

Safety Data Sheet

according to Regulation (EC) No 1907/2006 (REACH) Classifications according to Regulation (EC) No 1272/2008. Printdate 16 Aug 2022

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product name:

Roxithromycin

1.1. Catalog No.:

674897

1.2. Relevant identified uses of the substance or mixture Identified: Laboratory chemical uses: R&D

uses:

1.3. Uses advised against:

HPC Standards GmbH Am Wieseneck 7

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1.4. Emergency telephone number

HPC Standards Tel. +49 34291 3372-36 This number is only available during office hours.

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 Acute toxicity, Oral (Category 4), H302 Classification according to EU Directives 67/548/EEC or 1999/45/EC Xn Harmful R22

2.2. Label elements

2.2.1. Pictogram



2.2.2.

Signal word Warning Hazard statement(s) H302 Harmful if swallowed. Precautionary statement(s) none Supplemental Hazard Statements None 2.3 Other hazards - none



3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances Chemical characterization : Natural product Synonyms : Erythromycin 9-(-O-[2-methoxyethoxy]methyloxime) Formula : C41H76N2O15 Molecular Weight : 837,05 g/mol CAS-No. : 80214-83-1 Hazardous ingredients according to Regulation (EC) No 1272/2008 Component Classification Concentration Roxithromycin CAS-No. 80214-83-1 Acute Tox. 4; H302 <= 100 % Hazardous ingredients according to Directive 1999/45/EC Component Classification Concentration Roxithromycin CAS-No. 80214-83-1 Xn, R22 <= 100 %

3.1.1. Formula

C41H76N2O15

3.1.2. Molecular Weight (g/mol)

837.05

3.1.3. CAS-No.

80214-83-1



4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed no data available

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. 5.2 Special hazards arising from the substance or mixture Carbon oxides, nitrogen oxides (NOx) 5.3 Advice for firefighters Wear self contained breathing apparatus for fire fighting if necessary. 5.4 Further information no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Avoid breathing dust.
For personal protection see section 8.
6.2 Environmental precautions
Do not let product enter drains.
6.3 Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal containers for disposal. 6.4 Reference to other sections For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.Normal measures for preventive fire



protection. For precautions see section 2.2. 7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: 2 - 8 °C

7.3 Specific end use(š) A part from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters 8.2 Exposure controls

Appropriate engineering controls Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of accordance with applicable laws and good laboratory practices. contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry Hands Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Respiratory protection

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator.For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
a) Appearance Form: solid
b) Odour no data available
c) Odour Threshold no data available
d) pH no data available
e) Melting point/freezing

- point
- no data available f) Initial boiling point and
- boiling range no data available
- Flash point no data available
- g) Flash point no data available h) Evapouration rate no data available
- Flammability (solid, gas) no data available
- j) Upper/lower
- flammability or
- explosive limits
- no data available

- k) Vapour pressure no data available
 l) Vapour density no data available
 m) Relative density no data available
 n) Water solubility no data available
 o) Partition coefficient: noctanol/



water no data available p) Auto-ignition temperature no data available q) Decomposition temperature no data available r) Viscosity no data available s) Explosive properties no data available 9.2 Other safety information no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
no data available
10.2 Chemical stability
Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions
no data available
10.4 Conditions to avoid
no data available
10.5 Incompatible materials
Strong oxidizing agents
10.6 Hazardous decomposition products
Other decomposition products - no data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects Acute toxicity LD50 Oral - rat - 830 mg/kg Remarks: Behavioral:Change in motor activity (specific assay). Lungs, Thorax, or Respiration:Other changes. Nutritional and Gross Metabolic:Weight loss or decreased weight gain. Skin corrosion/irritation no data available Serious eye damage/eye irritation no data available Respiratory or skin sensitisation no data available Germ cell mutagenicity no data available Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. Reproductive toxicity no data available Specific target organ toxicity - single exposure no data available Specific target organ toxicity - repeated exposure no data available Aspiration hazard no data available Additional Information RTECS: KF4990000 To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.



12. ECOLOGICAL INFORMATION

12.1 Toxicity no data available 12.2 Persistence and degradability no data available 12.3 Bioaccumulative potential no data available 12.4 Mobility in soil no data available 12.5 Results of PBT and vPvB assessment PBT/vPvB assessment not available as chemical safety assessment not required/not conducted 12.6 Other adverse effects no data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods Product Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Contaminated packaging Dispose of as unused product

14. TRANSPORT INFORMATION

14.1 UN number ADR/RID: - IMDG: - IATA: -14.2 UN proper shipping name ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods 14.3 Transport hazard class(es) ADR/RID: - IMDG: - IATA: -14.4 Packaging group ADR/RID: - IMDG: - IATA: -14.5 Environmental hazards ADR/RID: no IMDG Marine pollutant: no IATA: no 14.6 Special precautions for user no data available

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture no data available

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out



16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. For lab use only!