



SAFETY DATA SHEET

Revision Date 13-Jul-2016

Version 1

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

Product identifier

Product Name BLEPH-10 (sulfacetamide sodium ophthalmic solution, USP) 10%

Other means of identification

Product Code FP-65

Synonyms Sulfacetamide

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
400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054, USA
+1-800-272-5525

E-mail address SDS@Actavis.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)

| | |
|-----------------------------|------------|
| Carcinogenicity | Category 2 |
| Reproductive toxicity | Category 2 |
| Effects on or via lactation | Yes |

Label elements

Emergency Overview

Warning

Hazard statements

H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child
H362 - May cause harm to breast-fed children



| | | |
|--|--|--------------------------------------|
| Appearance Liquid | Physical state Liquid | Odor No information available |
| Chemical Name Sulfacetamide Sodium | Symptoms Irritation, stinging and burning. | |
| Chemical Name Sulfacetamide Sodium | Medical Conditions Aggravated by Exposure This medication is contraindicated in individuals who have a hypersensitivity to sulfonamides or to any ingredient of the preparation. | |
| Polysorbate 80 | Hypersensitivity to the material | |

Precautionary statements

- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- 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
- P201 - Obtain special instructions before use
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash face, hands and any exposed skin thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P308 + P313 - IF exposed or concerned: Get medical advice/attention

Other Information

Unknown Acute Toxicity 15.22% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS No. | EINECS | Weight-% |
|--------------------------------|------------|-----------|----------|
| Water | 7732-18-5 | 231-791-2 | 40 - 70* |
| POLYVINYL ALCOHOL USP PVA18-88 | 9002-89-5 | N/A | 7 - 13* |
| Sulfacetamide Sodium | 127-56-0 | 204-848-4 | 7 - 13* |
| Polysorbate 80 | 9005-65-6 | N/A | 0.1 - 1* |
| Benzalkonium Chloride | 63449-41-2 | 264-151-6 | <0.1* |

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

4. FIRST AID MEASURES

First aid measures

- Eye contact** Rinse immediately with plenty of water and seek medical advice.
- Skin Contact** Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation Remove to fresh air.
Ingestion Consult a physician if necessary.

Chemical Name
Sulfacetamide Sodium

Note to physicians
FOR TOPICAL EYE USE ONLY - NOT FOR INJECTION. FATALITIES HAVE OCCURRED, ALTHOUGH RARELY, DUE TO SEVERE REACTIONS TO SULFONAMIDES INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS. Sensitizations may recur when a sulfonamide is readministered, irrespective of the route of administration. Sensitivity reactions have been reported in individuals with no prior history of sulfonamide hypersensitivity. At the first sign of hypersensitivity, skin rash or other serious reaction, discontinue use of this preparation. Treat symptomatically.

Benzalkonium Chloride

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
Sensitivity to Static Discharge

Not impact sensitive.
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 See Section 12 for additional ecological information.
Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Avoid creating dust.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.
Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.
Incompatible materials None known based on information supplied.

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 health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

| | | | |
|-----------------------|--------------------------|-------------------|--------------------------|
| Physical state | Liquid | Appearance | Liquid |
| Color | No information available | Odor | No information available |
| Odor threshold | No information available | | |

Property

| | |
|--------------------------------------|--------------------------|
| pH | No information available |
| Melting point/freezing point | No information available |
| Boiling point / boiling range | No information available |
| Flash point | No information available |
| Evaporation rate | No information available |
| Flammability (solid, gas) | No information available |
| Flammability Limit in Air | |
| Upper flammability limit: | No information available |
| Lower flammability limit: | No information available |
| Vapor pressure | No information available |
| Vapor density | No information available |
| Specific Gravity | No information available |
| Water solubility | No information available |
| Solubility in other solvents | No information available |
| Partition coefficient | No information available |
| Autoignition temperature | No information available |
| Decomposition temperature | No information available |
| Explosive properties | No information available |
| Oxidizing properties | No information available |

Values

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

None known based on information supplied.

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 |
|-----------------------------------|-----------------------|----------------------|-----------------|
| Water | > 90 mL/kg (Rat) | N/A | N/A |
| POLYVINYL ALCOHOL USP PVA18-88 | > 20 g/kg (Rat) | N/A | N/A |
| Sulfacetamide Sodium | 16,500 mg/kg (mouse) | N/A | N/A |
| Polysorbate 80 | = 34500 µL/kg (Rat) | N/A | N/A |
| Benzalkonium Chloride | N/A | = 1420 mg/kg (Rat) | 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 |
|----------------------|---------------------------|---|--|--|
| Sulfacetamide Sodium | No information available. | No studies have been conducted in animals or in humans to evaluate the possibility of these effects with ocularly administered sulfacetamide. Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides, and long-term oral administration of sulfonamides has resulted in thyroid malignancies in these animals. | Pregnancy Category C. Animal reproduction studies have not been conducted with sulfonamide ophthalmic preparations. Kernicterus may occur in the newborn as a result of treatment of a pregnant woman at term with orally administered sulfonamides. There are no adequate and well controlled studies of sulfonamide ophthalmic preparations in pregnant women and it is not known whether topically applied sulfonamides can cause fetal harm when administered to a pregnant woman. This product should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. | Systemically administered sulfonamides are capable of producing kernicterus in infants of lactating women. Because of the potential for the development of kernicterus in neonates, a decision should be made whether to discontinue nursing or discontinue the drug taking into account the importance of the drug to the mother. |
| Polysorbate 80 | No information available. | Not suspected of being a | This product does not | It is not known whether the |

| | | | | |
|-----------------------|-----------------------------------|--|--|---|
| | | human carcinogen. | contain any known or suspected reproductive hazards. | 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. |
| Benzalkonium Chloride | Not Suspected of being a Mutagen. | This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP. | No information available. | No information available |

Target Organ Effects Eyes.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 15.22% of the mixture consists of ingredient(s) of unknown toxicity
The following values are calculated based on chapter 3.1 of the GHS document .
ATEmix (oral) 64928 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

40% of the mixture consists of components(s) of unknown hazards to the aquatic environment

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

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Not Listed
 DSL/NDSL Not Listed
 EINECS/ELINCS Not 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

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

| Chemical Name | ACGIH | IARC | NTP | OSHA |
|--|-------|---------|-----|------|
| POLYVINYL ALCOHOL USP PVA18-88 9002-89-5 | - | Group 3 | - | - |

*IARC (International Agency for Research on Cancer)
 Not classifiable as a human carcinogen*

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 No
 Chronic Health Hazard No
 Fire hazard No
 Sudden release of pressure hazard No
 Reactive Hazard No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

| Chemical Name | New Jersey | Massachusetts | Pennsylvania |
|--|------------|---------------|--------------|
| Dibasic Sodium Phosphate Anhydrous, USP 7558-79-4 | X | X | X |

16. OTHER INFORMATION

Revision Date 13-Jul-2016
 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