

According to REACH Regulations (EC) 1907/2006 and (EU) 2020/878

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product code : GA5441
 Product name : Rifaximin, Ph. Eur. grade
 CAS number : 80621-81-4
 Physical form : solid, substance
 REACH : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

1.2 Relevant identified uses of the substance or mixture and uses advised against

PC21: Laboratory chemicals.

1.3 Details of the supplier of the safety data sheet

Company name : Glentham Life Sciences Ltd Telephone : +44 (0) 1225 667 798
 Unit 5 Leafield Way Fax : +44 (0) 2033 978 909
 Corsham SN13 9SW Email : info@glentham.com
 United Kingdom Web : www.glentham.com

1.4 Emergency telephone number

Emergency telephone : NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 – 17.00 GMT) number

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008
 This product has no classification under CLP.

2.2 Label elements

Label elements under CLP according to (EC) 1272/2008
 This product has no label elements.

2.3 Other hazards

PBT
 This substance is not identified as a PBT substance.

3.0 Composition/information on ingredients

3.1 Substances

| Name | Identifier | % | Classification |
|---------------------------|---|-------|----------------|
| Rifaximin, Ph. Eur. grade | CAS: 80621-81-4 EC: REACH: Not applicable | 97.0% | Not classified |

4. First aid measures

4.1 Description of first aid measures

| | |
|--------------|--|
| Skin contact | Wash immediately with plenty of soap and water. |
| Eye contact | Bathe the eye with running water for 15 minutes. |
| Ingestion | Wash out mouth with water. |
| Inhalation | Consult a doctor. |

4.2 Most important symptoms and effects, both acute and delayed

| | |
|-----------------------------|---|
| Skin contact | There may be mild irritation at the site of contact. |
| Eye contact | There may be irritation and redness. |
| Ingestion | There may be irritation of the throat. |
| Inhalation | There may be irritation of the throat with a feeling of tightness in the chest. |
| Delayed / immediate effects | Immediate effects can be expected after short-term exposure. |

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment

No data available.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used.

5.2 Special hazards arising from the substance or mixture

Exposure hazards

In combustion emits toxic fumes.

5.3 Advice for fire-fighters

Wear protective clothing to prevent contact with skin and eyes. Wear self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Refer to section 8 of SDS for personal protection details.

6.2 Environmental precautions

Do not discharge into drains or rivers.

6.3 Methods and material for containment and cleaning up

Clean-up procedures

Wash the spillage site with large amounts of water.

6.4 Reference to other sections

Refer to section 8 of SDS.

7. Handling and storage

7.1 Precautions for safe handling

Handling requirements

Avoid the formation or spread of dust in the air.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Avoid contact with water or humidity. Keep container tightly closed. Store in cool, well ventilated area.

7.3 Specific end use(s)

No data available.

8. Exposure controls/personal protection

8.1 Control parameters

Workplace exposure limits

No workplace exposure limit control parameters set

8.2 Exposure controls

| | |
|------------------------|---|
| Engineering measures | No data available. |
| Respiratory protection | Respiratory protective device with particle filter. |
| Hand protection | Protective gloves. |
| Eye protection | Ensure eye bath is to hand. Safety glasses. |
| Skin protection | Protective clothing. |

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|---|---------------------|
| Physical state | Solid |
| Colour | Red |
| Odour | No data available. |
| Melting point/Freezing point | 200-205 °C (decomp) |
| Boiling point/initial boiling point/boiling range | No data available. |
| Flammability | No data available. |
| Lower/Upper explosion limit | No data available. |
| Flash Point | No data available. |
| Auto-ignition temperature | No data available. |
| Decomposition temperature | No data available. |
| pH | No data available. |
| Kinematic viscosity | No data available. |
| Solubility | No data available. |
| Partition coefficient n-octanol/water | No data available. |
| Vapour pressure | No data available. |
| Density/relative density | No data available. |
| Relative vapour pressure | No data available. |
| Particle characteristics | No data available. |

9.2 Other information

No data available.

10. Stability and reactivity

10.1 Reactivity

Stable under recommended transport or storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions

Decomposition may occur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal transport or storage conditions.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Materials to avoid

Strong acids. Strong oxidising agents.

11. Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity

No data available.

b) Skin corrosion/irritation

No data available.

c) Serious eye damage/irritation

No data available.

d) **Respiratory or skin sensitisation**

No data available.

e) **Germ cell mutagenicity**

No data available.

f) **Carcinogenicity**

No data available.

g) **Reproductive toxicity**

No data available.

h) **STOT-single exposure**

No data available.

i) **STOT-repeated exposure**

No data available.

j) **Aspiration hazard**

No data available.

11.2 **Symptoms / routes of exposure**

| | |
|-----------------------------|---|
| Skin contact | There may be mild irritation at the site of contact. |
| Eye contact | There may be irritation and redness. |
| Ingestion | There may be irritation of the throat. |
| Inhalation | There may be irritation of the throat with a feeling of tightness in the chest. |
| Delayed / immediate effects | Immediate effects can be expected after short-term exposure. |
| Other information | No data available. |

12. **Ecological information**

12.1 **Toxicity**

No data available.

12.2 **Persistence and degradability**

Biodegradable.

12.3 **Bioaccumulative potential**

No bioaccumulation potential.

12.4 **Mobility in soil**

No data available.

12.5 **Results of PBT and vPvB assessment**

This substance is not identified as a PBT substance.

12.6 **Endocrine disrupting properties**

This substance is not identified as having endocrine disrupting properties

12.7 **Other adverse effects**

No data available.

13. **Disposal considerations**

13.1 **Waste treatment methods**

Disposal operations

Transfer to a suitable container and arrange for collection by specialised disposal company.

NB

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. **Transport information**

This product does not require a classification for transport.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.

Authorisations/Restrictions

| | |
|--|--------------------|
| Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to authorisation: | No data available. |
| Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing on the market and use of certain dangerous substances: | No data available. |
| Regulation (EC) 1005/2009 on substances that deplete the ozone layer: | No data available. |
| Regulation (EC) 850/2004 on persistent organic pollutants, amended by (EU) No 2019/1021: | No data available. |

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

16. Other information

H-Statement Full Texts

Abbreviations Full Texts

| | |
|-----------|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ALARP | As low as is reasonably practicable |
| CAS | Chemical Abstracts Service |
| CLP | Classification, Labelling and Packaging Regulations |
| COSHH | Control of Substances Hazardous to Health |
| EC Number | European Community Number |
| EC50 | Effective Concentration 50% |
| EILINCS | European List of Notified Chemical Substances |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| GHS | Globally Harmonised System |
| HSE | Health & Safety Executive UK |
| IATA | International Air Transport Association |
| IM | Intramuscular |
| IMDG | The International Maritime Dangerous Goods Code |
| IP | Intraperitoneal |
| IV | Intravascular |
| LD50 | Lethal Dose 50% |
| LOEC | Lowest Observable Effective Concentration |
| LTEL | Long Term Exposure Limit |
| NOEC | No Observable Effective Concentration |
| OECD | Organisation for Economic Cooperations and Development |
| PBT | Persistent Bioaccumulative Toxic |
| PPE | Personal Protective Equipment |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Regulations Concerning the International Carriage of Dangerous Goods by Rail |
| SC | Subcutaneous |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| VOC | Volatile Organic Compounds |
| vPvB | Very Persistent and Very Bioaccumulative |
| WEL | Workplace Exposure Limits |

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Disclaimer: Glentham Life Sciences shall not be held liable for any damage resulting from handling or from contact with the above product. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This document does not guarantee the properties or quality of the product.