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 30812
2. Name or corporate name of registrant	CRODA EUROPE LIMITED
3. Permanent or legal address of registrant	CRODA EUROPE LIMITED, COWICK HALL, SNAITH, GOOLE, DN14 9AA, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	CRODA EUROPE LIMITED, BARNFIELD ROAD, LEEK, ST13 5QJ, UNITED KINGDOM CRODA EUROPE LIMITED, FOUNDRY LANE, DITTON, WIDNES, WA8 8UB, 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	05/06/2026

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

CRODA EUROPE LIMITED, BARNFIELD ROAD, LEEK, ST13 5QJ, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
OMEGA-3-ACID ETHYL ESTERS 90
2000006881

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

MHRA-GMDP MHRA-GMDP MHRA

	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Manufacture of omega-3 ethyl esters is a series of purification steps from Crude or Semi-Refined marine oil
E	General Finishing Steps
	E.1 Physical Processing Steps esterification, distillation, clathration, clay bleaching, carbon treatment, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

OMEGA-3-ACID TRIGLYCERIDES

2000006478

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Manufacture of omega-3-acid triglycerides is a series of purification steps from Crude or Semi-Refined Marine Oil
E	General Finishing Steps
	E.1 Physical Processing Steps esterification, distillation, clathration, glycerolysis, clay bleaching, carbon treatment, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FISH OIL, RICH IN OMEGA-3 ACIDS

4000016939

B	Extraction of Active Substance from Natural Sources
	B.2 Animal Source Extraction
	B.6 Purification of Extracted Substance - ANIMAL
E	General Finishing Steps
	E.1 Physical Processing Steps Distillation, Clay Bleaching, Carbon Treatment, Filtration
	E.2 Primary Packaging

MHRA-GMDP MHRA

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.4 Biological Testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FISH OIL, RICH IN OMEGA-3 ACIDS (4000016939)

TITANIUM DIOXIDE (1000009323)

Name and address of the site

CRODA EUROPE LIMITED, FOUNDRY LANE, DITTON, WIDNES, WA8 8UB, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
ZINC OXIDE
2000008399

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Bead milling and dispersion in oil or water
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
TITANIUM DIOXIDE
1000009323

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps

MHRA-GMDP MHRA

	E.1 Physical Processing Steps Bead milling and dispersion in oil or water
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

MHRA-GMDP
MHRA
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