SILFAR® 350

Silicone Antifoams (HACCP)

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.

$(H_3C)_3Si\text{-}(OSi(CH_3)_2\text{-})_nOSi(CH_3)_3$

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:
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.

Technical data

General Characteristics

Property	Condition	Value	Method
Acidity (direct titration)	-	max. 5 mg/kg	-
Active substance	-	100 %	-
Appearance	-	clear, colorless and odorless	-
Density	25 °C	0.965 - 0.973 g/cm^3	DIN 51757
Flash point	-	> 300 °C	ISO 2592
Ignition temperature (liquids)	-	approx. 450 °C	DIN 51794
Refractive index	25 °C	1.402 - 1.404	-
Solidifying point	-	-50 °C	-
Viscosity, kinematic	25 °C	333 - 367 mm^2/s	DIN 53019
Volatility	-	max. 0.3 %	USP

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

All the information provided is in accordance with the present state of our knowledge. Nonetheless, we disclaim any warranty or liability whatsoever and reserve the right, at any time, to effect technical alterations. The information provided, as well as the product's fitness for an intended application, should be checked by the buyer in preliminary trials. Contractual terms and conditions always take precedence. This disclaimer of warranty and liability also applies particularly in foreign countries with respect to third parties' rights.

Applications

- Food
- Pharma

Application details

SILFAR® 350 is used both in the pharmaceutical and food sectors. In the pharmaceutical sector it is used in antiflatulence 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.

Packaging and storage

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.

QR Code SILFAR® 350

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

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