDIOL – The EU Vegetable Oil and Protein meal Industry Association (FEDIOL).

In total, 14 use levels of dimethyl polysiloxane (E 900) referred to niche products. These levels, 11 for flavoured drinks (FC 14.1.4) and three for meat preparations as defined by Regulation (EC) No 853/2004 (FC 08.2), were included in the analysis as no other use levels were available for these food categories.

Appendix A provides the use levels of dimethyl polysiloxane (E 900) in foods as reported by industry.

### 3.3.2. Summarised data extracted from the Mintel's Global New Products Database

The Mintel GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 3 million food and beverage products of which more than 1,100,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 24 out of its 27 member countries, Norway and UK presented in the Mintel GNPD.[13]

[12] https://www.efsa.europa.eu/en/data/call/160524

[13] Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.

For the purpose of this scientific opinion, Mintel's GNPD[14] was used for checking the labelling of food and beverage products and food supplements for dimethyl polysiloxane (E 900) within the EU food market as the database contains the compulsory ingredient information on the label.

According to Mintel's GNPD, dimethyl polysiloxane (E 900) was labelled on 111 products in the last 5 years. These products belong to different Mintel subcategories. The two subcategories with the highest percentage of food products labelled with dimethyl polysiloxane (E 900) within the subcategory were 'Sports Drinks' (1%) and 'Shortening & Lard' (0.8%). For a complete overview of the percentages per subcategory with at least one food labelled with dimethyl polysiloxane (E 900), see Appendix B. The average percentage of foods labelled to contain dimethyl polysiloxane (E 900) in these subcategories was 0.08%.

### 3.3.3. Food consumption data used for exposure assessment

**EFSA Comprehensive European Food Consumption Database**

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a). Consumption surveys added in the Comprehensive database in 2015 were also taken into account in this assessment.[10]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons may not be appropriate. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the Comprehensive Database includes the currently best available food consumption data across Europe.

**Table 3:** Population groups considered for the exposure estimates of dimethyl polysiloxane (E 900)

| Population | Age range | Countries with food consumption surveys covering more than 1 day |
|---|---|---|
| Infants | From more than 12 weeks up to and including 11 months of age | Bulgaria, Denmark, Finland, Germany, Italy, UK |
| Toddlers[(a)] | From 12 months up to and including 35 months of age | Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK |
| Children[(b)] | From 36 months up to and including 9 years of age | Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK |
| Adolescents | From 10 years up to and including 17 years of age | Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Netherlands, Spain, Sweden, UK |
| Adults | From 18 years up to and including 64 years of age | Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK |
| The elderly[(b)] | From 65 years of age and older | Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Netherlands, Sweden, UK |

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011a) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013.
(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Comprehensive Database (EFSA, 2011a).

Food consumption data of infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 3).

Consumption records are codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system

[14] http://www.gnpd.com/sinatra/home/accessed on 20/12/2019

(FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure assessments. In practice, the FoodEx food codes were matched to the FCS food categories.

**Food categories considered for the exposure assessment of dimethyl polysiloxane (E 900)**

The food categories in which the use of dimethyl polysiloxane (E 900) is authorised according to Annex II to Regulation (EC) No 1333/2008 were selected from the nomenclature of the Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b). The two food categories for which use levels were reported for dimethyl polysiloxane (E 900) according to Annex III to Regulation (EC) No 1333/2008 (FC 04.1.1 Entire fresh fruit and vegetables and FC 08.2 Meat preparations as defined by Regulation (EC) No 853/2004) were also selected.

Some food categories or their restrictions/exceptions are not referenced in the Comprehensive Database and could therefore not be considered in the present exposure assessment. This was the case for two food categories (Appendix C) and may have resulted in an underestimation of the exposure. These food categories were (in ascending order of the FCS codes):

- 06.6 Batters. Not taken into account as not referenced in the Comprehensive Database.
- 14.1.2 Fruit juices as defined by Directive 2001/112/EC25 and vegetable juices, only *Sød … saft and sødet … saft*, and pineapple juice. Only pineapple juice was included in the exposure assessment, as *Sød … saft and sødet … saft* are not referenced in the FoodEx system.

For the following food categories, the restrictions/exceptions that apply to the use of dimethyl polysiloxane (E 900) could not be considered, and therefore the whole food category was included in the exposure assessment. This applied to five food categories (Appendix C) and may have resulted in an overestimation of the exposure. These food categories were (in ascending order of the FCS codes):

- 02.1 Fats and oils essentially free from water (excluding anhydrous milkfat), only oils and fats for frying. Considering that it is not possible to select only the consumption of oils and fats for frying and that many oils and fats can be used for baking, the full food category was considered.
- 02.2.2 Other fat and oil emulsions, including spreads as defined by Council Regulation (EC) No 1234/2007[15] and liquid emulsions, only oils and fats for frying. Considering that it is not possible to select only the consumption of oils and fats for frying and that many oils and fats can be used for baking, the full food category was considered.
- 04.2.3 Canned or bottled fruit or vegetable. The category of canned fruit is available in the FoodEx nomenclature and was selected. Concerning the vegetables, as there is no category of canned vegetables, only vegetables which can usually be canned were considered, including:
    - Cultivated Fungi,
    - Legumes, beans, green, without pods: green beans, green peas and green lentils,
    - Sweet corn.
- 14.2.3 Cider and perry, excluding *cidre bouché*. The full food category was considered because the exception represents a small part of the whole food category.
- 17.1 Food supplements supplied in a solid form, excluding food supplements for infants and young children, only food supplements in effervescent tablet form. The full FC 17 was taken into account, because the form cannot be differentiated in the Comprehensive Database. This food category was only considered in the 'food supplements consumers only' scenario.

Overall, 15 food categories were included in the regulatory maximum level exposure assessment scenario, including the two food categories for which use levels were reported for dimethyl polysiloxane (E 900) due to Annex III authorisation (Appendix C).

For the refined scenario, five food categories were considered based on use levels for three food categories authorised according to Annex II and two food categories authorised according to Annex III (Appendix C). The use level for one of these two food categories was for a niche product belonging to FC 08.2. Meat preparations as defined by Regulation (EC) No 853/2004, namely chicken preparations (Appendix A). This use level was applied to all foods categorised in FC 08.2 and could therefore have resulted in an overestimation of the exposure to dimethyl polysiloxane (E 900) in the refined scenarios. The Panel noted that this also applied to the regulatory maximum level exposure assessment scenario.

[15] Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products. OJ L 299, 16.11.2007, p. 1.

## 3.4. Exposure estimates

### 3.4.1. Exposure to dimethyl polysiloxane (E 900) from its use as a food additive

The Panel estimated the chronic dietary exposure to dimethyl polysiloxane (E 900) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to dimethyl polysiloxane (E 900) was calculated by multiplying concentrations of dimethyl polysiloxane (E 900) per food category (Appendix D) with their respective consumption amount per kilogram body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered not adequate to assess repeated exposure.

The exposure was estimated in this way for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 3). Based on these distributions, the mean and 95th percentiles of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain was not estimated.

The exposure to dimethyl polysiloxane (E 900) was estimated based on two different sets of concentration data: (1) MPLs as set down in Annex II to Regulation (EC) No 1333/2008 (defined as the *regulatory maximum level exposure assessment scenario*); and (2) reported use levels (defined as the *refined exposure assessment scenario*). To also consider the possible additional exposure from the presence of dimethyl polysiloxane (E 900) Annex III authorisation in the *regulatory maximum level exposure assessment scenario*, the reported use levels for dimethyl polysiloxane (E 900) for FC 04.1.1 Entire fresh fruit and vegetables and FC 08.2 Meat preparations as defined by Regulation (EC) No 853/2004) were also included in this scenario. The two scenarios are discussed in detail below.

These scenarios do not consider exposure to dimethyl polysiloxane (E 900) through the intake of food supplements. This source of exposure was covered in an additional scenario detailed below (*food supplements consumers only scenario*). The possible additional exposure from its use in accordance with Annex III to Regulation (EC) No 1333/2008 was only considered for the food categories for which use levels were provided.

**Regulatory maximum level exposure assessment scenario**

The regulatory maximum level exposure assessment scenario of dimethyl polysiloxane (E 900) was based on the MPLs as set in Annex II to Regulation (EC) No 1333/2008 and listed in Table 2 and use levels for two food categories in accordance with Annex III to Regulation (EC) No 1333/2008.

The Panel considers the exposure estimates derived following this scenario as the most conservative since it is assumed that that the population will be exposed to the food additive present in food at the MPL over a longer period of time.

**Refined exposure assessment scenario**

The refined exposure assessment scenario of dimethyl polysiloxane (E 900) was based on use levels reported by food industry. This exposure scenario considers only those food categories for which these data were provided to the Panel.

Appendix C summarises the use levels of dimethyl polysiloxane (E 900) used in the refined exposure assessment scenario. Based on the available data set, the Panel calculated two refined exposure estimates based on two model populations:

- The brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to dimethyl polysiloxane (E 900) present at the maximum reported use level for one food category. This exposure estimate is calculated as follows:
  - Combining food consumption data with the maximum of the reported use levels for the main contributing food category at the individual level.
  - Using the mean of the typical reported use levels for the remaining food categories.

- The non-brand-loyal consumer scenario: It was assumed that a consumer is exposed long term to dimethyl polysiloxane (E 900) present at the mean of the typical reported use levels in food for all food categories.

**Exposure assessment for 'Food supplement consumers only' scenario**

Dimethyl polysiloxane (E 900) is authorised in FC 17 Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children. As exposure via food supplements may deviate largely from the one via food, and the number of food supplement consumers may be low depending on populations and surveys, an additional scenario was calculated in order to reflect additional exposure to food additives from food supplements. As no use levels were reported for food supplements, this scenario was estimated using MPLs. For the remaining food categories (5/13 categories), the mean of the typical reported use levels was used.

As FC 17 does not consider food supplements for infants and toddlers as defined in the legislation, exposure to dimethyl polysiloxane (E 900) from food supplements was not estimated for these two population groups.

This scenario included six food categories (Appendix C).

**Dietary exposure to dimethyl polysiloxane (E 900)**

Table 4 summarises the estimated exposure to dimethyl polysiloxane (E 900) from its use as a food additive in six population groups (Table 3) for the different exposure scenarios. Detailed results per population group and survey are presented in Appendix D.

**Table 4:** Summary of dietary exposure to dimethyl polysiloxane (E 900) from its use as a food additive in the regulatory maximum level exposure assessment scenario and in the refined exposure assessment scenarios, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

| | Infants (12 weeks–11 months) | Toddlers (12–35 months) | Children (3–9 years) | Adolescents (10–17 years) | Adults (18–64 years) | The elderly (≥ 65 years) |
|---|---|---|---|---|---|---|
| **Regulatory maximum level exposure assessment scenario** | | | | | | |
| • Mean<br>• 95th percentile | 0.02–0.06<br>0.09–0.18 | 0.03–0.23<br>0.11–0.51 | 0.04–0.19<br>0.11–0.44 | 0.03–0.14<br>0.08–0.30 | 0.02–0.07<br>0.05–0.20 | 0.01–0.05<br>0.03–0.11 |
| **Refined exposure assessment scenario** | | | | | | |
| **Brand-loyal scenario** | | | | | | |
| • Mean<br>• 95th percentile | 0.02–0.04<br>0.05–0.17 | 0.02–0.15<br>0.06–0.49 | 0.02–0.16<br>0.08–0.38 | 0.02–0.11<br>0.07–0.27 | 0.01–0.05<br>0.04–0.17 | 0.01–0.03<br>0.02–0.07 |
| **Non-brand-loyal scenario** | | | | | | |
| • Mean<br>• 95th percentile | 0.01–0.03<br>0.05–0.09 | 0.02–0.06<br>0.06–0.15 | 0.01–0.05<br>0.04–0.11 | 0.01–0.03<br>0.03–0.08 | 0.01–0.02<br>0.02–0.05 | 0.01–0.02<br>0.02–0.04 |

In the *regulatory maximum level exposure assessment scenario*, mean exposure to dimethyl polysiloxane (E 900) from its use as a food additive ranged from 0.01 mg/kg bw per day in the elderly to 0.23 mg/kg bw per day in toddlers. The 95th percentile of exposure to dimethyl polysiloxane (E 900) ranged from 0.03 mg/kg bw per day in the elderly to 0.51 mg/kg bw per day in toddlers.

