

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 2021
2. Name or corporate name of registrant FUCHS LUBRICANTS (UK) PLC
3. Permanent or legal address of registrant FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, 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 27/03/2024

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

FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

PARAFFIN LIGHT LIQUID
2000008090

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
	B.6 Purification of Extracted Substance - MINERAL

E	General Finishing Steps
	E.1 Physical Processing Steps 5 micron or better filtration.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

PARAFFIN SOFT YELLOW

2000008087

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
	B.6 Purification of Extracted Substance - MINERAL
E	General Finishing Steps
	E.1 Physical Processing Steps Mixing of waxes and oils. Better than 5 micron filtration. Vacuum steam stripping and Fullers Earth treatment followed by high vacuum steam deodorisation.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

PARAFFIN LIQUID

2000008089

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
	B.6 Purification of Extracted Substance - MINERAL
E	General Finishing Steps
	E.1 Physical Processing Steps 5 micron or better filtration.
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

PARAFFIN SOFT WHITE

2000008088

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
	B.6 Purification of Extracted Substance - MINERAL
E	General Finishing Steps
	E.1 Physical Processing Steps 5 micron or better filtration. Vacuum steam stripping, Fullers Earth treatment and high vacuum steam deodorisation.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
- PARAFFIN LIGHT LIQUID (2000008090)
 - PARAFFIN SOFT YELLOW (2000008087)
 - PARAFFIN LIQUID (2000008089)
 - PARAFFIN SOFT WHITE (2000008088)