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 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 NORGINE LIMITED, UNIT 2A, PARKWAY, PEN-Y-FAN INDUSTRIAL ESTATE, CRUMLIN, NEWPORT, NP11 3EF, 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	04/09/2026

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	3rd Country Distributor
SODIUM SULPHATE ANHYDROUS (3000014477)	**JOST CHEMICAL COMPANY**, 8130 LACKLAND ROAD, ST LOUIS, 63114, UNITED STATES	

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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	**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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

MACROGOL 3350 (2000012179)

Name and address of the site

NORGINE LIMITED, UNIT 2A, PARKWAY, PEN-Y-FAN INDUSTRIAL ESTATE, CRUMLIN, NEWPORT, NP11 3EF, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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SODIUM SULPHATE ANHYDROUS (3000014477)	**JOST CHEMICAL COMPANY**, 8130 LACKLAND ROAD, ST LOUIS, 63114, UNITED STATES	
MACROGOL 3350 (2000012179)	**UNION CARBIDE CORPORATION**, 355 HIGHWAY 3142, HAHNVILLE, 70057-2611, UNITED STATES	

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