Material Safety Data Sheet

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

DEXTROMETHORPHANI HYDROBROMIDUM

Publication: 12/03/2022
Revision: 27/12/2024
Version: 01

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Dextromethorphan hydrobromide Dextromethorphani hydrobromidum Dextromethorfan hydrobromide Dextrométhorphane (bromhydrate de) Dextromethorphanhydrobromid
N° CAS:	6700-34-1
N° EC:	204-750-1

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
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Attention

Hazard statements:

H302	Harmful if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements:	
P264	Wash hands 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.
P330	Rinse mouth.
P501	Dispose of contents/container to approved waste disposal plant.
Additional applicable label elements:	

2.3 Other hazards

Sensitive persons may have an allergic reaction.

May cause irritation to eyes, skin and respiratory system.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Dextromethorphan hydrobromide
IUPAC name:	(1*S*,9*S*,10*S*)-4-methoxy-17-methyl-17-azatetracyclo[7.5.3.$0^{1,10}$.$0^{2,7}$]heptadeca-2(7),3,5-triene;hydrate;hydrobromide
Synonyms:	Dextromethorphan hydrobromide monohydrate Methorate Drixoral Cough Romilar
N° CAS:	6700-34-1
N° EC:	204-750-1
Molecular Formula:	$C_{18}H_{26}BrNO,H_2O$
Content:	99.0 per cent to 101.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	If you feel unwell, consult an anti-poison centre or a doctor.
After inhalation:	Bring the person into the fresh air and make sure they can breathe easily. Place the affected person in a stable side position. Consult a physician immediately.
After skin contact:	Wash skin with soap and water (15 – 20 minutes). Remove contaminated clothing. Call a doctor immediately.

After eye contact:	Rinse immediately and thoroughly with water (15 – 20 minutes), keeping eyes wide open. Remove contact lenses, if possible. Continue rinsing. Get medical attention if irritation develops.
After ingestion:	Rinse mouth. Perform artificial respiration if necessary. If you feel unwell, call an anti-poison centre or doctor.

4.2 Most important symptoms and effects, both acute and delayed

Ingestion: Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
Drowsiness, dizziness, excitation, metal confusion and gastrointestinal disturbances have been described following dextromethorphan.
Side effects of dextromethorphan use can include: body rash/itching, nausea, vomiting, drowsiness, dizziness, blurred vision, dilated pupils, sweating, fever, hypertension, shallow respiration, diarrhoea, urinary retention. It can also cause other gastrointestinal disturbances.
Overexposure can cause ataxia (loss of muscle co-ordination), excitement and motor activity changes. Allergic reactions have also been reported.
When injected directly into the blood stream, some studies suggest that dextromethorphan has potential to cause Olney's lesions.

Eye: Direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with wind bum). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

Skin: Skin contact is not thought to produce harmful effects (as classified using animal models). Systemic harm, however, has been identified following exposure of animals by at least one o route and the material may still produce health damage following entry through wounds, lesions or abrasions.

Inhaled: Inhalation of dust or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally distress.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray. Carbon dioxide (CO_2). Foam. Dry chemical. Use extinguishing agent suitable for surrounding fire.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Possible formation of toxic fumes. Nitrogen oxides. Hydrogen bromide.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Do not intervene without suitable safety equipment. Self-contained breathing apparatus. Full 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

Evacuate personnel to a safe place. Avoid the formation of dust. Do not breathe dust. Avoid contact with skin, eyes or clothing. Ventilate contaminated area.

For emergency responders

Evacuate personnel to a safe place. Avoid the formation of dust. Do not breathe dust. Avoid contact with skin, eyes or clothing. Do not intervene without suitable safety equipment.

6.2 Environmental precautions

Avoid release into the environment. Stop leak if safe to do so.

6.3 Methods and material for containment and cleaning up

For containment: Clean up leaked/spilled material.

Methods for cleaning up: Mechanically dispose of the product. Contain and/or absorb spillage with inert material (sand, vermiculite or other suitable material) and place in a suitable container.

Other information: Take waste or solid residues to an approved waste disposal company.

6.4 Reference to other sections

For further information, see section 13.

For information on safe handling, see section 7.

For information on personal protective equipment, see section 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Ensure that the workplace is properly ventilated. Do not eat, drink or smoke when using this product. Always wash hands after handling this product. Remove contaminated clothing and shoes.
Personal protection:	Wear personal protective equipment. Avoid contact with skin, eyes or clothing.
Technical protective measures:	Ensure that the workplace is properly ventilated. Avoid formation of dust.
Handling:	The dust particles can form a highly inflammable and explosive mixture with air. Always wash hands after handling this product.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep in tightly closed packaging.

