

Material Safety Data Sheet

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

EN

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DIMENHYDRINATUM

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

1.1 Product identifier

Product name: Dimenhydrinate
Dimenhydrinatum
Dimenhydrinaat
Dimenhydrinate
Dimenhydrinat

N° CAS: 523-87-5

N° EC: 208-350-8

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

Acute Tox. 4	H302+H312
Skin Irr. 2	H315
Eye Irr. 2	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302+H312	Harmful if swallowed or contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

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Precautionary statements:

P260	Do not breathe dust.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Dust explosive.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Dimenhydrinate
IUPAC name:	2-benzhydryloxy- <i>N,N</i> -dimethylethanamine;8-chloro-1,3-dimethyl-7 <i>H</i> -purine-2,6-dione
Synonyms:	Dramamine Diphenhydrinate Gravol Motion-Aid
N° CAS:	523-87-5
N° EC:	208-350-8
Molecular Formula:	C ₂₄ H ₂₈ ClN ₅ O ₃
Content:	Diphenhydramine (C ₁₇ H ₂₁ NO): 53.0 per cent to 55.5 per cent (dried substance). 8-Chlorotheophylline (C ₇ H ₇ ClN ₄ O ₂): 44.0 per cent to 46.5 per cent (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
After skin contact:	Wash off with plenty of water and soap for at least 15 minutes. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.
After eye contact:	After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.
After ingestion:	Call a physician immediately.
Self-protection of the first aider:	Pay attention to self-protection!

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4.2 Most important symptoms and effects, both acute and delayed

Exposure to high concentrations may cause hallucinations and distorted perceptions.

Target organs: Eyes, ears, central nervous system.

4.3 Indication of any immediate medical attention and special treatment needed

When symptoms indicate toxicity, immediate medical treatment is necessary. If possible, show this data sheet.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, carbon dioxide, dry chemical powder, foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

In case of fire may be liberated: Carbon monoxide, Nitrogen oxides, hydrogen chloride.

5.3 Advice for firefighters

Surrounding fires: Do not inhale explosion and combustion gases. Contaminated extinguishing water must be collected separately. It may not be discharged into the sewer.

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 generation of dust. Wear personal protection equipment. Wear breathing apparatus if exposed to vapours/dust.

For emergency responders

Avoid generation of dust. Wear personal protection equipment. Wear breathing apparatus if exposed to vapours/dust.

6.2 Environmental precautions

Do not allow to enter drains/surface water/groundwater.

6.3 Methods and material for containment and cleaning up

Carefully take up dry. Vacuum residues. Collect the material according to section 13.

6.4 Reference to other sections

For personal protective equipment, see section 8.

For disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: The product is combustible, fine dust (< 63 µ) may form explosive mixture.

Personal protection: Not available.

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Technical protective measures:

All work processes must always be designed so that the following is as low as possible: Inhalation, skin contact, eye contact. Avoid generation of dust.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Keep container tightly closed.

Conditions for safe storage, including any incompatibilities:

Keep in a well-ventilated place.

Storage – away from:

Protect from light and humidity.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Limits for occupational safety: the substance is not listed.

Valid are the general dust limits for 8 h.

8.2 Exposure controls

Appropriate engineering control

Immediately change contaminated clothing. Wash thoroughly after handling. General room ventilation is adequate unless the process generates dust or fumes. Work clothing should be removed in a change room on site and laundered professionally. Employees should shower and change into street clothes before leaving the facility. Prevent the accumulation of dust in the work area by thorough periodic cleaning of the area.

Individual protection measures

Eye/face protection:

Eye protection is required.

Skin protection:

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Hand protection:

Glove material: PVC, Butyl-/Nitrile rubber. Layer thickness: 0.11 mm. The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the standard EN374 derived from it. This recommendation applies only to the product stated in the safe data sheet and supplied by us as well as to the purpose specified by us. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.

Respiratory protection:

Is required whenever air contamination (dust, mist, or vapors) is generated by the process. A NIOSH-approved high efficiency toxic dust/mist/fume respirator is recommended.

Thermal hazards:

Not determined.

Environmental exposure control

Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder or colourless crystals.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	6.5 – 7.5 (10 g/L H ₂ O)
Melting/freezing point:	102 °C to 106 °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:	Freely soluble in ethanol (96%).
Solubility in water:	Slightly soluble in water: 3.0 g/L (20 °C).
Partition coefficient (n-octanol/water):	- 0.39
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Bulk density: 400 - 600 kg/m³

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Oxidising agents.

10.4 Conditions to avoid

Light and elevated temperature.

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10.5 Incompatible materials

Oxidising agents, alkali, acids.

10.6 Hazardous decomposition products

In case of fire, see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	LDL0 (orl, wmn) 100 mg/kg AEMED3, 22, 1481, 1993 LD50 (orl, rat) 1320 mg/kg NIIRDN 6, 346, 1982 LD50 (ivn, rat) 200 mg/kg CLDND LD50 (orl, mus) 203 mg/kg NIIRDN 6, 346, 1982 LD50 (ipr, mus) 149 mg/kg NIIRDN 6, 346, 1982 Reference: RTECS # XH5082000 Exposure to high concentrations may cause hallucinations and distorted perceptions.
Skin corrosion/irritation:	Causes skin irritation. Harmful in contact with skin.
Serious eye damage/irritation:	Causes serious eye irritation.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Chronic toxicity: May be able to cause congenital malformation in the foetus. Target organs: Eyes, ears, central nervous system. To the best of our knowledge, the chemical physical, and toxicological properties have not been thoroughly investigated. Adverse reaction symptoms: Sedation, sleepiness, dizziness, disturbed coordination, epigastric distress, urticaria, anaphylactic shock, photosensitivity, chills, hypotension, headache, palpitations, tachycardia, extrasystoles, haemolytic anaemia, agranulocytosis, thrombocytopenia, fatigue, confusion, excitation, nervousness, tremor, irritability, insomnia, euphoria, paraesthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions, anorexia, nausea, vomiting, diarrhoea, constipation, urinary frequency, difficult urination, urinary retention, early menses.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Irritating to eyes.
Skin contact:	Irritating to skin. Harmful in contact with skin.

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Inhalation: Not available.
Ingestion: Harmful if swallowed.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

lms, pigeon : LD50 >200 mg/kg (JAPMA8 46, 140, 1957)

12.2 Persistence and degradability

Degradable.

12.3 Bioaccumulative potential

Low, as $\log P < 3$.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Contains no PBT or vPvB ingredient.

12.6 Other adverse effects

On the basis of the data available concerning eliminability/degradation and bioaccumulation potential, longer-term harm to the environment is improbable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Product waste and residues must be disposed of according to current laws.

Packaging: Non-contaminated packages may be recycled. Handle contaminated packaging 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) : Not classified.

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

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14.5 Environmental hazards

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

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:



Risk phrases:

R21/22 Harmful in contact with skin and if swallowed.

R36 Irritating to eyes.

R38 Irritating to skin.

Safety phrases:

S22 Do not breathe dust.

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.

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

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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

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