In the *refined exposure assessment scenario*, mean exposure to dimethyl polysiloxane (E 900) from its use as a food additive ranged from 0.01 mg/kg bw per day in adults and the elderly to 0.16 mg/kg bw per day in children in the *brand-loyal scenario*. The high exposure (95th percentile) to dimethyl polysiloxane (E 900) ranged from 0.02 mg/kg bw per day in the elderly to 0.49 mg/kg bw per day in toddlers. In the *non-brand-loyal scenario*, mean exposure to dimethyl polysiloxane (E 900) from its use as a food additive ranged from 0.01 mg/kg bw per day in infants, children, adolescents, adults and the elderly to 0.06 mg/kg

bw per day in toddlers. The 95th percentile of exposure to dimethyl polysiloxane (E 900) ranged from 0.02 mg/kg bw per day in adults and the elderly to 0.15 mg/kg bw per day in toddlers.

In the *food supplements consumers only scenario*, mean exposure to dimethyl polysiloxane (E 900) from its use as a food additive ranged from 0.01 mg/kg bw per day in adolescents, adults and the elderly to 0.07 mg/kg bw per day in children. The 95th percentile of exposure to dimethyl polysiloxane (E 900) ranged from 0.02 mg/kg bw per day in adults and the elderly to 0.10 mg/kg bw per day in children.

### Main food categories contributing to exposure to dimethyl polysiloxane (E 900) for the regulatory maximum level exposure assessment scenario

In the *regulatory maximum level exposure assessment scenario*, FC 14.1.4 Flavoured drinks was the main contributing food category to the total mean exposure estimates for all population groups. Other important food categories contributing to the total mean exposure in this scenario were FC 12.5 Soups and broths (for all population groups except toddlers) and FC 02.1 fats and oils essentially free from water (excluding anhydrous milkfat).

### Main food categories contributing to exposure to dimethyl polysiloxane (E 900) using the refined exposure assessment scenario

The main contributing food category in the *brand-loyal refined exposure assessment scenario* was FC 04.1.1 Unprocessed fruits and vegetables for infants, for children, toddlers and the elderly, while for children, adolescents and adults, the main contributing food category was FC 14.1.4 Flavoured drinks.

The main contributing food category in the *non-brand-loyal refined exposure assessment scenario* was FC 04.1.1 Unprocessed fruits and vegetables for all population groups, except for adolescents for which FC 14.1.4 Flavoured drinks contributed most to the exposure. (Appendix E).

The Panel identified potential brand loyalty to FC 14.1.4. Flavoured drinks and considered that dimethyl polysiloxane (E 900) could change the organoleptic properties due to its sweet taste, the Panel therefore considered the brand-loyal refined estimated exposure scenario as the most appropriate and realistic scenario for the risk characterisation of dimethyl polysiloxane (E 900).

### Uncertainty analysis

Potential sources of uncertainties in the exposure assessment of dimethyl polysiloxane (E 900) have been presented above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 5.

**Table 5:** Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

| Sources of uncertainties | Direction [(a)] |
|---|---|
| Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard | +/– |
| Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days | + |
| Correspondence of reported use levels to the food items in the Comprehensive Database: uncertainties to which types of food the levels refer | +/– |
| Uncertainty in possible national differences in use levels of food categories | +/– |
| Concentration data:<br>– use levels considered applicable to all foods within the entire food category, whereas on average 0.08% of the foods, belonging to Mintel's food subcategories with at least one food labelled with the additive, was labelled with the additive<br>– levels used for flavoured drinks reported for niche products | <br>+<br><br>+ |
| The three food categories which were considered in the refined exposure assessment scenarios out of all authorised food categories according to Annex II to Regulation (EC) No 1333/2008 (n = 14), corresponded to 28% to 99.8% of the amount (g of foods by body weight) of foods consumed in the Consumption Database that could potentially contain the additive | – |

| Sources of uncertainties | Direction [a] |
|---|---|
| Food categories selected for the exposure assessment:<br>– exclusion of food categories due to missing FoodEx linkage (n = 2/14 for MPL scenario)<br>– inclusion of food categories without considering the restriction/exception (n = 3 MPL scenario/n = 2 refined scenarios out of 14 food categories)<br>– no data for certain food categories which were therefore not considered in the exposure estimates (n = 11/14 FCs for the refined scenario) | –<br>+<br>– |
| Regulatory maximum level exposure assessment scenario:<br>– exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008 and due Annex III to Regulation (EC) No 1333/2008 authorisation | + |
| Refined exposure assessment scenarios:<br>– exposure calculations based on the maximum or mean levels (reported use from industries) | +/– |

(a): +, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Dimethyl polysiloxane (E 900) is authorised in 14 food categories according to Annex II to Regulation N°1333/2008 (Table 2). For three of these food categories use levels were provided, as well as for foods of two food categories in which dimethyl polysiloxane (E 900) is authorised according to Annex III to Regulation N°1333/2008.

The Panel noted that 14 out of 25 food subcategories, categorised following the Mintel GNPD nomenclature, in which dimethyl polysiloxane (E 900) was labelled according to the Mintel GNPD were included in the refined exposure assessment. These 14 food subcategories represented approximately 75% of the food products labelled with dimethyl polysiloxane (E 900) in this database. The label information of Mintel GNPD does not include all foods in which dimethyl polysiloxane (E 900) will be used, because the labelling of food additives present due to use according to Annex III is not mandatory.

The percentage of foods per subcategory labelled to contain dimethyl polysiloxane (E 900) was maximally about 1% (Appendix B). In the assessment, it was assumed that 100% of the foods belonging to an authorised food category contained the additive.

Considering the direction of all uncertainties (Table 5), the Panel concluded that the exposure to dimethyl polysiloxane (E 900) from its use as a food additive according to Annex II for the *regulatory maximum level exposure assessment scenario* was overestimated for the European countries considered in the Comprehensive Database. The refined exposure assessment scenario also led to an overestimation of the exposure from its use as a food additive according to Annex II, especially because

- 75% of the food products labelled with dimethyl polysiloxane (E 900) in the Mintel GNPD were included in the refined scenarios;
- it was assumed that all foods belonging to an authorised food category contained dimethyl polysiloxane (E 900).

The Panel noted that food categories which may contain dimethyl polysiloxane (E 900) due to Annex III (Parts 1, 2, 4, 5) authorisation were partially considered in the exposure assessment.

### 3.4.2. Exposure to dimethyl polysiloxane from uses other than as a food additive

Dimethyl polysiloxane is also used in cosmetic products, as an excipient in pharmaceutical products and as a processing aid in food. Quantification of exposure via all these sources is not known and was therefore not considered in this opinion.

## 3.5. Biological and Toxicological data

The Panel noted that E 900 is a mixture of polymers and the analytical methods used for characterising the fate of the mixture in mammalians reflects the sum of the toxicokinetics, but not that of individual components. Even in a study in rats (Dow-Corning-Corporation-Health-And-Environmental-Sciences 2000, 2001(Documentation provided to EFSA No 24)) in which radiolabelled substance was administered, the kinetics of any single component were not characterised.

Biological and toxicological studies performed with dimethyl polysiloxanes that do not comply with the EU specifications for E 900 with respect to viscosity (below 100 centistokes) have been considered as complementary information for the assessment of the food additive.

Information on the characterisation of the different dimethyl polysiloxane fluids used in the toxicological studies is provided in Appendix F.

### 3.5.1. Absorption, distribution, metabolism and excretion

**Animal studies**

*Mice*

Male Buckberg mice (12 animals/group, body weight 25 g) were given a single oral dose by gavage of (1) sesame oil (control group), (2) silica (6 mg/kg bw – the amount of silica comparable to that in 'DC Antifoam A' and 'DC Antifoam M' (See Appendix F for information on the test material)), (3) 'DC Antifoam A'[16] (0.5 ml/kg bw), (4) 'DC A Emulsion' (1.67 ml/kg bw which represents the same amount of dimethyl polysiloxane as in group 3),(5) 'DC Antifoam 351' (0.5 mL/kg, a preparation similar to 'DC Antifoam M'[17] with viscosity of 350 centistokes), (6) 'DC Antifoam 352 Emulsion' (1.67 mL/kg bw, a 30% emulsion made from 'DC Antifoam 351' and (7) 'DC 360 Medical Grade 350 centistokes dimethyl polysiloxane fluid' (0.5 mL/kg bw, contains no free silica or free emulsifiers). At 4, 12 and 24 h after treatment, four mice from each group were anaesthetised and urine and bile were taken for silicon analysis by emission spectroscopy. There were no statistically significant differences in urinary or biliary silicon concentrations, except for a statistically significant increased ($p < 0.05$, estimated by the Panel to be approximately to 10-fold higher than the control) concentration in urine and bile from group (3) and (4). The authors did not give the precise dose for these groups and did not quantify the amount found in bile or urine. They stated that the increase in silicon only represented a negligible amount of the dose administered for absorption from the gastrointestinal tract (Dow-Corning-Corporation-Research-Department, 1974, Documentation provided to EFSA No. 8)).

*Rats*

The absorption of '$^{14}$C-dimethyl polysiloxane' (viscosity of 10 centistokes)[18] was studied in Fischer 344 rats given a single oral dose of 1,000 mg/kg bw by gavage. The first part of the study consisted of two exposure groups (4 males and 4 females, respectively; body weight of 146–203 g) and a control group (2 rats/sex; not dosed) that were housed in metabolic cages for 96 h following administration of the test substance for collection of excreta. In the second part of the study, whole body autoradiography was used for the *in vivo* assessment of tissue distribution of radiolabelled dimethyl polysiloxane (four males and four females, body weight of 146–203 g) at 12, 24, 48 and 96 h following administration of the test substance. The majority of the radioactivity was rapidly excreted; the recovery was 93.4% in female rats and 91.0%in male rats. The vast majority of excreted test substance was recovered in the faeces (99.9% and 99.6% in females and males, respectively); all radioactivity recovered in the faeces was attributed to unchanged dimethyl polysiloxane. Whole body autoradiography showed that radioactivity was concentrated in the contents of the gastrointestinal tract at 12, 24 and 48 h post-exposure. No radioactivity was present in tissues or organs at 96 h post-exposure. The study authors concluded that following oral administration, the vast majority of $^{14}$C-dimethyl polysiloxane was not absorbed but excreted unchanged in the faeces (Dow-Corning-Corporation-Health-And-Environmental-Sciences, 2000(Documentation provided to EFSA No. 23)).

The absorption of '$^{14}$C-dimethyl polysiloxane' (viscosity of 350 centistokes) was studied in four male and four female Fischer 344 rats, body weight 145–202 g, given a single oral dose of 1,000 mg/kg bw by gavage. The control group consisted of two rats/sex. The animals were housed in metabolic cages for 96 h following administration of the test substance. In the second part of the study, whole body autoradiography of rats was used for assessing the tissue distribution of radiolabelled dimethyl polysiloxane (four males and four females, body weight of 145–202 g) at 12, 24, 48 and 96 h following administration of the test substance. In female rats 93.6% and in male rats 97.4% of the radioactivity was recovered. Less than 0.1% was excreted by other ways than the faeces (99.98% of

[16] DC Antifoam A is a mixture of 93% polydimethylsiloxane (CAS No 63148-62-9) and 7% silica treated with polydimethylsiloxane (CAS No 67762-90-7) (Documentation provided to EFSA No 5).

[17] DC Antifoam M is a mixture of 91% polydimethylsiloxane (CAS No 63148-62-9), 6% silica and 3% polydimethylsiloxane hydroxy-terminated (CAS No 70131-67-8) (Documentation provided to EFSA No 5).

[18] The Panel noted that this test material does not comply with EU specifications for E 900 regarding the viscosity.

the total recovered dose in both males and females were found in the faeces). All radioactivity recovered in the faeces was attributed to unchanged dimethyl polysiloxane. The whole-body autoradiography showed that the radioactivity was concentrated in the contents of the gastrointestinal tract at 12, 24 and 48 h post-exposure. No radioactivity was present in tissues and organs at 96 h post-exposure. The study authors concluded that $^{14}$C-dimethyl polysiloxane was excreted unchanged in the faeces following oral administration (Dow-Corning-Corporation-Health-And-Environmental-Sciences, 2001(Documentation provided to EFSA No 24)).

Lukasiak and co-workers examined the absorption and distribution of 'OM-300' (dimethyl polysiloxane oil, viscosity of 300 centistokes) in male Wistar rats ((Lukasiak et al., 2001). The study results were considered by the Panel to be unreliable as the method was not considered to be specific for the analysis of the test material. Furthermore, few data are provided and those data that are provided are reported as amounts (e.g. micrograms in blood) rather than as concentrations. The Panel considered the study as not reliable.

*Monkeys*

Three Rhesus monkeys received a single oral dose (gavage) of $^{14}$C-labelled dimethyl polysiloxane fluid (identical to 'DC Antifoam A' but silica-free, viscosity 397 centistokes) at dose levels of 1.15, 13.7 or 18.0 mg/kg bw. Approximately 0.5–0.9% of the dose was recovered in the expired air; the pulmonary half-life was 4.6 h. Less than 0.1% of the dose was lost as volatiles from the urine, flatus and faeces. Approximately 2.1–2.5% of the dose was recovered in the urine (half-life of 24 h), 0.1–0.3% in the bile (in the first 24 h) and 80–92% in the faeces (over 92 h). The peak blood levels were below 1 μg/mL (detection limit) (Dow-Corning-Corporation-Research-Department, 1974 Documentation provided to EFSA No. 8)).

