

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 33889
2. Name or corporate name of registrant	BASF PHARMA (CALLANISH) LIMITED
3. Permanent or legal address of registrant	BASF PHARMA (CALLANISH) LIMITED, BREASCLETE, CALLANISH, ISLE OF LEWIS, HS2 9ED, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	BASF PHARMA (CALLANISH) LIMITED, BREASCLETE, CALLANISH, ISLE OF LEWIS, HS2 9ED, 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	23/04/2024

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

BASF PHARMA (CALLANISH) LIMITED, BREASCLETE, CALLANISH, ISLE OF LEWIS, HS2 9ED, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

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1000002806

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance

	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) SMB Purification / Flash refining
E	General Finishing Steps
	E.1 Physical Processing Steps final refining & purification
	E.2 Primary Packaging Special Requirements Other: Material is sensitive to oxidation, must be kept under a gas blanket of oxygen free nitrogen.
	E.3 Secondary Packaging Special Requirements Other: Material is sensitive to oxidation, must be kept under a gas blanket of oxygen free nitrogen.
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

DOCOSAHEXAENOIC ACID

1000002929

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) SMB purification / Flash Refining
E	General Finishing Steps
	E.1 Physical Processing Steps SMB Refining Purification
	E.2 Primary Packaging Special Requirements Other: Material sensitive to oxidation must be stored under nitrogen blanket
	E.3 Secondary Packaging Special Requirements Other: Material sensitive to oxidation must be stored under nitrogen blanket
F	Quality Control Testing

	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.3 Microbiological testing (including sterility testing)