

Dimethicone

1 Nonproprietary Names

BP: Dimeticone
PhEur: Dimeticinum
USPNF: Dimethicone

2 Synonyms

ABIL; dimethylpolysiloxane; dimethylsilicone fluid; dimethylsiloxane; *Dow Corning Q7-9120*; E900; methyl polysiloxane; poly(dimethylsiloxane); *Sentry*.

3 Chemical Name and CAS Registry Number

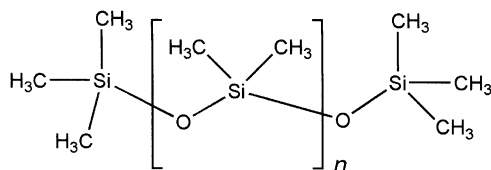
α -(Trimethylsilyl)- ω -methylpoly[oxy(dimethylsilylene)]
[9006-65-9]

4 Empirical Formula Molecular Weight

The PhEur 2002 describes dimethicone as a polydimethylsiloxane obtained by hydrolysis and polycondensation of dichlorodimethylsilane and chlorotrimethylsilane. The degree of polymerization ($n = 20$ –400) is such that materials with kinematic viscosities nominally between 20 and 1300 mm²/s (20–1300 cSt) are produced. Dimethicones with a nominal viscosity of 50 mm²/s (50 cSt) or lower are intended for external use only.

The USPNF 20 describes dimethicone as a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $[-(\text{CH}_3)_2\text{SiO}-]_n$ stabilized with trimethylsiloxy end-blocking units of the formula $[(\text{CH}_3)_3\text{SiO}-]$, where n has an average value such that the corresponding nominal viscosity is in a discrete range between 20 and 30 000 mm²/s (20–30 000 cSt).

5 Structural Formula



6 Functional Category

Antifoaming agent; emollient.

7 Applications in Pharmaceutical Formulation or Technology

Dimethicones of various viscosities are widely used in cosmetic and pharmaceutical formulations. In topical oil-in-water emulsions dimethicone is added to the oil phase as an antifoaming agent. Dimethicone is hydrophobic and is also widely used in topical barrier preparations. Therapeutically, dimethicone may be used with simethicone in oral pharmaceutical formula-

tions used in the treatment of flatulence. Dimethicone is also used to form a water-repellent film on glass containers. *See* Table I.

Table I: Uses of dimethicone.

Use	Concentration (%)
Creams, lotions and ointments	10–30
Oil–water emulsions	0.5–5.0

8 Description

Dimethicones are clear, colorless liquids available in various viscosities; *see* Section 4.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for dimethicone.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Acidity	+	+
Specific gravity	—	+ ^(a)
Viscosity (kinematic) of the nominal stated value	90–110%	+ ^(a)
Refractive index	—	+ ^(a)
Mineral oils	+	—
Phenylated compounds	+	—
Heavy metals	≤ 5 ppm	≤ 5 ppm
Volatile matter (for dimethicones with a viscosity greater than 50 mm ² /s (50 cSt))	≤ 0.3%	—
Loss on heating	—	+ ^(a)
Bacterial endotoxins (coating of containers for parenteral use)	—	+
Assay (of polydimethylsiloxane)	—	97.0–103.0%

^(a) The USPNF 20 specifies limits for these tests specific to the nominal viscosity of the dimethicone.

10 Typical Properties

Acid value: < 0.01

Density: 0.94–0.98 g/cm³ at 25 °C

Refractive index: $n_D^{25} = 1.401$ –1.405

Solubility: miscible with ethyl acetate, methyl ethyl ketone, mineral oil, and toluene; soluble in isopropyl myristate, very slightly soluble in ethanol; practically insoluble in glycerin, propylene glycol, and water.

Surface tension: 20.5–21.2 mN/m at 25 °C

11 Stability and Storage Conditions

Dimethicones should be stored in an airtight container in a cool, dry, place; they are stable to heat and are resistant to most chemical substances although they are affected by strong acids. Thin films of dimethicone may be sterilized by dry heat for at least 2 hours at 160°C. Sterilization of large quantities of dimethicone by steam autoclaving is not recommend since excess water diffuses into the fluid causing it to become hazy. However, thin films may be sterilized by this method. Gamma irradiation may also be used to sterilize dimethicone. Gamma irradiation can, however, cause cross-linking with a consequent increase in the viscosity of fluids.

12 Incompatibilities

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13 Method of Manufacture

Dimethicone is a poly(dimethylsiloxane) obtained by hydrolysis and polycondensation of dichlorodimethylsilane and chlorotrimethylsilane. The hydrolysis products contain active silanol groups through which condensation polymerization proceeds. By varying the proportions of chlorotrimethylsilane, which acts as a chain terminator, silicones of varying molecular weight may be prepared. Different grades of dimethicone are produced that may be distinguished by a number placed after the name indicating the nominal viscosity. For example, *ABIL 20* (Goldschmidt UK Ltd) has a nominal kinematic viscosity of 18–22 mm²/s (18–22 cSt). See also Section 4.

14 Safety

Dimethicone is generally regarded as a relatively nontoxic and nonirritant material although it can cause temporary irritation to the eyes. In pharmaceutical formulations it may be used in oral and topical preparations. Dimethicones are also used extensively in cosmetic formulations and in certain food applications.

The WHO has set a tentative estimated acceptable daily intake of dimethicone with a relative molecular mass in the range of 200–300 at up to 1.5 mg/kg body-weight.⁽¹⁾

Injection of silicones into tissues may cause granulomatous reactions. Accidental intravascular injection has been associated with fatalities.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Dimethicone is flammable and should not be exposed to naked flames or heat.

16 Regulatory Status

Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets, topical creams, emulsions, and lotions). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Cyclomethicone.

18 Comments

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19 Specific References

- 1 FAO/WHO. Evaluation of certain food additives. Twenty-third report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1980; No. 648.

20 General References

Calogero AV. Regulatory review. *Cosmet Toilet* 2000; 115(May): 24, 26, 27.

21 Author

PJ Weller.

22 Date of Revision

27 May 2002.