

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 12862 |
| 2. Name or corporate name of registrant | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED |
| 3. Permanent or legal address of registrant | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, D95 BUILDING, THANE ROAD, NOTTINGHAM, NG90 2DB, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, 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 | 14/04/2025 |

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

RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

3rd Country Manufacturer

3rd Country
Distributor

IBUPROFEN LYSINE (2000011938)	SOLARA ACTIVE PHARMA SCIENCES , RS NO. 33 & 34, MATHUR ROAD, PERIYAKALAPET, PUDUCHERRY, IN 605014, INDIA
	IOL CHEMICALS AND PHARMACEUTICALS LIMITED , MANSA ROAD (TRIDENT COMPLEX), DISTRICT BARNALA, FATEHGARH CHANNA VILLAGE, PUNJAB, IN-148101, INDIA
	SOLARA ACTIVE PHARMA SCIENCES , A1/B SIPCOT INDUSTRIAL COMPLEX, KUDIKADU, CUDDALORE, TAMIL NADU, IN-607005, INDIA
	BASF , HIGHWAY 77 SOUTH, BISHOP, 78343, UNITED STATES
IBUPROFEN SODIUM (2000011939)	IOL CHEMICALS AND PHARMACEUTICALS LIMITED , MANSA ROAD (TRIDENT COMPLEX), DISTRICT BARNALA, FATEHGARH CHANNA VILLAGE, PUNJAB, IN-148101, INDIA
	SOLARA ACTIVE PHARMA SCIENCES , RS NO. 33 & 34, MATHUR ROAD, PERIYAKALAPET, PUDUCHERRY, IN 605014, INDIA
PHENYLEPHRINE HYDROCHLORIDE (2000008067)	MALLADI , UNIT 3, 7B AND 7C, SIPCOT INDUSTRIAL COMPLEX, RANIPET, RANIPET, TAMIL NADU, IN-632403, INDIA
	SOLARA ACTIVE PHARMA SCIENCES , RS NO. 33 & 34, MATHUR ROAD, PERIYAKALAPET, PUDUCHERRY, IN 605014, INDIA
IBUPROFEN (1000008918)	BASF CORPORATION , HIGHWAY 77 SOUTH, BISHOP, 78343, UNITED STATES
	IOL CHEMICALS AND PHARMACEUTICALS LIMITED , MANSA ROAD (TRIDENT COMPLEX), DISTRICT BARNALA, FATEHGARH CHANNA VILLAGE, PUNJAB, IN-148101, INDIA
CETYLPIRIDINIUM (1000006275)	VERTELLUS HEALTH AND SPECIALITY PRODUCTS LLC , 215 NORTH CENTENNIAL STREET, ZEELAND, 49464-1309, UNITED STATES
BENZOCAINE (1000009160)	CHANGZHOU SUNLIGHT , 216 YUNNAN WEST ROAD, BENNIU TOWN, XINBEI DISTRICT, CHANGZHOU CITY, JIANGSU PROVINCE, CN 213134, CHINA
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)	EMBIO LIMITED , PLOT NO E21-22, MIDC INDUSTRIAL ESTATE, RAIGAD DISTRICT, MAHAD, MAHARASHTRA, IN-402309, INDIA
	MALLADI , UNIT 3, 7B AND 7C, SIPCOT INDUSTRIAL COMPLEX, RANIPET, RANIPET, TAMIL NADU, IN-632403, INDIA
CALCIUM CARBONATE D/C (4000003925)	SUDEEP PHARMA , 129/1/A, G.I.D.C. ESTATE, NANDESARI, VADODARA, GUJARAT, IN 391340, INDIA

FLURBIPROFEN (1000002036)	HY-GRO CHEMICALS PHARMTEK PRIVATE LIMITED. , PLOT NO. 174, PROGRESSIVE INDUSTRIAL SOCIETY, I.D.A. BOLLARAM, BOLLARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN 502325, INDIA
	SUN PHARMACEUTICAL INDUSTRIES LIMITED. , A7/A8 MIDC INDUSTRIAL AREA, AHMEDNAGAR, MAHARASHTRA, IN-414111, INDIA
MENTHOL (1000001243)	ANHUI FENGLE PERFUME CO LIMITED , 1 TIANHU ROAD, HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, HEFEI, ANHUI, CN-230088, CHINA
SODIUM ASCORBATE (2000007558)	CSPC WEISHENG PHARMACEUTICAL (SHIJIAZHUANG) CO., LIMITED. , NO. 898 ZHONGSHANG EAST ROAD, HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, CN-050 035, CHINA
ASCORBIC ACID (1000009903)	CSPC WEISHENG PHARMACEUTICAL (SHIJIAZHUANG) CO., LIMITED. , NO. 898 ZHONGSHANG EAST ROAD, HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, CN-050 035, CHINA
CALCIUM CARBONATE (2000008145)	J.M. HUBER MICROPOWDERS INC. , 3150 GARDNER EXPRESSWAY, QUINCY, 62305, UNITED STATES
	SUDEEP PHARMA , 129/1/A, G.I.D.C. ESTATE, NANDESARI, VADODARA, GUJARAT, IN 391340, INDIA
AMYLMETACRESOL (1000000573)	BIOXERA , PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421506, INDIA
	ANQUI LU'AN PHARMACEUTICAL CO LIMITED , XIAO HE YA, NORTH PART OF THE ANQUI CITY, ANQUI, SHANDONG PROVINCE, CN-262100, CHINA
PARACETAMOL (1000009609)	SPECGX LLC , RALEIGH PHARMACEUTICAL PLANT, 8801 CAPITAL BOULEVARD, RALEIGH, 27616-3116, UNITED STATES
	SPECGX LLC , 100 LOUIS LATZER DRIVE, GREENVILLE, 62246, UNITED STATES
2,4-DICHLOROBENZYL ALCOHOL (3000009479)	BIOXERA , PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421506, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	IBUPROFEN (1000008918)
	2,4-DICHLOROBENZYL ALCOHOL (3000009479)