

# SAFETY DATA SHEET

Creation Date 12-May-2015

Revision Date 20-Dec-2025

Revision Number 5

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200)

## 1. Identification

<b>Product Name</b>	Roxithromycin
<b>Cat No. :</b>	<b>AC459570000; AC459570050; AC459570250</b>
<b>CAS No</b>	80214-83-1
<b>Synonyms</b>	No information available

**Recommended Use**  
**Uses advised against**

Laboratory chemicals.  
Food, drug, pesticide or biocidal product use.

## Details of the supplier of the safety data sheet

### Company

Fisher Scientific Company  
One Reagent Lane  
Fair Lawn, NJ 07410  
Tel: (201) 796-7100

Acros Organics  
One Reagent Lane  
Fair Lawn, NJ 07410

### 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

This chemical is considered hazardous according to [US] OSHA (29 CFR 1910.1200, 2024)

Acute oral toxicity	Category 4
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## 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

**Ingestion**

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

**Disposal**

Dispose of contents/container to an approved waste disposal plant

**Hazards not otherwise classified (HNOC)**

None identified

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

No information available

**3. Composition/information on Ingredients**

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

**4. 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.

**Inhalation**

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

**Ingestion**

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

**Most important symptoms and effects**

None reasonably foreseeable.

**Notes to Physician**

Treat symptomatically

**5. Fire-fighting measures**

**Suitable Extinguishing Media** Water spray, carbon dioxide (CO<sub>2</sub>), dry chemical, alcohol-resistant foam.

**Unsuitable Extinguishing Media** No information available

**Flash Point** > 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
<b>Sensitivity to Mechanical Impact</b>	No information available
<b>Sensitivity to Static Discharge</b>	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	Flammability	Instability	Physical hazards
	2	1	0	N/A

**6. Accidental release measures**

<b>Personal Precautions</b>	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.
<b>Environmental Precautions</b>	Should not be released into the environment. See Section 12 for additional Ecological Information.

<b>Methods for Containment and Clean Up</b>	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.
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**7. Handling and Storage**

<b>Handling</b>	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.
<b>Storage.</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Strong acids. Bases. Oxidizing agent.

**8. Exposure controls / personal protection**

<b>Exposure Guidelines</b>	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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<b>Engineering Measures</b>	Ensure adequate ventilation, especially in confined areas.
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**Personal Protective Equipment**

<b>Eye/face Protection</b>	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.
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<b>Skin and body protection</b>	Wear appropriate protective gloves and clothing to prevent skin exposure.
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<b>Respiratory Protection</b>	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.
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**Recommended Filter type:** Particulates filter conforming to EN 143.

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Appearance

**Physical State** Solid

**Color**

**Odor**

**Odor Threshold**

### Property

**Melting Point/Range**

**Values** 111 - 118 °C / 231.8 - 244.4 °F

### Remarks

### • Method

**Softening Point**

No data available

**Boiling Point/Range**

Not applicable

**Flash Point**

> 110 °C / > 230 °F

**Method** - No information available

**Flammability (liquid)**

Not applicable

Solid

**Flammability (solid,gas)**

No information available

**Explosion Limits**

No data available

**Autoignition Temperature**

No data available

**Decomposition Temperature**

No data available

**pH**

Not applicable

**Viscosity**

Not applicable

Solid

**Water Solubility**

No information available

**Solubility in other solvents**

No information available

**Partition Coefficient (n-octanol/water)**

No data available

**Vapor Pressure**

No data available

**Density / Specific Gravity**

No data available

**Bulk Density**

No data available

**Vapor Density**

Not applicable

Solid

**Particle characteristics**

No data available

### Other Information

**Molecular Formula** C14 H76 N2 O15

**Molecular Weight** 837.05

**Evaporation Rate** Not applicable - Solid

## 10. Stability and reactivity

**Reactive Hazard** None known, based on information available

**Stability** Stable under recommended storage conditions.

**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 (CO<sub>2</sub>)

**Hazardous Polymerization** Hazardous polymerization does not occur.

**Hazardous Reactions** None under normal processing.

## 11. Toxicological information

### Information on expected route of exposure

<b>Inhalation</b>	Not an expected route of exposure.
<b>Ingestion</b>	May be harmful if swallowed.
<b>Eyes</b>	Avoid contact with eyes.
<b>Skin</b>	Avoid contact with skin.

**Toxicology data for the components**

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

**Toxicologically Synergistic Products** No information available

**(b) skin corrosion/irritation;** No data available

**(c) serious eye damage/irritation;** No data available

**(d) respiratory or skin sensitization;**

<b>Respiratory</b>	No data available
<b>Skin</b>	No data available

**(e) germ cell mutagenicity;** No data available

**(f) 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				

**(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.

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

**Endocrine Disrupting Properties** This product does not contain any known or suspected endocrine disruptors.

**12. Ecological information****Ecotoxicity**

Do not empty into drains.

<b>Persistence and Degradability</b>	No information available
<b>Bioaccumulation/ Accumulation</b>	No information available.
<b>Mobility</b>	No information available.

### 13. Disposal considerations

<b>Waste Disposal Methods</b>	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.
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### 14. Transport information

<b>DOT</b>	Not regulated
<b>TDG</b>	Not regulated
<b>IATA</b>	Not regulated
<b>IMDG/IMO</b>	Not regulated

### 15. Regulatory Information

#### United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Roxithromycin	80214-83-1	-	-	-

#### Legend:

**TSCA** US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

<b>TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances &amp; Mixtures, Under TSCA Section 6(h) (PBT)</b>	Not applicable
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<b>TSCA 12(b) - Notices of Export</b>	Not applicable
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#### International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Roxithromycin	80214-83-1	-	-	-	-	-	X	-	-	-

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

#### U.S. Federal Regulations

##### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

##### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

<b>CWA (Clean Water Act)</b>	Not applicable
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<b>Clean Air Act</b>	Not applicable
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**OSHA - Occupational Safety and Health Administration** Not applicable

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**California Proposition 65** This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations** Not applicable

#### **U.S. Department of Transportation**

Reportable Quantity (RQ): N  
DOT Marine Pollutant N  
DOT Severe Marine Pollutant N

**U.S. Department of Homeland Security** This product does not contain any DHS chemicals.

#### **Other International Regulations**

**Mexico - Grade** Slight risk, Grade 1

#### **Authorisation/Restrictions according to EU REACH**

Component	CAS No	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	80214-83-1	-	Use restricted. See entry 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

#### **Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?**

Not applicable

#### **Other International Regulations**

Component	CAS No	Seveso III Directive (2012/18/EC) -	Seveso III Directive (2012/18/EC) -	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)

		Qualifying Quantities for Major Accident Notification	Qualifying Quantities for Safety Report Requirements		
Roxithromycin	80214-83-1	Not applicable	Not applicable	Not applicable	Not applicable

## 16. Other Information

<b>Prepared By</b>	Product stewardship (Regulatory Affairs) Thermo Fisher Scientific email - begel.sdsdesk@thermofisher.com
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<b>Print Date</b>	20-Dec-2025
<b>Revision Summary</b>	Updated to the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) which published its Final Rule in the Federal Register revising the Hazard Communication Standard (HCS/HazCom), 29 CFR 1910.1200 (2024) (HCS §1910.1200, 2024), May 20, 2024, effective July 19, 2024.

### 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**