One Rhesus monkey received a single oral dose (gavage) of $^{14}$C-labelled dimethyl polysiloxane (identical to 'DC Antifoam M' but silica-free, viscosity 932 centistokes) at a dose level of 21.8 and another monkey at a dose level of 41.8 mg/kg bw of $^{14}$C-labelled dimethyl polysiloxane identical to DC 360 Medical Grade (335 cs). After 72 hours, 0.02 and 0.01% of the radioactivity were recovered in the expired air, 0.02 and < 0.001% in the urine and 97 and 93% of the respective monkeys in the faeces. Less than 0.01% of the low dose was found in the sum of around 40 different tissues examined 72 hours after dosing. Analysis of faeces from the high dose animal revealed that the parent compound was excreted unchanged (Dow-Corning-Corporation-Research-Department, 1974 Documentation provided to EFSA No. 8)).

**Human studies**

Four men and two women received a single oral dose of 'DC Antifoam A'[19] and 'DC Antifoam M'[20] (100 mg/kg bw in sesame oil). In addition, three men and two women received a single oral dose of 'DC A Emulsion' and 'DC M Emulsion' (100 mg/kg bw, containing 30% of 'DC Antifoam A' and 'DC Antifoam M', respectively). Total and organosoluble (methyl ethyl ketone-soluble) urinary silicon output, as well as organosoluble (toluene-soluble) silicon output in expired air were measured. Administration of 'DC Antifoam M' and 'DC M Emulsion' did not result in an increase of silicon in urine or in expired air, whereas administration of 'DC Antifoam A' and 'DC A Emulsion' resulted in an increase in the urinary excretion of silicon (average: 1.8 and 3.3 % for 'DC Antifoam A' and 'DC A Emulsion', respectively, over 6 days; half-life of 24 h for both test substances). At least 0.5 % of the dose was recovered in expired air (half-life of 8 h); however, the exhaled material consisted principally of low molecular weight cyclosiloxanes (octamethylcyclotetrasiloxane and decamethylcyclotetrasiloxane) which should not be present in the food additive (Dow-Corning-Corporation-Research-Department, 1974 Documentation provided to EFSA No. 8)).

Overall, dimethyl polysiloxane (various compositions and different viscosities – 10, 350 and 1,000 centistokes) is only absorbed to a very limited extent from the gastrointestinal tract following oral administration to mice, rats, monkeys and humans. The vast majority (more than 99.9%) of the orally administered dimethyl polysiloxane is excreted unchanged in the faeces. When comparing the two rat studies (same strain of rats, F344), applying a pure dimethyl polysiloxane fluid with two different viscosities (10 and 350 centistokes) resulted in no differences in absorption and excretion.

From the data available in humans, the Panel noted that the low molecular weight cyclosiloxanes present in the test material (DC antifoam A) are absorbed from the GI tract. For this reason, the

[19] Antifoam A contains 9.75% of cyclosiloxanes.
[20] Antifoam M contains < 0.02% of cyclosiloxanes.

Panel reiterates the recommendation for an amendment of the EU specifications in order to ensure the absence of cyclosiloxanes in the food additive E 900.

### 3.5.2. Acute toxicity

'DC 200 fluids' (viscosity 350 centistokes (See Appendix F for information on the test material)) was reported to be of low acute oral toxicity in rats (Rowe et al., 1948).

### 3.5.3. Short-term and subchronic toxicity

**Mice**

In a 90-day study in compliance with GLP, CD-1 mice (15 animals/sex per group, 7 weeks old) were administered dimethyl polysiloxane fluid (viscosity of $35^{18}$ centistokes) at 0, 5 and 10 % in the diet (equivalent to 0, 10,000 and 20,000 mg/kg bw per day of dimethyl polysiloxane) (Dow-Corning-Corporation-Toxicology-Department, 1989a (Documentation provided to EFSA No. 14)). Animals were observed daily clinical signs of toxicity, appearance, behavioural changes and mortality. The stool was examined visually and the perianal region was examined for evidence of anal leakage of the fluid. Body weights and food consumption were recorded weekly. At termination, major organs were collected, weighed and examined for histopathological changes. Slight to moderate anal leakage of fluid was observed in the 10 % group and almost all animals showed slight to moderate oily fur conditions throughout the entire study period. Food consumption was significantly increased in both treatment groups. No other significant findings were noted.

CD-1 mice (six animals/sex per group) were given 1, 5 or 10 % dimethyl polysiloxane fluid (viscosity of $35^{18}$ or 1,000 centistokes) in food for 28 days (equivalent to 0, 2,000, 10,000 and 20,000 mg/kg bw per day of dimethyl polysiloxane). Slight anal leakage was noted following administration of 5 % of the 35 centistoke dimethyl polysiloxane, slight to severe anal leakage following administration of 10 % of the 35 centistoke dimethyl polysiloxane and normal to moderate following administration of 10% of the 1,000 centistoke dimethyl polysiloxane. Statistically significant increased food consumption was observed at the two highest dose levels. No other significant findings were reported (United States Environmental Protection Agency, 1994c, as referred to by JECFA (2009)).

**Rats**

Male Wistar rats (five animals/group) were administered 0 or 5% 'OM-300' (dimethyl polysiloxane oil, viscosity of 300 centistokes (See Appendix F for information on the test material)) in the diet for 12 days (Lukasiak et al., 2001). After study termination, the brain, kidney, liver, spleen, cardiac muscle, wall of the small intestine, suprarenal gland, pancreas and lung were examined histologically. No histological changes and no other signs of toxicity were reported.

In a 28-day study performed in compliance with GLP and in accordance with OECD Guideline No 407 at that time (WIL-Research-Laboratories-Inc., 1995d, Documentation provided to EFSA No 42)), Fischer 344 rats (10 animals/sex/group) were given 0, 10,000, 25,000, 50,000 and 100,000 mg/kg 'DC 200 fluid' (viscosity of $10^{18}$ centistokes (See Appendix F for information on the test material)) in the diet (equal to 0, 978/1,043, 2,545/2,706, 5,244/5,623 and 11,228/12,058 mg/kg bw per day in males/females, respectively). Clinical signs consisted of urogenital matting (yellow, clear, wet or dry) of the fur at 50,000 mg/kg (in one-half of the animals) and in the fur as well as many other parts of the body at 100,000 mg/kg in all animals. Corneal opacities (identified as corneal crystals) were observed in almost all rats, with the highest incidences in the three highest dose groups, lowest in the control group and intermediate in the lowest dose group. At the microscopic examination hyperplasia, haemorrhage (only in the high-dose group), granulomatous inflammation and suppurative inflammation of the corneal stroma were each observed at an incidence of 15–50 % at the two highest dose levels. Moreover, hyperplasia of the corneal epithelium was observed in 30 % of males and females at 50,000 mg/kg. As the ocular effects were only observed on the cornea, the study report authors suggested that the matting of the fur and the corneal effects were possibly a result of direct contact with the test substance in the feed, or with the test substance and/or a metabolite excreted in the faeces. The Panel agreed with this. Mean food consumption was increased in the 50,000 and 100,000 mg/kg groups in both males and females. Mean triglycerides, and low density and very low density lipoprotein cholesterol levels were significantly decreased in males at 25,000 and 50,000 mg/kg and in both sexes at 100,000 mg/kg. Other significant changes in serum biochemistry

included increased blood urea nitrogen values in the male 10,000 mg/kg group, decreased glucose in the male 25,000 mg/kg group and a decreased albumin/globulin ratio in the females 100,000 mg/kg group. Significant organ weight changes included increased mean relative kidney weights in the male at 50,000 and 100,000 mg/kg and decreased relative brain weights in the females at 25,000 and 50,000 mg/kg groups.

Another 28-day study performed in compliance with GLP and in accordance with OECD Guideline No 407 at that time was conducted in rats with a 'DC 200 fluid' (viscosity 350 centistokes (See Appendix F for information on the test material)) (WIL-Research-Laboratories-Inc., 1995c, Documentation provided to EFSA No 41)). Fischer 344 rats (10 animals/sex per group) were given 0, 10,000, 25,000, 50,000 and 100,000 mg/kg in the diet (equal to 0, 950/1,013, 2,428/2,562, 4986/5,286 and 10,615/11,325 mg/kg bw per day in males/females, respectively). Clinical signs consisted of an increased incidence of matting of the fur at 100,000 mg/kg. Corneal opacities (identified as corneal crystals) were observed in all treated rats and in 18/20 control group rats, and keratitis with corneal vascularisation was present in 0, 3, 3, 3 and 14 rats in the control, 10,000, 25,000, 50000 and 100,000 mg/kg groups, respectively. At the microscopic examination, hyperplasia and granulomatous inflammation of the corneal stroma were present in all treated groups in a dose-related manner (incidence of stromal hyperplasia: 5, 15, 25 and 80%; granulomatous inflammation: 5, 15, 15 and 65% at the 10,000, 25,000, 50,000 and 100,000 mg/kg groups, respectively); these lesions were not observed in the control group. Mineralisation of the cornea sub-epithelium was observed in all groups including the control group (incidences from 50 to 95%) but was more severe in treated rats compared to control rats. As the ocular effects were only observed on the cornea, the study report authors suggested that the matting of the fur and the corneal effects were possibly a result of direct contact with the test substance in the feed, or with the test substance and/or a metabolite excreted in the faeces. Mean food consumption was increased in the male 25,000 and in both sexes at 50,000 and 100,000 mg/kg diet groups.

Sprague Dawley rats (10 animals/sex per treatment group, 20 animals/sex in the control group), were given 1% in the diet 'DC 200 fluid' at different viscosities ($50^{18}$, 350, 1,000, 10,000 and 60 000 centistokes (See Appendix F for information on the test materials)) (equal to 183/180, 192/180, 190/182, 190/175 and 180/177 mg/rat per day in males/females, respectively, of dimethyl polysiloxane) in the diet for 90 days (MacDonald et al., 1960). Food consumption was recorded for each group of five animals. Individual body weights were recorded at the start of the study and at day 45 and 90. Haematological examinations were performed on half of the males and half of the females in each dosage group at the start and at day 45 and 90. At day 90, all animals were sacrificed and examined for gross pathological changes, organ weights were determined and histopathological examination was conducted on tissues. No adverse effects were noted.

A 90-day study performed in compliance with GLP and in accordance with OECD Guideline No 408 at that time was conducted in rats with three different 'DC 6370 fluids' (dimethyl polysiloxane with viscosity of $35^{18}$, 350 and 1,000 centistokes (See Appendix F for information on the test materials)) (Dow-Corning-Corporation-Toxicology-Department, 1989b (Documentation provided to EFSA No. 15)). Sprague Dawley rats (20 animals/sex per group) were administered 0 (two control groups), 1, 5 and 10% in the diet (equivalent to 0, 900, 4,500 and 9,000 mg/kg bw per day of dimethyl polysiloxane). Animals were observed daily for clinical signs of toxicity, appearance, behavioural changes and mortality. The stool was examined visually and the perianal region was examined for evidence of anal leakage of the fluid. Body weights and food consumption were recorded weekly. Ophthalmological examination was performed prior to initiation and prior to termination of the study. At termination, blood and urine samples were collected for haematology and clinical chemistry and urinalysis, and major organs were collected, weighed and examined for histopathological changes. Slight to marked anal leakage of fluid was observed at 10% for all viscosities; the amount of anal leakage decreased with increasing viscosity. Slight anal leakage was also observed in some rats given diets with 5% of low viscosity fluid (35 centistokes). Few statistically significant increases in body weight were observed in the treated groups, but most of the body weight data were comparable between treated and control rats. Significantly higher food consumption was observed in the 5 and 10 % groups, especially in the males, of all viscosity fluids. The eye examination revealed corneal opacities and neovascularisation in treated rats and the microscopic examination of the eyes showed minimal to mild chronic inflammation of the cornea in treated animals of both sexes in a non-dose-related manner. Mineralisation of the cornea was also noted in some animals. According to the authors of the study report, the corneal effects may have been due to direct ocular irritation from the test substances in the feed. Three lymphomas were recorded in treated males with two lymphatic lymphomas in male

rats given 10 % of 1,000 centistokes fluid and one undifferentiated lymphoma in a male given 1 % of 35 centistokes fluid.

