

Landesdirektion Sachsen

Union Format for Registration of Manufacturer, Importer or Distributor of Active Substances to be used as Starting Materials in Medicinal Products for Human Use

1. Registration Number : DE_SN_01/L24.2-5117/102
2. Name or corporate name of registrant : Wacker Chemie AG
3. Permanent or legal address of registrant : Friedrich-von-Heyden-Platz 1, Nünchritz, 01612, Deutschland
4. Address(es) of site(s) where registered activities take place : Friedrich-von-Heyden-Platz 1, Nünchritz, 01612, Deutschland
5. National legal basis of registration : § 67 Arzneimittelgesetz (Sect. 67 German Drug Law)
6. Name of responsible officer of the competent authority of the member state validating the registration : Klaus Hartmann
7. Signature :
8. Date : 2019-01-30

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site: Wacker Chemie AG, Friedrich-von-Heyden-Platz 1, Nünchritz, 01612, Deutschland

1. MANUFACTURING OPERATIONS

Active Substance : Simethicone SILFAR S 184
(DE_SN_01/L24.2-5117/102 API No. 1)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps filtration Filtration E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : Simethicone emulsion 30% SILFAR SE 4
(DE_SN_01/L24.2-5117/102 API No. 2)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing F.2 Microbiological testing excluding sterility testing</i>

Active Substance : Simethicone emulsion 20% SE 2 MC
(DE_SN_01/L24.2-5117/102 API No. 3)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing F.2 Microbiological testing excluding sterility testing</i>

Active Substance : Simeticon SILFAR® S 188
 (DE_SN_01/L24.2-5117/102 API No. 4)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps filtration Filtration E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	<p>Simethicone SILFAR® S 184 (DE_SN_01/L24.2-5117/102 API No. 1)</p> <p>Simethicone emulsion 30% SILFAR® SE 4 (DE_SN_01/L24.2-5117/102 API No. 2)</p> <p>Simethicone emulsion 20% SE 2 MC (DE_SN_01/L24.2-5117/102 API No. 3)</p> <p>Simeticon SILFAR® S 188 (DE_SN_01/L24.2-5117/102 API No. 4)</p>

Any restrictions or clarifying remarks to the scope of these registered operations (for all users) : Microbiological testing is carried out in the contract lab CUP Laboratorien Dr. Freitag GmbH in Radeberg.
 Die mikrobiologische Prüfung erfolgt bei dem Auftragnehmer CUP Laboratorien Dr. Freitag GmbH in Radeberg.