SAFETY DATA SHEET

Atropine Sulfate Formulation

SECTION 1. IDENTIFICATION

Product name: Atropine Sulfate Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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 OSHA Hazard Communication Standard (29 CFR 1910.1200)
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.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 0.9091 - &lt;= 1.1111</td>
</tr>
<tr>
<td>Atropine Sulfate</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 firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides
Chlorine compounds
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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.

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:
SECTION 8. EXPOSURE CONTROLS/PERSOAL 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>Benzyl alcohol</td>
<td>100-51-6</td>
<td>TWA</td>
<td>10 ppm</td>
<td>US WEEL</td>
</tr>
<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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

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

Eye protection

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

Skin and body protection

Material: Work uniform or laboratory coat.
Remarks: 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
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

Appearance: liquid
Color: Translucent-colorless to pale yellow
Odor: No data available
Odor Threshold: No data available
pH: 3.0 - 6.5
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: No data available
Density: 0.900 - 1.100 g/cm³
Solubility(ies):
Water solubility: No data available
Partition coefficient: n-
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: > 200 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

**Effects on fetal development**
- Test Type: Embryo-fetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

### Atropine Sulfate:

**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

- 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

**Effects on fetal development**
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Intravenous injection
- Developmental Toxicity: LOAEL: 50 mg/kg body weight
- Result: Abnormalities of the musculoskeletal system.

**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 con-
centrations of 50 ppmV/6h/d or less.

Repeated dose toxicity

Components:

Benzyl alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (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 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** 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:** 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:** log Pow: 1.05

**Atropine Sulfate:**
- **Partition coefficient: n-octanol/water:** 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.
Do not dispose of waste into sewer.
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

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
49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Reproductive toxicity

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
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Atropine Sulfate Formulation

版次 2.4
修订日期: 04/04/2023
SDS 号: 7665457-00006
最后发布日期: 10/01/2022
首次发布日期: 12/14/2020

US State Regulations
Pennsylvania Right To Know
- Water: 7732-18-5
- Benzyl alcohol: 100-51-6

The ingredients of this product are reported in the following inventories:
- DSL: not determined
- AICS: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information
NFPA 704:
- Flammability: 1
- Health: 0
- Instability: 1
- Special hazard: *

HMIS® IV:
- HEALTH: *
- FLAMMABILITY: 1
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/'" represents the absence of a chronic hazard.

Full text of other abbreviations
- USA WEEL: USA, Workplace Environmental Exposure Levels (WEEL)
- US WEEL / TWA: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Organiz-
**SAFETY DATA SHEET**

**Atropine Sulfate Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number</th>
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<tr>
<td>2.4</td>
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Revision Date: 04/04/2023

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.

US / Z8