

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 10762
2. Name or corporate name of registrant TATA CHEMICALS EUROPE LIMITED
3. Permanent or legal address of registrant TATA CHEMICALS EUROPE LIMITED, NATRIUM HOUSE, WINNINGTON LANE, NORTHWICH, CW8 4GW, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place TATA CHEMICALS EUROPE LIMITED, MOND HOUSE, WINNINGTON LANE, NORTHWICH, CW8 4DT, 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 27/03/2024

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

TATA CHEMICALS EUROPE LIMITED, MOND HOUSE, WINNINGTON LANE, NORTHWICH, CW8 4DT, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

SODIUM BICARBONATE
1000009540

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation

E	General Finishing Steps
	E.1 Physical Processing Steps Drying & Sieving
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 SODIUM BICARBONATE (1000009540)