

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

CETIRIZINI DIHYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

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Revision: 03/02/2022

Version: 00



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Cetirizine dihydrochloride
Cetirizini dihydrochloridum
Cetirizine dihydrochloride
Cétirizine (dichlorhydrate de)
Cetirizindihydrochlorid

N° CAS: 83881-52-1

N° EC: 620-533-8

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

| | | |
|----------------------------|-------------------------|--------------------------|
| Public utility foundation: | Belgisch Antigifcentrum | Centre Antipoisons Belge |
| Telephone: | (+32) (0)70 245 245 | (Service 24/7) |
| Web page: | www.antigifcentrum.be | www.centreantipoisons.be |

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4 H302+H332

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302+H332 Harmful if swallowed or if inhaled.

Precautionary statements:

P261 Avoid breathing dust.

P264 Wash hands and face thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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P304+P340

P501

Additional applicable label elements:

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Dispose of contents/container in accordance with local/regional/national/inter-national regulation.

Not applicable.

2.3 Other hazards

Special health hazards: Dizziness, nausea, vomiting, dryness of mouth.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

| | |
|--------------------|---|
| Product name: | Cetirizine dihydrochloride |
| IUPAC name: | (RS)-2-[2-[4-[(4-Chlorophenyl)phenylmethyl]piperazin-1-yl]ethoxy]acetic acid dihydrochloride. |
| Synonyms: | Alerlisin Reactine Zyrtec |
| N° CAS: | 83881-52-1 |
| N° EC: | 620-533-8 |
| Molecular Formula: | C ₂₁ H ₂₇ Cl ₃ N ₂ O ₃ |
| Content: | 99.0 per cent to 101.0 per cent (dried substance). |

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|---------------------|--|
| General notes: | Symptoms of poisoning may not appear until after many hours. For this reason, a medical check-up is necessary at least 48 hours after an accident. |
| After inhalation: | Remove the affected person to fresh air. Give artificial respiration if required. |
| After skin contact: | Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothes and shoes. Call a physician. |
| After eye contact: | Assure adequate flushing of water by separating the eyelids with fingers. Flush with copious amounts of water for at least fifteen minutes. |
| After ingestion: | Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician. |

4.2 Most important symptoms and effects, both acute and delayed

Dizziness, nausea, vomiting and dryness of mouth.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide, dry chemical or water spray. Fight larger fires with water jet or alcohol resistant foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained breathing apparatus for firefighting if necessary. Wear protective clothing to prevent contact with skin and eyes.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use personal protective equipment. Avoid dust formation. Avoid Breathing dust. Ensure adequate ventilation.

For emergency responders

Use personal protective equipment. Avoid dust formation. Avoid Breathing dust. Ensure adequate ventilation.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For precautions for safe handling, see section 7.

For information on personal protective equipment, see section 8.

For disposal considerations, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid formation of dust and aerosols. Normal measures for preventive fire protection.

Personal protection: Not available.

Technical protective measures: Provide appropriate exhaust ventilation at places where dust is formed.

Handling: Use appropriate safety equipment.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Keep container tightly closed.

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Conditions for safe storage, including any incompatibilities:

Keep container in a dry and well-ventilated place.

Storage – away from:

Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Keep away from food and drink. Work under hood.

Individual protection measures

Eye/face protection: Use safety glasses.

Skin protection: Wear appropriate protective clothing to prevent skin exposure. Immediately change contaminated clothing. Wash hands and face after working with substance.

Hand protection: Wear appropriate 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 made 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.

Glove material: The choice of a suitable glove does not only depend on the material, but also on other quality characteristics and varies from manufacturer to manufacturer.

Penetration time of glove material: keep in mind that you can find out the exact breakthrough time from the glove manufacturer.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95(US) or a type P1(EN143) respirator. Do not inhale substance.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white powder.

Odour: Characteristic.

Odour threshold: Not available.

pH: 1.2 to 1.8 (5.0% w/v solution in water)

Melting/freezing point: Melting point: about 220°C

Initial boiling point: Not available.

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|---|---|
| Boiling range: | Not available. |
| Flash point: | Not available. |
| Evaporation rate: | Not available. |
| Flammability (solid/gas): | The substance is not flammable. |
| Upper/lower flammability or explosive limits: | Not available. |
| Vapour pressure: | Not available. |
| Vapour density: | Not available. |
| Relative density: | Not available. |
| Solubility: | Practically insoluble in acetone and in methylene chloride. |
| Solubility in water: | Freely soluble in water. Hygroscopic solid. |
| Partition coefficient (n-octanol/water): | Not available. |
| Auto-ignition temperature: | Not available. |
| Decomposition temperature: | Not available. |
| Viscosity: | Not available. |
| Explosive properties: | The product does not present an explosion hazard. |
| Oxidising properties: | Not available. |

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

With strong oxidising agents and strong acids.

10.4 Conditions to avoid

Strong oxidising agents.

10.5 Incompatible materials

Strong bases and strong acids.

10.6 Hazardous decomposition products

Gives out toxic fumes of oxides of nitrogen and hydrogen chloride, carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Harmful if swallowed or if inhaled.
Oral LD50 (dog): 320 mg/kg

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| | |
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| | Oral LD50 (rat): 365 mg/kg |
| Skin corrosion/irritation: | Based on available data; the classification criteria are not met. |
| Serious eye damage/irritation: | Based on available data; the classification criteria are not met. |
| Respiratory/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: | Chronic Exposure: IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH. NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA. |
| Reproductive toxicity: | Based on available data; the classification criteria are not met. |
| Summary of evaluation of the CMR properties: | Not available. |
| STOT-single exposure: | Based on available data; the classification criteria are not met. |
| STOT-repeated exposure: | Based on available data; the classification criteria are not met. |
| Aspiration Hazard: | Based on available data; the classification criteria are not met. |
| Other: | Not available. |

11.2 Additional information on potential adverse human health effects and symptoms

| | |
|---------------|---|
| Eye contact: | Not available. |
| Skin contact: | Not available. |
| Inhalation: | Harmful if inhaled. Effects and symptoms: dizziness, nausea, vomiting and dryness of mouth. |
| Ingestion: | Harmful if swallowed. Effects and symptoms: dizziness, nausea, vomiting and dryness of mouth. |
| Aspiration: | Not available. |

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

General information:

Danger to water class 3 (D) (Self-classification): danger to water high.

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Do not discharge into groundwater, surface water or sewers, even in small quantities.

Danger to drinking water even when very small amounts leak into the substrate.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

The use and/or disposal of this material is not expected to cause adverse effects upon animals, plants, humans other organisms or the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Must not be disposed of together with household waste or end up in the sewage system.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not dangerous goods.

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SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Not applicable.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

| | |
|--------------|---|
| ADR: | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CAS: | Chemical Abstracts Service (division of the American Chemical Society) |
| EC (number): | European Community (number) |
| IATA: | International Air Transport Association |
| ICAO: | International Civil Aviation Organization |
| IMDG: | International Maritime Code for Dangerous Goods |
| IUPAC: | International Union of Pure and Applied Chemistry |
| PBT: | Persistent, Bioaccumulative and Toxic substance |
| RID: | Regulations Concerning the International Transport of Dangerous Goods by Rail |
| STOT: | Specific Target Organ Toxicity |
| UN (number): | United Nations (number) |
| vPvB: | very Persistent and very Bioaccumulative |

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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