according to 1907/2006/EC, Article 31

Page 1/7 Printing date 29.06.2023 Revision: 29.06.2023 Version number 1.0

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

· 1.1 Product identifier

- Trade name: <u>Ciprofloxacin hydrochloride</u> Ciprofloxacini hydrochloridum
- · Article number: 133659, 102832
- · CAS Number:
- 86393-32-0
- EC number:
- 617-845-1
- **1.2 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

1.3 Details of the supplier of the safety data sheet Fagron UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

- Further information obtainable from: Emergency response telephone number: +44 (0) 845 652 2525
- **1.4 Emergency telephone number:** Emergency response telephone number: +44 (0) 845 652 2525

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
- Eye Irrit. 2 H319 Causes serious eye irritation.
- · 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008 The substance is classified and labelled according to the GB CLP regulation.
- · Hazard pictograms



P280

- · Signal word Warning
- · Hazard statements
- H319 Causes serious eye irritation.
- Precautionary statements P264 Wash the
 - Wash thoroughly after handling.
 - Wear eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.



according to 1907/2006/EC, Article 31

Page 2/7 Printing date 29.06.2023 Revision: 29.06.2023 Version number 1.0

Trade name: Ciprofloxacin hydrochloride Ciprofloxacini hydrochloridum

P337+P313 If eye irritation persists: Get medical advice/attention.

(Contd. of page 1)

· 2.3 Other hazards

· Results of PBT and vPvB assessment

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

SECTION 3: Composition/information on ingredients

- · 3.1 Substances
- CAS No. Description CAS: 86393-32-0 Ciprofloxacin hydrochloride Ciprofloxacini hydrochloridum
- Identification number(s)
 EC number: 617-845-1

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:
- Water
- Foam
- Fire-extinguishing powder
- Carbon dioxide
- Use fire extinguishing methods suitable to surrounding conditions.
- 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.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Ensure adequate ventilation Avoid formation of dust.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

(Contd. on page 3)



Safety data sheet according to 1907/2006/EC, Article 31

Page 3/7 Printing date 29.06.2023 Revision: 29.06.2023 Version number 1.0

Trade name: Ciprofloxacin hydrochloride Ciprofloxacini hydrochloridum

(Contd. of page 2)

- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 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.

SECTION 7: Handling and storage

• 7.1 Precautions for safe handling No special precautions are necessary if used correctly.

- · 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: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep container tightly sealed.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as 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.
- · Respiratory protection: Suitable respiratory protective device recommended.
- Hand protection

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.

(Contd. on page 4)

GB



according to 1907/2006/EC, Article 31

Printing date 29.06.2023 Revision: 29.06.2023 Version number 1.0

Trade name: Ciprofloxacin hydrochloride Ciprofloxacini hydrochloridum

(Contd. of page 3)

· Eye/face protection



Tightly sealed goggles

· Body protection: Protective work clothing

SECTION 9: Physical and chemic	al properties
· 9.1 Information on basic physical and chemica	Il properties
General Information	
· Physical state	Solid
· Colour:	Whitish
· Odour:	Odourless
· Odour threshold:	Not determined.
 Melting point/freezing point: 	318–320°C
Boiling point or initial boiling point and boiling	
range	Undetermined.
· Flammability	Product is not flammable.
 Lower and upper explosion limit 	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
 Decomposition temperature: 	Not determined.
·pH	3–4.5
· Viscosity:	
 Kinematic viscosity 	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Not determined.
 Partition coefficient n-octanol/water (log 	
value)	Not determined.
· Vapour pressure:	Not applicable.
 Density and/or relative density 	
· Density:	Not determined.
 Relative density 	Not determined.
· Vapour density	Not applicable.
· 9.2 Other information	
· Appearance:	
· Form:	Crystalline powder
· Important information on protection of health	
and environment, and on safety.	
Auto-ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
Molecular weight	385.82 g/mol
	(Contd. on page 5)

(Contd. on page 5)





Page 4/7

Safety data sheet according to 1907/2006/EC, Article 31

Page 5/7 Printing date 29.06.2023 Revision: 29.06.2023 Version number 1.0

Trade name: Ciprofloxacin hydrochloride Ciprofloxacini hydrochloridum

Change in condition		
Evaporation rate	Not applicable.	
Information with regard to physical hazard		
classes		
Explosives	Void	
Flammable gases	Void	
Aerosols	Void	
Oxidising gases	Void	
Gases under pressure	Void	
Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit		
flammable gases in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions Reacts with strong oxidising agents.
- \cdot 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- **10.6 Hazardous decomposition products:** Nitrogen oxides (NOx)

Hydrogen chloride (HCl) Hydrogen fluoride

SECTION 11: Toxicological information

· 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

- · Acute toxicity
- · LD/LC50 values relevant for classification:
- Oral LD50 >5000 mg/kg (mouse)

>5000 mg/kg (rat)

· Serious eye damage/irritation Causes serious eye irritation.

(Contd. on page 6)



(a.

according to 1907/2006/EC, Article 31

Page 6/7 Printing date 29.06.2023 Revision: 29.06.2023 Version number 1.0

Trade name: Ciprofloxacin hydrochloride Ciprofloxacini hydrochloridum

• **11.2 Information on other hazards** • **Endocrine disrupting properties** Substance is not listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 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.
- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

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.

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.

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

SECTION 14: Transport information

 14.1 UN number or ID number ADR, IMDG, IATA 	not regulated	
 14.2 UN proper shipping name ADR, IMDG, IATA 	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
 14.4 Packing group ADR, IMDG, IATA 	not regulated	
· 14.5 Environmental hazards:	Not applicable.	
	(Co	ntd. on page 7)

(Contd. on page 7)



(Contd. of page 5)

Safety data sheet according to 1907/2006/EC, Article 31

Page 7/7 Printing date 29.06.2023 Revision: 29.06.2023 Version number 1.0

Trade name: Ciprofloxacin hydrochloride Ciprofloxacini hydrochloridum

		(Contd. of page
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk accord	ing to	
IMO instruments	Not applicable.	
· UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not 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.

· Department issuing SDS:

Fagron UK

Quality Assurance

• Contact: quality@fagron.co.uk

• Abbreviations and acronyms:

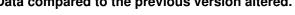
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- 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 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

** Data compared to the previous version altered.





GB