

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	13/03/2024

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

NALOXONE (1000000209)

3rd Country Manufacturer

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

3rd Country Distributor

CODEINE PHOSPHATE (2000007940) **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

BUPRENORPHINE (1000007171) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

FENTANYL (1000002290) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

PARACETAMOL (1000009609) **SPECGX LLC**, RALEIGH PHARMACEUTICAL PLANT, 8801 CAPITAL BOULEVARD, RALEIGH, 27616, UNITED STATES

METHYLPHENIDATE HYDROCHLORIDE (2000008305) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

ACETAMINOPHEN (3000006363) **SPECGX LLC**, RALEIGH PHARMACEUTICAL PLANT, 8801 CAPITAL BOULEVARD, RALEIGH, 27616, UNITED STATES

DIPHENOXYLATE HYDROCHLORIDE (2000007757) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

METHADONE (1000000638) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

FENTANYL CITRATE (2000007584) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

OXYMORPHONE (1000016087) **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 HYDROCHLORIDE (2000007614) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

SUFENTANIL CITRATE (2000006818) **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

DEXTROAMPHETAMINE (3000005676) **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

METHYLPHENIDATE (1000009492) **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

NOSCAPINE HYDROCHLORIDE (2000008165) **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

OXYMORPHONE HYDROCHLORIDE (2000014978) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

METHADONE HYDROCHLORIDE (2000008337) **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

MORPHINE SULPHATE (2000008246) **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

OXYCODONE HYDROCHLORIDE (2000006722) **SPECGX LLC**, 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES

SUFENTANIL (1000008500) **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

NALTREXONE BASE ANHYDROUS
(3000013154)

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
PARACETAMOL (1000009609)
ACETAMINOPHEN (3000006363)

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