

# 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, NORGINE HOUSE, WIDEWATER PLACE, MOORHALL ROAD, HAREFIELD, UXBRIDGE, UB9 6NS, 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	01/06/2023

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

SODIUM

SULPHATE

ANHYDROUS

(3000014477)

**JOST CHEMICAL COMPANY**, 8130 LACKLAND  
ROAD, ST LOUIS, 63114, UNITED STATES

3rd Country Distributor

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)