An additional dietary 90-day study was performed in male rats in compliance with GLP (100 animals/group) to either confirm or disregard whether the lymphomas observed in the experiment described above were treatment-related (Dow-Corning-Corporation, 1989b (Documentation provided to EFSA No. 15)). Sprague Dawley rats were assigned to each of two control groups and to each of three test groups and given 10% of 'DC 6370 fluids' (viscosities of $35^{19}$, 350 and 1,000 centistokes (See Appendix F for information on the test material)) (equivalent to 9,000 mg/kg bw per day of dimethyl polysiloxane). The animals were examined as described in the previous study. All treatment groups displayed higher mean food consumption. No other significant findings were noted. The data from the study did not confirm the previous observation of an increased number of lymphoma in treated animals (Dow-Corning-Corporation-Toxicology-Department, 1989b (Documentation provided to EFSA No. 15)).

In a 90-day study performed in compliance with GLP and in accordance with OECD Guideline No 408 at that time (WIL-Research-Laboratories-Inc., 1995a, (Documentation provided to EFSA No 39)). Fischer 344 rats (15 animals/sex per group) were given 'DC 200 fluid' (viscosity: $10^{18}$ centistokes (See Appendix F for information on the test material)) in the diet at 0, 5,000, 10,000, 25,000 and 50,000 mg/kg (equal to 0, 351/395, 718/792, 1,780/2,025 and 3,773/4,348 in males/females, respectively). Clinical signs consisted of matting at the base of the tail and the anogenital region at 50,000 mg/kg (all males and most females), as well as matting of other parts of the body at a higher incidence at 50,000 mg/kg males and females. Corneal opacities were observed in almost all rats with dose–response relationship in the severity. At the microscopic examination, suppurative inflammation of the corneal stroma (0/15, 1/15, 0/15, 6/15 and 8/15 for males; 0/15, 0/15, 0/15, 0/15 and 4/15 for females in control, 5,000, 10,000, 25,000 and 50,000 mg/kg groups, respectively) and neovascularisation of the corneal stroma were observed in one male at 25,000 mg/kg and in two females at 50,000 mg/kg. The authors of the study report suggested that the matting of the fur and the corneal effects were possibly a result of direct contact with the test substance in the feed, or with the test substance and/or a metabolite excreted in the faeces. Incidental increase in mean food consumption was observed in the 10,000, 25,000 and 50,000 mg/kg groups in male and females. Mean total cholesterol, high density lipoprotein cholesterol and phospholipid levels were significantly decreased in all males treated groups except for the cholesterol and phospholipid means at 5,000 mg/kg. Other significant changes in serum biochemistry included a lower mean creatinine value in males at 25,000 mg/kg, an increase in mean total bilirubin in females at 5,000 mg/kg, an increase in the mean total protein value in females at 10,000 mg/kg and an increase in the mean albumin value in females at 25,000 mg/kg. Regarding urinalysis, a decreased pH was observed in males at 50,000 mg/kg.

Another 90-day study performed in compliance with GLP and in accordance with OECD Guideline No 408 at that time was conducted in rats with a 'DC 200 fluid' (350 centistokes (See Appendix F for information on the test material)) (WIL-Research-Laboratories-Inc., 1995b, Documentation provided to EFSA No 40). Fischer 344 (15 animals/group) were given 0, 5,000, 10,000, 25,000 and 50,000 mg/kg in the diet (equal to 0, 312/352, 618/716, 1,590/1,790 and 3,347/3,824 in males/females, respectively. To further investigate the potential of the test substance to induce corneal opacities during dietary and gavage routes of administration, the test substance was also administered daily by gavage to two groups rats (15 animals/sex per group) at dose levels of 0, 500 or 2,500 mg/kg bw per day for 90 days. Clinical signs consisted of matting at the base of the tail occasionally in the male 2 500 mg/kg bw per day gavage group and infrequently in females 2,500 mg/kg bw per day gavage group during weeks 8–13. Matting was not reported in animals given the test substance in the diet at the two highest dose levels (from approximately 1 600 to 3 800 mg/kg bw per day). Corneal opacities (identified as corneal crystals) were observed in all animals in all groups (control and treated). After 1 week of treatment, corneal opacities occurred generally more frequently in the dietary groups when compared to the diet control group, gavage control and gavage-treated groups. After 2 weeks of treatment, most of the treated animals (both dietary and gavage) had corneal opacities while most of the males and half of the females in the diet and gavage control groups had corneal opacities. All animals in all groups had corneal opacities after 3 weeks of treatment. The severity of the corneal opacities was increased in a dose-related manner in all treatment groups when compared to the control groups. At the microscopic examination, suppurative inflammation of the corneal epithelium occurred at a dose-related increased incidence in all treatment groups when compared to the control groups. The study report authors suggested that the matting of the fur and the corneal effects possibly was a result of direct contact with the test substance in the feed, or with the test substance

and/or a metabolite excreted in the faeces. Mean food consumption was increased at 20,000 mg/kg in females and at 50,000 mg/kg in both genders.

### Rabbits

Adult New Zealand albino rabbits (three animals/sex per treatment group, six animals/sex in the control group) were given 0 or 1% in the diet of either 'DC 360 fluid' (viscosity: $50^{18}$ or 350 centistokes (See Appendix F for information on the test material)) or 'DC Antifoam A' ((See Appendix F for information on the test material)) for 8 months (Carson et al., 1966). Animals were observed daily and body weights were recorded weekly. Haematological and urinary examinations were performed at the start of the study and after 4 and 8 months. Additionally, at 8 months, blood urea nitrogen, serum cholesterol, alkaline phosphatase and glutamic pyruvic transaminase were determined. At the end of the study, organs were weighed, and macro- and microscopic examination was performed. No significant differences between treated animals and controls were reported.

### Dogs

Dogs (two animals/group, body weight and age not specified but it is mentioned that the dogs were nearly full grown at the start of the study) were given for 3 months in the diet 'DC Antifoam A' ((See Appendix F for information on the test material)) at 0, 300, 1,000 and 3,000 mg/kg bw per day, 5 days per week (Child et al., 1951). Due to poor reporting and limitations of the study (e.g. study design, dog general health, changes in the diet), this study was not considered for the hazard identification.

A 13-week oral toxicity study was conducted in dog with DC Medical Antifoam 351 (See Appendix F for information on the test material) (Atlas Chemical Industries, 1969 (Documentation provided to EFSA No. 2)). Dogs (three animals/sex per group) received 120, 380 or 1,200 mg/kg bw per day. Body weight, water and food consumption were recorded. Urine output was measured once a week for a 24- hour period. At week 2 and 4, values for haematology and clinical chemistry were determined. At termination, blood and urine samples were collected for haematology and clinical chemistry and urinalysis, and major organs were collected, weighed and examined for histopathological changes. Soft stools were reported to occur in all treatment groups, including control, with the presence of mucus and, in some instances, blood. Mean weight of thyroid, heart and pituitary gland was increased in the high-dose group in males. Mean weight of spleen was increased at 1,200 and 380 mg/kg bw per day in male and mean weight of gonads was increased in all dose groups compared to the control group in males. No gross or histological lesions related to administration of DC Medical Antifoam 351 were observed. In females, increase in mean gonads weight at 120 mg/kg bw per day was observed.

A 120-day oral toxicity study was conducted in dogs with dimethyl polysiloxane (91%) and 'siloxanes and silicones, di-Me, hydroxy-terminated 2.9% in MS antifoam M' (See Appendix F for information on the test material) (University of Birmingham, 1968 (Documentation provided to EFSA No 38)). Dogs (four animals/sex per group) received 300 mg/kg bw per day for 120 days followed by 5 days of recovery period. Body weight was recorded weekly. At termination, blood and urine samples were collected for haematology and clinical chemistry and urinalysis, and major organs were collected, weighed and examined for histopathological changes. A non-statistically significant decrease in body weight has been observed in the treated animals in the first 3 weeks of treatment followed by a recovery in the following weeks. No changes in haematological parameter were observed. No significant findings were noted at macroscopic and microscopic examination except for one dog in which a healed gastric ulcer was observed.

Overall, dimethyl polysiloxane with different viscosities have been administered in the diet in mice (28 and 90 days) and in rats in three 28-day studies and in five 90-day studies, whit most of the studies performed with GLP standards. Most of the studies in both mice and rats showed anal leakage and matting in the urogenital area, and an increase in food consumption. Corneal opacities and other effects on cornea such as inflammation and vascularisation have been observed in some rat studies at doses ranging from 900 to 12,000 mg/kg bw per days. These effects were suggested by the authors to be caused by direct contact with the test substance in the feed, or with the test substance and/or a metabolite excreted in the faeces. The Panel agrees with the suggestion of the authors. In some studies, corneal effects were also observed in the control. This was most likely due to contamination from cages with exposed animals. The Panel noted that in old studies in rabbits and dogs described above, no corneal effects were observed.

### 3.5.4. Genotoxicity

Available genotoxicity studies including those mentioned in a report of the Cosmetic Ingredient Review (CIR) Expert Panel (CIR, 2003) and for which the unpublished study reports were available to the Panel are summarised in Appendix G.

Dimethyl polysiloxane (as well as some structurally related substances) did not induce gene mutations in several bacterial reverse mutation tests in the presence and absence of metabolic activation when tested at concentrations up to 10,000 μg/plate. 'Dimethyl silicones and siloxanes' (a mixture that contains a substance with the CAS No 63148-62-9) did not induce mutations in CHO cells in an *in vitro* mammalian cell gene mutation test using the Hprt gene nor did it induce chromosomal aberrations in CHO cells *in vitro* when tested in the presence and absence of metabolic activation at concentrations up to 10,000 μg/mL, respectively. There is, however, some uncertainty about the actual concentrations of 'dimethyl silicones and siloxanes' in the cell cultures of these assays because it was stated in some study reports that, due to the low solubility of 'dimethyl silicones and siloxanes', an extract was prepared (with cell culture medium in some studies or ethanol in other studies), but the concentrations of 'dimethyl silicones and siloxanes' in these extracts were not reported. In the study report of one *in vitro* mammalian cell gene mutation test, it was stated that ethanol was used as solvent; however, in the light of the information given in other study reports, the actual concentration of 'dimethyl silicones and siloxanes' seems to be uncertain also in this study.

In two *in vivo* micronucleus assays, 'dimethyl silicones and siloxanes' did not induce increased frequencies of micronuclei in peripheral blood of mice after single i.p. administration. Whereas the relevance of one study result is low because the concentration of 'dimethyl silicones and siloxanes' in the extract used for dosing of animals was not reported, the result of the other study can be considered relevant because the concentrations of 'cyclics' and 'linears' of 'Dimethyl silicones and siloxanes' in the ethanol extract used for dosing of animals were analysed by gas chromatography and the doses expressed as 'cyclics' and 'linears' were calculated.

In addition, a dominant lethal assay has been performed in mice (strain, number of animals/group, age and body weight were not specified). 'DC 700 vapour booster pump fluid' (viscosity of $7^{18}$ centistokes (See Appendix F for information on the test material)) was given as a single intraperitoneal injection at 5,000 or 10,000 mg/kg bw. No mutagenic potential of the test compound was reported (Kennedy et al., 1976). The Panel noted that the study was conducted before OECD TG 478 was established and that it was only poorly reported.

No alerts for genotoxicity have been identified using the OECD QSAR toolbox, using as input in one case the chemical structure of the monomer and in a second case the CAS No 63148-62-9 of the polymer.

Overall, based on the available information, the Panel concluded that there is no concern with respect to genotoxicity of dimethyl polysiloxane (E 900).

### 3.5.5. Chronic toxicity and carcinogenicity

**Mice**

Mice (of an outbred strain form the Laboratory Animals Centre Carshalton Surrey, 40–50/sex per group) were given a 'silicone antifoam agent' (containing 94% dimethyl polysiloxane silicone oil and 6% finely divided silicon dioxide, according to the authors the polymers in the silicone oil resembled those of 'DC Antifoam A' except that the low molecular weight compounds had been excluded in the oil) in the diet at levels of 0, 0.25 and 2.5 % (equal to 580 and 5,800 mg dimethyl polysiloxane silicone/kg) for 76 weeks (Cutler et al., 1974). Surviving animals were sacrificed at week 80 and a microscopical examination was performed on all tissues. Five animals of each sex from the 2.5% group were at week 75 transferred to the control diet for 8 days before they were sacrificed after which the whole body was analysed for silicone content. Silicone was not detected in the bodies of the high-dose mice. The incidence of superficial ulcers of the stomach was statistically increased in males of the mid-dose group, but not in males of the high-dose group. The incidence of simple cysts in the ovaries was high in the mid-dose group females, but not in the high-dose group. Other non-neoplastic histopathological changes were scattered among the groups or occurred at a low incidence in one group. The authors considered the non-neoplastic histopathological lesions unrelated to treatment. The Panel agreed with this conclusion. There was no increase in the incidence of malignant or benign tumours in the group receiving dimethyl polysiloxane oil in their diet.

