

# 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 46227   |
| 2. Name or corporate name of registrant   | SAFIC-ALCAN UK LIMITED   |
| 3. Permanent or legal address of registrant   | SAFIC-ALCAN UK LIMITED, 812 BIRCHWOOD BOULEVARD,<br>BIRCHWOOD, WARRINGTON, WA3 7QZ, UNITED KINGDOM   |
| 4. Address(es) of site(s) where registered activities take place  | H.W. COATES LIMITED, MIDDLEWICH ROAD INDUSTRIAL ESTATE,<br>BYLEY, MIDDLEWICH, CW10 9NT, UNITED KINGDOM<br><br>SAFIC-ALCAN UK LIMITED, 812 BIRCHWOOD BOULEVARD,<br>BIRCHWOOD, WARRINGTON, WA3 7QZ, 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   | 27/05/2026   |

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

**H.W. COATES LIMITED**, MIDDLEWICH ROAD INDUSTRIAL ESTATE, BYLEY, MIDDLEWICH, CW10 9NT, UNITED KINGDOM

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

#### A Importation

| Active Substance            | 3rd Country Manufacturer  | 3rd Country Distributor |
|-----------------------------|---|-------------------------|
| GUAIFENESIN<br>(3000005625) | <b>NOURYON FUNCTIONAL CHEMICALS B.V.</b> , LISPINWEG 6, HERKENBOSCH,<br>NL-6075 CE, NETHERLANDS |                         |

|                                   |  |
|-----------------------------------|--|
| HYDROQUINONE<br>(1000008752)      | <b>EASTMAN CHEMICAL COMPANY</b> , 200 SOUTH WILCOX DRIVE, KINGSPORT,<br>37660, UNITED STATES   |
| PARACETAMOL<br>(1000009609)       | <b>FARMSON PHARMACEUTICAL GUJARAT PVT LIMITED</b> , PLOT NO. 28-35<br>G.I.D.C. INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT,<br>GUJARAT, IN-391340, INDIA |
| CYANOCOBALAMIN<br>(4000010977)    | <b>HEBEI HUARONG PHARMACEUTICAL CO. LIMITED.</b> , 50 NORTH 2ND RING<br>ROAD EAST, CHANGAN QU, SHIJIAZHUANG, HEBEI SHENG, CN-050000,<br>CHINA                |
| SODIUM FEREDETATE<br>(4000007079) | <b>NOURYON FUNCTIONAL CHEMICALS B.V.</b> , LISPINWEG 6, HERKENBOSCH,<br>NL-6075 CE, NETHERLANDS  |
| TINIDAZOLE (1000009326)           | <b>ZHEJIANG SUPOR PHARMACEUTICALS CO., LIMITED</b> , YUEDONG ROAD,<br>PAOJIANG INDUSTRIAL ZONE, SHAOXING, ZHEJIANG, RC-312071, CHINA                         |

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

### B Distribution

AZITHROMYCIN DIHYDRATE (2000007794)  
PREDNISOLONE ACETATE (2000007916)  
GUAIFENESIN (3000005625)  
HYDROQUINONE (1000008752)  
SIMETHICONE (1000009128)  
PARACETAMOL (1000009609)  
ENALAPRIL MALEATE (2000007672)  
PRAZIQUANTEL (1000015572)  
CISAPRIDE (1000009097)  
CYANOCOBALAMIN (4000010977)  
METFORMIN HYDROCHLORIDE (2000008338)  
FAMOTIDINE (1000002421)  
NEOMYCIN SULPHATE (2000008175)  
N-ACETYLCYSTEINE (3000005344)  
TACROLIMUS (1000002882)  
DOXYCYCLINE HYCLATE (4000006937)  
SODIUM FEREDETATE (4000007079)  
SUCRALFATE (1000009411)  
TRIMETHOPRIM (1000009283)  
TINIDAZOLE (1000009326)  
ENROFLOXACIN (1000017859)  
METRONIDAZOLE BENZOATE (2000008258)  
DEXAMETHASONE (1000003334)

EXEMESTANE (1000000183)  
DOXYCYCLINE MONOHYDRATE (2000007682)  
BENZAEPRIIL HYDROCHLORIDE (2000006111)

