SAFETY DATA SHEET

Atropine Sulfate Formulation

SECTION 1. IDENTIFICATION

Product name : Atropine Sulfate Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity : Category 2

GHS label elements
Hazard pictograms : 🔄

Signal Word : Warning
Hazard Statements : H361 Suspected of damaging fertility or the unborn child.
Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.
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Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Benzenemethanol</td>
<td>100-51-6</td>
<td>&gt;= 0.9091 - &lt;= 1.1111</td>
</tr>
<tr>
<td>Atropine Sulfate</td>
<td>No data available</td>
<td>5908-99-6</td>
<td>&gt;= 0.1818 - &lt;= 0.2222</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility or the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides
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Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Avoid inhalation of vapor or mist.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Take care to prevent spills, waste and minimize release to the environment.
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Conditions for safe storage
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

Materials to avoid
- Do not store with the following product types:
  - Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine Sulfate</td>
<td>5908-99-6</td>
<td>TWA</td>
<td>2 µg/m³ (OEB 4)</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Eye

- Wipe limit: 20 µg/100 cm²

Engineering measures
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Essentially no open handling permitted.
- Use closed processing systems or containment technologies.
- If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - Filter type: Combined particulates and organic vapor type

Hand protection
- Material: Chemical-resistant gloves
  - Remarks: Consider double gloving.

Eye protection
- Wear safety glasses with side shields or goggles.
  - Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection
- Work uniform or laboratory coat.
  - Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
  - Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
  - When using do not eat, drink or smoke.
  - Wash contaminated clothing before re-use.
  - The effective operation of a facility should include review of
engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>liquid</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Translucent-colorless to pale yellow</td>
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<tr>
<td><strong>Odor</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>3.0 - 6.5</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative vapor density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>0.900 - 1.100 g/cm³</td>
</tr>
<tr>
<td><strong>Solubility(ies)</strong></td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Autoignition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
                     Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
                          Exposure time: 4 h
                          Test atmosphere: dust/mist
                          Method: OECD Test Guideline 403

Components:

Benzyl alcohol:
Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
                          Exposure time: 4 h
                          Test atmosphere: dust/mist
                          Method: OECD Test Guideline 403

Atropine Sulfate:
Acute oral toxicity : LD50 (Rat): 500 mg/kg
LD50 (Mouse): 75 mg/kg
LD50 (Rabbit): 600 mg/kg
LD50 (Guinea pig): 1,100 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Benzyl alcohol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Benzyl alcohol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Atropine Sulfate:  
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity  
Not classified based on available information.

Components:

Benzyl alcohol:  
Species: Mouse  
Application Route: Ingestion  
Exposure time: 103 weeks  
Method: OECD Test Guideline 451  
Result: negative

Atropine Sulfate:  
Species: Rat  
Application Route: Intraperitoneal injection  
Exposure time: 28 month(s)  
NOAEL: 2.5 mg/kg bw/day  
Result: negative  
Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Reproductive toxicity  
Suspected of damaging fertility or the unborn child.

Components:

Benzyl alcohol:  
Effects on fertility: Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Atropine Sulfate:  
Effects on fetal development: Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative
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Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat, male
- Application Route: Ingestion
- General Toxicity Parent: LOAEL: 62.5 mg/kg body weight
- Result: Reduced fertility

Effects on fetal development:
- Test Type: Fertility/early embryonic development
- Species: Rat, female
- Application Route: Intraperitoneal injection
- General Toxicity Parent: LOAEL: 1 mg/kg body weight
- Result: Effect on estrous cycle

Reproductive toxicity - Assessment:
- Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

STOT-single exposure:
- Not classified based on available information.

Components:
Atropine Sulfate:
- Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure:
- Not classified based on available information.

Components:
Atropine Sulfate:
- Routes of exposure: Inhalation
- Target Organs: Eye, Central nervous system
- Assessment: Shown to produce significant health effects in animals at concentrations of 50 ppmV/6h/d or less.

Repeated dose toxicity:

Components:
Benzy alcohol:
- Species: Rat
- NOAEL: 1.072 mg/l
- Application Route: Inhaled (dust/mist/fume)
- Exposure time: 28 Days
- Method: OECD Test Guideline 412
Atropine Sulfate:
Species: Rabbit
LOAEL: 59 mg/kg
Application Route: Subcutaneous
Exposure time: 100 d
Target Organs: Central nervous system
Symptoms: Convulsions, respiratory depression
Species: Rat
LOAEL: 0.5 mg/kg
Application Route: Inhalation
Exposure time: 21 d
Target Organs: Eye
Symptoms: Dilatation of the pupil
Species: Dog
LOAEL: 0.5 mg/kg
Application Route: Inhalation
Exposure time: 21 d
Target Organs: Eye
Symptoms: Dilatation of the pupil

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Atropine Sulfate:
General Information: Target Organs: Central nervous system
Symptoms: dry mouth, Blurred vision, tachycardia, constipation, central nervous system effects, restlessness, Fatigue, delirium, mental depression

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:

Benzyl alcohol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 310
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

\[
\text{NOEC (Daphnia magna (Water flea)): 51 mg/l}
\]
Exposure time: 21 d
Method: OECD Test Guideline 211

**Atropine Sulfate:**

Toxicity to daphnia and other aquatic invertebrates:

\[
\text{EC50 (Daphnia magna (Water flea)): 356 mg/l}
\]
Exposure time: 48 h

### Persistence and degradability

**Components:**

**Benzyl alcohol:**

Biodegradability:

- Result: Readily biodegradable.
- Biodegradation: 92 - 96 %
- Exposure time: 14 d

**Bioaccumulative potential**

**Components:**

**Benzyl alcohol:**

Partition coefficient: n-octanol/water

\[ \text{log Pow: 1.05} \]

**Atropine Sulfate:**

Partition coefficient: n-octanol/water

\[ \text{log Pow: 1.83} \]

**Mobility in soil**

No data available

**Other adverse effects**

No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

Not regulated as a dangerous good
SAFETY DATA SHEET

Atropine Sulfate Formulation

Version 2.1
Revision Date: 04/09/2021
SDS Number: 7665459-00003
Date of last issue: 12/22/2020
Date of first issue: 12/14/2020

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

DSL : not determined
AICS : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transporta-
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

CA / Z8