

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 25136 |
| 2. Name or corporate name of registrant | SIGMA-ALDRICH COMPANY LIMITED |
| 3. Permanent or legal address of registrant | SIGMA-ALDRICH COMPANY LIMITED, THE OLD BRICKYARD, NEW ROAD, GILLINGHAM, SP8 4XT, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | SIGMA-ALDRICH COMPANY LTD (TRADING AS SAFC), THE OLD BRICKYARD, NEW ROAD, GILLINGHAM, SP8 4XT, 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

SIGMA-ALDRICH COMPANY LTD (TRADING AS SAFC), THE OLD BRICKYARD, NEW ROAD, GILLINGHAM, SP8 4XT, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

| Active Substance | 3rd Country Manufacturer | 3rd Country Distributor |
|---------------------------|---|---|
| UREA C-13 (2000007284) | ALDRICH CHEMICAL COMPANY LLC , 3858 BENNER ROAD, MIAMISBURG, 45342-4304, UNITED STATES | ALDRICH CHEMICAL COMPANY LLC , 3858 BENNER ROAD, MIAMISBURG, 45342-4304, UNITED STATES |

PYRUVIC ACID-1-13C
(4000016889)

ALDRICH CHEMICAL COMPANY LLC, 3858
BENNER ROAD, MIAMISBURG, 45342-4304,
UNITED STATES

ALDRICH CHEMICAL COMPANY LLC, 3858
BENNER ROAD, MIAMISBURG, 45342-4304,
UNITED STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
 UREA C-13 (2000007284)
 PYRUVIC ACID-1-13C (4000016889)