

Safety Data Sheet

acc. to OSHA HCS (29 CFR 1910.1200)

Printing date 06/03/2015

Reviewed on 06/03/2015

1 Identification

- **Product identifier**
- **Trade name:** CIPRO® HC OTIC 0.2%, 1%
- **Article number:** No other identifiers
- **Recommended use and restriction on use**
- **Recommended use:** Pharmaceutical Product
- **Restrictions on use:** Contact manufacturer.
- **Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**
Alcon Laboratories, Inc.
6201 S. Freeway
Fort Worth, Texas 76134 USA
Tel 1-817-551-4444
E-mail: safety.datasheets@alcon.com
- **Emergency telephone number:**
ChemTel Inc.
(800)255-3924, +1 (813)248-0585

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Additional information:**

There are no other hazards not otherwise classified that have been identified.
0 percent of the mixture consists of ingredient(s) of unknown toxicity.

- **Label elements**

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS08

- **Signal word** Danger

- **Hazard-determining components of labeling:**

Ciprofloxacin hydrochloride Monohydrate (micronized)

- **Hazard statements**

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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H317 May cause an allergic skin reaction.

· **Precautionary statements**

- P284 Wear respiratory protection.
- P261 Avoid breathing dust/fume/gas/mist/vapors/spray
- P280 Wear protective gloves.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P321 Specific treatment (see on this label).
- P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.
- P363 Wash contaminated clothing before reuse.
- P304+P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P302+P352 If on skin: Wash with plenty of water.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Contains Ciprofloxacin hydrochloride Monohydrate (micronized). May produce an allergic reaction.

· **Hazard description:**

· **WHMIS-symbols:**

As of 11 February 2015, the current WHMIS system is being replaced by the GHS system. This is the classification under the older system.

Not hazardous under WHMIS.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

* - Indicates a long term health hazard from repeated or prolonged exposures.

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Substances**

· **CAS No. Description**

7789-20-0 deuterium oxide

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- **Chemical characterization: Mixtures**

- **Dangerous components:**

Ciprofloxacin hydrochloride Monohydrate (micronized)	<1.0%
<ul style="list-style-type: none"> ⚠ Resp. Sens. 1, H334 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; STOT SE 3, H335 	

4 First-aid measures

- **Description of first aid measures**
- **General information:** Take affected persons out into the fresh air.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:** Remove contact lenses if worn.
- **After swallowing:** Do not induce vomiting; immediately call for medical help.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
Breathing difficulty
Allergic reactions
- **Danger** Danger of impaired breathing.
- **Indication of any immediate medical attention and special treatment needed**
Severe allergic skin reaction, bronchial spasms and anaphylactic shock are possible.
Medical supervision for at least 48 hours.
If necessary oxygen respiration treatment.
Treat skin and mucous membrane with antihistamine and corticoid preparations.
Contains Ciprofloxacin hydrochloride Monohydrate (micronized). May produce an allergic reaction.
In cases of irritation to the lungs, initial treatment with corticoid steroid inhalants.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **For safety reasons unsuitable extinguishing agents:** None.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.
- **Additional information** No further relevant information available.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Use respiratory protective device against the effects of fumes/dust/aerosol.
Ensure adequate ventilation.
Isolate area and prevent access.
- **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.

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Dilute with plenty of water.

- **Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to item 13.
Send for recovery or disposal in suitable receptacles.

- **Reference to other sections**

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**

- **Precautions for safe handling**

Open and handle receptacle with care.
Avoid splashes or spray in enclosed areas.
Use only in well ventilated areas.

- **Information about protection against explosions and fires:** No special measures required.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** Provide ventilation for receptacles.

- **Information about storage in one common storage facility:** Store away from foodstuffs.

- **Further information about storage conditions:** None.

- **Specific end use(s):** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- **Additional information:** No further relevant information available.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
Avoid contact with the eyes and skin.

- **Engineering controls:** No further relevant information available.

- **Breathing equipment:**



Combined Organic Vapor and Particulate Respirator is recommended for use during all processing activities.

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Not required under normal conditions of use.

- **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**

Contact lenses should not be worn.



Safety glasses

- **Body protection:** Protective work clothing

- **Limitation and supervision of exposure into the environment**

No further relevant information available.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Suspension

Color: Whitish

- **Odor:** Faint, acetic

- **Odor threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: 101 °C (214 °F)

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not applicable.

- **Auto-ignition temperature:** Not determined.

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Not determined.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

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- **Vapor pressure:** Not determined.
- **Density at 20 °C (68 °F):** 1.11 g/cm³ (9.263 lbs/gal)
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with Water:** Fully miscible.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:** None.
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** May cause sensitisation by inhalation and skin contact.
- **Subacute to chronic toxicity:** No further relevant information available.
- **Additional toxicological information:** Toxic and/or corrosive effects may be delayed up to 24 hours.
- **Carcinogenic categories**

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Probable Routes of Exposure

Inhalation.
Eye contact.
Skin contact.

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- **Acute effects (acute toxicity, irritation and corrosivity):**
May cause sensitisation by inhalation and skin contact.
- **Repeated Dose Toxicity:**
May cause damage to organs through prolonged or repeated exposure.
Repeated exposures may result in skin and/or respiratory sensitivity.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** Do not release into bodies of water.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes. Residual materials should be treated as hazardous.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|-------------------------------------|---------------|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Not Regulated |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Not Regulated |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Not Regulated |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Not Regulated |
| · Environmental hazards: | |
| · Marine pollutant: | No |

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- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **United States (USA)**
- **SARA**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

- **TSCA (Toxic Substances Control Act):**

7789-20-0 | deuterium oxide

- **Proposition 65 (California)**

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **State Right to Know Listings**

None of the ingredients is listed.

- **Canadian substance listings:**

- **Canadian Domestic Substances List (DSL)**

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· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

None of the ingredients is listed.

· **Other regulations, limitations and prohibitive regulations**

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 06/03/2015 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

WHMIS: Workplace Hazardous Materials Information System (Canada)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· **Sources**

SDS Prepared by:

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