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 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)

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
FP-65 BLEPH-10 (sulfacetamide sodium ophthalmic solution, USP) 10%

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

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

*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
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  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  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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available</td>
</tr>
<tr>
<td>pH</td>
<td>No information available</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>No information available</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
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>&gt; 90 mL/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>POLYVINYL ALCOHOL USP PVA18-88</td>
<td>= 23854 mg/kg (Rat) &gt; 20 g/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Sulfacetamide Sodium</td>
<td>16,500 mg/kg (mouse)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>= 34500 µL/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>N/A</td>
<td>= 1420 mg/kg (Rat)</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>Sulfacetamide Sodium</td>
<td>No information available.</td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>No information available.</td>
<td>Not suspected of being a</td>
<td>This product does not</td>
<td>It is not known whether the</td>
</tr>
</tbody>
</table>


FP-65 BLEPH-10 (sulfacetamide sodium ophthalmic solution, USP) 10%

| 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 component(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

<table>
<thead>
<tr>
<th>Legend:</th>
<th>TSCA - United States Toxic Substances Control Act Section 8(b) Inventory</th>
<th>DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List</th>
<th>EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Not Listed</td>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYVINYL ALCOHOL USP PVA18-88 9002-89-5</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dibasic Sodium Phosphate Anhydrous, USP 7558-79-4</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

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