

Material Safety Data Sheet

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

HYOSCINI BUTYLBROMIDUM

EN

FORM-06-14-01 (V00)

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

1.1 Product identifier

Product name: Hyoscine butylbromide
Hyoscini butylbromidum
Hyoscine butylbromide
Scopolamine (butylbromure de)
Butylscopolaminiumbromid

N° CAS: 149-64-4

N° EC: 205-744-1

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: 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

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 thoroughly after handling.

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

P301+P312 IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.

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P330	Rinse mouth.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Hyoscine butylbromide
IUPAC name:	[(1S,2S,4R,5R)-9-butyl-9-methyl-3-oxa-9-azoniatricyclo[3.3.1.0 ^{2,4}]nonan-7-yl](2S)-3-hydroxy-2-phenylpropanoate;bromide
Synonyms:	Buscapine Scopolamine butylbromide Buscopan
N° CAS:	149-64-4
N° EC:	205-744-1
Molecular Formula:	C ₂₁ H ₃₀ BrNO ₄
Content:	98.0 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:	First-aiders should ensure they are protected. Never pour anything into the mouth of an unconscious person.
After inhalation:	Remove person from danger area. Supply person with fresh air and consult doctor according to symptoms. If the person is unconscious, place in a stable side position and consult a doctor. If not breathing, give artificial respiration.
After skin contact:	Wash thoroughly using copious water - remove contaminated clothing immediately. If skin irritation occurs (redness etc.), consult doctor.
After eye contact:	Remove contact lenses. Wash thoroughly for at least 15 minutes using copious water. Seek medical help if necessary. Pilocarpine 1% can be used if necessary.
After ingestion:	Rinse the mouth thoroughly with water. Do not induce vomiting - give plenty of water to drink. Consult doctor immediately. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.

4.2 Most important symptoms and effects, both acute and delayed

If applicable, delayed symptoms and effects can be found in section 11. In certain cases, the symptoms of poisoning may only appear after an extended period/after several hours.

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The following may occur:

Irritation of the respiratory tract, irritation of the eyes, irritation of the skin, rapid pulse, dizziness.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment. Decontamination. Elementary aid.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Adapt to the nature and extent of fire. Use water/ dry extinguisher/ chemical foam/ alcohol resistant foam/ Water jet spray/ CO₂

Unsuitable extinguishing media: High volume water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire the following can develop: Oxides of carbon, oxides of nitrogen, hydrogen bromide, toxic gases, explosive dust/air mixture.

5.3 Advice for firefighters

Surrounding fires: In case of fire and/or explosion do not breathe fumes. Dispose of contaminated extinction water according to official regulations.

Protection against fire: Protective respirator with independent air supply. Full protection, if necessary.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unprotected persons away. Ensure sufficient supply of air. Avoid build-up of dust. Remove possible causes of ignition - do not smoke. Avoid contact with eyes or skin.

For emergency responders

Keep unprotected persons away. Ensure sufficient supply of air. Avoid build-up of dust. Remove possible causes of ignition - do not smoke. Avoid contact with eyes or skin.

6.2 Environmental precautions

If leakage occurs, dam up.

Resolve leaks if this possible without risk.

Prevent surface and ground-water infiltration, as well as ground penetration.

Prevent from entering drainage system.

If accidental entry into drainage system occurs, inform responsible authorities.

6.3 Methods and material for containment and cleaning up

Pick up mechanically and dispose of according to section 13.

Collect spilled material with a dust-trapping sweeping agent or a suitable vacuum cleaner.

As a precaution, douse dust with water.

6.4 Reference to other sections

For personal protective equipment, see section 8.

