

Material Safety Data Sheet

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

EN

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HISTAMINI DIHYDROCHLORIDUM

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

1.1 Product identifier

Product name: Histamine dihydrochloride
Histamini dihydrochloridum
Histamine dihydrochloride
Histamine (dichlorhydrate d')
Histamindihydrochlorid

N° CAS: 56-92-8

N° EC: 200-298-4

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

Resp. Sens. 1	H334
Skin Irr. 2	H315
Skin Sens. 1	H317
Eye Irr. 2	H319
STOT 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s):

Health Hazard

Irritant

Hazard statements:

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H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H315	Causes skin irritation.
H317	May cause an allergic reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash skin thoroughly after handling.
P311	Call a POISON CENTER/ doctor/... if experiencing respiratory symptoms.
P321	Specific treatment.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
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:	Histamine dihydrochloride
IUPAC name:	2-(1H-imidazol-5-yl)ethanamine;dihydrochloride
Synonyms:	2-(4-Imidazolyl)ethylaniline dihydrochloride Histamine hydrochloride
N° CAS:	56-92-8
N° EC:	200-298-4
Molecular Formula:	C ₅ H ₁₁ Cl ₂ N ₃
Content:	98.5% - 101.0% equivalent of histamine (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	When in doubt or if symptoms are observed, get medical advice.
After inhalation:	No special measures necessary.
After skin contact:	Wash immediately with water and soap. Change contaminated, saturated clothing. Wash contaminated clothing prior to re-use.
After eye contact:	Rinse immediately carefully and thoroughly with eyebath or water. In case of eye irritation, consult an ophthalmologist.

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After ingestion:

Call a physician in any case! Do NOT induce vomiting. If major quantity of dust is swallowed or inhaled, immediately drink water.

4.2 Most important symptoms and effects, both acute and delayed

No known symptoms to date.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Not available.

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: Not available.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with skin, eyes and clothes. Use personal protection equipment.

For emergency responders

Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2 Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Make sure spills can be contained, e.g., in sump pallets or kerbed areas. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

For containment: Collect in closed and suitable containers for disposal. Treat the recovered material as prescribed in the section on waste disposal.

For cleaning up: Take up carefully when dry.

6.4 Reference to other sections

See protective measures under sections 7 and 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

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Precautions for safe handling:	None.
Personal protection:	None.
Technical protective measures:	None.
Handling:	None.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep/Store only in original container.
Conditions for safe storage, including any incompatibilities:	None.
Storage – away from:	None.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

None.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection:	Safety eyeglasses with side protection.
Skin protection:	Immediately remove any contaminated clothing, shoes, or stockings. Wash contaminated clothing prior to re-use.
Hand protection:	<p>The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. DIN-/EN-Norms EN ISO 374 DIN EN 420 Suitable material NBR (Nitrile rubber), PVA (Polyvinyl alcohol), PVC (Polyvinyl chloride).</p> <p>Breakthrough time (maximum wearing time): > 60 m.</p> <p>Thickness of the glove material: > 0.5 mm.</p>
Respiratory protection:	If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. Suitable respiratory protection apparatus: Full-/half-/quarter-face masks (DIN EN 136/140). Filtering device (full mask or mouthpiece) with filter: ABEK-P3.
Thermal hazards:	Not determined.

Environmental exposure control

See section 7. No additional measures needed.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

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Appearance:	White or almost white crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	244 °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.
Relative density:	Not available.
Solubility:	Soluble in alcohol.
Solubility in water:	Very 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

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not applicable.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong oxidizers.

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10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	LD50 Oral - Mouse – 2534 mg/kg (Histamine dihydrochloride)
Skin corrosion/irritation:	Irritant.
Serious eye damage/irritation:	Irritant.
Respiratory/skin sensitisation:	Not sensitizing.
Germ cell mutagenicity:	No indications of human germ cell mutagenicity.
Carcinogenicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Reproductive toxicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Summary of evaluation of the CMR properties:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
STOT-single exposure:	Not applicable.
STOT-repeated exposure:	Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Harmless to aquatic organisms up to the tested concentration.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No indication of bioaccumulation potential.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PVT/vPvB criteria of REACH, Annex XIII

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12.6 Other adverse effects

None.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Delivery to an approved waste disposal company. Contaminated packages must be completely emptied and can be re-used after proper cleaning. Handle contaminated packages in the same way as the substance itself.

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) : No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous good in sense of these transport regulations.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None.

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

Not applicable.

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:



Irritating

Risk phrases:

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

Safety phrases:

Not available.

15.2 Chemical safety assessment

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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)
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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