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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
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

Material Name: Streptozocin Sterile Powder

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric Acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>Streptozocin</td>
<td>18883-66-4</td>
<td>242-646-8</td>
<td>82</td>
</tr>
</tbody>
</table>

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:
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.

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### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Contact</td>
<td>Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.</td>
</tr>
<tr>
<td>Skin Contact</td>
<td>Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove to fresh air and keep patient at rest. Seek medical attention immediately.</td>
</tr>
</tbody>
</table>

---

### 5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Category</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extinguishing Media</td>
<td>Use carbon dioxide, dry chemical, or water spray.</td>
</tr>
<tr>
<td>Hazardous Combustion Products</td>
<td>Carbon dioxide, carbon monoxide, and oxides of nitrogen</td>
</tr>
<tr>
<td>Fire Fighting Procedures</td>
<td>During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.</td>
</tr>
<tr>
<td>Fire / Explosion Hazards</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
</tbody>
</table>

---

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Category</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and Safety Precautions</td>
<td>Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.</td>
</tr>
<tr>
<td>Measures for Cleaning / Collecting</td>
<td>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.</td>
</tr>
<tr>
<td>Measures for Environmental Protections</td>
<td>Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.</td>
</tr>
<tr>
<td>Additional Consideration for Large Spills</td>
<td>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>
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


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
Molecular Formula: Mixture
Color: Pale yellow
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
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.
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
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

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End of Safety Data Sheet