

ATROPINI SULFAS

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

1.1 Product identifier

Product name: Atropine sulfate
Atropini sulfas
Atropinesulfaat
Atropine (sulfate d')

N° CAS: 5908-99-6

N° EC: 200-235-0

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. 3	H301
Acute Tox. 3	H311
Acute Tox. 3	H331

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301 Toxic if swallowed.

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H311	Toxic in contact with skin.
H331	Toxic if inhaled.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P311	Call a POISON CENTER/doctor.
P312	Call a POISON CENTER/doctor if you feel unwell.
P321	Specific treatment (see on this label).
P322	Specific measures (see on this label).
P330	Rinse mouth.
P361	Take off immediately all contaminated clothing.
P363	Wash contaminated clothing before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Atropine sulfate
IUPAC name:	Bis[(1R,3r,5S)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl(2RS)-3-hydroxy-2-phenylpropanoate] sulfate monohydrate
Synonyms:	Atropine sulphate monohydrate Atropisol
N° CAS:	5908-99-6
N° EC:	200-235-0
Molecular Formula:	C ₃₄ H ₄₈ N ₂ O ₁₀ S·H ₂ O
Content:	99.0 per cent to 101.0 per cent (anhydrous substance).

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3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Instantly remove any clothing soiled by the product. Remove breathing apparatus only after soiled clothing has been completely removed. In case of irregular breathing or respiratory arrest provide artificial respiration.
After inhalation:	Supply fresh air or oxygen; call for doctor. In case of unconsciousness bring patient into stable side position for transport.
After skin contact:	Instantly wash with water and soap and rinse thoroughly.
After eye contact:	Rinse opened eye for several minutes under running water. Then consult doctor.
After ingestion:	Do not induce vomiting; instantly call for medical help. Seek medical treatment.

4.2 Most important symptoms and effects, both acute and delayed

Dilation of pupils. Unconsciousness. Cramp

4.3 Indication of any immediate medical attention and special treatment needed

Medical supervision for at least 48 hours

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	CO ₂ , extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

- Can be released in case of fire:
- Nitrogen oxides (NO_x)
 - Carbon monoxide (CO)
 - Carbon dioxide (CO₂)
 - Sulphur oxides (SO_x)

5.3 Advice for firefighters

Surrounding fires:	Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.
Protection against fire:	Wear self-contained breathing apparatus.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear protective equipment. Keep unprotected persons away.

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For emergency responders

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

Do not allow product to reach sewage system or water bodies.

6.3 Methods and material for containment and cleaning up

Collect mechanically.

Dispose of contaminated material as waste according to section 13.

For dust removal, use appropriate industrial vacuum cleaners or central vacuum systems.

Ensure adequate ventilation.

6.4 Reference to other sections

See section 7 for information on safe handling.

See section 8 for information on personal protection equipment.

See section 13 for information on disposal.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Thorough dedusting. Ensure good ventilation/exhaustion at the workplace. Open and handle container with care.

Personal protection:

Not available.

Technical protective measures:

Information about protection against explosions and fires: Keep breathing equipment ready. Keep ignition sources away - Do not smoke. Protect against electrostatic charges.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Storage class 6.1 - Poisonous Substance

Conditions for safe storage, including any incompatibilities:

Requirements to be met by storerooms and containers: Store only in the original container. Use only containers specifically permitted for this substance/product.

Further information about storage conditions: Keep container tightly sealed. Store in cool, dry conditions in well-sealed containers.

Protect from heat and direct sunlight. Protect from the effects of light. Store in a locked cabinet or with access restricted to technical experts or their assistants.

Recommended storage temperature: 15 - 25 °C

Storage – away from:

Protected from light. Do not store with foodstuffs, animal feed and flammable materials. Store away from oxidising agents.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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Additional information about design of technical systems: No further data; see chapter 7.

8.1 Control parameters

Components with critical values that require monitoring at the workplace: Not required.

Additional information: The lists that were valid during the compilation were used as basis.

8.2 Exposure controls

Appropriate engineering control

General protective and hygienic measures: Keep away from foodstuffs, beverages and food. Instantly remove any soiled and impregnated garments. Wash hands during breaks and at the end of the work. Avoid contact with the eyes and skin. Store protective clothing separately.

Individual protection measures

Eye/face protection: Tightly sealed safety glasses.

Skin protection: Protective work clothing.

