

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
Product Identifier

Perihal Produk: **Roxithromycin**
 Product Description: **Roxithromycin**
 Cat No. : 459570000; 459570050; 459570250
 CAS No 80214-83-1
 Molecular Formula C14 H76 N2 O15

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

Recommended Use Laboratory chemicals.
 Uses advised against No Information available

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SECTION 2: HAZARDS IDENTIFICATION
Classification of the substance or mixture

Acute oral toxicity	Category 4 (H302)
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Label Elements

Signal Word
Warning
Hazard Statements

H302 - Harmful if swallowed

Precautionary Statements

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Prevention

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

Response

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

Storage

P403 - Store in a well-ventilated place

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Other Hazards

This product does not contain any known or suspected endocrine disruptors

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %
Roxithromycin	80214-83-1	>95

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General Advice

If symptoms persist, call a physician.

Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

Inhalation

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

Self-Protection of the First Aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

Most important symptoms and effects, both acute and delayed

None reasonably foreseeable.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media

Water spray, carbon dioxide (CO₂), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

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No information available.

Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Carbon monoxide (CO), Nitrogen oxides (NO_x), Carbon dioxide (CO₂).

Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

Environmental precautions

Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and Material for Containment and Cleaning Up

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Conditions for Safe Storage, Including any Incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place.

Specific End Uses

Use in laboratories.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Exposure Controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to

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control hazardous materials at source

Personal protective equipment

Eye Protection	Wear safety glasses with side shields (or goggles)
Hand Protection	Protective gloves
Skin and body protection	Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves.
(Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators
Recommended Filter type:	Particulates filter conforming to EN 143 To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly When RPE is used a face piece Fit Test should be conducted

<u>Hygiene Measures</u>	Handle in accordance with good industrial hygiene and safety practice
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<u>Environmental exposure controls</u>	No information available
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance		
Physical State	Solid	
Odor	No information available	
Odor Threshold	No data available	
pH	Not applicable	
Melting Point/Range	111 - 118 °C / 231.8 - 244.4 °F	
Softening Point	No data available	
Boiling Point/Range	Not applicable	
Flash Point	> 110 °C / > 230 °F	Method - No information available
Evaporation Rate	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
Vapor Pressure	No data available	
Vapor Density	Not applicable	Solid
Specific Gravity / Density	No data available	
Bulk Density	No data available	
Water Solubility	No information available	
Solubility in other solvents	No information available	

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Partition Coefficient (n-octanol/water)

Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
Viscosity	Not applicable	Solid
Explosive Properties	No information available	
Oxidizing Properties	No information available	

Molecular Formula	C14 H76 N2 O15
Molecular Weight	837.05

SECTION 10: STABILITY AND REACTIVITY

Reactivity

None known, based on information available.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

Hazardous Polymerization	No information available.
Hazardous Reactions	None under normal processing.

Conditions to Avoid

Incompatible products. Excess heat. Avoid dust formation.

Incompatible Materials

Strong acids. Bases. Oxidizing agent.

Hazardous Decomposition Products

Carbon monoxide (CO). Nitrogen oxides (NOx). Carbon dioxide (CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Product Information

(a) acute toxicity;

Oral	Category 4
Dermal	No data available
Inhalation	No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Roxithromycin	830 mg/kg (Rat)	-	-

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(b) skin corrosion/irritation;	No data available
(c) serious eye damage/irritation;	No data available
(d) respiratory or skin sensitization;	
Respiratory	No data available
Skin	No data available
(e) germ cell mutagenicity;	No data available
(f) carcinogenicity;	No data available
	There are no known carcinogenic chemicals in this product
(g) reproductive toxicity;	No data available
(h) STOT-single exposure;	No data available
(i) STOT-repeated exposure;	No data available
Target Organs	No information available.
(j) aspiration hazard;	Not applicable
	Solid
Symptoms / effects, both acute and delayed	No information available.

Endocrine Disrupting Properties	Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.
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SECTION 12: ECOLOGICAL INFORMATION

<u>Ecotoxicity effects</u>	Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.
<u>Persistence and degradability</u>	No information available
<u>Bioaccumulative potential</u>	No information available
<u>Mobility in soil</u>	No information available.
<u>Endocrine Disruptor Information</u>	This product does not contain any known or suspected endocrine disruptors
<u>Other adverse effects</u>	No information available

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SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from Residues/Unused Products

Waste is classified as hazardous Dispose of in accordance with the European Directives on waste and hazardous waste Dispose of in accordance with local regulations

Contaminated Packaging

Dispose of this container to hazardous or special waste collection point.

Other Information

Waste codes should be assigned by the user based on the application for which the product was used Do not empty into drains

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

Not regulated

Road and Rail Transport

Not regulated

IATA

Not regulated

Special Precautions for User

No special precautions required

SECTION 15: REGULATORY INFORMATION

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

International Inventories

X = listed

Component	EINECS	TSCA	DSL	PICCS	ENCS	ISHL	IECSC	AICS	KECL
Roxithromycin	-	-	-	-	-	X	-	-	-

National Regulations

Persistent Organic Pollutant

This product does not contain any known or suspected substance

Ozone Depletion Potential

This product does not contain any known or suspected substance

SECTION 16: OTHER INFORMATION

Legend

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

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WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

POW - Partition coefficient Octanol:Water

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

Key literature references and sources for data

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

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22-Mar-2025

Revision Summary

Not applicable.

In accordance with local and national regulations: Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

Disclaimer

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End of Safety Data Sheet