SAFETY DATA SHEET

1. Identification

Product identifier: Endotoxin

Other means of identification:
- Catalog number: 1235503

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

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790, US
- 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: Specific target organ toxicity, single exposure; Category 1

OSHA hazard(s): Not classified.

Label elements

Signal word: Danger

Hazard statement: Causes damage to organs.

Precautionary statement:
- Prevention: Wash thoroughly after handling.
- Response: If exposed: Call a poison center/doctor.
- Storage: Store locked up.
- Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Mixture

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endotoxin</td>
<td></td>
<td>67924-63-4</td>
<td>0.011</td>
</tr>
</tbody>
</table>

Non-hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anhydrous Lactose</td>
<td></td>
<td>63-42-3</td>
<td>90.9</td>
</tr>
<tr>
<td>Polyethylene Glycol 8000</td>
<td></td>
<td>25322-68-3</td>
<td>9.09</td>
</tr>
</tbody>
</table>
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

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically.

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

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
Use water spray to cool unopened containers. 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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

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

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. Use of a designated area is recommended for handling of potent materials.

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

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

Exposure guidelines
No exposure standards allocated.

Appropriate engineering controls
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Individual protection measures, such as personal protective equipment
Eye/face protection
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection

Hand protection
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other
For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory protection
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards
Not available.

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
Lyophilized cake.

Physical state
Solid.

Form
Lyophilized cake.

Odor
Not available.

Odor threshold
Not available.

pH
Not available.

Initial boiling point and boiling range
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

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 density
Not available.

Relative density
Not available.

Solubility in water
Freely soluble.

Partition coefficient (n-octanol/water)
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Stable at normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials

Hazardous decomposition products
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

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

Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.
Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical, and toxicological characteristics


Delayed and immediate effects of exposure


Medical conditions aggravated by exposure


Acute toxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anhydrous Lactose (CAS 63-42-3)</td>
<td>Oral Rat</td>
<td>LD50 &gt; 10 g/kg</td>
</tr>
<tr>
<td>Endotoxin (CAS 67924-63-4)</td>
<td>Acute Other Rat</td>
<td>LD50 7.6 mg/kg, Intraperitoneal</td>
</tr>
<tr>
<td>Polyethylene Glycol 8000 (CAS 25322-68-3)</td>
<td>Acute Oral Rat</td>
<td>LD50 &gt; 50 g/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation

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

Serious eye damage/eye irritation

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

Respiratory sensitization

Due to lack of data the classification is not possible.

Skin sensitization

Due to lack of data the classification is not possible.

Germ cell mutagenicity

Due to lack of data the classification is not possible.

Carcinogenicity

Due to lack of data the classification is not possible.

This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Reproductive toxicity

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

| Reproductivity | 1 - 200 microgram/kg Reproductivity and development study, administered one time during gestation. Result: Increase in resorptions and malformations in the offspring. Species: Guinea pig 1 mg Reproductivity and development study, administered intravenously during gestation. Result: Resorptions and fetal mortality, but no increase in congenital defects. Species: Rat Anhydrous Lactose 400 - 4000 mg/kg Reproductivity study Result: High maternal mortality. Species: Rabbit Endotoxin Reproductivity and development study, administered intraperitoneally during gestation. Result: Increase in hydrocephalus and/or neuronal necrosis in the fetuses. Species: Rat Anhydrous Lactose Reproductivity study Result: External and visceral defects were increased. Species: Rat |

Specific target organ toxicity - single exposure

Causes damage to organs.

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

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

Ecotoxicity

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<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>LC50</td>
<td>35252 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>73493 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability: No data is available on the degradability of this product.
Bioaccumulative potential: Not available.
Mobility in soil: Not available.
Other adverse effects: Not available.

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: Not available.
Hazardous waste code: Not available.
Waste from residues / unused products: Dispose of in accordance with local regulations. 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: Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT: Not regulated as a hazardous material by DOT.
IATA: Not regulated as a dangerous good.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: No information available.

15. Regulatory information

US federal regulations: CERCLA/SARA Hazardous Substances - Not applicable.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories: Immediate Hazard - Yes, Delayed Hazard - No, Fire Hazard - No, Pressure Hazard - No, Reactivity Hazard - No
SARA 302 Extremely hazardous substance: No
SARA 311/312 Hazardous chemical: No

Other federal regulations
Food and Drug Administration (FDA): Not regulated.

US state regulations: California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
</tbody>
</table>

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<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>10-19-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>09-18-2014</td>
</tr>
<tr>
<td>Version #</td>
<td>02</td>
</tr>
<tr>
<td>Further information</td>
<td>Not available.</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

Revision Information

This document has undergone significant changes and should be reviewed in its entirety.