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

Product identifier
Chemical Name Gentamycin Sulfate Ophthalmic Solution, Pred G

Other means of identification
Product Code FP-62
Synonyms None

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

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)

Reproductive toxicity Category 2

Label elements

Emergency Overview

Warning

Hazard statements
H361 - Suspected of damaging fertility or the unborn child

(Bad file name)
Precautionary statements
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P321 - Specific treatment (see supplemental first aid instructions on this label)
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P264 - Wash face, hands and any exposed skin thoroughly after handling
P337 + P313 - If eye irritation persists: Get medical advice/attention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P405 - Store locked up
P501 - Dispose of contents/container to an approved waste disposal plant

Other Information

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Medical Conditions Aggravated by Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin Sulfate</td>
<td>Hypersensitivity to aminoglycosides, impaired kidney function, myasthenia gravis, myasthenia gravis, parkinsonism, and eighth-cranial-nerve impairment.</td>
</tr>
</tbody>
</table>

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>POLYVINYL ALCOHOL USP PVA18-88</td>
<td>9002-89-5</td>
<td>N/A</td>
<td>15 - 40*</td>
</tr>
<tr>
<td>Dibasic Sodium PhosphateAnhydrous, USP</td>
<td>7558-79-4</td>
<td>231-448-7</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>SODIUM CHLORIDE USP</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Gentamicin Sulfate</td>
<td>1405-41-0</td>
<td>215-778-9</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>63449-41-2</td>
<td>264-151-6</td>
<td>1 - 5*</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**

Gentamicin Sulfate

Benzalkonium Chloride

**Note to physicians**

In the event of overdosage or toxic reactions, peritoneal dialysis or hemodialysis will aid in the removal of gentamicin from the blood. These procedures are of particular importance inpatients with impaired renal function.

Treat symptomatically.

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin Sulfate</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>100</td>
</tr>
<tr>
<td>1405-41-0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appropriate engineering controls

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

Powder Handling LEV or Down flow booth or ventilated enclosure

Solutions/Suspensions and coated tablet handling (no powders or aerosols) Not Applicable

Packaging (uncoated tablets, hot side work) LEV at hopper and filter

Laboratory Powder Handling or aerosol generation VBSE, BSC or Glove Box

Personal Decontamination Procedure/Controls Not Applicable

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

Powder Handling 1/2 mask, gloves, long sleeved GMP clothing and safety equipment for the area

Solutions/Suspensions and coated tablet handling (no powders or aerosols) Gloves, long sleeved GMP clothing and safety equipment for the area

Packaging (uncoated tablets, hot side work) Gloves, long sleeved GMP clothing and safety equipment for the area

Laboratory Powder Handling or aerosol generation Minimum required Lab PPE, gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<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>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>
</tbody>
</table>
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>POLYVINYL ALCOHOL USP PVA18-88</td>
<td>= 23854 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Dibasic Sodium PhosphateAnhydrous, USP</td>
<td>= 17 g/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SODIUM CHLORIDE USP</td>
<td>= 3000 mg/kg (Rat)</td>
<td>&gt; 10 g/kg (Rabbit)</td>
<td>&gt; 42 g/m^3 (Rat) 1 h</td>
</tr>
<tr>
<td>Gentamicin Sulfate</td>
<td>&gt; 5 g/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>Gentamicin Sulfate</td>
<td>No information available. Aminoglycoside antibiotics have been found to be non-mutagenic.</td>
<td>No information available.</td>
<td>Pregnancy Category C: This medication has been shown to depress newborn body weights, kidney weights, and median glomerular counts in newborn rats when administered systemically to pregnant rats in daily doses of approximately 500 times the maximum recommended ophthalmic dose in humans. There are no adequate and well controlled studies in pregnant women. This medication should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.</td>
<td>It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.</td>
</tr>
</tbody>
</table>
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

**Numerical measures of toxicity - Product Information**

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

- **ATEmix (oral)**: 7347 mg/kg
- **ATEmix (dermal)**: 41619 mg/kg

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Toxic to aquatic life with long lasting effects

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM CHLORIDE USP 7647-14-5</td>
<td>N/A</td>
<td>4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static</td>
<td>340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static 1000: 48 h Daphnia magna mg/L EC50</td>
</tr>
</tbody>
</table>

**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>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Not Listed</td>
</tr>
<tr>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**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

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</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>USP PVA18-88</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9002-89-5</td>
<td></td>
<td></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)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CWA - Reportable Quantities</th>
<th>CWA - Toxic Pollutants</th>
<th>CWA - Priority Pollutants</th>
<th>CWA - Hazardous Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dibasic Sodium PhosphateAnhydrous, USP 7558-79-4</td>
<td>5000 lb</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Hazardous Substances RQs</th>
<th>CERCLA/SARA RQ</th>
<th>Reportable Quantity (RQ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dibasic Sodium PhosphateAnhydrous, USP 7558-79-4</td>
<td>5000 lb</td>
<td>-</td>
<td>RQ 5000 lb final RQ</td>
</tr>
</tbody>
</table>

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 PhosphateAnhydrous, USP 7558-79-4</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>02-Oct-2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision Note</td>
<td>No information available</td>
</tr>
<tr>
<td>Disclaimer</td>
<td>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.</td>
</tr>
</tbody>
</table>

End of Safety Data Sheet