

Material Safety Data Sheet

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

EN

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TRIPROLIDINI HYDROCHLORIDUM

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

1.1 Product identifier

Product name:	Triprolidine hydrochloride Triprolidini hydrochloridum Triprolidine hydrochloride Triprolidine (chlorhydrate de) Triprolidinhydrochlorid
N° CAS:	6138-79-0
N° EC:	627-740-2

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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. 3	H301
Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301	Toxic if swallowed.
H315	Causes skin irritation.

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H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see on this label).
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Triprolidine hydrochloride
IUPAC name:	2-[(E)-1-(4-methylphenyl)-3-pyrrolidin-1-ylprop-1-enyl]pyridine;hydrate;hydrochloride
Synonyms:	Triprolidine hydrochloride monohydrate Venen Pro-Actidil
N° CAS:	6138-79-0
N° EC:	627-740-2
Molecular Formula:	C ₁₉ H ₂₂ N ₂ , HCl, H ₂ O
Content:	It contains not less than 98.5 % and not more than 101.0 % of C ₁₉ H ₂₂ N ₂ ,HCl, calculated with reference to the anhydrous substance.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. Obtain medical attention.
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4.2 Most important symptoms and effects, both acute and delayed

POTENTIAL HEALTH EFFECTS

Usual adult dose

The usual oral adult dose of Triprolidine hydrochloride is 2.5 mg every four to six hours.

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Adverse effects

Adverse effects may include drowsiness; thickening of mucus; sore throat and fever; unusual bleeding or bruising; unusual tiredness or weakness; difficult or painful urination; swelling; dryness of mouth, nose, or throat; stomach pain; chills; clay - collared stools or dark urine; diarrhoea; headache; itching; dizziness; fast or irregular heartbeat; nightmares; and unusual excitement, restlessness, nervousness, or irritability. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose effects

Overdose effects include clumsiness or unsteadiness; severe drowsiness; severely dry mouth, nose, or throat; flushed face; troubled breathing; fast or irregular heartbeat; feeling faint; hallucinations; seizures; and trouble sleeping.

Acute

Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic

Possible hyper sensitization.

Inhalation

May cause irritation. Remove to fresh air.

Eye

May cause irritation. Flush with copious quantities of water.

Skin

May cause irritation. Flush with copious quantities of water.

Ingestion

May cause irritation if ingested. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract. Effects may occur quickly and last up to 12 hours.

MEDICAL CONDITIONS

Aggravated by exposure

Hypersensitivity to material, active alcoholism, bladder neck obstruction, enlarged prostate gland, urinary retention, and glaucoma.

Cross sensitivity

Persons sensitive to other antihistamines may be sensitive to this material also.

Pregnancy comments

Adequate and well-controlled studies in humans have not been done. However, studies in animals have not shown that Triprolidine causes adverse effects on the foetus.

4.3 Indication of any immediate medical attention and special treatment needed

Overdose Treatment:

Treatment of antihistamine overdose should be symptomatic and supportive and may include the following:

1. Induce vomiting (syrup of ipecac recommended) with precaution against aspiration.
2. Gastric lavage (isotonic or 0.45% sodium chloride solution) if patient is unable to vomit within 3 hours of ingestion.
3. Saline cathartics (milk of magnesia) are sometimes used.
4. Use vasopressors to treat hypotension, however, epinephrine should NOT be used.
5. Provide supportive treatment in the form of intravenous fluids and oxygen.
6. Avoid the use of stimulants (analeptic agents), since they may cause seizures.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Fire and explosion hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.

5.3 Advice for firefighters

Surrounding fires: As with all fires, evacuate personnel to a safe area.

Protection against fire: Fire-fighters should use self-contained breathing equipment and protective clothing.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use proper personal protective equipment as indicated in section 8.

For emergency responders

Use proper personal protective equipment as indicated in section 8.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Spill response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: As a general rule, when handling the material avoid all contact and inhalation of dust, mists and/or vapours associated with material.

Personal protection: Not available.

Technical protective measures: Not available.

Handling: Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

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Conditions for safe storage, including any incompatibilities:

Store in tight, light-resistant container. This material should be handled and stored per label instructions to ensure product integrity.

Storage – away from:

Not available.

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

Ventilation: No special ventilation requirements.

Individual protection measures

Eye/face protection: Safety goggles.

Skin protection: Protect exposed skin.

Hand protection: Gloves: Rubber.

Respiratory protection: When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

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, crystalline powder.

Odour: Slight unpleasant odour.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 116 – 118 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

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Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96 per cent), practically insoluble in ether.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
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 storage conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerisation: Not known.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (rat): 840 mg/kg Oral LD ₅₀ (mouse): 163 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Listed as Carcinogen? NTP: No. IARC: No. OSHA: No. Other: No.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.

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STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	RTECS Number: UT76580000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause irritation.
Skin contact:	May cause irritation.
Inhalation:	May cause irritation.
Ingestion:	May cause irritation if ingested. This material is well absorbed from the gastrointestinal tract. Effects may occur quickly and last up to 12 hours. Toxic if swallowed.
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

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in a manner consistent with federal, state, and local regulations.

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 available.

14.2 UN proper shipping name

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

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14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

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

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 available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Toxic



Irritant

Risk phrases:

R25 Toxic if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases:

S1 Keep locked up.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S46 If swallowed, seek medical advice immediately and show this container or label.

15.2 Chemical safety assessment

Not available.

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)

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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

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