Hand protection: The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves

Butyl rubber, BR. Recommended thickness of the material: ≥ 0.7 mm

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

Value for the permeation: Level ≤ 6

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection: In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.

Short term filter device: Filter AEBK/EN 141

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 or colourless crystals.

Odour: Odourless.

Odour threshold: Not determined.

pH: 5 (at 20 °C)

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Melting/freezing point:	189 - 192 °C
Initial boiling point:	Not determined.
Boiling range:	Not determined.
Flash point:	Not applicable.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	Not determined.
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	Steam pressure: Not applicable.
Vapour density:	Not applicable.
Relative density:	Not determined.
Solubility:	Freely soluble in ethanol (96 per cent).
Solubility in water:	Very soluble in water. 2000 g/l at 20 °C
Partition coefficient (n-octanol/water):	Not determined.
Auto-ignition temperature:	Not determined.
Decomposition temperature:	150 (2.5 K/min) °C
Viscosity:	Not applicable.
Explosive properties:	Product is not explosive.
Oxidising properties:	Not available.

9.2 Other information

Settled apparent density:	~ 350 kg/m ³ (at 20 °C)
Solids content:	100.0 %

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

Reacts with strong oxidizing agents.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Carbon monoxide (CO) and carbon dioxide (CO₂). Nitrogen oxides (NO_x). Sulphur oxides (SO_x).

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Fatal if swallowed or if inhaled.		
	LD/LC50 values that are relevant for classification:		
	5908-99-6 atropine sulphate monohydrate		
	Oral	LD ₅₀	600 mg/kg (rat)
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.		
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.		
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.		
Reproductive toxicity:	Based on available data, the classification criteria are not met.		
Summary of evaluation of the CMR properties:	Not available.		
STOT-single exposure:	Based on available data, the classification criteria are not met.		
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:	Not available.
Skin contact:	Toxic in contact with skin.
Inhalation:	Toxic if inhaled.
Ingestion:	Toxic if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:	
5908-99-6 atropine sulphate monohydrate	
LC ₅₀	460 (96h) mg/L (leuciscus idus) (OECD 203)

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

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Not available.

Additional ecological information:

General notes: Water danger class 3 (Self-assessment): extremely hazardous for water.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Disposal according to official regulations. Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Disposal in a licensed hazardous waste landfill or incineration plant according to local official regulations.

Waste disposal key number: CH VeVA Code: 07 05 13 (S)

European waste catalogue:

07 00 00 WASTES FROM ORGANIC CHEMICAL PROCESSES

07 05 00 Wastes from the MFSU of pharmaceuticals

07 05 08* Other still bottoms and reaction residues

Uncleaned packagings: Recommendation: Disposal must be made according to official regulations.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), UN1544
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ADR	1544 ALKALOIDS, SOLID, N.O.S. (atropine sulphate monohydrate)
	IMDG, IATA	ALKALOIDS, SOLID, N.O.S. (atropine sulphate monohydrate)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ADR	Class: 6.1 (T2) Toxic substances. Label: 6.1
	IMDG, IATA	Class: 6.1 Toxic substances. Label: 6.1

14.4 Packing group

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

14.5 Environmental hazards

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

14.6 Special precautions for user

Warning: Toxic substances.

Kemler Number: 60

EMS Number: F-A,S-A

Stowage Category: A

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 (LQ)	500 g
	Excepted quantities (EQ)	Code: E4
		Maximum net quantity per inner packaging: 1 g
		Maximum net quantity per outer packaging: 500 g
IMDG	Transport category	2
	Tunnel restriction code	D/E
	Limited quantities (LQ)	500 g
	Excepted quantities (EQ)	Code: E4
		Maximum net quantity per inner packaging: 1 g
		Maximum net quantity per outer packaging: 500 g
	UN "Model Regulation": UN1544, ALKALOIDS, SOLID, N.O.S. (atropine sulphate monohydrate), 6.1, II	

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Danger

Risk phrases:

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

Safety phrases:

S1 Keep locked up.
S7/9 Keep container tightly closed and in a well-ventilated place.
S20/21 When using do not eat, drink or smoke.
S27 Take off immediately all contaminated clothing.
S28 After contact with skin, wash immediately with plenty of water and soap.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S46 If swallowed, seek medical advice immediately and show this container or label.

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S51 Use only in well-ventilated areas.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

S64 If swallowed, rinse mouth with water (only if the person is conscious).

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 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

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(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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