Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 2021

2: Name of authorisation holder FUCHS LUBRICANTS (UK) PLC

FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW

CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU,

UNITED KINGDOM

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UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

4: Legally registered address of authorisation holder

Confidential

8: Authorisation Date 28/07/2020

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

3: Address(es) of manufacturing site(s)

6: Legal Basis of authorisation

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.6] Liquids for internal use

[1.2.1.11] Semi-solids

[1.2.1.17] Other non-sterile medicinal products

Liquid Mineral hydrocarbon SI 1073 1966. Soft paraffin - BP/EP: used as excipients, Liquid & Light L

[1.2.2] Batch certification

Issue Date: 28 Jul 2020

