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#### 1 Identification

- · Product identifier
- · Trade name: Ciprofloxacin Hydrochloride
  Ciprofloxacini hydrochloridum
- · Article number: 102832
- CAS Number: 86393-32-0 EC number: 617-845-1
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Pharma Active ingredients
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Fagron Services B.V. Molenwerk 13, UITGEEST, 1911DB Netherlands

Phone: +31251361400

Supplier Azelis Australia Suite 217 117 Old Pittwater Road Brookvale NSW 2100 Australia

Phone: +61 0299392188 Fax: +61 0299392799 e-mail: info@azelis.com.au

- · Further information obtainable from: info@fagron.com.au
- · Emergency telephone number:

In case of emergency, please call your local poisons:

Emergency Australia: 13 11 26

Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free) | ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only )

## 2 Hazard(s) Identification

· Classification of the substance or mixture

Serious eye damage/irritation - Category 2A H319 Causes serious eye irritation.

- · Label elements
- · GHS label elements

The substance is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms





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- · Signal word Warning
- · Hazard statements

Causes serious eve irritation.

· Precautionary statements

Wash thoroughly after handling.

Wear eye protection / face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

- Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · **vPvB**: Not applicable.

#### 3 Composition and Information on Ingredients

- · Chemical characterisation: Substances
- · CAS No. Description

CAS: 86393-32-0 Ciprofloxacin Hydrochloride

Ciprofloxacini hydrochloridum

- Identification number(s)
- · EC number: 617-845-1

#### 4 First Aid Measures

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

Seek immediate medical advice.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## **5 Fire Fighting Measures**

Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Water

Foam

Fire-extinguishing powder

Carbon dioxide

· Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

In case of fire, the following can be released:

Carbon monoxide (CO)

Nitrogen oxides (NOx)



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Hydrogen chloride (HCI)

Hydrogen fluoride (HF)

Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

Mouth respiratory protective device.

#### **6 Accidental Release Measures**

· Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

Keep away from ignition sources.

Avoid formation of dust.

**Environmental precautions:** 

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

· Methods and material for containment and cleaning up:

Pick up mechanically.

Ensure adequate ventilation.

Dispose of the material collected according to regulations.

Dispose contaminated material as waste according to section 13.

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

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of dust.

· Information about fire - and explosion protection:

Dust can combine with air to form an explosive mixture.

Keep ignition sources away - Do not smoke.

Keep respiratory protective device available.

- Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions:

Keep container tightly sealed.

Protect from exposure to the light.

Protect from heat and direct sunlight.

This product is hygroscopic.

· Specific end use(s) No further relevant information available.

## 8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.



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- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin. Do not inhale dust / smoke / mist.

- · **Respiratory protection:** Suitable respiratory protective device recommended.
- Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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:



Tightly sealed goggles

Face protection

· Body protection: Protective work clothing

## 9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Crystalline powder

Colour: WhitishOdour: OdourlessOdour threshold: Not determined.

· pH-value: 3–4.5

· Change in condition

Melting point/freezing point: 318–320°C
 Initial boiling point and boiling range: Undetermined.
 Flash point: Not applicable.

Flammability (solid, gas): Product is not flammable.

Decomposition temperature: Not determined.Ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard



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· Explosion limits:

· Lower: Not determined. · Upper: Not determined. · Vapour pressure: Not applicable. · Density: Not determined. · Relative density Not determined. Vapour density Not applicable. · Evaporation rate Not applicable.

· Solubility in / Miscibility with

Not determined. · Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

· Dvnamic: Not applicable. Kinematic: Not applicable.

· Other information No further relevant information available.

### 10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

· Possibility of hazardous reactions

Reacts with oxidising agents.

Risk of dust explosion if enriched with fine dust in the presence of air.

- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- Hazardous decomposition products:

Irritant gases/vapours

Poisonous gases/vapours

Carbon monoxide and carbon dioxide

Nitrogen oxides (NOx)

Hydrogen chloride (HCI)

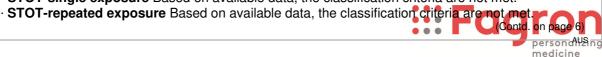
Hydrogen fluoride

## 11 Toxicological Information

- Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:

Oral LD50 >5000 mg/kg (mouse) >5000 mg/kg (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.



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personalizing medicine

· Aspiration hazard Based on available data, the classification criteria are not met.

### 12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- **Ecotoxical effects:**
- · Remark: Harmful to fish
- Additional ecological information:
- General notes:

Harmful to aquatic organisms

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB**: Not applicable.
- · Other adverse effects No further relevant information available.

#### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

#### 14 Transport information

· UN-Number · ADG, IMDG, IATA	not regulated	
· UN proper shipping name · ADG, IMDG, IATA	not regulated	
· Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	not regulated	
· Packing group · ADG, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.	::: Eggro

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UN "Model Regulation":

not regulated

#### 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- Australian Inventory of Industrial Chemicals Substance is not listed.
- Standard for the Uniform Scheduling of Medicines and Poisons Substance is not listed.
- · Australia: Priority Existing Chemicals Substance is not listed.
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · National regulations:
- Other regulations, limitations and prohibitive regulations

Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)

· 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.

- · Department issuing SDS: Product Safety Department
- Contact:
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Serious eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A

· \* Data compared to the previous version altered.

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