Cyclomethicone

1 Nonproprietary Names

USP–NF: Cyclomethicone

2 Synonyms

Dimethylcyclopolysiloxane; *Dow Corning 245 Fluid*; *Dow Corning 246 Fluid*; *Dow Corning 345 Fluid*; polydimethylcyclosiloxane.

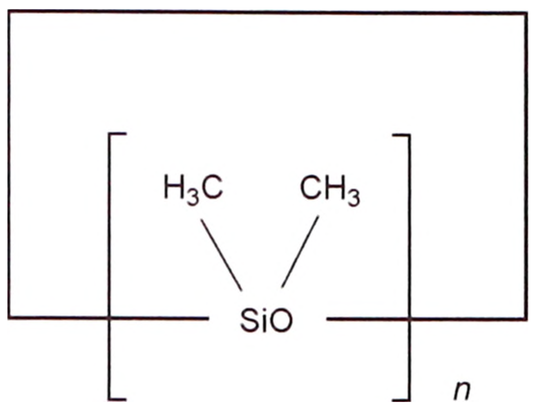
3 Chemical Name and CAS Registry Number

Cyclopolydimethylsiloxane [69430-24-6]

4 Empirical Formula and Molecular Weight

The USP 40–NF 35 S1 describes cyclomethicone as a fully methylated cyclic siloxane containing repeating units of the formula $[-(CH_3)_2SiO-]_n$ in which n is 4, 5, or 6, or a mixture of them.

5 Structural Formula



6 Functional Category

Emollient; humectant; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Cyclomethicone is mainly used in topical pharmaceutical and cosmetic formulations such as water-in-oil creams.[1–3] The use of cyclomethicone pentamer has been evaluated in mucoadhesive vaginal emulsions to control the release of progesterone.[4]

Cyclomethicone has been used in cosmetic formulations, at concentrations of 0.1–50%, since the late 1970s and is now the most widely used silicone in the cosmetics industry. Its high volatility and mild solvent properties make it ideal for use in topical formulations. Its low heat of vaporization means that when applied to skin it has a 'dry' feel.

See also Dimethicone.

8 Description

Cyclomethicone occurs as a clear, colorless and tasteless volatile liquid.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for cyclomethicone.

Test	USP 40–NF 35 S1
Identification	+
Limit of nonvolatile residue	≤0.15%
Assay of $(C_2H_6OSi)_n$ calculated as the sum of cyclomethicone 4, cyclomethicone 5, and cyclomethicone 6	≥98.0%
Assay of individual cyclomethicone components	95.0–105.0%

10 Typical Properties

Solubility Soluble in ethanol (95%), isopropyl myristate, isopropyl palmitate, mineral oil, and petrolatum at 80°C; practically insoluble in glycerin, propylene glycol, and water.

See also Table II.

11 Stability and Storage Conditions

Cyclomethicone should be stored in an airtight container in a cool, dry, place.

12 Incompatibilities

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13 Method of Manufacture

Cyclomethicone is manufactured by the distillation of crude polydimethylsiloxanes.

14 Safety

Cyclomethicone is generally regarded as a relatively nontoxic and nonirritant material. Although it has been used in oral pharmaceutical applications, cyclomethicone is mainly used in topical pharmaceutical formulations. It is also widely used in cosmetics.[5] Studies of the animal and human toxicology of cyclomethicone suggest that it is nonirritant and not absorbed through the skin. Only small amounts are absorbed orally; an acute oral dose in rats produced no deaths.[6,7]

The Cosmetic Ingredient Review (CIR) Expert Panel have assessed cyclomethicone and concluded that the material is safe as used in the present practices of use and concentration.[6,8]

See also Dimethicone.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

Table II: Typical physical properties of selected commercially available cyclomethicones.

Grade	Boiling point (°C)	Flash point (°C)	Freezing point (°C)	Refractive index at 25°C	Surface tension (mN/m)	Specific gravity at 25°C	Viscosity (kinematic) (mm^2/s)	Water content (%)
Dow Corning 245 Fluid	205	77	<−50	1.397	18.0	0.95	4.0	0.025
Dow Corning 246 Fluid	245	93	<−40	1.402	18.8	0.96	6.8	0.025
Dow Corning 345 Fluid	217	77	<−50	1.398	20.8	0.957	6.0	0.025