### Rats

In a 1-year study, albino FDRL rats (10 animals/sex in the control group and 5 animals/sex per treatment group,) were given 0 or 1 % in the diet of either 'DC 360 fluid' (equivalent to 500 mg/kg bw per day of dimethyl polysiloxan) (viscosity of 50[18] or 350 centistokes (See Appendix F for information on the test material)) or 'DC Antifoam A' (equivalent to about 290 mg/kg bw per day of dimethyl polysiloxane) (Carson et al., 1966). Body weight and food consumption were recorded weekly. After 3, 6 and 12 months, haematological and urinary examinations were performed. At termination, major organs were collected, weighed and examined for histopathological changes. Males of the Antifoam A group showed significantly ($p < 0.05$) greater growth as compared to control animals. No other significant differences were reported.

In a 2-year study Wistar rats (25 animals/sex per group) were given 0 or 0.3% 'DC Antifoam A' (See Appendix F for information on the test material) in the diet (equivalent to 139 mg/kg bw per day of dimethyl polysiloxane and assuming that the content of dimethyl polysiloxane in 'DC Antifoam A' is about 93%) (Rowe et al., 1950). Haematological examinations were performed periodically in a group of 10 female rats (treated and control) during the course of the study. At termination, blood samples were collected for haematology and clinical chemistry, and major organs were collected, weighed and examined for histopathological changes. The average final body weight of treated male rats was increased compared to that of the controls. No other effects were reported.

A combined 24 months chronic oral toxicity and carcinogenicity study in compliance with GLP and in accordance with OECD Guideline 453 at that time was conducted in rats (WIL-Research-Laboratories-Inc., 2003 (Documentation provided to EFSA No 43)). Fischer 344 (90 animals/sex per group) were given 0, 100, 300 and 1,000 mg/kg bw per day 'DC 200 fluid' (viscosity of 10 centistokes[18] (See Appendix F for information on the test material)) in the diet for 12 and 24 months. Clinical signs consisted of slightly increased incidences of wet or dried yellow material on various body parts (primarily the urogenital and anogenital areas) in males at all dose levels in females at the two highest dose levels. The incidence of corneal opacities was slightly increased in high-dose males and in females at the two highest dose levels and was generally noted during the first year of the study and throughout the second year for both the carcinogenicity and chronic recovery groups. At the microscopic examination a higher, statistically significant ($p < 0.05$ or $p < 0.01$) incidence of minimal to mild keratitis (characterised by small numbers of inflammatory cells, usually mononuclear cells admixed with fewer numbers of neutrophils) within the corneal stroma was observed at all dose levels in the carcinogenicity group. A higher incidence of bilateral keratitis was also observed at all dose levels in the carcinogenicity group in comparison to the control group in which the lesion usually was unilateral. Keratitis was observed at similar incidences and severities in treated and control females in the chronic recovery groups and at slightly higher incidences in the treated males in the chronic recovery group. The study report authors suggested the corneal effects most likely to be the results of local irritation and the matting of the fur to be most likely related to the test substance passing through the gastrointestinal tract. Inflammation of the nasolacrimal duct in nasal level III (very close to the ostium in the conjunctiva) was observed in some animals from all groups, but with a slightly higher incidence ($p < 0.05$) and severity in the male high-dose carcinogenicity group. The authors of the study report considered the increased inflammation of the nasolacrimal duct at the nasal level III to be secondary to the draining of the test substance from the eye into the duct and there causing local irritation. No other significant non-neoplastic findings were noted. Regarding neoplastic changes, a statistically significant increase ($p < 0.05$) in the incidence of pancreatic islet cell adenomas was observed in the male high-dose carcinogenicity group. Islet cell adenomas are common age-related lesions found in rats, mice, dogs, ferrets and cattle (Rosol et al., 2013). The incidences may vary among studies and can reach 15–25% as seen in the male controls and high-dose males of the chronic recovery group of the present study, respectively. Moreover, as indicated by the authors of the study, the incidences of the islet cell adenomas in the male groups of the present study were within the historical control ranges for Fischer 344 rats in the NTP historical database.

Therefore, the Panel agreed with the authors that the increased incidence of islet cell adenomas in males of the 1,000 mg/kg per day group was not related to treatment with the test article. No other significant neoplastic findings were noted.

In a 26-month carcinogenicity study performed in compliance with GLP and accordance with the 'Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives' of the Japanese Ministry of Health and Welfare (Kawabe et al., 2005), Fischer 344 rats (50 animals/sex per group) were given 'KS66' (See Appendix F for information on the test material; viscosity of

approximately 310 centistokes, test material contains 8% of silica) in the diet at 0, 1.25 and 5% (equal to 0, 530/445 and 2,234/1,894 mg/kg bw per day in males/females, respectively) for 104 weeks. Animals were examined twice daily for general health and signs of toxicity. At termination, blood samples were collected for haematology, and major organs were collected, weighed and examined for gross pathological and histopathological changes, including eyes. No treatment-related changes were reported for clinical signs, survival rates, food consumption and haematology data. There was a significant increase in final body weights in females at both doses along with significant decreases in relative organ weights in kidney, brain and heart and at the lower dose for relative liver and adrenal weights. A decrease in relative liver weight was also observed in the high-dose males. The Panel considered the decreases of relative organ weights to be of no toxicological concern. No toxicologically relevant treatment-related effects or increased incidences of any non-neoplastic or neoplastic lesions were reported. The Panel identified the highest dose tested, 1,894 and 2,234 mg/kg bw per day for females and males, respectively, as NOAELs. Considering that the test material contained 92% of dimethyl polysiloxane, these NOAELs correspond to 1,742 and 2,055 mg dimethyl polysiloxane/kg bw per day.

Oral administration of dimethyl polysiloxane in the diet to rats for up to 2 years resulted in matting of the fur (predominantly in the urogenital and/or anogenital areas), corneal effects/lesions inflammation of the nasolacrimal duct (WIL-Research-Laboratories-Inc., 2003) (Documentation provided to EFSA No 43), whereas no treatment-related effects were reported in another 2-year dietary study in rats (Kawabe et al., 2005) or in older studies performed in rats (Carson et al., 1966), (Rowe et al., 1950), and in mice (Cutler et al., 1974).

Overall, the Panel considered that dimethyl polysiloxane was not carcinogenic and did not cause any systemic toxicity. The matting of the fur, corneal effects and inflammation of the nasolacrimal duct was considered to be caused by direct contact with the test substance in the feed or with the test substance excreted in the faeces.

### 3.5.6. Reproductive and developmental toxicity

**Reproductive toxicity studies**

A three-generation toxicity study was performed in Weanling rats (30 females and 10 males per group; strain, body weight not specified) (Frazer, 1959 (Documentation provided to EFSA No. 29)). Rats received 0, 0.01 or 0.1% 'DC Antifoam A' ((See Appendix F for information on the test material)) in the diet (equivalent to 0, 4.5 or 45 mg/kg bw per day of dimethyl polysiloxane). After 16 weeks, the animals were mated (one male caged together with three females for 21 days). Ten males and 30 females were chosen randomly from the offspring in each group (generation I), fed the same diet as their parents (generation 0), and mated after 15 weeks. Ten males and 30 females were chosen randomly from the offspring in each group (generation I), were mated (as for generation 0) and 30 female and 10 male offspring were randomly selected (generation II). In generation 0, the body weights were recorded weekly until study week 15; in generation I and II, body weights were recorded weekly until the animals were 15 and 13 weeks old, respectively. The reproductive performance was evaluated by considering a male as sterile if none of the females in the case produced a litter and a female as sterile if no litter was produced after being caged with a fertile male for 21 days. The number of litters born in each group and the number of pups in each litter was recorded and litters containing more than eight pups were culled to that number; litters with a lower number of pups were left unchanged. The survival rate at post-natal day 21 was also recorded. Haematological examinations (total erythrocyte, lymphocyte, monocyte and granulocyte counts, and haemoglobin) were performed after 25 weeks in generation I and after 20 weeks in generation II (five animals of each sex from each group). Surviving animals were sacrificed after 2 years (generation 0), 28 weeks (generation I) and 23 weeks (generation II) and 3 females from each group of each generation were chosen randomly for histological examination of main organs (no details). Organ weights (heart, spleen, liver, kidneys, stomach, intestine, caecum, adrenals, ovaries and uterus) were recorded for 10 females of each group in generation I and II, and testes weight were recorded for males. Significant differences in body weight between control and treated groups were noted in generation I and II without a consistent trend to decreased or increased weight between particular groups; the study report authors concluded that the observed changes were not of toxicological significance. Regarding reproductive performance, the survival rate of the generation 0 offspring was slightly higher in the high dose group as compared to controls, but lower ($p < 0.01$) in the generation I offspring; the study report authors considered these findings to be of doubtful significance in the

absence of other signs of toxicity. No other significant differences were reported. The Panel noted that the reporting of the study was limited and the highest dose only 45 mg dimethyl polysiloxane/kg bw per day.

**Developmental studies**

**Rats**

In a prenatal developmental toxicity study, pregnant Wistar rat was daily exposed by gavage to 0, 380, 1,200 or 3,800 mg DC Antifoam A/kg bw per day (See Appendix F for information on the test material) from gestation day (GD) 6 to 15 for 10 consecutive days (Atlas Chemical Industries, 1970 (Documentation provided to EFSA No. 3)). The authors noted that of the 240 females that were caged to male rats only approximately 40% was mated. From these mated females, 25 per group were assigned to the dose groups. In addition, in all those groups, only 67 females were pregnant at term, altogether. The number of pregnant females at term was 13, 19, 18 or 17 for the control, low-, mid- or high-dose group. On GD 20, a Caesarian section was performed. The number of corpora lutea, implantation sites, early and late resorptions, live and dead fetuses and fetal weight were recorded. One-third of the fetuses were used for visceral screening and the remaining two-third for skeletal examination. The number of mated rats (sperm positive or vaginal plug) 24 in the control and 25 in the group dosed with DC Antifoam A. No treatment-related developmental effects were observed. This study cannot be used for hazard assessment due to the aberrant fertility conditions of the animals and the low number of pregnant females at Caesarian section.

In a prenatal developmental toxicity study, female rats (strain, number of animals/group, age and body weight not specified) were given 'DC 700 vapour booster pump fluid' (viscosity of $7^{18}$ centistokes (See Appendix F for information on the test material))) by oral gavage at 0, 300 or 1,000 mg/kg bw per day during GDs 6–15 (Kennedy et al., 1976). On 20 the females were sacrificed, fetuses were taken by Caesarean section and uterus and ovaries were examined. The number of implantation sites, and live and dead pups were counted, approximately one-third of the pups were examined grossly, and the remaining pups were examined for skeletal abnormalities. No adverse effects were reported. The reporting of the study was very limited.

**Rabbits**

In a prenatal developmental toxicity study, time-mated New Zealand white rabbits (n = 20–22 per group) were fed 0, 0.5, 1.0 or 2.5% DC Antifoam A in the diet (equivalent to 0, 152, 303 or 756 mg DC Antifoam A/kg bw per day) from GD 6 through the morning of GD 19 (Siddiqui et al. 1994; only abstract available). No clinical signs, differences in body or liver weight were observed in the does. The number of resorptions, and fetal weight were not affected. No treatment-related effects were observed at fetal external, visceral or skeletal examination. The author concluded that not treatment-related developmental effects were observed. The Panel noted that as only an abstract was available, this study cannot be used for hazard assessment.

Overall, dimethyl polysiloxane was tested in a dietary three-generation toxicity study in rats (Frazer, 1959 (Documentation provided to EFSA No 29)). The Panel noted that the highest dose tested was only 45 mg dimethyl polysiloxane/kg bw per day. No adverse effects were reported in a prenatal developmental toxicity study in rats up to 1,000 mg/kg bw per day (Kennedy et al., 1976). Furthermore, in a prenatal developmental study in rats, no treatment-related developmental effects up to doses of 3,800 mg DC Antifoam A/kg bw per day by gavage were observed. Developmental effects of DC Antifoam A in the diet up to 2% (equivalent to 756 mg/kg bw per day) was also studied in New Zealand White rabbits and no treatment-related effects were observed. None of the studies could be used for hazard assessment due to the different limitations mentioned above.

### 3.5.7. Other studies and case reports

**Effects on eyes**

*Humans*

In humans, dimethyl polysiloxane fluids of various viscosities (also called silicone oils) are used as an intraocular tamponade during retinal detachment repairs. Retinal and corneal lesions (keratopathy and degeneration of the corneal endothelium) have been reported as a complication of their use.

An examination by light microscopy of corneal tissue from two patients with corneal complications after intraocular injection of silicone oil showed increased cellularity and irregularity of stromal collagen

fibres, endothelial cell degeneration and loss of endothelial cells. This was accompanied by flattening and thinning of the remaining cells and attenuation of cell borders as determined by electron microscopy (Choi et al., 1993).

