

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
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)


Reproductive toxicity	Category 2
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Label elements

Emergency Overview

Warning

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



(Bad file name)

Appearance Liquid	Physical state Liquid	Odor No information available
Chemical Name Gentamicin Sulfate	Symptoms The most frequent reactions observed include ocular discomfort, irritation upon instillation of the medication and punctate keratitis. These reactions have resolved upon discontinuation of the medication. Reactions occurring most often from the presence of the anti-infective ingredient are allergic sensitizations. The reactions due to the steroid component in decreasing order of frequency are: elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing. Secondary Infection: The development of secondary ocular infection has occurred after use of combinations containing steroids and antimicrobials. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs.	
Chemical Name Gentamicin Sulfate	Medical Conditions Aggravated by Exposure Hypersensitivity to aminoglycosides, impaired kidney function, myasthenia gravis, parkinsonism, and eighth-cranial-nerve impairment.	

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

*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

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.

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.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL
Gentamicin Sulfate 1405-41-0	N/A	N/A	N/A	100

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

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

Property	Values
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

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
POLYVINYL ALCOHOL USP PVA18-88	> 20 g/kg (Rat)	N/A	N/A
Dibasic Sodium Phosphate Anhydrous, USP	= 17 g/kg (Rat)	N/A	N/A
SODIUM CHLORIDE USP	= 3000 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Gentamicin Sulfate	> 5 g/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
Gentamicin Sulfate	No information available. Aminoglycoside antibiotics have been found to be non-mutagenic.	No information available.	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.	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.

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
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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

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

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)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Dibasic Sodium Phosphate Anhydrous, USP 7558-79-4	5000 lb	-	-	X

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)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Dibasic Sodium Phosphate Anhydrous, USP 7558-79-4	5000 lb	-	RQ 5000 lb final RQ RQ 2270 kg final RQ

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	X	X	X

Phosphate Anhydrous, USP 7558-79-4			
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16. OTHER INFORMATION

Revision Date 18-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