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For disposal instructions, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid build-up of dust. Remove possible causes of ignition - do not smoke. Avoid contact with eyes or skin. Eating, drinking, smoking, as well as food-storage, is prohibited in work-room.
Personal protection:	General hygiene measures for the handling of chemicals are applicable. Wash hands before breaks and at end of work.
Technical protective measures:	Ensure good ventilation. Avoid build-up of dust. If applicable, suction measures at the workstation or on the processing machine necessary. Take measures against electrostatic charging, if necessary.
Handling:	Handle and open container with care. Observe directions on label and instructions for use. Use working methods according to operating instructions. Keep away from food, drinks, and animal feeding stuffs. Remove contaminated clothing and protective equipment before entering areas in which food is consumed.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep out of access to unauthorised individuals. Store product closed and only in original packing. Not to be stored in gangways or stair wells.
Conditions for safe storage, including any incompatibilities:	Store in a well-ventilated place. Store in a dry place. Store cool.
Storage – away from:	Do not store with oxidizing agents. Protect from direct sunlight and warming.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under the WEL or AGW values, suitable breathing protection should be worn. Applies only if maximum permissible exposure values are listed here.

Individual protection measures

Eye/face protection:	Tight fitting protective goggles with side protection (EN 166).
Skin protection:	Protective working garments (e.g. safety shoes EN ISO 20345, long-sleeved protective working garments).

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Hand protection:	Chemical resistant protective gloves (EN 374). Recommended: Protective nitrile gloves (EN 374). Minimum layer thickness in mm: 0,43. Permeation time (penetration time) in minutes: 480. Protective hand cream recommended. The breakthrough times determined in accordance with EN 16523-1 were not obtained under practical conditions. The recommended maximum wearing time is 50% of breakthrough time. Final selection of glove material must be made taking the breakthrough times, permeation rates and degradation into account. Selection of a suitable glove depends not only on the material but also on other quality characteristics and varies from manufacturer to manufacturer. In the case of mixtures, the resistance of glove materials cannot be predicted and must therefore be tested before use. The exact breakthrough time of the glove material can be requested from the protective glove manufacturer and must be observed.
Respiratory protection:	Normally not necessary. On dust formation: If applicable, filter P2 (EN 143), code colour white. Observe wearing time limitations for respiratory protection equipment.
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:	Not available.
Odour threshold:	Not available.
pH:	5.5 – 6.5 (5% aqueous solution)
Melting/freezing point:	139 °C - 141 °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 methylene chloride, sparingly soluble in anhydrous ethanol.
Solubility in water:	Freely soluble in water: 500 g/l (20 °C).
Partition coefficient (n-octanol/water):	1.1

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Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Product is not explosive. Creation of explosive dust/air mixtures possible.
Oxidising properties:	No.

9.2 Other information

Molecular weight: 440.37 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable with proper storage and handling.

10.3 Possibility of hazardous reactions

No dangerous reactions are known.

10.4 Conditions to avoid

Light, exposure to moist air or water.

10.5 Incompatible materials

Avoid contact with strong oxidizing agents.

10.6 Hazardous decomposition products

CO_x, NO_x and HBr

No decomposition when used as directed.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 1040 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
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:	Not available.

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11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Irritation of the eyes may occur.
Skin contact:	Irritation of the skin may occur.
Inhalation:	Irritation of the respiratory tract may occur.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

LC₅₀ (Golden Orfe): 2000.0 mg/L
EC₅₀ (Pseudomonas putida, 16h): 21.0 g/L

12.2 Persistence and degradability

Log Pow: 3.0

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

For the substance/mixture/residual amounts: The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances. (2014/955/EU)

07 05 13 solid wastes containing hazardous substances

Recommendation: Sewage disposal shall be discouraged. Pay attention to local and national official regulations. E.g. suitable incineration plant. E.g. dispose at suitable refuse site.

For contaminated packing material: Pay attention to local and national official regulations. Empty container completely. Uncontaminated packaging can be recycled. Dispose of packaging that cannot be cleaned in the same manner as the substance.

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.

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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.

14.5 Environmental hazards

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

14.6 Special precautions for user

Unless specified otherwise, general measures for safe transport must be followed.

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

Non-dangerous material according to Transport Regulations.

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.

S25 Avoid contact with eyes.

S46 If swallowed, seek medical advice immediately and show this container or label.

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)

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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

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