SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Roxithromycin

Product Number : R4393
Brand : Sigma
REACH No. : 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.
CAS-No. : 80214-83-1

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

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Pte Ltd
1 Science Park Road
#02-14 The Capricorn
Singapore Science Park Road II
SINGAPORE 117528
SINGAPORE

Telephone : +65 6779 1200
Fax : +65 6779 1822

1.4 Emergency telephone number

Emergency Phone # : 1-800-262-8200

SECTION 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

For the full text of the H-Statements mentioned in this Section, see Section 16.

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Xn Harmful R22

For the full text of the R-phrases mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008
Pictogram

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

SECTION 3: Composition/information on ingredients

3.1  Substances
Chemical characterization : Natural product
Synonyms : Erythromycin 9-(-O-[2-methoxyethoxy]methylloxime)

Formula : \( \text{C}_{41}\text{H}_{76}\text{N}_{2}\text{O}_{15} \)
Molecular Weight : 837.05 g/mol
CAS-No. : 80214-83-1

Hazardous ingredients according to Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roxithromycin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No.</td>
<td>80214-83-1</td>
<td>Acute Tox. 4; H302 &lt;= 100 %</td>
</tr>
</tbody>
</table>

Hazardous ingredients according to Directive 1999/45/EC

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roxithromycin</td>
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<td></td>
</tr>
<tr>
<td>CAS-No.</td>
<td>80214-83-1</td>
<td>Xn, R22 &lt;= 100 %</td>
</tr>
</tbody>
</table>

For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16

SECTION 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

SECTION 5: Firefighting 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.
SECTION 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.

6.4 Reference to other sections
For disposal see section 13.

SECTION 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(s)
A part from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 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 contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min
Material tested:Dermatri® (KCL 740 / Aldrich Z677272, Size M)
Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested: Dermatrix® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374
If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

**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.

### SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Data Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Appearance</td>
<td>Form: solid</td>
</tr>
<tr>
<td>b) Odour</td>
<td>no data available</td>
</tr>
<tr>
<td>c) Odour Threshold</td>
<td>no data available</td>
</tr>
<tr>
<td>d) pH</td>
<td>no data available</td>
</tr>
<tr>
<td>e) Melting point/freezing point</td>
<td>no data available</td>
</tr>
<tr>
<td>f) Initial boiling point and boiling range</td>
<td>no data available</td>
</tr>
<tr>
<td>g) Flash point</td>
<td>no data available</td>
</tr>
<tr>
<td>h) Evaporation rate</td>
<td>no data available</td>
</tr>
<tr>
<td>i) Flammability (solid, gas)</td>
<td>no data available</td>
</tr>
<tr>
<td>j) Upper/lower flammability or explosive limits</td>
<td>no data available</td>
</tr>
<tr>
<td>k) Vapour pressure</td>
<td>no data available</td>
</tr>
<tr>
<td>l) Vapour density</td>
<td>no data available</td>
</tr>
<tr>
<td>m) Relative density</td>
<td>no data available</td>
</tr>
<tr>
<td>n) Water solubility</td>
<td>no data available</td>
</tr>
<tr>
<td>o) Partition coefficient: n-octanol/water</td>
<td>no data available</td>
</tr>
<tr>
<td>p) Auto-ignition temperature</td>
<td>no data available</td>
</tr>
<tr>
<td>q) Decomposition temperature</td>
<td>no data available</td>
</tr>
<tr>
<td>r) Viscosity</td>
<td>no data available</td>
</tr>
</tbody>
</table>
s) Explosive properties  no data available

t) Oxidizing properties  no data available

9.2 Other safety information
no data available

SECTION 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

SECTION 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.
SECTION 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

SECTION 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.

SECTION 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

SECTION 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
SECTION 16: Other information

Full text of H-statements referred to under sections 2 and 3.

Acute Tox.          Acute toxicity
H302               Harmful if swallowed.

Full text of R-phrases referred to under sections 2 and 3

Xn          Harmful
R22         Harmful if swallowed.

Further information

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