

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 15343 |
| 2. Name or corporate name of registrant | MALLINCKRODT CHEMICAL LIMITED |
| 3. Permanent or legal address of registrant | MALLINCKRODT CHEMICAL LIMITED, PERTH HOUSE, MILLENNIUM WAY,
CHESTERFIELD, S41 8ND, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities
take place | MALLINCKRODT CHEMICAL LIMITED , PERTH HOUSE, MILLENNIUM
WAY, CHESTERFIELD, S41 8ND, UNITED KINGDOM

EXPEDITORS INTERNATIONAL (UK) LIMITED, UNIT 2, 62 MOSLEY ROAD,
TRAFFORD PARK, MANCHESTER, M17 1NB, 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 | 03/03/2025 |

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

MALLINCKRODT CHEMICAL LIMITED , PERTH HOUSE, MILLENNIUM WAY, CHESTERFIELD, S41 8ND, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

SUFENTANIL CITRATE (2000006818)

3rd Country Manufacturer

SPECGX LLC, 3600 NORTH SECOND STREET, ST LOUIS, 63147,
UNITED STATES

3rd Country Distributor

METHADONE HYDROCHLORIDE (2000008337)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
OXYMORPHONE HYDROCHLORIDE (2000014978)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
NALTREXONE HYDROCHLORIDE (2000007614)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
DEXTROAMPHETAMINE (3000005676)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
BUPRENORPHINE HYDROCHLORIDE (2000008277)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
NALOXONE HYDROCHLORIDE (2000008238)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
COCAINE HYDROCHLORIDE (2000007943)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
DIPHENOXYLATE HYDROCHLORIDE (2000007757)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
METHYLPHENIDATE HYDROCHLORIDE (2000008305)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
DEXTROAMPHETAMINE SULPHATE (2000009340)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
OXYMORPHONE (1000016087)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
ACETAMINOPHEN (3000006363)	SPECGX LLC , RALEIGH PHARMACEUTICAL PLANT, 8801 CAPITAL BOULEVARD, RALEIGH, 27616-3116, UNITED STATES
FENTANYL CITRATE (2000007584)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
OXYCODONE HYDROCHLORIDE (2000006722)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

NALMEFENE HYDROCHLORIDE (2000007444)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
METHADONE (1000000638)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
NOSCAPINE HYDROCHLORIDE (2000008165)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
SUFENTANIL (1000008500)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
NOSCAPINE (1000009663)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
NALTREXONE BASE ANHYDROUS (3000013154)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
NALBUPHINE HYDROCHLORIDE (2000008240)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
NALOXONE (1000000209)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
METHYLNALTREXONE BROMIDE (2000010193)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
CODEINE PHOSPHATE (2000007940)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
MORPHINE SULPHATE (2000008246)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
FENTANYL (1000002290)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
METHYLPHENIDATE (1000009492)	SPECGX LLC , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
PARACETAMOL (1000009609)	SPECGX LLC , RALEIGH PHARMACEUTICAL PLANT, 8801 CAPITAL BOULEVARD, RALEIGH, 27616-3116, UNITED STATES

BUPRENORPHINE (1000007171)

SPECGX LLC, 3600 NORTH SECOND STREET, ST LOUIS, 63147,
UNITED STATES

HYDROCODONE BITARTRATE
(4000009774)

SPECGX LLC, 3600 NORTH SECOND STREET, ST LOUIS, 63147,
UNITED STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
ACETAMINOPHEN (3000006363)
PARACETAMOL (1000009609)

Name and address of the site

EXPEDITORS INTERNATIONAL (UK) LIMITED, UNIT 2, 62 MOSLEY ROAD, TRAFFORD PARK, MANCHESTER, M17 1NB, UNITED
KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
PARACETAMOL (1000009609)
IBUPROFEN (1000008918)
ACETAMINOPHEN (3000006363)
MAGNESIUM STEARATE - SODIUM LAURYL SULPHATE MIXTURE (1000004991)
PARACETAMOL COMPRESSIBLE 90% - COMPAP (2000014123)