**Name and address of the site**

**SAFIC-ALCAN UK LIMITED**, 812 BIRCHWOOD BOULEVARD, BIRCHWOOD, WARRINGTON, WA3 7QZ, UNITED KINGDOM

**2. IMPORTATION AND DISTRIBUTION OPERATIONS**

**A Importation**

| <b>Active Substance</b>                    | <b>3rd Country Manufacturer</b>  | <b>3rd Country Distributor</b> |
|--|--|--------------------------------|
| FAMOTIDINE<br>(1000002421)                 | <b>ALEMBIC PHARMACEUTICALS LTD</b> , VILLAGE PANELAV, PO TAJPURA, NEAR BASKA, TALUKA HALOL, PANCHMAHAL, GUJARAT, IN-389350, INDIA  |                                |
| AZITHROMYCIN<br>DIHYDRATE (2000007794)     | <b>ZHEJIANG GUOBANG PHARMACEUTICAL CO. LTD.</b> , NO. 6 WEIWU ROAD, HANGZHOU GULF SHANGYU ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHANGYU, ZHEJIANG, CN-312 369, CHINA    |                                |
| ENROFLOXACIN<br>(1000017859)               | <b>ZHEJIANG GUOBANG PHARMACEUTICAL CO. LTD.</b> , NO. 6 WEIWU ROAD, HANGZHOU GULF SHANGYU ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHANGYU, ZHEJIANG, CN-312 369, CHINA    |                                |
| CYANOCOBALAMIN<br>(4000010977)             | <b>HEBEI HUARONG PHARMACEUTICAL CO. LIMITED.</b> , 50 NORTH 2ND RING ROAD EAST, CHANGAN QU, SHIJIAZHUANG, HEBEI SHENG, CN-050000, CHINA  |                                |
| TRIMETHOPRIM<br>(1000009283)               | <b>SHOUGUANG FUKANG PHARMACEUTICAL CO. LTD</b> , NORTH-EAST OF DONGWAIHUAN ROAD, DONGCHENG INDUSTRIAL AREA, SHOUGUANG, SHANDONG PROVINCE, CN-262700, CHINA                     |                                |
| PRAZQUANTEL<br>(1000015572)                | <b>HISUN PHARMACEUTICAL (NANTONG) CO., LTD.</b> , NO. 18, 4TH HAIBIN ROAD, RUDONG COASTAL, ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU, CN-226407, CHINA                       |                                |
| DOXYCYCLINE<br>MONOHYDRATE<br>(2000007682) | <b>YANCHENG SUHAI PHARMACEUTICALS COMPANY LIMITED</b> , HUAFENG INDUSTRIAL PARK, DAFENG PORT ECONOMIC ZONE, DAFENG DISTRICT, YANCHENG CITY, JIANGSU PROVINCE, CN-224100, CHINA |                                |
| SODIUM FEREDETATE<br>(4000007079)          | <b>NOURYON FUNCTIONAL CHEMICALS B.V.</b> , LISPINWEG 6, HERKENBOSCH, NL-6075 CE, NETHERLANDS   |                                |
| NEOMYCIN SULPHATE<br>(2000008175)          | <b>YICHANG SANXIA PHARMACEUTICAL COMPANY LIMITED</b> , NO. 8 ZIYANG ROAD, DIAJUN DISTRICT, YICHANG, HUBEI, CN-443002, CHINA  |                                |

