

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 10524
2. Name or corporate name of registrant	THOMAS SWAN & COMPANY LIMITED
3. Permanent or legal address of registrant	THOMAS SWAN & COMPANY LIMITED, ROTARY WAY, CONSETT, DH8 7ND, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	THOMAS SWAN & COMPANY LIMITED, ROTARY WAY, CONSETT, DH8 7ND, 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	20/11/2024

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

THOMAS SWAN & COMPANY LIMITED, ROTARY WAY, CONSETT, DH8 7ND, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

TITANIUM SALICYLATE
2000008598

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance

E	General Finishing Steps
	E.1 Physical Processing Steps Drying, micronising and packaging is carried out off site by a contractor. Samples are sent to Thomas Swan to be tested by the QC department. Batch records are sent to Thomas Swan and recorded.
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

BENZALKONIUM CHLORIDE

2000010983

A	Manufacture of Active Substance by Chemical Synthesis
	A.4 Other The process to make benzalkonium chloride (BKC) is a simple 'all-in, all-out' chemical synthesis. This means the raw materials are charged to the reactor vessel and once the reaction is complete, a solution in water is produced and discharged.
E	General Finishing Steps
	E.1 Physical Processing Steps The product is discharged to containers in the form of a solution.
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

TITANIUM PEROXIDE

1000009322

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Drying and packaging is carried out off site by a contractor. Samples are sent to Thomas Swan to be tested by the QC department. Batch records are sent to Thomas Swan and recorded.
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

CHLOROXYLENOL

1000004583

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Not specified
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
- TITANIUM SALICYLATE (2000008598)
 - TITANIUM PEROXIDE (1000009322)
 - CHLOROXYLENOL (1000004583)