

Atropine sulfate

Safety Data Sheet

247405

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Date of issue: 07/11/2011 Revision date 05/02/2020

Supersedes 17/10/2019

Version: 3.1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance 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
EC Index-No.	: 614-011-00-9
EC-No.	: 200-235-0
CAS-No.	: 5908-99-6
Product code	: 247405
Synonyms	: Tropine tropate
Product group	: Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category	: Pharmaceutical
Function or use category	: Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - Nederland
 T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number	: Supplier contact information: +31(0)23-5319093 (M-F 09:00-17:00) +31(0)6-30109355 (outside office hours)
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Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (inhal.), Category 2

H330

Acute toxicity (oral), Category 2

H300

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Blurred vision. Fever. Possible oedema of the upper respiratory tract. Gastrointestinal complaints. May produce irregular heart beat and nervous symptoms. Damage to central nervous system. Very toxic by inhalation.

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]** Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP)

:



GHS06

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H330 - Fatal if inhaled.

H300 - Fatal if swallowed.

Precautionary statements (CLP)

: P260 - Do not breathe dust.

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P310 - Immediately call a POISON CENTER/doctor

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients**3.1. Substances**

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Atropine sulfate	(CAS-No.) 5908-99-6 (EC-No.) 200-235-0 (EC Index-No.) 614-011-00-9	99 - 101	Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Oral), H300

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air Seek medical attention immediately If not breathing, give artificial respiration.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse Seek medical advice.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical advice.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects	: Nervous system disorder.
Symptoms/effects after inhalation	: Shortness of breath.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry powder Foam Carbon dioxide Water spray.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: sulphur dioxide Nitrogen oxides Carbon oxides (CO, CO ₂).

5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Wear self-contained breathing apparatus, rubber boots and thick rubber gloves.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate ventilation. Avoid raising dust. Do not breathe dust.

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment. See Headings 7 and 8.

6.1.2. For emergency responders

Protective equipment : Use self-contained breathing apparatus and chemically protective clothing.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. Hose down area with water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures. Material should be handled in a laboratory hood whenever possible.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from sunlight.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Atropine sulfate (5908-99-6)		
EU	IOELV TWA (mg/m ³)	0.0072 mg/m ³

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Hand protection:

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Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dust production: dust mask with filter type P3

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder. Crystalline solid.
Molecular mass	: 694.83 g/mol
Colour	: White Colourless.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4.5 - 6.2
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 185 - 195 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: > °C
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in ethanol Soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions

May decompose under the influence of light.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

Light (daylight).

10.5. Incompatible materials

Strong oxidizers

Bases.

10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides

Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Fatal if inhaled. Fatal if swallowed.

Atropine sulfate (5908-99-6)	
LD50 oral rat	600 mg/kg

Skin corrosion/irritation : Not classified
pH: 4.5 - 6.2

Serious eye damage/irritation : Not classified
pH: 4.5 - 6.2

Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

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Atropine sulfate (5908-99-6)	
LC50 fish 1	468 g/l 96 h
LC50 other aquatic organisms 1	661 mg/l Streptocephalus proboscideus, 24 h

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations



13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Product/Packaging disposal recommendations : Dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
1544	1544
14.2. UN proper shipping name	
ALKALOIDS, SOLID, N.O.S.	Alkaloid salts, solid, n.o.s.
14.3. Transport hazard class(es)	
6.1	6.1
	
14.4. Packing group	
II	II
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

. Overland transport

Classification code (ADR) : T2

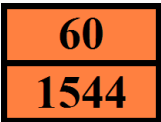
Special provisions (ADR) : 43, 274

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Limited quantities (ADR)	: 500g
Excepted quantities (ADR)	: E4
Packing instructions (ADR)	: P002, IBC08
Special packing provisions (ADR)	: B4
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAH, L4BH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Packages (ADR)	: V11
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9, S19
Hazard identification number (Kemler No.)	: 60
Orange plates	: 
Tunnel restriction code (ADR)	: D/E
EAC code	: 2X

- Air transport

PCA Excepted quantities (IATA)	: E4
PCA Limited quantities (IATA)	: Y644
PCA limited quantity max net quantity (IATA)	: 1kg
PCA packing instructions (IATA)	: 669
PCA max net quantity (IATA)	: 25kg
CAO packing instructions (IATA)	: 676
CAO max net quantity (IATA)	: 100kg
Special provisions (IATA)	: A3, A4, A6, A801
ERG code (IATA)	: 6L

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

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Atropine sulfate is not on the REACH Candidate List

Atropine sulfate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1	Additional information	Modified	change of logo
1.1	Formula		
1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
2.2	Precautionary statements (CLP)	Added	
2.2	Precautionary statements (CLP)	Modified	
7.2	Maximum storage period	Removed	
7.2	Storage temperature	Added	
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
9.1	Melting point	Modified	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : Supplier. EP.

Full text of H- and EUH-statements:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
H300	Fatal if swallowed.
H330	Fatal if inhaled.

SDS EU (REACH Annex II) ducheфа nieuwe logo

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.