

Atropine sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 31/01/2023 Revision date: 07/07/2026 Supersedes version of: 31/01/2023 Version: 2.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Atropine sulfate
Chemical name	: Atropine sulfate monohydrate
EC Index-No.	: 614-011-00-9
EC-No.	: 200-235-0
CAS-No.	: 5908-99-6
Product code	: 202100243

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

Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

Uses advised against

Restrictions on use	: Not for food, drug or home use
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1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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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- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

Fatal if swallowed. Fatal if inhaled.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS06

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H330 - Fatal if inhaled.
H300 - Fatal if swallowed.

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Precautionary statements (CLP) :

- P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P271 - Use only outdoors or in a well-ventilated area.
- P284 - Wear respiratory protection.
- P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
- P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P310 - Immediately call a POISON CENTER or doctor.
- P320 - Specific treatment is urgent (see supplemental first aid instruction on this label).
- P321 - Specific treatment (see supplemental first aid instruction on this label).
- P330 - Rinse mouth.
- P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
- P405 - Store locked up.
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



GHS06

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Other information : Active substance (in pharmaceutical products).
Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Atropine sulfate monohydrate	CAS-No.: 5908-99-6 EC-No.: 200-235-0 EC Index-No.: 614-011-00-9	≤ 100	Acute Tox. 2 (Inhalation), H330 (ATE=0,05 mg/l/4h) Acute Tox. 2 (Oral), H300 (ATE=5 mg/kg bodyweight)

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. Immediately call a POISON CENTER/doctor.

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.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after inhalation : Fatal if inhaled.
Symptoms/effects after ingestion : Fatal if swallowed.

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 : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.
Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white. almost white.
Appearance	: Crystalline powder. Crystals.
Molecular mass	: 695 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 185 – 195 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 4,5 – 6 (2% Aqueous solution)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: > 1000 g/l

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Partition coefficient n-octanol/water (Log Kow)	: < 2 (estimated value)
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Fatal if swallowed.
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Fatal if inhaled.

Atropine sulfate monohydrate (5908-99-6)

LD50 oral rat	> 5 – ≤ 50 mg/kg (estimated value)
LC50 Inhalation - Rat (Dust/Mist)	> 0,05 – ≤ 0,5 mg/l/4h (estimated value)
Skin corrosion/irritation	: Not classified (Lack of data) pH: 4,5 – 6 (2% Aqueous solution)
Serious eye damage/irritation	: Not classified (Lack of data) pH: 4,5 – 6 (2% Aqueous solution)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

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11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

Atropine sulfate monohydrate (5908-99-6)

LC50 - Fish [1]	> 100 mg/l (96 Hours, Golden orfe) (OECD 203 method)
EC50 - Crustacea [1]	> 100 mg/l (24 Hours, Daphnia magna (Water flea))

12.2. Persistence and degradability

Atropine sulfate monohydrate (5908-99-6)

Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

Atropine sulfate monohydrate (5908-99-6)

Partition coefficient n-octanol/water (Log Kow)	< 2 (estimated value)
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Atropine sulfate monohydrate (5908-99-6)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 1544	UN 1544	UN 1544

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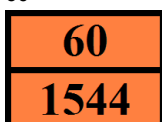
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
14.2. UN proper shipping name		
ALKALOID SALTS, SOLID, N.O.S.	ALKALOIDS SALTS, SOLID, N.O.S.	Alkaloid salts, solid, n.o.s.
Transport document description		
UN 1544 ALKALOID SALTS, SOLID, N.O.S., 6.1, II, (D/E)	UN 1544 ALKALOIDS SALTS, SOLID, N.O.S., 6.1, II	UN 1544 Alkaloid salts, solid, n.o.s., 6.1, II
14.3. Transport hazard class(es)		
6.1	6.1	6.1
		
14.4. Packing group		
II	II	II
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-A	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
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
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Transport by sea

Special provisions (IMDG)	: 43, 274
Limited quantities (IMDG)	: 500 g
Excepted quantities (IMDG)	: E4
Packing instructions (IMDG)	: P002
IBC packing instructions (IMDG)	: IBC08

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IBC special provisions (IMDG)	: B21, B4
Tank instructions (IMDG)	: T3
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: A wide range of toxic solids, generally of vegetable origin. Toxic if swallowed, by skin contact or by inhalation.

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, A5, A6, A801
ERG code (IATA)	: 6L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Not listed on the Explosives Precursors list (EU)

Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	Added
	Revision date	Added
1.2	Restrictions on use	Modified

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Indication of changes		
Section	Changed item	Comments
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects after inhalation	Modified
4.2	Symptoms/effects after ingestion	Modified
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after eye contact	Removed
4.3	Other medical advice or treatment	Removed
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Added
6.1	General measures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Precautions for safe handling	Modified
7.1	Hygiene measures	Modified
7.1	Additional hazards when processed	Removed
7.2	Storage conditions	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.3	Specific end uses	Removed
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
8.2	Eye protection	Modified

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Indication of changes		
Section	Changed item	Comments
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	Molecular mass	Added
9	Colour	Added
9	Appearance	Added
9	pH	Added
9	Melting point	Added
9	Partition coefficient n-octanol/water (Log Kow)	Added
9	Odour	Removed
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 oral rat	Modified
12.1	EC50 - Crustacea [1]	Modified
12.1	LC50 - Fish [1]	Modified
12.1	LC50 Inhalation - Rat (Dust/Mist)	Modified
12.1	Ecology - general	Removed
13.1	Product/Packaging disposal recommendations	Removed
13.1	Regional waste regulation	Removed
14	UN-No. (RID)	Added
14	Number of blue cones/lights (ADN)	Added
14	Equipment required (ADN)	Added
14	Excepted quantities (ADN)	Added
14	Limited quantities (ADN)	Added
14	Danger labels (ADN)	Added
14	Classification code (ADN)	Added
14	Proper Shipping Name (RID)	Added
14	Hazard identification number (RID)	Added
14	Colis express (express parcels) (RID)	Added
14	Special provisions for carriage - Loading, unloading and handling (RID)	Added
14	Special provisions for carriage – Packages (RID)	Added
14	Transport category (RID)	Added
14	Special provisions for RID tanks (RID)	Added
14	Tank codes for RID tanks (RID)	Added
14	Portable tank and bulk container special provisions (RID)	Added

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Indication of changes		
Section	Changed item	Comments
14	Portable tank and bulk container instructions (RID)	Added
14	Mixed packing provisions (RID)	Added
14	Special packing provisions (RID)	Added
14	Packing instructions (RID)	Added
14	Excepted quantities (RID)	Added
14	Limited quantities (RID)	Added
14	Special provisions (RID)	Added
14	Packing group (RID)	Added
14	Classification code (RID)	Added
14.1	UN-No. (ADN)	Added
14.2	Proper Shipping Name (ADN)	Added
14.2	Proper Shipping Name (ADR)	Modified
14.3	Danger labels (RID)	Added
14.4	Packing group (ADN)	Added
14.6	Special provisions (ADN)	Added

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.

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. 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.