Conditions for safe storage, including any incompatibilities:	Keep in a well-ventilated place. Store in a cool and dry place.
Storage – away from:	Store protected from light and heat. Alkalis, oxidizing agents.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure limit: 10 microgram/m^3

8.2 Exposure controls

Appropriate engineering control

Ensure that the workplace is properly ventilated. Appropriate technical measures. Emergency eye showers and safety showers should be installed near any place of potential exposure. Avoid the formation of dust. Do not breathe dust. Do not eat, drink or smoke when using this product. Handle in accordance with good industrial hygiene and safety practices. Keep away from foodstuff and drink, including animal feed. Remove all contaminated clothing and footwear.

Individual protection measures

Eye/face protection:	Close-fitting safety goggles. EN 166. Avoid contact with eyes.
Skin protection:	Wear suitable protective clothing. Avoid contact with skin or clothing.
Hand protection:	Wear suitable gloves resistant to chemical penetration. Please observe the instructions provided by the manufacturer regarding the permeability and penetration time of the substance. DIN/EN 374. Avoid contact with skin. Always wash hands after handling this product.
Respiratory protection:	In case of dust formation: dust mask. EN 149.
Thermal hazards:	Not determined.

Environmental exposure control

Avoid release into the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Almost white, crystalline powder.
Odour:	Faint.
Odour threshold:	Not available.
pH:	5.2 – 6.5 (20 °C)
Melting/freezing point:	About 125 °C, with decomposition.
Initial boiling point:	Not available.
Boiling range:	Not available.

Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96%).
Solubility in water:	Sparingly 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 explosive.
Oxidising properties:	Not oxidising.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is not reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Protect from light and heat.

10.5 Incompatible materials

Alkaline substances. Oxidising substances.

10.6 Hazardous decomposition products

Thermal decomposition releases: Nitrogen oxides. Hydrogen bromide. Possible formation of toxic gases.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Harmful if swallowed.

	Oral LD50 (Guinea pig): 336 mg/kg Oral LD50 (mouse): 165 mg/kg Oral LD50 (rat): 350 mg/kg Intravenous LD50 (cat): 19 800 µg/kg Intravenous LD50 (mouse): 35 mg/kg Intravenous LD50 (rabbit): 15 mg/kg Subcutaneous LD50 (Guinea pig): 150 mg/kg Subcutaneous LD50 (mouse): 153 mg/kg Subcutaneous LD50 (rat): 600 mg/kg
Skin corrosion/irritation:	May cause irritation in case of skin contact.
Serious eye damage/irritation:	May cause irritation in case of eye contact.
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:	Based on available data, the classification criteria are not met. This material in not considered to be carcinogen by IARC, NTP or 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:	Respiratory tract irritation. Narcotic effects.
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:	May cause irritation in case of skin contact.
Skin contact:	May cause irritation in case of eye contact. Direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with wind bum). Slight abrasive damage may also result.
Inhalation:	Inhalation of dust or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally distress.
Ingestion:	Harmful if swallowed. Drowsiness, dizziness, excitation, metal confusion, gastrointestinal disturbances, rash/itching, nausea, vomiting, blurred vision, dilated pupils, sweating, fever, hypertension, shallow respiration, diarrhoea, urinary retention. Overexposure can cause ataxia (loss of muscle co-ordination), excitement and motor activity changes. When injected directly into the blood stream, some studies suggest that dextromethorphan has potential to cause Olney's lesions.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Very toxic to aquatic life with long-lasting effects.
LC50 (fish 96h): 4.9 mg/l
IC50 (algae, 72h): 2.4 mg/l
EC50 (daphnia, 48h): 14.5 mg/l

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 applicable.

12.6 Other adverse effects

Do not discharge into sewer or waterways.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment methods: Dispose of contents/packaging in accordance with the sorting instructions of a recognized collection company. Do not discharge into drains or watercourses.

Recommendations for disposal of products/packaging: Disposal in accordance with legal provisions.

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) :	3077

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Dextromethorphan hydrobromide monohydrate)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	9

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	III

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Environmentally hazardous: Yes. Marine pollutant: Yes.

14.6 Special precautions for user

Kemler number: 90

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

Not applicable.

14.8 Additional transport information

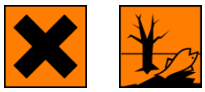
ADR Limited quantities (LG): 5kg

ADR Excepted quantities (EQ): E1

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.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R63 Possible risk of harm to the unborn child.

R64 May cause harm to breastfed babies.

Safety phrases:

S22 Do not breathe dust.

S36 Wear suitable protective clothing.

S60 This material and its container must be disposed of as hazardous waste.

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 Bioaccumalative

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

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