

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 240
2. Name or corporate name of registrant THORNTON & ROSS LIMITED
3. Permanent or legal address of registrant THORNTON & ROSS LIMITED, MANCHESTER ROAD, LINTHWAITE, HUDDERSFIELD, HD7 5QH, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place THORNTON & ROSS LIMITED, MANCHESTER ROAD, LINTHWAITE, HUDDERSFIELD, HD7 5QH, 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 12/03/2018

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

THORNTON & ROSS LIMITED, MANCHESTER ROAD, LINTHWAITE, HUDDERSFIELD, HD7 5QH, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

MAGNESIUM HYDROXIDE PASTE CONCENTRATED
2000005940

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Hydration of Magnesium Oxide
F	Quality Control Testing

	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

DIETHYLAMINE SALICYLATE SOLUTION

4000014860

A	Manufacture of Active Substance by Chemical Synthesis
	A.4 Other Diethylamine is added to water followed by Salicylic Acid where an exothermic reaction takes place to
F	Quality Control Testing
	F.1 Physical / Chemical testing