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## IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Inc
Pfizer Pharmaceuticals Group
Ramsgate Road
235 East 42nd Street
Sandwich, Kent
New York, New York 10017
CT13 9NJ
1-212-573-2222
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: Emergency telephone number:

Material Name: Streptomycin sulfate injection

Trade Name: Streptomycin Sulfate Injection, USP

Chemical Family: Mixture

Intended Use: Pharmaceutical product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

#### **Hazardous**

Ingredient	CAS Number	<b>EU EINECS List</b>	%
Streptomycin sulfate	3810-74-0	223-286-0	28
Sodium metabisulfite USP	7681-57-4	231-673-0	*
Phenol	108-95-2	203-632-7	*

Ingredient	CAS Number	<b>EU EINECS List</b>	%
Sodium citrate, anhydrous	68-04-2	200-675-3	*
Water for injection	7732-18-5	231-791-2	*

Additional Information: \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

## 3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid

Signal Word: DANGER

Statement of Hazard: Harmful if swallowed.

May cause allergic skin reaction. May damage the unborn child.

May cause damage to nervous system, blood, kidneys, hearing through prolonged or repeated

exposure.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and

abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Common adverse reactions associated with the clinial use of streptomycin include vestibular ototoxicity (nausea, vomiting, and vertigo); parasthesia of face; rash; fever; urticaria; angioneurotic edema; and eosinophilia. Streptomycin can cause fetal harm. Clinical use of this drug has caused effects on hearing, kidney toxicity (nephrotoxicity),

nervous system/brain toxicity (neurotoxicity).

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EU Indication of danger: Harmful

Irritant

Toxic to reproduction: Category 1

**EU Hazard Symbols:** 



**EU Risk Phrases:** 

R22 - Harmful if swallowed.

R43 - May cause sensitization by skin contact. R61 - May cause harm to the unborn child.

**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.

## 4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get

medical attention.

**Skin Contact:** Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs

or persists, get 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.

## 5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other

sulfur-containing compounds.

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

contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

## 6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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.

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**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: Avoid contact with eyes. Avoid contact with skin and clothing. Avoid breathing vapor or mist.

Wash thoroughly after handling.

**Storage Conditions:** Store under refrigeration in closed container.

**Storage Temperature:** 2-8°C (36-46°F)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium metabisulfite USP

ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA Australia TWA = 5 mg/m³ TWA

**Phenol** 

OSHA - Final PELS - TWAs: = 19 mg/m³ TWA = 5 ppm TWA

OSHA - Final PELs - Skin Notations: prevent or reduce skin absorption

ACGIH Threshold Limit Value (TWA) = 5 ppm TWA

ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the

cutaneous route = 1 ppm TWA

Australia TWA = 1 ppm TWA

= 4 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Streptomycin sulfate

Pfizer Occupational Exposure OEB 3 - Sensitizer (control exposure to the range of >10ug/m³ to < 100ug/m³, provide

**Band (OEB):** additional precautions to protect from skin contact)

Analytical Method: Analytical method available for Streptomycin. Contact Pfizer Inc for further information.

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

within the OEB range.

**Personal Protective Equipment:** 

Hands: Rubber gloves

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with

large quantities.

Respiratory protection: Not required for the normal use of this product. If airborne exposures are within or exceed the

Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection

factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

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Physical State:LiquidColor:ColorlessOdor:Faint amine-like odorMolecular Formula:Mixture

Molecular Weight: Mixture

**pH:** 5 - 8

## 10. STABILITY AND REACTIVITY

Stability: Stable Conditions to Avoid: None known

Incompatible Materials: Strong acids and oxidizers

Hazardous Decomposition Products: None expected under normal conditions.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual

ingredients.

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

Streptomycin sulfate

Mouse Oral LD50 430 mg/kg Rat Oral LD50 430 mg/kg

Rat Subcutaneous LD50 600 mg/kg

Phenol

Rat Oral LD50 317 mg/kg Rat Dermal LD50 669 mg/kg Rat Inhalation LC50 316 mg/m³

<u>Irritation / Sensitization: (Study Type, Species, Severity)</u>

Phenol

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Streptomycin sulfate

Embryo / Fetal Development Mouse 1200 mg/kg/day LOAEL Fetotoxicity

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

See below

Sodium metabisulfite USP

IARC: Group 3

**Phenol** 

IARC: Group 3

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## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment

should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

**Phenol** 

RCRA - U Series Wastes waste number U188

# **14. TRANSPORT INFORMATION**

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

## 15. REGULATORY INFORMATION

EU Symbol:

EU Indication of danger: Harmful Irritant

Toxic to reproduction: Category 1

**EU Risk Phrases:** 

R22 - Harmful if swallowed.

R43 - May cause sensitization by skin contact. R61 - May cause harm to the unborn child.

**EU Safety Phrases:** 

S36/37 - Wear suitable protective clothing and gloves.

S53 - Avoid exposure - obtain special instructions before use.

### **OSHA Label:**

**DANGER** 

Harmful if swallowed.

May cause allergic skin reaction.

May damage the unborn child.

May cause damage to nervous system, blood, kidneys, hearing through prolonged or repeated exposure.

### Canada - WHMIS: Classifications

## WHMIS hazard class:

Class D, Division 2, Subdivision A

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Sodium citrate, anhydrous

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS List** 200-675-3

Water for injection

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS List** 231-791-2

Streptomycin sulfate

**California Proposition 65** developmental toxicity, initial date 1/1/91

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS List** 223-286-0

Sodium metabisulfite USP

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present Standard for the Uniform Scheduling Schedule 5

for Drugs and Poisons:

**EU EINECS List** 231-673-0

**Phenol** 

= 1.0 % de minimis concentration **CERCLA/SARA 313 Emission reporting** 

**CERCLA/SARA Hazardous Substances** = 1000 lb final RQ and their Reportable Quantities: = 454 kg final RQ

= 10000 lb upper threshold TPQ **CERCLA/SARA - Section 302 Extremely Hazardous TPQs** = 500 lb lower threshold TPQ

**CERCLA/SARA - Section 302 Extremely Hazardous** = 1000 lb EPCRA RQ

**Substances EPCRA RQs** 

Inventory - United States TSCA - Sect. 8(b)

Present Australia (AICS): Present Standard for the Uniform Scheduling Schedule 2

for Drugs and Poisons: Schedule 4 Schedule 5 Schedule 6 **EU EINECS List** 203-632-7

16. OTHER INFORMATION

Prepared by: Toxicology and Hazard Communication Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**