Ten patients who developed corneal complications (requiring keratoplasty) after silicone oil-induced keratopathy showed, in some cases, corneal oedema, corneal hypaesthesia, endothelial opacification, band keratopathy and peripheral corneal vascularisation. Histologically, retrocorneal membranes and different degrees of stromal hypercellularity, superficial stroma calcification and vascularisation were noted in these patients (Foulks et al., 1991).

The eight cases of oculopathy found in the Eudravigilance database were reported by the pharmaceutical company responsible for the products which were named in conjunction with the observed adverse event.

Eight cases of keratopathy were reported taken from a publication. In all the cases, silicone oil was applied locally and a retained in the eye. In the cases, silicone oil-induced keratopathy has been developed. From these reports in which silicone oil was causing the keratopathy it can be deduced that the effect was clearly due to the local application and not due to systematic exposure.

*Animals*

Injection of dimethyl polysiloxane (identity not specified) in the anterior chamber of the eyes of rabbits (14 animals) and cats (7 animals) induced a 40% reduction in retinal endothelial cell density in the location of the silicone oil bubble. In rabbits, progressive corneal stromal thinning, with gradual development of a retrocorneal membrane at the junction of endothelial contact with the silicone oil, was observed. In cats, persistent stromal oedema, peripheral vascularisation, irregular plaques on the endothelium, epithelial ulceration and corneal thinning occurred (Sternberg et al., 1985).

A second study in adult albino rabbits in which silicone oil (identity not specified) was injected into the eyes following vitrectomy showed damage to the corneal endothelial layer, ranging from loose intercellular connections to severe damage of the plasma membranes in degenerating the cells (Versura et al., 2001).

In a study with anaesthetised pigmented rabbits, 0.7–1.0 mL of oxygenated generic dimethyl polysiloxane (viscosity of 500, 1,000 and 12,500 centistokes) or medical-grade dimethyl polysiloxane 360 (viscosity of 1,000 centistokes (See Appendix F for information on the test material)) was placed in an eye cup (formed by the lids and hanging sutures) for 3–6 h. The untreated eye served as control. Light microscopic examination of the eyes immediately after treatment showed intracellular oedema of the epithelium and some vacuolisation of the superficial cells. Increased epithelial and whole corneal thickness was subsequently observed which persisted for several days in most cases. A marked irregularity in the thickness of the epithelium and cornea was observed in most treated eyes by 3 days. At 3–7 days after treatment, the most common findings were irregular thickening of the epithelium and a general disorganisation of the normal epithelial architecture. Transmission electron microscopic examination at 5 days showed mild intracellular epithelial oedema, particularly in the basal cell layers and in the middle layers of the cornea in rabbits exposed to medical-grade dimethyl polysiloxane. The generic dimethyl polysiloxane of the lowest viscosities caused a more intense reaction (Refojo et al., 1985).

In an eye irritation study in New Zealand White rabbits (three males/group), 0.1 mL of 'DC 200 fluid (viscosity of 2,[18] 100, 500, 1,000 or 12,500 centistokes (See Appendix F for information on the test material)) was instilled in the conjunctival sac of the right eye. The untreated left eye served as control. Observations were made at 1, 6, 24, 48 and 72 h following treatment. All fluids caused mild transitory conjunctival redness (grade 1) with higher viscosity grades giving more persistent redness (up to 2 days after instillation). No effects on the cornea or iris were observed (Dow-Corning-Corporation-Health-And-Environmental-Sciences-Toxicology-Department, 1982 (Documentation provided to EFSA No. 10)).

The Panel considered that dimethyl polysiloxane may damage the cornea in humans and animals following intra-ocular treatment but noted that this is not relevant for its use as a food additive.

**Other human data**

*Clinical studies*

Several short-term studies (ranging from a single oral dose to up to four consecutive oral doses) were performed to determine the suitability of dimethyl polysiloxane (dimethicone) as an agent to reduce gastrointestinal gas and improve the quality of ultrasound investigations of the abdomen. The studies recruited 20 patients (Gladisch et al., 1985) and 28 patients (Sommer et al. 1977). Jacyna et al. (1984) also tested dimethyl polysiloxane when combined with antacids in 60 subjects. In an

8-week study, Smart and Atkinson (1990) compared the efficacy of a dimethicon/antacid containing preparation (n = 28) vs. an alginate/antacid containing preparation (n = 25) in patients with reflux oesophagitis.

None of the studies indicated any adverse effects from the administration of dimethyl polysiloxane or any of the dimethyl polysiloxane-containing preparations.

*Spontaneous reporting of adverse reactions*

From the Eudravigilance database,[21] 153 cases reports were identified using the search term "dimethicone"; most of them reporting on non-serious effects.

However, cases of mesothelioma or others with lung malignancies were identified and were considered by the Panel as serious[22]:

*Mesothelioma*

The Eudravigilance database contained 30 cases of mesothelioma. When assessing the available information, in all cases it is said that they are observed after using Gold Bond which is a series of skin care products containing dimethyl polysiloxane as indicated by the reporting pharmaceutical company responsible for the products. The skin care products are available on the market as body powder and body powder spray among other application forms. It is further said that 22 of the patients suffered from an asbestos-induced disease or had asbestos exposure in their history.

From these reports, it can be deduced that mesothelioma was observed in patients who were mostly exposed to asbestos in their history, besides eight patients. All patients had used a skin care product available on the market as body powder and body powder spray and were exposed by the inhalation route or transdermal route and not by the oral route. Hence, the observed events are not relevant for the assessment of dimethyl polysiloxane as a food additive.

*Lung cancer*

The Eudravigilance database contained 26 cases of lung cancer. When assessing the available information, in all cases it is said that they are observed after using Gold Bond which is a series of skin care products containing dimethyl polysiloxane as indicated by the reporting pharmaceutical company responsible for the products. The skin care products are available on the market as body powder and body powder spray among other application forms. It is further said that 24 of the patients suffered from an asbestos-induced disease or had asbestos exposure in their history.

From these reports, it can be deduced that the lung cancer was observed in patients who were exposed to asbestos in their history, besides two patients. All patients had used a skin care product available on the market as body powder and body powder spray and were exposed by the inhalation route or transdermal route and not by the oral route. Hence, the observed events are not relevant for the assessment of dimethyl polysiloxane as a food additive.

Overall, the Panel considered that the reported cases of mesothelioma or other lung cancers were most likely almost exclusively associated with a pre-existing asbestos-induced disease and/or a history of asbestos exposure. These cases were also associated with the use of a body powder and/or body powder spray containing multiple components, in addition to dimethyl polysiloxane, via routes of exposure (inhalation/transdermal) not relevant to dimethyl polysiloxane use as a food additive.

## 3.6. Discussion

Specifications for dimethyl polysiloxane (E 900) are defined in the Commission Regulation (EU) No 231/2012. Having evaluated information submitted by interested parties on dimethyl polysiloxane and its manufacturing process, the Panel would recommend that specifications should be updated in order to better describe the material used as a food additive and ensure its safety of use:

- Include the range of the weight average molecular weight (Mw) and number average molecular weight (Mn) for dimethyl polysiloxane used as a food additive E 900.
- Include a maximum limit for cyclopolysiloxanes.

[21] The pharmacovigilance database of the European Medicines Agency (EMA).

[22] A serious adverse event is any event that is fatal or life-threatening permanently/significantly disabling (impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life) requires or prolongs hospitalisation causes a congenital anomaly requires intervention to prevent permanent impairment or damage. Available online: https://apps.who.int/medicinedocs/en/d/Jh2992e/2.html

- Include a maximum limit for copper since copper-based catalysts are used in the manufacturing process.
- Setting lower limits for toxic elements (arsenic, lead, mercury).
- Revising the name of the substance to 'poly(dimethylsiloxane).'

The Panel noted that the test materials in some toxicological studies were preparations of dimethyl polysiloxane containing silica. The Panel was of opinion that, provided that the test item was considered relevant, this presence of silica in the test material did not affect the outcome of these toxicological studies.

Dimethyl polysiloxane (various compositions and different viscosities – 10, 350 and 1,000 centistokes) was only absorbed to a very limited extent from the gastrointestinal tract following oral administration to mice, rats, monkeys and humans. The vast majority (more than 99.9%) of the orally administered dimethyl polysiloxane was excreted unchanged in the faeces.

The acute toxicity of dimethyl polysiloxane is low. There is no concern with respect to genotoxicity of dimethyl polysiloxane (E 900).

In short-term and subchronic toxicity studies in mice, rats and dogs, anal leakage and matting in the urogenital area were reported. Corneal opacities and other effects on cornea such as inflammation and vascularisation have been observed in some rat studies at doses ranging from 900 to 100,000 mg/kg bw per day. Similarly, in chronic toxicity and carcinogenicity studies in mice and rats matting of the fur (predominantly in the urogenital and/or anogenital areas) along with effects on the cornea and inflammation of the nasolacrimal duct were observed.

The Panel agrees with the suggestion of the authors that these effects were caused by direct contact with the test substance in the feed, or with the test substance in the faeces and not due to systemic exposure. A local effect is supported by the following:

- The vast majority of dimethyl polysiloxane is not absorbed and thus excreted via faeces, consequently contaminating beddings and cages.
- Additional contamination of beddings and cages would occur from feed spillage.
- Dimethyl polysiloxane is a surfactant and has ocular irritating effects. It is expected that due to this local irritative effect the rats would have scratched their eyes.
- The cornea is not directly vascularised and, therefore, it is not expected to be a target through systemic exposure.
- Dimethyl polysiloxane has been demonstrated to damage the cornea in humans and rabbits following intra-ocular treatment only.

Overall, the Panel considered that oral exposure of dimethyl polysiloxane did not result in any systemic adverse effects in any species and dose tested. From a 26-month toxicity study in rats (Kawabe et al., 2005), an NOAEL of 1,742 and 2,055 mg dimethyl polysiloxane/kg bw per day for females and males, respectively, was identified. The Panel noted that the test item was reported not to be used as a food additive in the EU (Appendix F), nevertheless, the Panel considered it relevant for the risk assessment of the food additive E 900 because the viscosity complied with the one indicated in the EU specifications.

The NOAEL identified from the study of Kawabe et al. (2005) is supported by the combined 24 months chronic oral toxicity and carcinogenicity study in rats (WIL-Research-Laboratories-Inc., 2003 (Documentation provided to EFSA No 43)) in which no adverse effects were seen even at the highest dose tested of 1,000 mg/kg bw per day. The latter study used a low viscosity test item of 10 centistokes, which is outside the viscosity range given in the EU specifications for E 900. Since the low viscosity implies a low molecular weight distribution, compared to E 900, the test item at 10 centistokes can be considered to be a worse case regarding the extent of the absorption.

The Panel considered that the NOAEL of 1,742 mg/kg body weight per day could be used to derive an ADI for dimethyl polysiloxane (E 900). Using an uncertainty factor of 100, the Panel derived an ADI of 17 mg/kg bw per day for dimethyl polysiloxane (E 900).

Dietary exposure to dimethyl polysiloxane (E 900) from its use as a food additive according to Annex II of Regulation 1333/2008 was calculated according to different exposure scenarios based on MPLs and reported use levels, as described in Section 3.4. Two food categories that may contain dimethyl polysiloxane (E 900) according to Annex III of Regulation (EC) No 1333/2008 were also considered in these exposure scenarios.

The exposure estimates in the *regulatory maximum level exposure assessment scenario* reached at the mean 0.23 mg/kg bw per day and 0.51 mg/kg bw per day at the 95th percentile, both for toddlers

(Table 4). The Panel noted that the estimated long-term exposures based on this scenario are very likely conservative, as this scenario assumes that all foods and beverages listed under the Annex II of Regulation (EC) No 1333/2008 contain dimethyl polysiloxane (E 900) as a food additive at the MPL.

Considering that dimethyl polysiloxane (E 900) is authorised in flavoured drinks and changes the organoleptic properties of these drinks, the Panel selected the brand-loyal refined exposure assessment scenario as the most relevant scenario for risk characterisation. In this scenario, mean exposure to dimethyl polysiloxane (E 900) from its use as a food additive ranged from 0.01 mg/kg bw per day in adults and the elderly to 0.16 mg/kg bw per day in children. The 95$^{th}$ percentile of exposure to dimethyl polysiloxane (E 900) ranged from 0.02 mg/kg bw per day in the elderly to 0.49 mg/kg bw per day in toddlers.

The Panel considered also the exposure estimates in the refined scenarios as overestimates of the exposure to dimethyl polysiloxane (E 900) from its use as a food additive according to Annex II of Regulation 1333/2008. This was mainly due to the assumption that all foods belonging to the food categories included in these scenarios contained dimethyl polysiloxane (E 900) at the reported use levels.

The Panel also noted that the refined exposure estimates are based on information provided on the reported use levels of dimethyl polysiloxane (E 900). If actual practice changes, these refined estimates may no longer be representative and should be updated.

## 4. Conclusions

Taking into account the toxicological data available, the Panel established an ADI of 17 mg/kg bw per day for dimethyl polysiloxane (E 900) based on the NOAEL of 1,742 mg/kg bw per day, the highest dose tested, and by applying an uncertainty factor of 100. Accordingly, the ADI for dimethyl polysiloxane (E 900) of 1.5 mg/kg bw per day, established by the SCF in 1990, is withdrawn.

The exposure estimates for the different population groups of all exposure scenarios did not exceed the ADI of 17 mg/kg bw per day for dimethyl polysiloxane (E 900). The Panel concluded that there is no safety concern at the reported uses and use levels for dimethyl polysiloxane (E 900).

## 5. Recommendations

The Panel recommended that the European Commission considers:

- Setting lower limits for toxic elements (arsenic, lead and mercury) in the EU specifications for dimethyl polysiloxane (E 900) in order to ensure the food additive will not be a significant source of exposure to those toxic elements in food.
- Including the range of the weight average molecular weight (Mw) and number average molecular weight (Mn) in the EU specifications for dimethyl polysiloxane (E 900).
- Including a maximum limit for cyclopolysiloxanes in the EU specifications for dimethyl polysiloxane (E 900).
- Including a maximum limit for copper in the EU specifications for dimethyl polysiloxane (E 900)
- Revising the name of the substance to 'poly(dimethylsiloxane)'.

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## Abbreviations

| | |
|---|---|
| ADI | acceptable daily intake |
| ANS | EFSA Panel on Food Additives and Nutrient Sources added to Food |
| bw | body weight |
| CAS | Chemical Abstracts Service |
| CONTAM | EFSA Panel on Contaminants |
| ECHA | European Chemical Agency |
| FAF | EFSA Panel on Food Additives and Flavourings |
| FC | food category |
| FCS | food categorisation system |
| FDE | Food Drink Europe |
| GNPD | Global New Products Database |
| GD | gestation day |
| JECFA | Joint FAO/WHO Expert Committee on Food Additives |
| LOD | limit of detection |
| MPL | maximum permitted level |
| Mn | number average molecular weight |
| Mw | weight average molecular weight |
| NOAEL | no observed adverse effect level |
| OECD | Organisation for Economic Co-operation and Development |
| QS | *quantum satis* |
| SCF | Scientific Committee on Food |
| TemaNord | is a publishing series for results of the often research-based work that working groups or projects under Nordic Council of Ministers have put in motion |
| TPC | total polar compounds content |
| WHO | World Health Organization |

## Appendix A – Summary of reported use levels (mg/kg or mg/L as appropriate) of dimethyl polysiloxane (E 900) provided by industry

## Appendix B – Number and percentage of food products labelled with dimethyl polysiloxane (E 900) out of the total number of food products present in the Mintel GNPD per food subcategory between 2014 and 2019

## Appendix C – Concentration levels of dimethyl polysiloxane (E 900) used in the exposure assessment scenarios (mg/kg or mL/kg as appropriate)

## Appendix D – Summary of total estimated exposure of dimethyl polysiloxane (E 900) from its use as a food additive for the regulatory maximum level exposure assessment scenario and the refined exposure assessment scenarios per population group and survey: mean and 95th percentile (mg/kg bw per day)

## Appendix E – Main food categories contributing to exposure to dimethyl polysiloxane (E 900) using the regulatory maximum level exposure assessment scenario and the refined exposure assessment scenarios (> 5% to the total mean exposure)

Appendixes A–E can be found in the online version of this output ('Supporting information' section).

# Appendix F – Characterisation of different dimethyl polysiloxane fluids used in the toxicological studies

**Table F.1:** Information on the characterisation of different dimethyl polysiloxane fluids used in the toxicological studies (Documentation provided to EFSA No 6 and 7)

| Reference | Test material (brand name) | Percentage of dimethyl polysiloxane | Viscosity (centistokes) | Is it used as a food additive? |
|---|---|---|---|---|
| Dow-Corning-Corporation-Research-Department, 1974 (Documentation provided to EFSA No 8) | DC Antifoam A[(a)] (fluid containing dispersed silica) | 93% | 1,500 | No |
| | DC Antifoam M[(b)] (fluid containing dispersed silica) | 91 | 1,000 | No |
| Lukasiak et al., 2001 | OM-300 | na | | na |
| Rowe et al., 1948 | DC 200 fluids | > 99% | 50 | No |
| | | > 99% | 350 | Yes |
| | DC Antifoam A | 93% | 1,500 | No |
| WIL-Research-Laboratories-Inc., 1995a; WIL-Research-Laboratories-Inc., 1995d (Documentation provided to EFSA No 39 and 42) | DC 200 fluid | > 99% | 10 | No |
| WIL-Research-Laboratories-Inc., 1995b; WIL-Research-Laboratories-Inc., 1995c. (Documentation provided to EFSA No 40 and 41) | DC 200 fluids | > 99% | 350 | Yes |
| Dow-Corning-Corporation-Toxicology-Department, 1989b (Documentation provided to EFSA No 15) | DC 6370 fluid | > 99% | 35 | No |
| | | Data not available | 350 | No |
| | | Data not available | 1,000 | No |
| MacDonald et al., 1960 | DC 200 fluid | > 99% | 50 | No |
| | | > 99% | 350 | Yes |
| | | > 99% | 1,000 | Yes |
| | | > 99% | 10,000 | No |
| | | > 99% | 60,000 | No |
| Carson et al., 1966 | DC 360 fluid | > 99% | 50 | No |
| | | > 99% | 350 | No |
| | DC Antifoam A | 93% | 1,500 | No |
| Child et al., 1951 | DC Antifoam A | 93% | 1,500 | No |
| Kennedy et al., 1976 | DC 700 vapour booster pump fluid | Data not available | 7 | No |
| Cutler et al., 1974 | Silicone antifoam agent (DC Antifoam A except that material of low MW has been excluded) | 93% | 1,500 | No |
| WIL-Research-Laboratories-Inc., 2003 (Documentation provided to EFSA No 43) | DC 200 fluid | > 99% | 10 | No |
| Rowe et al., 1950 | DC Antifoam A | 93% | 1,500 | No |
| Kawabe et al., 2005 | KS66[(d)] | 92% | 300 mPa s[(c)] | No[(e)] |
| Frazer, 1959. (Documentation provided to EFSA No 29) | DC Antifoam A | 93% | 1,500 | No |

| Reference | Test material (brand name) | Percentage of dimethyl polysiloxane | Viscosity (centistokes) | Is it used as a food additive? |
|---|---|---|---|---|
| Hobbs et al., 1972 | DC 200 fluid | >99% | 50 | No |
| | | >99% | 350 | Yes |
| Refojo et al., 1985 | Medical-grade dimethyl polysiloxane 360 | >99% | 1,000 | No |
| Dow-Corning-Corporation-Health-And-Environmental-Sciences-Toxicology-Department, 1982 (Documentation provided to EFSA No 10) | DC 200 fluid | 1 | 2 | No |
| | | > 99% | 100 | No |
| | | > 99% | 500 | No |
| | | > 99% | 1,000 | Yes |
| | | > 99% | 12,500 | No |
| Dow-Corning-Corporation, 1978 (Documentation provided to EFSA No 9) | Dimethyl silicones and siloxanes 'DC 200 fluid' CAS No 63148-62-9) | 99,96 | 100 | No |
| | | 99,9 | 1,000 | Yes |
| | Hexamethylldisiloxane 'DC 200 fluid' (CAS No 107-46-0) | 100% CAS 107 -46-0 | 0.65 | No |
| SRI International, 1980. (Documentation provided to EFSA No 36) | Dimethylpolysiloxane (CAS No 9006-65-9) | No data | No data | No |
| Hazleton France, 1988. (Documentation provided to EFSA No 30) | Dimethyl polysiloxane (CAS No 63148-62-9) 'as supplied or emulsion in tween 80; emulsions were performed in water using teen 80 at 10%)' | > 99.5% dimethyl polysiloxane, CAS 63148-62-9. It may contain up to 0.5% impurities which are cyclic siloxanes | approx. 350 $mm^2/s$ at 25°C | No |
| Dow-Corning-Corporation, 1989c (Documentation provided to EFSA No 16) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 0 | No data | No |
| Dow-Corning-Corporation, 1990a (Documentation provided to EFSA No 21) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 2.8 | No data | No |
| Dow-Corning-Corporation, 1990b (Documentation provided to EFSA No 22) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 100 | 350 | No |
| NTIS, 1988 (Documentation provided to EFSA No 33) | Dimethyl siloxanes and silicones (CAS No 63148-62-9) | No data | No data | No |
| Microbiological Associates, 1994 (Documentation provided to EFSA No 32) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | No data | No data | No |
| Dow Corning Corporation, 1989a (Documentation provided to EFSA No 14) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 79 | No data | No |
| Dow-Corning-Corporation, 1989g (Documentation provided to EFSA No 19) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 74 | No data | No |
| Dow Corning Corporation, 1986c (Documentation provided to EFSA No 13) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 79 | No data | No |
| Dow-Corning-Corporation, 1989e (Documentation provided to EFSA No 17) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 79 | No data | No |

| Reference | Test material (brand name) | Percentage of dimethyl polysiloxane | Viscosity (centistokes) | Is it used as a food additive? |
|---|---|---|---|---|
| Dow-Corning-Corporation, 1989f (Documentation provided to EFSA No 18) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 79 | No data | No |
| Dow Corning Corporation, 1989b (Documentation provided to EFSA No 15) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 79 | No data | No |
| Dow-Corning-Corporation, 1989h (Documentation provided to EFSA No 20) | Dimethyl silicones and siloxanes (CAS No 63148-62-9) | 79 | No data | No |
| Atlas Chemical Industries, 1969 (Documentation provided to EFSA No. 2) | Dimethyl silicones and siloxanes; 95% in DC medical antifoam 351 compound (CAS No 63148-62-9) | No data | 364 | No |
| University of Birmingham, 1968 (Documentation provided to EFSA No 38) | Dimethyl silicones and siloxanes 91% (CAS No 63148-62-9) | 91 | 3,000 | No |
| | Siloxanes and silicones, di-Me, hydroxy terminated 2.9% in antifoam M (CAS No 70131-67-8) | 2.9% CAS 70131-67-8 | 3,000 | No |
| Atlas Chemical Industries, 1969 (Documentation provided to EFSA No 3) | Dimethyl silicones and siloxanes 93% (CAS No 63148-62-9) | 83 | 1,500 | No |
| | Dimethyl silicones and siloxanes, reaction products with silica 7% in Dow Corning Antifoam A (CAS No 67762-90-7) | 7% CAS 67762-90-7 | 1,500 | No |

(a): DC Antifoam A is a mixture of 93% polydimethylsiloxane (CAS No 63148-62-9) and 7% silica treated with polydimethylsiloxane (CAS No 67762-90-7) (Documentation provided to EFSA No 6).
(b): DC Antifoam M is a mixture of 91% polydimethylsiloxane (CAS No 63148-62-9), 6% silica and 3% polydimethylsiloxane hydroxy-terminated (CAS No 70131-67-8) (Documentation provided to EFSA No 6).
(c): Considering a specific gravity of approximately 0.97, 300 millipascal per second correspond to approximately 310 centistokes.
(d): Test material contains 8% of silica.
(e): KS-66 is not used as a food additive in Europe; Kawabe et al. (2005) study may refer to the use in non-EU regions or to the use at the time (Documentation provided to EFSA No 6).

