

Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension

SECTION 1 - IDENTIFICATION

Product Identifier: Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension, USP

Synonyms: 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid.
9-fluoro-11(beta),17,21-trihydroxy-16(alpha)methylpregna-1,4-diene-3,20-dione

NDC Code: 72485-625-13

Recommended Use: Pharmaceutical

Manufacturer: Ophthapharm AG
Riethofstrasse 1
CH-8442 Hettlingen
Switzerland

Telephone: +1855-473-6847

Email: quality@sentiss.ch

SECTION 2 - HAZARD(S) IDENTIFICATION

Classification of the substance or mixture

GHS classification: Reproductive Toxicity, Category 1B, H360; May damage fertility or the unborn child.

Hazard pictograms (GHS):



Signal word (GHS): Danger

Hazard statements (GHS): H360 - May damage fertility or the unborn child.

Precautionary statements (GHS): 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.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Other hazards which do not result in classification: No additional information available

Unknown acute toxicity (GHS_US): Not applicable

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Name	Product identifier	%	GHS classification
Ciprofloxacin hydrochloride monohydrate (active)	(CAS-No.) 86393-32-0	0.1 - 0.5	Not classified
Boric acid	(CAS-No.) 10043-35-3	0.1-0.7	Repr. 1B, H360
Dexamethasone (active)	(CAS-No.) 50-02-2	0.1 - 0.5	Eye Irrit. 2B, H320 Repr. 2, H361 STOT RE 2, H373

*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret
 Full text of hazard classes and H-statements: see section 16

SECTION 4 – FIRST-AID MEASURES

Description of first aid measures

- General** : Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention.
- Inhalation** : If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- Skin Contact** : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- Eye Contact** : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
- Ingestion** : Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

Most important symptoms and effects (acute and delayed): May damage fertility or the unborn child.

Immediate medical attention and special treatment, if necessary: Treat symptomatically.

Section 5– FIRE-FIGHTING MEASURES

Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical

- Fire hazard : No particular fire or explosion hazard.
- Reactivity : No dangerous reactions known.

Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension**Special protective equipment and precautions for fire-fighters**

Firefighting instructions:	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting water from entering the environment.
Protection during firefighting:	Do not enter fire area without proper protective equipment, including respiratory protection. Wear a self-contained breathing apparatus. Wear fire/flame resistant/retardant clothing.

Section 6 – ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

General measures: Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Protective equipment: Refer to section 8
Emergency procedures: Evacuate unnecessary personnel.

For emergency responders

Protective equipment: Refer to section 8
Emergency procedures: Ventilate area.

Environmental precautions Prevent entry to sewers and public waters.

Methods and material for containment and cleaning up

For containment Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
Methods for cleaning up Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

See Heading 8 - Exposure control and personal protection.

Section 7 – HANDLING AND STORAGE**Precautions for safe handling**

Precautions for safe handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not handle until all safety precautions have been read and understood. Obtain special instructions before use. Avoid contact with skin, eyes and clothing.
Hygiene measures: Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage conditions: Keep only in the original container in a cool well-ventilated place. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).
Incompatible products: Strong acids. Strong bases

Section 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Ciprofloxacin hydrochloride monohydrate : Not established.

Boric acid	:	ACGIH	Local name	Boric acid
		ACGIH	ACGIH TWA (mg/m ³)	2 mg/m ³ (I - Inhalable particulate matter)
		ACGIH	ACGIH TWA (mg/m ³)	6 mg/m ³ (I - Inhalable particulate matter)
		ACGIH	Remark (ACGIH)	TLV [®] Basis: URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
		ACGIH	Regulatory reference	ACGIH 2019

Dexamethasone : Not established.

Appropriate engineering controls

Appropriate engineering controls : Avoid splashing. Ensure good ventilation of the workstation.
 Environmental exposure controls : Avoid release to the environment.

Individual protection measures/Personal protective equipment

Personal protective equipment : Avoid all unnecessary exposure
 Hand protection : Use rubber gloves
 Eye protection : In case of splashing or aerosol production: protective goggles.
 Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.
 Other information : Do not eat, drink or smoke during use.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Physical state:	:	Liquid
Appearance/Color	:	White to off-white suspension
Odor	:	No data available
Odor threshold	:	No data available
pH	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Flammability (solid, gas)	:	Nonflammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	No data available
Log Pow	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive limits	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Other Information	:	No additional information available

SECTION 10 – STABILITY AND REACTIVITY

Reactivity	:	No dangerous reactions known.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Hazardous polymerization will not occur.
Conditions to avoid	:	None known.
Incompatible materials	:	Strong acids. Strong bases.
Hazardous decomposition products	:	None known.

SECTION 11 – TOXICOLOGICAL INFORMATION**Information on toxicological effects**

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Ciprofloxacin Hydrochloride Monohydrate

LD50 oral rat > 2000 mg/kg

Boric Acid

LD50 oral rat ≥ 2660 mg/kg
LD50 dermal rabbit > 2000 mg/kg
LC50 inhalation rat (mg/l) > 2 mg/l/4h

Dexamethasone

LD50 oral rat > 3000 mg/kg

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : May damage fertility or the unborn child.
STOT-single exposure : Not classified
STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified
Viscosity, kinematic : No data available
Likely routes of exposure : Inhalation. Skin and eye contact.
Symptoms/effects : May damage fertility or the unborn child.

Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension**SECTION 12 - ECOLOGICAL INFORMATION****Toxicity****Boric Acid**

LC50 fish 1	≥ 1.02 g/l <i>Carassius auratus</i> , 3 days
EC50 crustacea	658 – 875 mg/l 48 hours
LOEC (chronic)	> 97 mg/l <i>salmo gairdneri</i>

Persistence and degradability**Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension USP**

Persistence and degradability : Not established.

Boric acid

Persistence and degradability : Not readily biodegradable.

Ciprofloxacin

Persistence and degradability : Not readily biodegradable.

Dexamethasone

Persistence and degradability : Readily biodegradable.

Biodegradation : > 95 %

Bioaccumulative potential**Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension USP**

Bioaccumulative potential : Not established.

Boric acid

BCF fish 1 : 34 mg/l *Oncorhynchus tshawytscha*, 90 days at 12° C

Log Pow : -0.757 at 25 degrees C

Mobility in soil**Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension USP**

Ecology - soil : Not established.

Other adverse effects: Avoid release to the environment

SECTION 13 - DISPOSAL CONSIDERATIONS**Disposal methods**

Sewage disposal recommendations : Do not dispose of waste into sewer

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations

Ecology - waste materials : Avoid release to the environment

SECTION 14 - TRANSPORT INFORMATION

Department of Transportation (DOT)

In accordance with DOT : Not regulated

Transport by sea : Not regulated

Air transport : Not regulated



MATERIAL SAFETY DATA SHEET

Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension

SECTION 15 - REGULATORY INFORMATION

US Federal Regulation

Ciprofloxacin Hydrochloride Monohydrate

EPA TSCA Regulatory Flag Exempt from TSCA: Pharmaceutical/drug substance

Boric Acid

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Dexamethasone

Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State regulations

California Proposition 65 : This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16 - OTHER INFORMATION

The information given herein is in good faith and to the best of our knowledge, but no warranty expressed or implied is made.

Revision Date: 11/07/2023

Revision Number: 0

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this MSDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this MSDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.