SECTIO N 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Atropine Sulfate Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
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@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTIO N 2. HAZARDS IDENTIFICATION

GHS Classification
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/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTIO N 3. COMPOSITION/INFORMATION ON INGREDIENTS
SAFETY DATA SHEET
Atropine Sulfate Formulation

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

## 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;= 1 &lt;- 5</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>&gt;= 1 &lt;- 5</td>
</tr>
<tr>
<td>Atropine Sulfate</td>
<td>5908-99-6</td>
<td>&gt;= 0.1 &lt;- 1</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 products**: Carbon oxides
Metal oxides
Chlorine compounds

**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
SAFETY DATA SHEET

Atropine Sulfate Formulation

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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.

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.

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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Eye</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>20 µg/100 cm²</td>
<td></td>
</tr>
</tbody>
</table>

**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.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
SAFETY DATA SHEET

Atropine Sulfate Formulation

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-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
SAFETY DATA SHEET

Atropine Sulfate Formulation

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: 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

Sodium chloride:
Acute oral toxicity : LD50 (Rat): 3,550 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg
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

Sodium chloride:
Species: Rabbit
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

Sodium chloride:
Species: Rabbit
Result: No eye irritation

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
Sodium chloride:
- Test Type: Local lymph node assay (LLNA)
- Routes of exposure: Skin contact
- Species: Mouse
- Result: negative

Germ cell mutagenicity
- Not classified based on available information.

Components:

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

Sodium chloride:
- Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
  Result: positive
  Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
  Result: positive
  Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Result: positive
  Test Type: Chromosome aberration test in vitro
  Result: positive
  Test Type: Chromosome aberration test in vitro
  Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: positive
SAFETY DATA SHEET

Atropine Sulfate Formulation


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

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

Sodium chloride:
Species: Rat  Application Route: Ingestion  Exposure time: 2 Years  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

Effects on fetal development: Test Type: Embryo-fetal development
Atropine Sulfate Formulation

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

Effect Type: Ingestion
- 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 concentrations of 50 ppmV/6h/d or less.

Repeated dose toxicity

Components:
- Benzyl alcohol:
  - Species: Rat
  - NOAEL: 1.072 mg/l
SAFETY DATA SHEET

Atropine Sulfate Formulation

Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Sodium chloride:
Species: Rat
LOAEL: 2,533 mg/kg
Application Route: Ingestion
Exposure time: 2 y

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:

Benzy 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

Sodium chloride:

Toxicity to fish:
LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 4,136 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
EC50: > 2,000 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms:
EC10: > 1,000 mg/l

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.
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

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.
: Not applicable
SAFETY DATA SHEET

Atropine Sulfate Formulation

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

All abbreviations are listed in alphabetical order.


Revision Date: 22.12.2020

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8