



MATERIAL SAFETY DATA SHEET

Revision date: 17-Mar-2011

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Emergency telephone number:
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Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Rifampin for Injection

Trade Name:	Not applicable
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Reddish brown powder cake
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
Suspected of damaging the unborn child.

Additional Hazard Information:
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: Clinical use of this drug has caused skin rash, fever, nausea, vomiting, headache, drowsiness, changes in liver function, inflammation of the liver (hepatitis), kidney dysfunction, red discoloration of urine, blood clotting irregularities, and changes in blood cell levels.

EU Indication of danger: Harmful
Toxic to Reproduction: Category 3

EU Hazard Symbols:
Xn



EU Risk Phrases:

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification
(NOHSC):

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2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Rifampicin	13292-46-1	236-312-0	Xn;R22; Repr. Cat. 3; R63	98.4

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium formaldehyde sulfoxylate - NF	149-44-0	205-739-4	Not Listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Rifampicin

Pfizer OEL TWA-8 Hr:	200µg/m ³
Latvia OEL - TWA	Listed

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Wear impervious gloves as minimum protection.

Eyes: Wear safety glasses as minimum protection.

Skin: Wear impervious protective clothing when handling this compound.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder cake	Color:	Reddish brown
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Slightly Soluble: Water		
Melting/Freezing Point (°C):	183-188		

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10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Rifampicin

Rat	Oral	LD 50	1720 mg/kg
Mouse	Oral	LD 50	885 mg/kg

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Rifampicin

26 Week(s)	Rat	Oral	400 mg/kg/day	LOEL	Liver, Kidney
4 Day(s)	Monkey	Oral	20 mg/kg/day	LOEL	Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Rifampicin

Embryo / Fetal Development	Rat	No route specified	150 mg/kg/day	LOEL	Teratogenic
Embryo / Fetal Development	Mouse	No route specified	150 mg/kg/day	LOEL	Teratogenic
Embryo / Fetal Development	Rabbit	No route specified	150 mg/kg/day	NOEL	Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Rifampicin

Bacterial Mutagenicity (Ames)	Negative	
Sister Chromatid Exchange	Bone Marrow	Positive
Chromosome Aberration	Rodent germ cell	Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Rifampicin

60 Week(s)	Mouse	Oral	8400 mg/kg	LOEL	Tumors, Liver
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Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA. See below

Rifampicin

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful
Toxic to Reproduction: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Rifampicin

California Proposition 65

developmental toxicity, initial date 2/27/01
female reproductive toxicity, initial date 2/27/01
Listed

Australia (AICS):

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	236-312-0

Sodium formaldehyde sulfoxylate - NF	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	205-739-4

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet