

# 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 41200
2. Name or corporate name of registrant EUTICALS LIMITED
3. Permanent or legal address of registrant EUTICALS LIMITED, PRINCE WILLIAM AVENUE, SANDYCROFT, DEESIDE, CH5 2PX, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place EUTICALS LIMITED, PRINCE WILLIAM AVENUE, SANDYCROFT, DEESIDE, CH5 2PX, 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 01/08/2014

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

**EUTICALS LIMITED**, PRINCE WILLIAM AVENUE, SANDYCROFT, DEESIDE, CH5 2PX, UNITED KINGDOM

#### 1. MANUFACTURING OPERATIONS

##### Active substance

ETHYL SALICYLATE  
1000002536

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) PURIFICATION BY VACUUM DISTILLATION

E	General Finishing Steps
	E.1 Physical Processing Steps BLENDING
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

ISOSORBIDE-5-MONONITRATE DILUTED

4000007687

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) ADDITIONAL INFO
E	General Finishing Steps
	E.1 Physical Processing Steps .BLENDING, SIFTING
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

**Active substance**

PURE ISOSORBIDE-5-MONONITRATE

4000012894

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) RECRYSTALLISED FROM AQUEOUS MEDIUM
E	General Finishing Steps
	E.1 Physical Processing Steps DRYING,SIEVING,BLENDING
	E.2 Primary Packaging

	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

**Active substance**

ISOSORBIDE DINITRATE DILUTED  
4000009827

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) RECRYSTALLISED FROM MIXED ORGANIC SOLVENT/AQUEOUS MEDIUM
E	General Finishing Steps
	E.1 Physical Processing Steps DRYING, SIFTING, BLENDING WITH EXCIPIENTS
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

**Active substance**

FLUCYTOSINE  
1000002211

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) RECRYSTALLISATION FROM AQUEOUS MEDIUM
E	General Finishing Steps
	E.1 Physical Processing Steps DRYING, SIEVING AND BLENDING
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

TETRAHYDROFURFURYL SALICYLATE

4000006661

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) PURIFICATION BY VACUUM DISTILLATION
E	General Finishing Steps
	E.1 Physical Processing Steps BLENDING
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

DIETHYLAMINE SALICYLATE

2000007771

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) CRYSTALLISATION FROM NON-AQUEOUS MEDIUM
E	General Finishing Steps
	E.1 Physical Processing Steps DRYING, MILLING (DE-LUMPING), BLENDING
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

CARBIMAZOLE

1000006699

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Product crystallised from reaction mix by watering out. Product water washed.
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

HYDROXYETHYL SALICYLATE

3000003723

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) PURIFICATION BY VACUUM DISTILLATION
E	General Finishing Steps
	E.1 Physical Processing Steps BLENDING
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**2. IMPORTATION AND DISTRIBUTION OPERATIONS**

- B Distribution
- ETHYL SALICYLATE (1000002536)
  - ISOSORBIDE-5-MONONITRATE DILUTED (4000007687)
  - PURE ISOSORBIDE-5-MONONITRATE (4000012894)
  - SALICYLIC ACID (1000009710)
  - ISOSORBIDE DINITRATE DILUTED (4000009827)
  - FLUCYTOSINE (1000002211)
  - TETRAHYDROFURFURYL SALICYLATE (4000006661)
  - DIETHYLAMINE SALICYLATE (2000007771)
  - CARBIMAZOLE (1000006699)
  - HYDROXYETHYL SALICYLATE (3000003723)