

1. Identification

Product identifier	Rifampin	
Other means of identification		
Catalog number	1604009	
CAS number	13292-46-1	
Synonyms	Rifampicin * Rifamycin AMP	
Chemical name	Rifamycin, 3-[[[4-methyl-1-piperazinyl]imino]methyl]-	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Germ cell mutagenicity	Category 2
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning	
Hazard statement	Harmful if swallowed. Suspected of causing genetic defects.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	Pharmacologically active material.	

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Rifampin	Rifampicin Rifamycin AMP	13292-46-1	100

4. First-aid measures

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed

Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Perform gastric lavage. Do not induce vomiting. Administer activated charcoal as a slurry. For severe nausea or vomiting, administer antiemetics. Forced diuresis may aid in the elimination of this material if renal function is normal. Hemodialysis may be of benefit.

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting equipment/instructions

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Material

Type

Value

Rifampin (CAS 13292-46-1)

TWA

0.5 mg/m³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

Reddish-brown.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

361.4 - 370.4 °F (183 - 188 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

< 0.0000001 kPa at 25 °C

Vapor density

Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	Very slightly soluble.
Solubility (other)	Chloroform: Freely soluble. Dimethyl sulfoxide: Soluble. Methanol: Soluble.
Auto-ignition temperature	968 °F (520 °C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Macrolide antibiotic.
Molecular formula	C43H58N4O12
Molecular weight	822.94
Percent volatile	0 %
pH in aqueous solution	4.5 - 6.5 Solution: 1%

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	None known.
Hazardous decomposition products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Harmful if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	Gastrointestinal disturbances. Bleeding or bruising. Dizziness. Fever. Headache. Muscle pain. Bone pain. Joint pain. Itching. Skin redness. Skin rash. Red-orange discoloration of skin, mucous membranes, and whites of the eyes. Sore mouth or tongue. Swelling of face. Yellow eyes and/or skin. Seizures. Liver damage. Kidney damage. Metabolic acidosis.

Information on toxicological effects

Acute toxicity	Harmful if swallowed.
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Product	Species	Test Results
Rifampin (CAS 13292-46-1)		
<u>Acute</u>		
Oral		
LD50	Rat	1570 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Germ cell mutagenicity	Suspected of causing genetic defects.	
Mutagenicity		
Mutagenicity, Chromatid break test in whole blood cells	Result: Positive.	

Mutagenicity

Mutagenicity, Chromosome aberration test in mouse spermatocytes

Result: Positive.

Mutagenicity, In vitro sister chromatid exchange test in mouse bone marrow

Result: Positive.

Mutagenicity, Mutagenicity test in mice, bacteria, and Drosophila

Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

Carcinogenicity

Result: In one strain, an increased incidence of hepatomas occurred in females, but there was no evidence of carcinogenicity in males. In another strain, there was no evidence of carcinogenicity in males or females.

Species: Mouse

Carcinogenicity

Result: Negative.

Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Rifampin (CAS 13292-46-1)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete. In rare occasions, this material has caused postnatal hemorrhage in the mother and infant following administration during the last few weeks of pregnancy.

Reproductivity

150 - 250 mg/kg Reproductivity

Result: Cleft palate and spina bifida occurred.

Species: Rat

Reproductivity

Result: No evidence of an increased incidence of birth defects, but imperfect bone formation and embryotoxicity occurred at high doses.

Species: Rabbit

Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Rifampin (CAS 13292-46-1) Listed: February 27, 2001

US - California Proposition 65 - CRT: Listed date/Female reproductive toxin

Rifampin (CAS 13292-46-1) Listed: February 27, 2001

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	07-01-2007
Revision date	10-23-2018
Version #	03
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