

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

Printing date 03.05.2011

Revision: 03.05.2011

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

- Product identifier

- Trade name: Epinastine Hydrochloride

- CAS Number:

108929-04-0

- Relevant identified uses of the substance or mixture and uses advised against d.n.d.

- Details of the supplier of the safety data sheet

- Manufacturer/Supplier:

TRIFARMA S.p.A.

Stabilimento di Ceriano Laghetto

Via delle Industrie n. 6

I - 20816 CERIANO LAGHETTO (MB)

Tel.: +39 02 9690018

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e-mail: chymars@trifarma.it

- Informing department: Product safety department.

- Emergency telephone number:

Dott. Paolo Volante

E-mail: chymars@trifarma.it

2 Hazards identification

- Classification of the substance or mixture

- Classification according to Regulation (EC) No 1272/2008



GHS06 skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.

- Classification according to Directive 67/548/EEC or Directive 1999/45/EC



T; Toxic

R25: Toxic if swallowed.

- Label elements

- Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

- Hazard pictograms



GHS06

- Signal word Danger

- Hazard statements

H301 Toxic if swallowed.

- Precautionary statements

P264 Wash thoroughly after handling.

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

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P321 Specific treatment (see on this label).

P330 Rinse mouth.

P405 Store locked up.

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

- Additional information:

Pharmaceutical Active Principle

Classification is updated to the community laws in force.

- Other hazards

- Results of PBT and vPvB assessment

- PBT: Not applicable.

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- vPvB: Not applicable.**3 Composition/information on ingredients**

- **Chemical characterization: Substances**
- **CAS No. Designation:**
108929-04-0 Epinastine Hydrochloride
- **Identification number(s):** -

4 First aid measures

- **Description of first aid measures**
- **General information**
Instantly remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration (DO NOT use mouth-to-mouth method).
- **After inhalation**
In case of unconsciousness bring patient into stable side position for transport.
Supply fresh air and call for doctor for safety reasons.
- **After skin contact** Instantly wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult doctor.
- **After swallowing**
Do not induce vomiting; instantly call for medical help.
Rinse out mouth.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
- **Advice for firefighters**
- **Protective equipment:**
Put on breathing apparatus.
Wear full protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:**
Do not allow to enter drainage system, surface or ground water.
Do not allow to enter the ground/soil.
- **Methods and material for containment and cleaning up:**
Collect mechanically.
Ensure adequate ventilation.
Dispose of the material collected according to regulations.
- **Reference to other sections**
See Section 8 for information on personal protection equipment.

7 Handling and storage

- **Handling**
- **Precautions for safe handling**
Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.

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- **Information about protection against explosions and fires:**
Keep breathing equipment ready.
Have fire extinguishing equipment ready in case of nearby fire.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and containers:** Store at room temperature.
- **Information about storage in one common storage facility:**
Do not store together with incompatible materials (see Section 10)
- **Further information about storage conditions:** Store at room temperature.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the compilation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
Take off immediately all contaminated clothing
Wash hands during breaks and at the end of the work.
Do not inhale dust / smoke / mist.
Pregnant women must strictly avoid inhalation or contact with the skin.
Ensure that washing facilities are available in the work place.
Avoid contact with the eyes and skin.
Do not eat or drink while working.
- **Breathing equipment:**
In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.
- **Protection of hands:**



Protective gloves.

- **Eye protection:**



Safety glasses

- **Body protection:** Protective work clothing.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **Appearance:**

Form:	Crystalline powder
Colour:	White
- **Odour:** Odourless
- **Molecular Weight** 285.80
- **Change in condition**

Melting point/Melting range:	273-275°C
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Boiling point/Boiling range: Not determined**- Flash point:** Not applicable**- Inflammability (solid, gaseous)** Product is not inflammable.**- Danger of explosion:** Product is not explosive.**- Density** Not determined**- Solubility in / Miscibility with****Water:** Soluble**- Alcohols:** Soluble in Methanol.**- Organic solvents:** DMSO**10 Stability and reactivity****- Reactivity****- Chemical stability****- Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.**- Possibility of hazardous reactions** No dangerous reactions known**- Hazardous decomposition products:**

Poisonous gases/vapours

Corrosive gases/vapours

Chlorine

Nitrogen oxides (NO_x)

Carbon monoxide and carbon dioxide

11 Toxicological information**- Information on toxicological effects****- Acute toxicity:****- LD/LC50 values that are relevant for classification:**

Oral LD50 192 mg/kg (rat)

- Primary irritant effect:**- on the skin:** May cause irritation**- on the eye:** May cause irritation**- Sensitization:** No sensitizing effect known.**12 Ecological information****- Toxicity****- Aquatic toxicity:** No further relevant information available.**- Additional ecological information:****- General notes:** Not known to be hazardous to water.**- Results of PBT and vPvB assessment****- PBT:** Not applicable.**- vPvB:** Not applicable.**13 Disposal considerations****- Waste treatment methods****- Recommendation**

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

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- Land transport ADR/RID (cross-border)



- **ADR/RID-GGVS/E Class:** 6.1 Toxic substances.
- **Code Classification:** T2
- **Kemler Number:** 60
- **UN-Number:** 2811
- **Packaging group:** III
- **Label:** 6.1
- **UN proper shipping name:** 2811 TOXIC SOLID, ORGANIC, N.O.S. (Epinastine Hydrochloride)

- Maritime transport IMDG:



- **IMDG Class:** 6.1
- **UN Number:** 2811
- **Label:** 6.1
- **Packaging group:** III
- **Correct technical name:** TOXIC SOLID, ORGANIC, N.O.S. (Epinastina Cloridrato)

- Air transport ICAO-TI and IATA-DGR:



- **ICAO/IATA Class:** 6.1
- **UN/ID Number:** 2811
- **Label:** 6.1
- **Packaging group:** III
- **Correct technical name:** TOXIC SOLID, ORGANIC, N.O.S. (Epinastina Cloridrato)

- **UN "Model Regulation":** UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III
- **Special precautions for user** Warning: Toxic substances.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS06

- **Signal word** Danger

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- Hazard statements

H301 Toxic if swallowed.

- Precautionary statements

P264 Wash thoroughly after handling.

P270 Do no eat, drink or smoke when using this product.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P321 Specific treatment (see on this label).

P330 Rinse mouth.

P405 Store locked up.

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

- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing data specification sheet: TRIFARMA SPA Stabilimento di Ceriano Laghetto**- Contact:**

Dott. Paolo Volante

E-mail: chymars@trifarma.it

- 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)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

- Bibliographic sources:

- Data Bank "ChemGes EB" - DR software GmbH

- Merck Index, 12th Ed.

- Sax's dangerous properties of industrial materials, 8th Ed.

- CEFIC

- ADR

- * Data compared to the previous version altered.

Classification is updated to the last EC Directives.