



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 12

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)

Acute toxicity - Oral	Category 4
Reproductive toxicity	Category 2

Label elements

Emergency Overview

Warning

Hazard statements

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

**Appearance** crystalline powder**Physical state** Solid**Odor** Odorless**Chemical Name**
Polymyxin B Sulfate**Symptoms**

The most frequent adverse reaction to this Ophthalmic Solution is local irritation consisting of increased redness, burning, stinging, and/or itching. This may occur on instillation, within 48 hours, or at any time with extended use. There are also multiple reports of hypersensitivity reactions consisting of lid edema, itching, increased redness, tearing, and/or circumocular rash. Photosensitivity has been reported in patients taking oral trimethoprim. Albuminuria, cylinduria, azotemia, and rising blood levels without any increase in dosage. Neurotoxic reactions: Facial flushing, dizziness progressing to ataxia, drowsiness, peripheral paresthesias (circumoral and stocking glove), apnea due to concurrent use of curariform muscle relaxants, other neurotoxic drugs or inadvertent overdosage, and signs of meningeal irritation with intrathecal administration, e.g., fever, headache, stiff neck and increased cell count and protein cerebrospinal fluid.

Chemical Name
Polymyxin B Sulfate**Medical Conditions Aggravated by Exposure**

Known hypersensitivity to this medication Avoid concurrent use of a curariform muscle relaxant and other neurotoxic drugs (ether, tubocurarine, succinylcholine, gallamine, decamethonium and sodium citrate) which may precipitate respiratory depression

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**

Chemical Name	CAS No.	EINECS	Weight-%
Polymyxin B Sulfate	1405-20-5	215-774-7	100

*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

persist, call a physician.

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 (NO _x). 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

Physical state	Solid	Appearance	crystalline powder
Color	white	Odor	Odorless
Odor threshold	No information available		

Property**pH****Melting point/freezing point****Boiling point / boiling range****Flash point****Evaporation rate****Flammability (solid, gas)****Flammability Limit in Air**

Upper flammability limit:

Lower flammability limit:

Vapor pressure**Vapor density****Specific Gravity****Water solubility****Solubility in other solvents****Partition coefficient****Autoignition temperature****Decomposition temperature****Explosive properties****Oxidizing properties****Values**

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

Soluble in water

No information available

No information available

No information available

No information available

No information available

No information available

Other Information**Molecular weight****VOC Content (%)****Density****Bulk density**

No information available

No information available

No information available

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 materialsNitrogen oxides (NO_x). 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**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Polymyxin B Sulfate	790 mg/kg (mouse)	N/A	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Polymyxin B Sulfate	No information available.	Long-term studies in animals to determine the carcinogenicity potential of this medication have not been conducted.	No information available.	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.

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**

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Not Listed
DSL/NDSL	Listed
EINECS/ELINCS	Listed

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

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

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

U.S. State Right-to-Know Regulations

16. OTHER INFORMATION

Revision Date 02-Oct-2018

Revision Note

No information available

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