

SAFETY DATA SHEET

1. Identification

Product identifier Atropine Sulfate

Other means of identification

 Catalog number
 1045009

 CAS number
 5908-99-6

Chemical name 1αH,5αH-Tropan-3-α-ol (±)-tropate (ester), sulfate (2:1) (salt) monohydrate

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD

20852-1790 United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 2

Acute toxicity, inhalation Category 2

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Fatal if swallowed. Fatal if inhaled.

Precautionary statement

Prevention Do not breathe dust. Wash thoroughly after handling. Use only outdoors or in a well-ventilated

area. In case of inadequate ventilation wear respiratory protection.

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to

fresh air and keep comfortable for breathing. Immediately call a poison center/doctor.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Atropine Sulfate

USP SDS US

4. First-aid measures

Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. Oxygen or artificial respiration if needed. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.

Skin contact Eve contact Ingestion

delayed

Rinse with water. Get medical attention if irritation develops and persists. Rinse with water. Get medical attention if irritation develops and persists.

Most important symptoms/effects, acute and use mouth-to-mouth method if substance is ingested. Get medical attention if symptoms occur. Anticholinergic effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do not

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. Tachydysrhythmias may respond to physostigmine or IV beta-blockers. Sodium bicarbonate is administered for widening QRS complex and ventricular dysrhythmias. In patients unresponsive to bicarbonate, consider lidocaine or amiodarone. For hypotension, infuse 10-20 mL/kg isotonic fluid. Administer dopamine or norepinephrine if hypotension persists. For severe hypertension, nitroprusside is preferred; labetalol, nitroglycerin, and phentolamine are alternatives. For rhabdomyolysis, administer 0.9% saline. Monitor input and output, electrolytes, CK, and renal function. Administer diuretics if needed to maintain urine output.. Peritoneal dialysis is not effective.

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials. Cool containers exposed to flames with water until well after the fire is out.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Material name: Atropine Sulfate USP SDS US Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

MaterialTypeValueAtropine Sulfate (CAS
5908-99-6)TWA0.004 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat,

disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head

cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of

existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or

quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline powder.
Color Colorless. White.

Odor Odorless.

Odor threshold Not available.
pH Not available.

Melting point/freezing point 365 - 383 °F (185 - 195 °C)

Initial boiling point and boiling

range

Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower Not available.

(%)

Not available.

Flammability limit - upper

Explosive limit - lower (%)

(%)

Not available.

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Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Very soluble.

Solubility (other) Chloroform: Slightly soluble.

Ethanol: Freely soluble. Ether: Very slightly soluble. Glacial acetic acid: Very soluble.

Glycerin: Freely soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Tropane derivative; tertiary amine. **Molecular formula** C17H23NO3.1/2H2O4S.1/2H2O

Molecular weight 694.83

pH in aqueous solution 4.5 - 6.2 Solution: 2%

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoidContact with incompatible materials.

Incompatible materials Strong bases. Tannins. Metals. Strong oxidizing agents. lodine.

Hazardous decomposition

products

irritation

NOx, SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation Fatal if inhaled.

Skin contact Knowledge about health hazard is incomplete.

Eye contact Knowledge about health hazard is incomplete.

Ingestion Fatal if swallowed.

Symptoms related to the physical, chemical, and

toxicological characteristics

Anticholinergics: Flushing. Dry skin and mucous membranes. Dilated pupils. Change in vision. Mood or mental change. Fever. Increased heart rate. Gastrointestinal disturbances. Urinary

retention. Hypertension. Abnormal movement.

Information on toxicological effects

Acute toxicity Fatal if inhaled. Fatal if swallowed.

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization
Skin sensitization
Knowledge about health hazard is incomplete.
Knowledge about health hazard is incomplete.
Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test

Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

Material name: Atropine Sulfate usp sps us

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Based on available data, the classification criteria are not met.

Epidemiological studies have not shown an association between therapeutic use of this material

during pregnancy and an increased incidence of birth defects.

Reproductivity

50 mg/kg Reproductivity / Developmental Result: No adverse effects on the fetus.

Species: Mouse

Reproductivity / Developmental, Chick eggs injected with 0.6

to 1.5 mg of atropine during incubation. Result: No birth defects observed.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

12. Ecological information

Ecotoxicity

Product Species Test Results

Atropine Sulfate (CAS 5908-99-6)

Aquatic

Acute

EC50 Crustacea Daphnia magna 356 mg/l, 24 hours 695 mg/l, 24 hours

LC50 Brine shrimp (Artemia salina)

Persistence and degradability

No data is available on the degradability of this product. No data available.

Bioaccumulative potential Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

UN number UN1544

UN proper shipping name Transport hazard class(es) Alkaloid salts, solid, n.o.s. (Atropine Sulfate)

Class 6.1 Subsidiary risk

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Packing group

IATA

UN number UN1544

UN proper shipping name Transport hazard class(es)

Alkaloid salts, solid, n.o.s. (Atropine Sulfate)

Class 6.1 Subsidiary risk -Packing group II

Other information

Passenger and cargo

Allowed with restrictions.

aircraft

Cargo aircraft only Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and

Not applicable.

the IBC Code



General information It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Material name: Atropine Sulfate USP SDS US

Safe Drinking Water Act

(SDWA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region Inventory name On inventory (yes/no)* Australia Australian Inventory of Chemical Substances (AICS) Yes Canada Domestic Substances List (DSL) No Canada Non-Domestic Substances List (NDSL) No Inventory of Existing Chemical Substances in China (IECSC) China No European Inventory of Existing Commercial Chemical Europe No

Substances (EINECS)

EuropeEuropean List of Notified Chemical Substances (ELINCS)NoJapanInventory of Existing and New Chemical Substances (ENCS)NoKoreaExisting Chemicals List (ECL)NoNew ZealandNew Zealand InventoryYesPhilippinesPhilippine Inventory of Chemicals and Chemical SubstancesYes

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

No

16. Other information, including date of preparation or last revision

 Issue date
 09-15-2008

 Revision date
 09-21-2018

Version # 05

Disclaimer

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Material name: Atropine Sulfate

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).