

# 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 5965  
2. Name or corporate name of registrant FINE ORGANICS LIMITED  
3. Permanent or legal address of registrant FINE ORGANICS LIMITED, SEAL SANDS, Middlesbrough, TS2 1UB, UNITED KINGDOM  
4. Address(es) of site(s) where registered activities take place FINE ORGANICS LIMITED, SEAL SANDS, Middlesbrough, TS2 1UB, 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 06/01/2026

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

**FINE ORGANICS LIMITED, SEAL SANDS, Middlesbrough, TS2 1UB, UNITED KINGDOM**

#### 1. MANUFACTURING OPERATIONS

##### Active substance

CLORSULON  
1000017828

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) Crystallisation
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

**Active substance**

FLUAZURON

1000022037

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) Crystallisation
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

**Active substance**

METARAMINOL BITARTRATE

2000017117

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) Crystallisation
E	General Finishing Steps
	E.2 Primary Packaging

	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

4-CYANO-3-(TRIFLUOROMETHYL)PHENYLISOTHIOCYANATE

1000022773

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) Crystallisation
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**2. IMPORTATION AND DISTRIBUTION OPERATIONS**

B Distribution

CLORSULON (1000017828)

FLUAZURON (1000022037)

METARAMINOL BITARTRATE (2000017117)

4-CYANO-3-(TRIFLUOROMETHYL)PHENYLISOTHIOCYANATE (1000022773)