

SILFAR[®] SE 4



Silicone Antifoam Emulsions

SILFAR[®] SE 4 is a silicone antifoam emulsion. It is recommended for the food and pharmaceutical sectors, fermentation processes and agrochemical formulations.

Technical data

General Characteristics

Property	Condition	Value	Method
Appearance	-	milky-white to beige	-
Active ingredients ("Simethicone", USP/EP)	-	30 %	-
Density	25 °C	1.0 g/cm ³	DIN 51757
Emulsifier	-	nonionic	-
Microbe count (USP) ⁽¹⁾	-	< 100 CFU/g	-
Solids content	-	31 - 34 %	Microwave oven
pH	20 °C	3.0 - 5.0	Indicator strips

¹Colony Forming Unit

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

- Pharma

Application details

1. Pharmaceutical use

SILFAR® SE 4 meets the purity requirements of the monograph „Simethicone Emulsion“ under the current version of the US Pharmacopoeia.

A monograph for simethicone emulsions does not exist in of the European Pharmacopoeia. However, the ingredients comply with the purity requirements of the corresponding monographs.

SILFAR® SE 4, is produced under cGMP and is suitable for use as an active pharmaceutical ingredient (API) e.g. in antifatulence and antacid preparations. It works by acting as an antifoam agent to prevent or relieve flatulence in alimentary canal and by forming a protective lining on e.g. the gastric mucous membrane.

It is often combined with fermentation preparations.

When administered to patients, preparations containing the antifoam SILFAR® SE 4 eliminate any flatulence that might hinder X-ray, ultrasonic or gastroscopic examinations.

SILFAR® SE 4 may also be used to make liquid preparations in suspension form.

SILFAR® SE 4 is also antifoam in fermentation and downstream processes, such as active-ingredient extraction and solvent recovery, especially when USP/EP compliant products are mandatory.

2. Use in food processing

SILFAR® SE 4 is a silicone fluid emulsion based on E 900 and may be used in Europe only as a processing aid for food. Therefore, it has to be ensured by the producer of the foodstuff that only technically unavoidable traces of the product remain in the final food.

SILFAR® SE 4 is used in strongly foaming, aqueous systems in the food sector (e.g. vegetables processing, beverages).

3. Contact with food

The ingredients of SILFAR® SE 4 are contained in the positive lists of the following regulations for essential commodities intended to come into contact with food:

Germany:

Recommendations of the BfR:

XIV. Plastics Dispersions

XV. Silicones

XXXVI: Paper and Board for Food Contact

Europe:

Regulation (EU) No. 10/2011 superseding Directive 2002/72/EC.

USA:

FDA 21 CFR:

§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

Regulatory sanctioning of the ingredients in a product does not imply that the finished product manufactured from those ingredients is considered safe by regulatory bodies. Responsibility for compliance with specific limits e.g. on migration/ extraction resides with the manufacturer of the finished product.

Further details and information on potential restrictions please see the datasheet on Regulatory Product Information.

4. Use in Agrochemical formulations

SILFAR® SE 4 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 CFR 180.910.

National regulations applicable in the countries concerned must be observed.

Packaging and storage

Storage

Further information for storage: Keep container tightly closed. Store container(s) at room temperature in a dry, well-ventilated place.

Storage beyond the shelf life 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.

Shelf life: 300 days

Additional information

SILFAR® SE 4 should be gently homogenized by stirring before use.

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® SE 4



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

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