



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Streptozocin Sterile Powder

Trade Name: Zanosar
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Citric Acid	77-92-9	201-069-1	*
Streptozocin	18883-66-4	242-646-8	82

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

3. HAZARDS IDENTIFICATION

Appearance: Sterile, freeze-dried powder pale yellow
Signal Word: WARNING

Statement of Hazard: Possible carcinogen and mutagen
May cause reproductive system effects
May cause harm to the unborn child.
May cause adverse effects on blood forming organs
Can cause gastrointestinal and kidney effects

Additional Hazard Information:
Short Term: May cause skin irritation. Not a skin sensitizer (based on components) Effects of ingestion are not known. Avoid swallowing this material.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include nausea, vomiting. Kidney dysfunction has been seen during clinical use. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Carcinogenic: Category 2
Mutagenic Category 2
Toxic to Reproduction; Category 3

EU Hazard Symbols:

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EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of 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: 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Carbon dioxide, carbon monoxide, and oxides of nitrogen

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.

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.

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7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: **Keep refrigerated.** Protect from light. Keep away from heat, sparks, and flames.

Storage Temperature: 2 - 8°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Streptozocin
Pfizer OEL TWA-8 Hr: 0.02 mg/m³

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

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

Personal Protective Equipment:

Hands: Wear two layers of disposable gloves.
Eyes: Safety glasses or goggles
Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.

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:	Freeze-dried preparation	Color:	Pale yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: Bases

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)

Streptozocin
Rat Intravenous LD 50 138 mg/kg
Mouse Intravenous LD 50 275 mg/kg

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Irritation / Sensitization: (Study Type, Species, Severity)

Streptozocin

Eye Irritation Rabbit No effect
Skin Sensitization - LLNA Mouse No effect

Citric Acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

Streptozocin

Reproductive & Fertility Rat Fertility
Embryo / Fetal Development Rat Teratogenic
Embryo / Fetal Development Rabbit Fetotoxicity

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

Streptozocin

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Positive
Mammalian Cell Mutagenicity *In Vitro* Hamster Lung Cells Positive
Sister Chromatid Exchange *In Vivo* Not specified Positive
Dominant Lethal Assay *Drosophila* Positive

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

Streptozocin

6 Month(s) Mouse Intraperitoneal 6 mg/kg/day LOAEL Tumors
1 Month(s) Hamster Intravenous 100 mg/kg/day LOAEL Tumors

Carcinogen Status: See below

Streptozocin

IARC: Group 2B
NTP: Reasonably Anticipated To Be A Carcinogen
OSHA: Present

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.

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Streptozocin
RCRA - U Series Wastes

waste number U206

14. TRANSPORT INFORMATION

This material is regulated for transportation as a hazardous material/dangerous good.

Proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Streptozocin), RQ
UN / ID No: UN 3077
Hazard class: 9
Packing group: III

For small quantities packed in combination packaging limited to inner packaging greater than 0.45 kg (1.0 lb.) and less than or equal to 5.0 kg (11lb.) net capacity/mass each and outer packaging less than or equal to 30 kg. (66 lb.) gross weight, the following will apply:

IATA / ICAO

IATA Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Streptozocin), RQ, Ltd. Qty.
IATA UN / ID No: UN 3077
IATA Hazard Class: 9
IATA Packing Group: III

IMDG

IMDG Proper shipping name: Environmentally Hazardous Substance, solid, n.o.s. (Streptozocin), RQ, Ltd. Qty.
IMDG UN / ID No: UN3077
IMDG Hazard Class: 9
IMDG Packing Group: III

DOT

DOT Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Streptozocin), RQ, Ltd. Qty.
DOT UN / ID No: UN 3077
DOT Hazard Class: 9
DOT Packing Group: III

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Carcinogenic: Category 2
Mutagenic Category 2
Toxic to Reproduction; Category 3

EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:

S22 - Do not breathe dust.
S35 - This material and its container must be disposed of in a safe way.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING

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Possible carcinogen and mutagen
May cause reproductive system effects
May cause harm to the unborn child.
May cause adverse effects on blood forming organs
Can cause gastrointestinal and kidney effects

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Citric Acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1

Streptozocin

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 0.454 kg final RQ = 1 lb final RQ
California Proposition 65	Carcinogen Developmental toxicity Female reproductive toxicity Male reproductive toxicity
EU EINECS List	242-646-8

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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 warranty of any kind, expressed or implied.

End of Safety Data Sheet