

SILFAR® 350

DIMETHICONE / SILICONE FLUID

Product description

Structural formula:



SILFAR® 350 is a polydimethylsiloxane obtained by hydrolysis and polycondensation of dichlorodimethylsilane and chlorotrimethylsilane. The degree of polymerization (n) is such that the mean kinematic viscosity is 350mm²/s at 25°C.

Properties

Regulatory status

Use as pharmaceutical excipient:

SILFAR® 350 complies with the requirements set down in the monographs "Dimeticone" (EP) and "Dimethicone" (USP / NF). Wacker explicitly rules out the use of SILFAR® 350 for parenteral applications.

Direct Food additive:

The ingredient(s) of the product SILFAR® 350 are listed in the paragraph FDA 21 CFR § 173.340 Defoaming Agents as Secondary Direct Food Additive permitted in Food for Human Consumption. However, no Food Safety Modernization Act (FSMA) compliant program is implemented for this product.

SILFAR® 350 is listed in the Regulation (EC) No 1333/2008 Annex II and III as amended by Regulations (EU) Nos 1129/2011 and 1130/2011 as E 900 polydimethylsiloxane. It meets the purity requirements as laid down in Regulation (EU) No. 231/2012 and is therefore approved as direct food additive within the EC under observance of the use restrictions in force for polydimethylsiloxane (E 900). SILFAR® 350 is certified according to HACCP principles. Hence, it meets the requirements on food hygiene in accordance with Regulation (EC) No. 852/2004.

Food Contact:

SILFAR® 350 complies with the Recommendation "XV Silicones" of the BfR concerning the manufacture of essential commodities that have contact with food.

SILFAR® 350 is listed under PM-Nr. 76721 in Regulation (EU) No. 10/2011 as an additive for plastic materials to come into contact with food and meets the

specifications under column (4) and (10). The product is not subject to a specific migration limit (SML).

SILFAR® 350 is suitable for use under FDA 21 CFR as follows:

§175.105 (ADHESIVES),

§175.300 (RESINOUS AND POLYMERIC COATINGS),

§176.170 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS)

§176.180 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH DRY FOOD).

§176.200 (DEFOAMING AGENTS USED IN COATINGS)

§176.210 (DEFOAMING AGENTS USED IN THE MANUFACTURE OF PAPER AND PAPERBOARD)

§177.1210 (CLOSURES WITH SEALING GASKETS FOR FOOD CONTAINERS).

§177.2800 (TEXTILES AND TEXTILE FIBERS).

§178.3120 (ANIMAL GLUE).

§178.3570 (LUBRICANTS WITH INCIDENTAL FOOD CONTACT)

§178.3910 (SURFACE LUBRICANTS USED IN THE MANUFACTURE OF METALLIC ARTICLES)

§181.28 (RELEASE AGENTS)

SILFAR® 350 meets the criteria for an exemption from the requirements of a tolerance when used as an additive in pesticide formulations to be applied to growing crops or raw agricultural commodities after harvest as specified in 40 CR 180.960.

National regulations applicable in the countries concerned must be observed.

Application

SILFAR® 350 is used both in the pharmaceutical and food sectors. In the pharmaceutical sector it is used in antifatulence and antacid preparations. It acts as an antifoam agent to prevent or relieve flatulence in the alimentary canal and forms a protective lining on e.g. the gastric mucous membrane.

SILFAR® 350 may be used to make tablets and coated tablets. It is often combined with fermentation preparations.

SILFAR® 350 is also used to control foam in fermentation and downstream processes, such as active-ingredient extraction and solvent recovery, especially when USP/EP compliant products are mandatory.

In the food sector, SILFAR® 350 is used predominantly to control foam in lipophilic systems (foods rich in oil or fat, e.g. deep-frying oil) or for surface treatment. SILFAR® 350 also serves as the base material in the production of antifoams compliant with the regulations pertaining to food for human consumption.

Storage

The 'Best use before end' date of each batch is shown on the product label.

Storage beyond the date specified on the label does not necessarily mean that the product is no longer usable. In this case however, the properties required for the intended use must be checked for quality assurance reasons.

Additional information

Produced according ISO 9001, ISO 14001

Safety notes

Comprehensive instructions are given in the corresponding Material Safety Data Sheets. They are available on request from WACKER subsidiaries or may be printed via WACKER web site <http://www.wacker.com>.

Product data		
Typical general characteristics	Inspection Method	Value
Appearance		clear, colorless and odorless
Density at 25 °C	DIN 51757	0,965 - 0,973 g/cm ³
Viscosity, kinematic at 25 °C	DIN 53018	333 - 363 mm ² /s
Refractive index at 25 °C		1,402 - 1,404
Active substance		100 %
Volatility	USP	max. 0,3 %
Acidity (direct titration)		max. 5 mg/kg
Solidifying point		-50 °C
Flash point	ISO 2592	> 300 °C
Ignition temperature (liquids)	DIN 51794	approx. 450 °C

These figures are only intended as a guide and should not be used in preparing specifications.

The data presented in this medium are in accordance with the present state of our knowledge but do not absolve the user from carefully checking all supplies immediately on receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The recommendations made in this medium should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies' raw materials are also being used. The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties' rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.

The management system has been certified according to DIN EN ISO 9001 and DIN EN ISO 14001

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For technical, quality, or product safety questions, please contact:

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