## Appendix G – Summary available genotoxicity studies

**Table G.1:** Summary of *in vitro* genotoxicity data for dimethyl polysiloxane

| Test system | Test material (See Appendix A for more details) | Test object | Concentration | Result | Reference | Comments |
|---|---|---|---|---|---|---|
| Reverse mutation (Ames test) | Dimethyl silicones and siloxanes 'DC 200 fluid' (100 and 1,000 cst CAS No 63148-62-9) | *S.* Typhimurium TA98, TA100, TA1535, TA1537, TA1538 ±S9 | 0.5, 5, 100, 500 μg/plate | Negative | Dow Corning corp, 1978. (Documentation provided to EFSA No 9) | Reliable with minor limitation. The study was mainly consistent with OECD TG 471 (1997) except that: No preliminary toxicity study was performed to select the maximum concentration to be tested. Only four concentrations were tested. The Panel considered this as only a minor deviation from the current version of the OECD TG 471 |
| | Heaxamethyldisiloxane 'DC 200 fluid' (0.65 cst CAS No 107-46-0) | | | | | |
| | Dimethylpolysiloxane (CAS No 9006-65-9) | *S.* Typhimurium TA98, TA100, TA1535, TA1537, TA1538 and E.Coli WP2 uvrA ±S9 | 33.3, 100, 333.3, 1000, 3333.3, 10000 μg/plate | Negative | SRI international, 1980. (Documentation provided to EFSA No 36) | Reliable with minor limitation. The study was mainly consistent with OECD TG 471 (1997) except that: the experiment was performed as plate incorporation assay only and that duplicate plates were used in two to three separate experiments. The Panel considered this as only a minor deviation from the current version of the OECD TG 471. However, the relevance of the study result for the evaluation of 'dimethyl silicones and siloxanes' is low because the fraction of 'dimethyl silicones and siloxanes' in the test material is not reported. Preliminary toxicity test was performed with strain TA100 at eight concentrations, between 3 and 10,000 μg/plate. No mutagenicity, bacterial toxicity or precipitation of the compound was observed |
| | Dimethyl polysiloxane (CAS No 63148-62-9) (as supplied or emulsion in tween 80; emulsions were performed in water using teen 80 at 10%) | *S.* Typhimurium TA98, TA100, TA1535. TA1537, TA1538 ±S9 | 1, 5, 10, 50, 100 μl/plate | Negative | Hazleton France, 1988. (Documentation provided to EFSA No 30) | Reliable with minor limitation. The study was mainly consistent with OECD TG 471 (1997) except that: the experiment was performed as plate incorporation assay only. The Panel considered this as only a minor deviation from the current version of the OECD TG 471. Study performed in compliance with GLP. Preliminary toxicity test was performed with TA98, -S9 (0.1, -0.5, 1, 5, 10, 50, 100 μl/plate). No bacterial toxicity was observed |

| Test system | Test material (See Appendix A for more details) | Test object | Concentration | Result | Reference | Comments |
|---|---|---|---|---|---|---|
| | Dow Corning compound containing < 0.1% 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) | *S.* Typhimurium TA98, TA100, TA1535, TA1537 and E.Coli WP2 uvrA ±S9 | 312.5, 625, 1250, 2500 and 5000 μg extract/ml | Negative | Dow Corning corp, 1989c. (Documentation provided to EFSA No 16) | Reliable with minor limitation. The study was mainly consistent with OECD TG 471 (1997) except that: No preliminary toxicity study was performed, and the experiment was performed as plate incorporation assay only. However, the relevance of the study result for the evaluation of 'dimethyl silicones and siloxanes' is low because an ethanol extract was tested that obviously contained only less than 0.1% of 'dimethyl silicones and siloxanes' |
| | Dow Corning compound (non-aqueous emulsion of polydimethylsiloxane in silicone glycol emulsified with hydrophobic silica) containing 2.8% 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) and 5% 'Dimethyl silicones and siloxane, reaction products with silica' (CAS No 67762-90-7) | *S.* Typhimurium TA98, TA100, TA1535, TA1537 and E.Coli WP2 uvrA ±S9 | 312.5, 625, 1250, 2500 and 5000 μg/ml | Negative | Dow Corning corp, 1990a. (Documentation provided to EFSA No 21) | Reliable with minor limitation. The study was mainly consistent with OECD TG 471 (1997) except that: No preliminary toxicity study was performed, and the experiment was performed as plate incorporation assay only. The Panel considered this as only a minor deviation from the current version of the OECD TG 471. However, the relevance of the study result for the evaluation of 'dimethyl silicones and siloxanes' is low because an emulsion was tested that obviously contained only less than 3% of 'dimethyl silicones and siloxanes' |
| | 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) (350 cst) | *S.* Typhimurium TA98, TA100, TA1535, TA1537 and E.Coli WP2 uvrA ±S9 | 312.5, 625, 1250, 2500 and 5000 μg/ml | Negative | Dow Corning corp, 1990b. (Documentation provided to EFSA No 22) | Reliable with minor limitation. The study was mainly consistent with OECD TG 471 (1997) except that: No preliminary toxicity study was performed, and the experiment was performed as plate incorporation assay only. The Panel considered this as only a minor deviation from the current version of the OECD TG 471 |

| Test system | Test material (See Appendix A for more details) | Test object | Concentration | Result | Reference | Comments |
|---|---|---|---|---|---|---|
| | Dimethyl silicones and siloxanes (CAS No 63148-62-9); purity 94%. It is a mixture that includes CAS No 63148-62-9 | *S.* Typhimurium TA98, TA100, TA1535, TA1537 ±S9 | 50, 158, 500, 1580 and 5000 μg/plate | Negative | NTIS, 1988. (Documentation provided to EFSA No 33) | Reliable with minor limitation. The procedures used complied with the OECD TG 471 (1983). Study performed in compliance with GLP. Preliminary toxicity test was performed with TA98 (up to 5000 μg per plate). No bacterial toxicity was observed. The study was mainly consistent with OECD TG 471 (1997) except that: Only four Salmonella strains were tested, and the experiment was performed as plate incorporation assay only. The Panel considered this as only a minor deviation from the current version of the OECD TG 471. However, the relevance of the study result for the evaluation of 'dimethyl silicones and siloxanes' is low because the fraction of 'dimethyl silicones and siloxanes' in the test material which is a mixture is not reported |
| | Dow Corning compound containing 3 wt.% 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) | *S.* Typhimurium TA98, TA100, TA1535, TA1537 and E.Coli WP2 uvrA (pKM101) and WP2 (pKM101) ±S9 | 100, 333, 1000, 3333, 5000 μg/ plate | Negative | Microbiologial ASSC INC, 1995. (Documentation provided to EFSA No 32) | Reliable with minor limitation. Study performed in compliance with GLP. Preliminary toxicity test was performed with TA100 and WP2 urvA, ±S9 (up to 5000 μg per plate). No bacterial toxicity was observed. The study was mainly consistent with OECD TG 471 (1997) except that: Only four Salmonella strains were tested, and the experiment was performed as preincubation (for 60 minutes) assay only. The Panel considered this as only a minor deviation from the current version of the OECD TG 471. However, the relevance of the study result for the evaluation of 'dimethyl silicones and siloxanes' is low because the test item contained only 3 wt. % of 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) |
| Forward mutation assay in CHO/HGPRT | 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) 79% in Dow Corning compound | CHO cells ±S9 | 31.3, 62.5, 125, 250, 500, 1000 μg extract/ml | Negative | Dow Corning corp, 1986b. (Documentation provided to EFSA No 12) | Reliable with limitation. The study was largely in compliance with OECD TG 476 (1984) applicable at the time when the study was performed, but the number of cells exposed was less than that recommended in the current version of OECD TG 476 (2016). |

| Test system | Test material (See Appendix A for more details) | Test object | Concentration | Result | Reference | Comments |
|---|---|---|---|---|---|---|
| | | | | | | However, the relevance of the study result is low because the actual concentrations of 'dimethyl silicones and siloxanes' were unclear.[(a)] Preliminary cytotoxicity study was performed (±S9) between 2 and 1000 μg/ml. No Toxicity was observed |
| | Dimethyl silicones and siloxanes (CAS No 63148-62-9) 79% in Dow Corning compound | CHO cells ±S9 | 312.5, 625, 1250, 2500, 5000 and 10000 μg/ml | Negative | Dow Corning corp, 1989 g (Documentation provided to EFSA No 19) | Reliable with limitation. The study was in compliance with OECD TG 476 (1984) applicable at the time when the study was performed, however, the number of cells exposed was less than that recommended in the current version of OECD TG 476 (2016). Ethanol was used as solvent. Preliminary cytotoxicity study was performed (±S9) between 19.5 and 10000 μg/ml. No Toxicity was observed |
| Chromosome aberration assay in CHO | Dimethyl silicones and siloxanes (CAS No 63148-62-9) 79% in Dow Corning compound | CHO cells ±S9 | 625, 1250, 2500, 5000 and 10000 μg/ml | Negative | Dow Corning corp, 1989f. (Documentation provided to EFSA No 18) | Reliable with limitation. The study was largely in compliance with OECD TG 473 (1983) applicable at the time when the study was performed, but the number of cells exposed (200 per concentration) and the treatment and sampling times (treatment for 6 h without S9, sampling after two additional hours in the presence of colcemid; treatment for 2 h with S9, sampling after 6 additional hours with colcemid present during the last 2 h) were not in compliance with the current version of OECD TG 476 (2016). However, the relevance of the study result is low because the actual concentrations of 'dimethyl silicones and siloxanes' were unclear[(b)] |

(a): The relevance of the study result is low because the actual concentrations of 'dimethyl silicones and siloxanes' were unclear based on what is stated in the study report: '*Since the material to be tested was a gel which was not soluble in any solvent compatible with the biological test system, an extraction procedure was used. Ten grams of the test material was extracted with 10 mL of absolute ethanol on a rotary shaker for 24 hours/37°C/150 rpm. The cultures (5 ml) were exposed to a wide range of extract concentrations.*' Thus, different concentrations of the extract in the cultures were tested for cytotoxicity and mutagenicity. However, the concentration of 'dimethyl silicones and siloxanes' in the extract was not reported.

(b): The relevance of the study result is low because the actual concentrations of 'dimethyl silicones and siloxanes' were unclear based on what is stated in the study report: '*Since the material to be tested was a gel which was not soluble in any solvent compatible with the biological test system, an extraction procedure was used. Ten grams of the test material was extracted with 10 mL of absolute ethanol on a rotary shaker for 24 hours/37°C/150 rpm. The cultures (5 ml) were exposed to a wide range of extract concentrations.*' Thus, different concentrations of the extract in the cultures were tested for cytotoxicity and mutagenicity. However, the concentration of 'dimethyl silicones and siloxanes' in the extract was not reported.

**Table G.2:** Summary of *in vivo* genotoxicity data for dimethyl polysiloxane

| Test system | Test material (See Appendix A for more details) | Test object | Route | Dose | Result | Reference | Comments |
|---|---|---|---|---|---|---|---|
| MN assay in peripheral blood | 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) 79% in Dow Corning compound | Swiss/ Webster mice (male and female) | IP (single dose) | 5 g/kg (MTD) | Negative | Dow Corning corp, 1986c. (Documentation provided to EFSA No 13) | Reliable with limitation. The study was largely in compliance with the OECD TG 474 (1983) applicable at the time when the study was performed but the number of cells scored (1000 per animal) was less than that recommended in the current version of OECD TG 474 (2016), i.e. 4000 per animal. Historical control data not reported. Sampling of peripheral blood cells, erythroblast was done after 24, 48 and 72 hrs. The relevance of the study result is low because the actual concentrations of 'dimethyl silicones and siloxanes' were unclear[(a)] |
| MN assay in peripheral blood | 'Dimethyl silicones and siloxanes' (CAS No 63148-62-9) 79% in Dow Corning compound | CD-1 mice (male and female) | IP (single dose) | 1.25, 2 and 2.5 g/kg in ethanol (representing 0.01, 0.016, 0.02 g/kg cyclics and 0.005, 0.008, 0.01 g/kg linears) | Negative | Dow Corning corp, 1989 h. (Documentation provided to EFSA No 20) | Reliable with limitation. The study was largely in compliance with the OECD TG 474 (1983) applicable at the time when the study was performed but the number of cells scored (1000 per animal) was less than that recommended in the current version of OECD TG 474 (2016), i.e. 4000 per animal. Historical control data not reported. Sampling of peripheral blood was done after 24, 48 and 72 hrs |
| Dominant lethal assay | Polydimethysiloxanes, Dow Corning 700 vapour booster pump fluid, 7 cst. | Albino male mice | IP (single dose) | 5, 10 g/kg | Negative | Kennedy et al., 1976 | Limited reliability. The study was performed before the OECD TG 478 was established. Matings were conducted during six weekly periods following treatment with fresh untreated females for each mating period. Mutation rates were evaluated on the basis of both early resorptions and decreases in viable embryos. One high-dose male died near the completion of the fifth week of mating and all males in this group were hypoactive for 3 –5 h following treatment. Data reported are limited. Number of animals per group is not reported |

Cst: Centistoke; MN: Micronucleus test; MTD: Maximum tolerated dose; IP: Intraperitoneal.

(a): The relevance of the study result is low because the actual concentrations of 'dimethyl silicones and siloxanes' were unclear based on what is stated in the study report: '*The test material is unsoluble in any known acceptable biological diluent. Testing was accomplished therefore, using an extract of the test material. The extract was prepared by continuous rotary shaking of 1 g test material in Ham's F-12 tissue culture fluid at 37°C/150 rpm/48 hours followed by sterile filtration (0.22μ Millipore$^{tm}$ filter). The cultures (5 mL) were exposed to a wide range of extract concentrations.*' Thus, different concentrations of the extract in the cultures were tested for cytotoxicity and mutagenicity. However, the concentration of 'dimethyl silicones and siloxanes' in the extract was not reported.