



SAFETY DATA SHEET

Revision Date 13-Jul-2016

Version 1

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

Product identifier

Chemical Name Gatifloxacin, Zymaxid Ophthalmic Solution 0.5%

Other means of identification

Product Code FP-63

Synonyms Gatifloxacin

Recommended use of the chemical and restrictions on use

Recommended Use conjunctivitis

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)

Effects on or via lactation	Yes
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Label elements

Emergency Overview

Hazard statements

H362 - May cause harm to breast-fed children

Appearance Liquid

Physical state Liquid

Odor No information available

Chemical Name

Gatifloxacin

Symptoms

Most common adverse reactions occurring in >1% of patients included worsening of conjunctivitis, eye irritation, dysgeusia, and eye pain.

Benzalkonium Chloride

Common adverse reactions of this medication are dry, burning, or stinging sensation in the eye. Exposure may include nausea, vomiting, cough, shortness of breath, headache.

Chemical Name Gatifloxacin	Medical Conditions Aggravated by Exposure None
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Precautionary statements

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No.	EINECS	Weight-%
PURIFIED WATER USP	7732-18-5	231-791-2	40 - 70*
SODIUM CHLORIDE USP	7647-14-5	231-598-3	15 - 40*
Gatifloxacin	180200-66-2	N/A	0.1 - 1*
EDETATE DISODIUM USP	6381-92-6	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
Gatifloxacin

Note to physicians

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

Benzalkonium Chloride

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.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL
Gatifloxacin 180200-66-2	N/A	N/A	N/A	400

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		

<u>Property</u>	<u>Values</u>
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
PURIFIED WATER USP	> 90 mL/kg (Rat)	N/A	N/A
SODIUM CHLORIDE USP	= 3000 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Gatifloxacin	=>5000 mg/kg oral 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
Gatifloxacin	In genetic toxicity tests, this medication was positive in 1 of 5 strains used in bacterial reverse mutations assays: Salmonella strain TA102. This medication was positive in in vitro mammalian cell mutation and chromosome aberration assays. This medication was positive in in vitro unscheduled DNA synthesis in rat hepatocytes but not human leukocytes. This medication was negative in in vivo micronucleus tests in mice, cytogenetics test in rats, and DNA repair test in rats. The findings may be due to the inhibitory effects of high concentrations on eukaryotic type II DNA topoisomerase.	There was no increase in neoplasms among B6C3F1 mice given this medication in the diet for 18 months at doses averaging 81 mg/kg/day in males and 90mg/kg/day in females. These doses are approximately 1600-fold and 1800 fold higher respectively, than the maximum recommended ophthalmic dose of 0.05 mg/kg/day in 50kg human. There was no increase in neoplasms among Fischer 344 rats given this medication in the diet for 2 years at doses averaging 47 mg/kg/day in males and 139 mg/kg/day in females (900 and 2800 fold higher, respectively than the maximum recommended ophthalmic dose). A statistically significant increase in the incidence of large granular lymphocyte leukemia was seen in males treated with a high dose of approximately 2000 fold higher than the maximum recommended ophthalmic dose. Fischer 344 rats have a higher spontaneous background rate of LGL leukemia and the incidence in high dose males only slightly exceeded the historical control range established for this strain.	There were no adverse effects on fertility or reproduction in rats given this medication orally at doses up to 200 mg/kg/day (approximately 4000 fold higher than the maximum recommended ophthalmic dose for this medication).	This medication is excreted in breast milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this medication is administered to a nursing woman.
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) 9506 mg/kg
ATEmix (dermal) 31717 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

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
INECS/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	No
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 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