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

Product identifier
Chemical Name: Polymyxin B Sulfate

Other means of identification
Product Code: 1405-20-5
Synonyms: Aerosporin

Recommended use of the chemical and restrictions on use
Recommended Use: Antibiotic

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer: Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address: SDS@Allergan.com

Emergency telephone number
Emergency Telephone: Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Acute toxicity - Oral</th>
<th>Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

Label elements

Emergency Overview

Warning

Hazard statements
H302 - Harmful if swallowed
H361 - Suspected of damaging fertility or the unborn child
Precautionary statements

P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/ container to an approved waste disposal plant
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymyxin B Sulfate</td>
<td>1405-20-5</td>
<td>215-774-7</td>
<td>100</td>
</tr>
</tbody>
</table>

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice

If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.

Eye contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms
Skin Contact  Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation  Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Ingestion  Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media  Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media  None known.

Specific hazards arising from the chemical  Fire may produce irritating, corrosive and/or toxic gases.

Explosion data  
Sensitivity to Mechanical Impact  Not impact sensitive.
Sensitivity to Static Discharge  Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters  As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions  Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions  Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.

Methods for containment  Prevent further leakage or spillage if safe to do so.

Methods for cleaning up  Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling  Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions  Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Incompatible materials  Nitrogen oxides (NOx). Irritating and toxic fumes and gases. Carbon monoxide. Keep away from heat/sparks/open flames/hot surfaces. — No smoking. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Fire.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Control parameters

Exposure Guidelines
This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Controls
The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Individual protection measures, such as personal protective equipment

PPE
The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply.

Eye/face protection
Tight sealing safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>white</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>crystalline powder</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td></td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No information available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
</tbody>
</table>

Other Information

Molecular weight                   | No information available      |
VOC Content (%)                    | No information available      |
Density                           | No information available      |
Bulk density                      | No information available      |

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.
Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials
Nitrogen oxides (NOx). Irritating and toxic fumes and gases. Carbon monoxide. Keep away from heat/sparks/open flames/hot surfaces. — No smoking. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Fire.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymyxin B Sulfate</td>
<td>790 mg/kg (mouse)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Delayed and immediate effects as well as chronic effects from short and long-term exposure

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymyxin B Sulfate</td>
<td>No information available.</td>
<td>Long-term studies in animals to determine the</td>
<td>No information available.</td>
<td>It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>carcinogenicity potential of this medication have not been conducted.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Target Organ Effects
Eyes.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 790 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Other adverse effects
No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes
Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging
Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION
15. REGULATORY INFORMATION

International Inventories

| Legend: | 
| --- | --- |
| TSCA | United States Toxic Substances Control Act Section 8(b) Inventory |
| DSL/NDSL | Canadian Domestic Substances List/Non-Domestic Substances List |
| EINECS/ELINCS | European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances |

US Federal Regulations

**SARA 313**
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute health hazard</td>
<td>Yes</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden release of pressure hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

**CWA (Clean Water Act)**
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

**California Proposition 65**
This product does not contain any Proposition 65 chemicals.

16. OTHER INFORMATION

Revision Date 02-Oct-2018
Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet