

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 27886
2. Name or corporate name of registrant	MINTEQ UK LIMITED
3. Permanent or legal address of registrant	MINTEQ UK LIMITED, LIFFORD LANE, KINGS NORTON, BIRMINGHAM, B30 3JW, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	SPECIALTY MINERALS, LIFFORD LANE, KINGS NORTON, BIRMINGHAM, B30 3JW, 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	14/11/2024

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

SPECIALTY MINERALS, LIFFORD LANE, KINGS NORTON, BIRMINGHAM, B30 3JW, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

CALCIUM CARBONATE
2000008145

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) PRECIPITATION METHOD

E	General Finishing Steps
	E.1 Physical Processing Steps Calcination, Precipitation, Screening, Drying , Packing
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
CALCIUM CARBONATE (2000008145)	SPECIALTY MINERALS INC. , 260 COLUMBIA STREET, ADAMS, 01220, UNITED STATES	SPECIALTY MINERALS INC. , 260 COLUMBIA STREET, ADAMS, 01220, UNITED STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	CALCIUM CARBONATE (2000008145)