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| N-ACETYLCYSTEINE<br>(3000005344)           | <b>WUHAN GRAND HOYO COMPANY LIMITED</b> , ROOM 1, 6TH FLOOR, BUILDING 3, INTERNATIONAL ENTERPRISE CENTRE, NO. T1, GUANSHAN 2ND ROAD, EAST LAKE HIGH TECH DEVELOPMENT ZONE, WUHAN, HUBEI PROVINCE, CN-430070, CHINA |
| METFORMIN<br>HYDROCHLORIDE<br>(2000008338) | <b>SHOUGUANG FUKANG PHARMACEUTICAL CO. LTD.</b> , NORTH-EAST OF DONGWAIHUAN ROAD, DONGCHENG INDUSTRIAL AREA, SHOUGUANG, SHANDONG PROVINCE, CN-262700, CHINA  |
| CISAPRIDE (1000009097)                     | <b>SHAOXING JINGXIN PHARMACEUTICAL CO., LIMITED.</b> , NO 31 WEISAN ROAD, HANGZHOU BAY SHANGYU ECONOMIC AND TECHNICAL DEVELOPMENT AREA, SHANGYU, SHAOXING, ZHEJIANG PROVINCE, CN-312 369, CHINA                    |
| HYDROQUINONE<br>(1000008752)               | <b>EASTMAN CHEMICAL COMPANY</b> , 200 SOUTH WILCOX DRIVE, KINGSPORT, 37660, UNITED STATES  |
| PREDNISOLONE<br>ACETATE (2000007916)       | <b>ZHEJIANG XIANJU PHARMACEUTICAL CO. LIMITED</b> , NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG PROVINCE, CN-317300, CHINA  |
| DOXYCYCLINE HYCLATE<br>(4000006937)        | <b>SHANDONG GUOBANG PHARMACEUTICAL CO., LTD.</b> , NO. 02131 XIANGJIANGXIYI STREET, ADVANCED MANUFACTURING INDUSTRIAL PARK, BINHAI ECONOMIC DEVELOPMENT ZONE, WEIFANG, SHANDONG, CN-261108, CHINA                  |
| EXEMESTANE<br>(1000000183)                 | <b>SHANDONG ANHONG PHARMACEUTICAL CO., LIMITED</b> , NO. 29 HUAYUAN STREET, LINHI COUNTY, DEZHOU CITY, SHANDONG PROVINCE, CN-251500, CHINA   |
| DEXAMETHASONE<br>(1000003334)              | <b>TIANJIN TIANYAO PHARMACEUTICALS CO LIMITED</b> , 19 XINYE 9TH STREET, WEST AREA OF TIANJIN ECONOMIC TECHNOLOGICAL DEVELOPMENT AREA, TIANJIN, CN-300 462, CHINA  |
| METRONIDAZOLE<br>BENZOATE (2000008258)     | <b>HUBEI HONGYUAN PHARMACEUTICAL TECHNOLOGY CO., LIMITED.</b> , NO. 8, HONGYUAN ROAD, ECONOMIC DEVELOPMENT ZONE, LUOTIAN COUNTY, FENGSHAN TOWN, HUANGGANG CITY, HUBEI, CN-438 600, CHINA                           |
| TINIDAZOLE (1000009326)                    | <b>ZHEJIANG SUPOR PHARMACEUTICALS CO., LIMITED</b> , YUEDONG ROAD, PAOJIANG INDUSTRIAL ZONE, SHAOXING, ZHEJIANG, RC-312071, CHINA  |
| ENALAPRIL MALEATE<br>(2000007672)          | <b>ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.</b> , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA  |

PARACETAMOL  
(1000009609)

**FARMSON PHARMACEUTICAL GUJARAT PVT LIMITED**, PLOT NO. 28-35  
G.I.D.C. INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT, GUJARAT,  
IN-391340, INDIA

GUAIFENESIN  
(3000005625)

**SYNTHOKEM LABS PVT LIMITED**, PLOT NO 1911, B-5, INDUSTRIAL ESTATE,  
SANATHNAGAR, HYDERABAD, IN-500 018, INDIA

TACROLIMUS  
(1000002882)

**JOYANG LABORATORIES**, NO. 9 NORTH HAIDOU ROAD, SHEYANG  
ECONOMIC DEVELOPMENT ZONE, YANCHENG, JIANGSU PROVINCE, CN  
224300, CHINA

SUCRALFATE  
(1000009411)

**ZHEJIANG HAISEN PHARMACEUTICAL CO., LIMITED.**, LIUSHI STREET,  
DONGYANG CITY, ZHEJIANG, CN-322104, CHINA

BENZAEPRI  
L HYDROCHLORIDE  
(2000006111)

**ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.**, XUNQIAO, LINHAI CITY,  
ZHEJIANG PROVINCE, CN-317024, CHINA

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TACROLIMUS (1000002882)

SUCRALFATE (100009411)

SIMETHICONE (100009128)

BENZAEPRIIL HYDROCHLORIDE (200006111)

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