

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/9

DIPHENHYDRAMINI HYDROCHLORIDUM

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01



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

1.1 Product identifier

Product name: Diphenhydramine hydrochloride
Diphenhydramini hydrochloridum
Difenhydraminehydrochloride
Diphénhydramine (chlorhydrate de)
Diphenhyraminhydrochlorid

N° CAS: 147-24-0

N° EC: 205-687-2

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: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
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

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

P264 Wash hands and face 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.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9



DIPHENHYDRAMINI HYDROCHLORIDUM

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01

MAGIS
PHARMA

P330	Rinse mouth.
P501	Dispose of contents/container to hazardous or special waste collection point.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Diphenhydramine hydrochloride
IUPAC name:	2-benzhydryloxy- <i>N,N</i> -dimethylethanamine;hydrochloride
Synonyms:	Allerdryl Benadryl
N° CAS:	147-24-0
N° EC:	205-687-2
Molecular Formula:	C ₁₇ H ₂₂ ClNO
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:	Consult a physician. Show this safety data sheet to the doctor in attendance.
After inhalation:	Provide fresh air. Get medical advice/attention if you feel unwell.
After skin contact:	Remove residues with water. Change contaminated clothing.
After eye contact:	Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.
After ingestion:	Give affected person large quantities of water in small amounts and induce vomiting. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

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:	Water fog, foam, extinguishing powder, dry chemical, chemical foam, alcohol resistant foam.
-------------------------------	---

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/9



MAGIS
PHARMA

DIPHENHYDRAMINI HYDROCHLORIDUM

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Combustible. May form dangerous gases and vapours in case of fire.

Can be released in case of fire: hydrochloric, nitrogen oxides (NO_x), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Surrounding fires: Use water spray jet to knock down vapours. Do not allow fire water to penetrate into surface or ground water.

Protection against fire: Wear self-contained breathing apparatus. Wear suitable 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

Avoid generation of dust. Do not breathe dust. Provide adequate ventilation. Wear personal protection equipment.

For emergency responders

Avoid generation of dust. Do not breathe dust. Provide adequate ventilation. Wear personal protection equipment.

6.2 Environmental precautions

Do not allow to penetrate into soil, water bodies or drains.

6.3 Methods and material for containment and cleaning up

Collect dry and place in appropriate containers for disposal, cleaning.

6.4 Reference to other sections

For disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid generation of dust.

Personal protection: Not available.

Technical protective measures: In case of dust: Provide adequate ventilation, and local exhaust as needed.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Preserve in tight, light-resistant containers.

Storage class: 11 (combustible solids).

Conditions for safe storage, including any incompatibilities: Store at room temperature.

Storage – away from: Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

Material Safety Data Sheet

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

DIPHENHYDRAMINI HYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

When dust and vapours form: Withdraw by suction. See also information in chapter 7, section storage.

Wash hands before breaks and at the end of the workday.

Individual protection measures

Eye/face protection: Tightly sealed safety glasses according to EN 166.

Skin protection: Wear suitable protective clothing. Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber.

Layer thickness: 0,11 mm.

Breakthrough time: > 480 min.

Observe the instructions of the glove manufacturer regarding permeability and breakthrough time.

Respiratory protection: In case of dust: Particulates filter P1 according to EN 143.

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, crystalline powder.

Odour: Odourless.

Odour threshold: Not available.

pH: 4 to 6 (1% solution/water)

Melting/freezing point: 168 °C to 170 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: > 100 °C

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/9



DIPHENHYDRAMINI HYDROCHLORIDUM

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01

Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96%).
Solubility in water:	Very soluble in water: 1000 g/L.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	> 150 °C
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

Light-sensitive.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Protect from excessive heat.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Can be released in case of fire: hydrochloric, nitrogen oxides (NO_x), carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 500 mg/kg
Skin corrosion/irritation:	Causes skin irritation.
Serious eye damage/irritation:	Extremely hazardous in case of eye contact.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	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.
Reproductive toxicity:	Not available.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/9



MAGIS
PHARMA

DIPHENHYDRAMINI HYDROCHLORIDUM

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: RTECS: KR7000000

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Causes serious eye irritation.

Skin contact: Causes skin irritation.

Inhalation: May be harmful if inhaled.

Ingestion: Harmful if swallowed.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Water Hazard Class: 2 (water pollutant).

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

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Waste key number 160506* (laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals). * = Evidence for disposal must be provided. Recommendation: Offer surplus and non-recyclable solutions to a licensed disposal company. 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.

Contaminated packaging: Waste key number 150107 (Glass packaging). Recommendation: Dispose of as unused product.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/9



MAGIS
PHARMA

DIPHENHYDRAMINI HYDROCHLORIDUM

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), ADR/RID: No.
IATA/ICAO (Air) : IMDG Marine pollutant: No.
IATA No.

14.6 Special precautions for user

Not a hazardous material with respect to transportation regulations.

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:



Risk phrases:

R22 Harmful if swallowed.

Safety phrases:

S20/21 When using do not eat, drink or smoke.

S24/25 Avoid contact with skin and eyes.

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.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/9



MAGIS
PHARMA

DIPHENHYDRAMINI HYDROCHLORIDUM

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01

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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be

Material Safety Data Sheet

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

DIPHENHYDRAMINI HYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 05/03/2022

Revision: 03/07/2024

Version: 01

