

## SAFETY DATA SHEET

Creation Date 12-May-2015

Revision Date 29-March-2024

Revision Number 4

### 1. Identification

**Product Name** Roxithromycin

**Cat No. :** J66213

**CAS-No** 80214-83-1  
**Synonyms** No information available

**Recommended Use** Laboratory chemicals.  
**Uses advised against** Food, drug, pesticide or biocidal product use.

#### Details of the supplier of the safety data sheet

##### Company

##### **Importer/Distributor**

Fisher Scientific  
112 Colonnade Road,  
Ottawa, ON K2E 7L6,  
Canada  
Tel: 1-800-234-7437

##### **Emergency Telephone Number**

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11

Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99

**CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

### 2. Hazard(s) identification

#### Classification

**WHMIS 2015 Classification** Classified as hazardous under the Hazardous Products Regulations (SOR/2015-17)

**Acute oral toxicity** Category 4

#### Label Elements

##### **Signal Word**

Warning

##### **Hazard Statements**

Harmful if swallowed

**Precautionary Statements****Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product

**Response**

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell  
Rinse mouth

**Disposal**

Dispose of contents/container to an approved waste disposal plant

### 3. Composition/Information on Ingredients

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

### 4. First-aid measures

<b>General Advice</b>	If symptoms persist, call a physician.
<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
<b>Skin Contact</b>	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
<b>Most important symptoms/effects Notes to Physician</b>	None reasonably foreseeable. Treat symptomatically

### 5. Fire-fighting measures

<b>Suitable Extinguishing Media</b>	Water spray, carbon dioxide (CO <sub>2</sub> ), dry chemical, alcohol-resistant foam.
<b>Unsuitable Extinguishing Media</b>	No information available
<b>Flash Point</b>	> 110 °C / > 230 °F
<b>Method -</b>	No information available
<b>Autoignition Temperature</b>	No information available
<b>Explosion Limits</b>	
<b>Upper</b>	No data available
<b>Lower</b>	No data available

**Sensitivity to Mechanical Impact** No information available  
**Sensitivity to Static Discharge** No information available

**Specific Hazards Arising from the Chemical**

Keep product and empty container away from heat and sources of ignition.

**Hazardous Combustion Products**

Carbon monoxide (CO). Nitrogen oxides (NOx). Carbon dioxide (CO<sub>2</sub>).

**Protective Equipment and Precautions for Firefighters**

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

**NFPA**

**Health**  
2

**Flammability**  
1

**Instability**  
0

**Physical hazards**  
N/A

**6. Accidental release measures****Personal Precautions**

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 for Containment and Clean Up**

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

**7. Handling and storage****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.

**Storage.**

Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Strong acids. Bases. Oxidizing agent.

**8. Exposure controls / personal protection****Exposure Guidelines**

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**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 control hazardous materials at source

**Personal protective equipment****Eye Protection**

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

**Hand Protection**

Wear appropriate protective gloves and clothing to prevent skin exposure.

Glove material	Breakthrough time	Glove thickness	Glove comments
Nitrile rubber Neoprene Natural rubber PVC	See manufacturers recommendations	-	Splash protection only

Inspect gloves before use. observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information) gloves are suitable for the task: Chemical compatibility,

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. gloves with care avoiding skin contamination.

**Respiratory Protection**

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

**Recommended Filter type:** Particulates filter conforming to EN 143

When RPE is used a face piece Fit Test should be conducted

**Environmental exposure controls**

No information available.

**Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Physical State</b>	Solid
<b>Appearance</b>	No information available
<b>Odor</b>	No information available
<b>Odor Threshold</b>	No information available
<b>pH</b>	Not applicable
<b>Melting Point/Range</b>	111 - 118 °C / 231.8 - 244.4 °F
<b>Boiling Point/Range</b>	Not applicable
<b>Flash Point</b>	> 110 °C / > 230 °F
<b>Evaporation Rate</b>	Not applicable
<b>Flammability (solid,gas)</b>	No information available
<b>Flammability or explosive limits</b>	
<b>Upper</b>	No data available
<b>Lower</b>	No data available
<b>Vapor Pressure</b>	No information available
<b>Vapor Density</b>	Not applicable
<b>Specific Gravity</b>	No information available
<b>Solubility</b>	No information available
<b>Partition coefficient; n-octanol/water</b>	No data available
<b>Autoignition Temperature</b>	No information available
<b>Decomposition Temperature</b>	No information available
<b>Viscosity</b>	Not applicable
<b>Molecular Formula</b>	C14 H76 N2 O15
<b>Molecular Weight</b>	837.05

## 10. Stability and reactivity

<b>Reactive Hazard</b>	None known, based on information available
<b>Stability</b>	Stable under recommended storage conditions.
<b>Conditions to Avoid</b>	Incompatible products. Excess heat. Avoid dust formation.
<b>Incompatible Materials</b>	Strong acids, Bases, Oxidizing agent
<b>Hazardous Decomposition Products</b>	Carbon monoxide (CO), Nitrogen oxides (NOx), Carbon dioxide (CO <sub>2</sub> )
<b>Hazardous Polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous Reactions</b>	None under normal processing.

## 11. Toxicological information

### Acute Toxicity

#### Product Information

#### Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Roxithromycin	830 mg/kg (Rat)	Not listed	Not listed

**Toxicologically Synergistic Products** No information available

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Irritation** No information available

**Sensitization** No information available

**Carcinogenicity** The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS-No	IARC	NTP	ACGIH	OSHA	Mexico
Roxithromycin	80214-83-1	Not listed	Not listed	Not listed	Not listed	Not listed

**Mutagenic Effects** No information available

**Reproductive Effects** No information available.

**Developmental Effects** No information available.

**Teratogenicity** No information available.

**STOT - single exposure** None known

**STOT - repeated exposure** None known

**Aspiration hazard** No information available

**Symptoms / effects, both acute and delayed** No information available

**Endocrine Disruptor Information** No information available

**Other Adverse Effects** The toxicological properties have not been fully investigated.

## 12. Ecological information

### Ecotoxicity

Do not empty into drains.

**Persistence and Degradability** No information available

**Bioaccumulation/ Accumulation** No information available.

**Mobility** No information available.

## 13. Disposal considerations

**Waste Disposal Methods** Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

## 14. Transport information

**DOT** Not regulated

**TDG** Not regulated

**IATA** Not regulated

## IMDG/IMO

Not regulated

## 15. Regulatory information

## International Inventories

Component	CAS-No	DSL	NDSL	TSCA	TSCA Inventory notification - Active-Inactive	EINECS	ELINCS	NLP
Roxithromycin	80214-83-1	-	-	-	-	-	-	-

Component	CAS-No	IECSC	KECL	ENCS	ISHL	TCSI	AICS	NZIoC	PICCS
Roxithromycin	80214-83-1	-	-	-	X	X	-	X	-

## Legend:

X - Listed '-' - Not Listed

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

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

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

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

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

## Canada

SDS in compliance with provisions of information as set out in Canadian Standard - Part 4, Schedule 1 and 2 of the Hazardous Products Regulations (HPR) and meets the requirements of the HPR (Paragraph 13(1)(a) of the Hazardous Products Act (HPA)).

## Other International Regulations

## Authorisation/Restrictions according to EU REACH

Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Roxithromycin	-	Use restricted. See item 75. (see link for restriction details)	-

## REACH links

<https://echa.europa.eu/substances-restricted-under-reach>

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

Component	CAS-No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Roxithromycin	80214-83-1	Not applicable	Not applicable	Not applicable	Not applicable

Component	CAS-No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Roxithromycin	80214-83-1	Not applicable	Not applicable	Not applicable	Not applicable

## 16. Other information

<b>Prepared By</b>	Product Safety Department Email: chem.techinfo@thermofisher.com www.thermofisher.com
<b>Creation Date</b>	12-May-2015
<b>Revision Date</b>	29-March-2024
<b>Print Date</b>	29-March-2024
<b>Revision Summary</b>	New emergency telephone response service provider.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of SDS**