

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number UK API 10336
2. Name or corporate name of registrant BASILDON CHEMICAL COMPANY LIMITED
3. Permanent or legal address of registrant BASILDON CHEMICAL COMPANY LIMITED, KIMBER ROAD,
ABINGDON, OX14 1RZ, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place BASILDON CHEMICAL COMPANY LIMITED, KIMBER ROAD,
ABINGDON, OX14 1RZ, UNITED KINGDOM
5. National legal basis of registration Regulation 327 of The Human Medicines Regulations 2012 (SI
2012/1916)
6. Name of responsible officer of the competent authority of the
member state validating the registration Confidential
7. Date 25/04/2023

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

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

BASILDON CHEMICAL COMPANY LIMITED, KIMBER ROAD, ABINGDON, OX14 1RZ, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

DIMETHICONE
3000011022

E	General Finishing Steps
	E.1 Physical Processing Steps Blending of Dimethicone fluids to achieve a specified viscosity
	E.2 Primary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.3 Microbiological testing (including sterility testing)

Active substance

SIMETHICONE

1000009128

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
E	General Finishing Steps
	E.1 Physical Processing Steps Unspecified
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

SIMETHICONE EMULSION

2000007727

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
E	General Finishing Steps
	E.1 Physical Processing Steps Unspecified
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.3 Microbiological testing (including sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

SIMETHICONE (1000009128)

SIMETHICONE EMULSION (2000007727)