

Safety Data Sheet

according to 1907/2006/EC (REACH), 1272/2008/EC (CLP), and OSHA
GHS

Printing date 09.06.2015

Revision: 09.06.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** CIPRO HYDROCHLORIDE 0.2% + HYDR
- **Article number:** No other identifiers
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
Uses: Pharmaceutical product
- **1.3 Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**
Alcon Cusí, S.A.
Camil Fabra, 58, Apartado 2
08320 El Masnou
Barcelona
Spain
Tel: +34 93 497 70 00
E-mail: safety.datasheets@alcon.com
- **1.4 Emergency telephone number:**
ChemTel Inc.
(800)255-3924, +1 (813)248-0585

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



health hazard

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



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 component(s) of unknown toxicity

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



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- **Signal word** Danger

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- **Hazard-determining components of labelling:**

Ciprofloxacin hydrochloride Monohydrate (micronized)

- **Hazard statements**

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

H317 May cause an allergic skin reaction.

- **Precautionary statements**

P285 In case of inadequate ventilation wear respiratory protection.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P272 Contaminated work clothing should 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 victim to fresh air and keep at rest in a position comfortable for breathing.

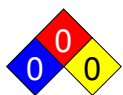
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P302+P352 IF ON SKIN: Wash with plenty of water.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Hazard description:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **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.

- **HMIS Long Term Health Hazard Substances**

None of the ingredients are listed.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:** None in reportable quantities.

- **Additional information:**

For the listed ingredients, the identity and exact percentages are being withheld as a trade secret.

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For the wording of the listed risk phrases refer to section 16.

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SECTION 4: First aid measures

- **4.1 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; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**
 - Breathing difficulty
 - Allergic reactions
- **Hazards** Danger of impaired breathing.
- **4.3 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 cortical steroid inhalants.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- **6.1 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.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**
 - Absorb liquid components with liquid-binding material.
 - Dispose contaminated material as waste according to item 13.
 - Send for recovery or disposal in suitable receptacles.
- **6.4 Reference to other sections**
 - See Section 7 for information on safe handling.

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

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SECTION 7: Handling and storage

- **7.1 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 fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients 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.
- **DNELs** No further relevant information available.
- **PNECs** No further relevant information available.
- **Additional information:** No further relevant information available.

- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
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.
- **Respiratory protection:**



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

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.

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- **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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **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.

SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form: Suspension

Colour: White

- **Odour:** Faint, acetic

- **Odour threshold:** Not determined.

- **pH-value at 20 °C (68 °F):** 4,3 - 5,3

- **Change in condition**

Melting point/Melting range: Not Determined.

Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

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

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

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not self-igniting.

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

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Vapour pressure:** Not determined.

- **Density:** Not determined.

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- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with water:** Soluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values relevant for classification:** None.
- **Primary irritant effect:**
 - on the skin:** No irritant effect.
 - on the eye:** No irritating effect.
- **Sensitisation:** 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.
- **Acute effects (acute toxicity, irritation and corrosivity):**
May cause sensitisation by inhalation and skin contact.
- **Sensitisation:**
 - May cause an allergic skin reaction.
 - 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.

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SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** Do not release into bodies of water.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **14.2 UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **14.3 Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Not Regulated
- **14.4 Packing group**
- **DOT, ADR, IMDG, IATA** Not Regulated
- **14.5 Environmental hazards:**
- **Marine pollutant:** No
- **14.6 Special precautions for user** Not applicable.
- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

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SECTION 15: Regulatory information

- 15.1 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 are listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

7732-18-5 | water

· Proposition 65 (California):

· Chemicals known to cause cancer:

None of the ingredients is 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 are listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed.

· Carcinogenic Categories

· EPA (Environmental Protection Agency)

None of the ingredients are listed.

· IARC (International Agency for Research on Cancer)

None of the ingredients are listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients are listed.

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

None of the ingredients are listed.

· Canada

· Canadian Domestic Substances List (DSL)

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· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients are listed.

· Canadian Ingredient Disclosure list (limit 1%)

None of the ingredients are 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.

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Substances of very high concern (SVHC) according to REACH, Article 57

None of the ingredients are listed.

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

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

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

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

Sources

SDS Prepared by:

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