

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

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| 1. Registration Number | UK API 322 |
| 2. Name or corporate name of registrant | NORGINE LIMITED |
| 3. Permanent or legal address of registrant | NORGINE LIMITED, ARC UXBRIDGE, BUILDING 01, SANDERSON ROAD, UXBRIDGE, UB8 1DH, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | NORGINE LIMITED, NEW ROAD, TIR-Y-BERTH, HENGOED, CF82 8SJ, 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 | 29/04/2025 |

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

NORGINE LIMITED, NEW ROAD, TIR-Y-BERTH, HENGOED, CF82 8SJ, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance 3rd Country Manufacturer

MACROGOL 3350
(2000012179)
AVESTA PHARMA PRIVATE LIMITED, PLOT NO 2,
GUT NO 189/1,189/2,191/2,191/6,194, AT & POST
ALONDE, TALUKA VIKRAMGAD, DISTRICT
PALGHAR, VIKRAMGAD, MAHARASHTRA, IN-
421303, INDIA

3rd Country Distributor

AVESTA PHARMA PRIVATE LIMITED, PLOT NO 2,
GUT NO 189/1,189/2,191/2,191/6,194, AT & POST
ALONDE, TALUKA VIKRAMGAD, DISTRICT
PALGHAR, VIKRAMGAD, MAHARASHTRA, IN-
421303, INDIA

SODIUM
SULPHATE **JOST CHEMICAL COMPANY**, 8130 LACKLAND
ANHYDROUS ROAD, ST LOUIS, 63114, UNITED STATES
(3000014477)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 MACROGOL 3350 (2000012179)