SAFETY DATA SHEET

Atropine Sulfate Formulation

Version 2.0  Revision Date: 22.12.2020  SDS Number: 7665464-00002  Date of last issue: 14.12.2020

Date of first issue: 14.12.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Atropine Sulfate Formulation

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

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;= 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>

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
- None known.

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.

### 5. FIREFIGHTING 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

**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 firefighters**
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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 vapour 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 labelled containers.
- Store in accordance with the particular national regulations.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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></td>
<td>Wipe limit 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 vapour type

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**Eye protection**

**Material**: 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**

**Material**: 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**

**Material**: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: liquid

**Colour**: Translucent-colorless to pale yellow

**Odour**: No data available

**Odour 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
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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
Vapour pressure : No data available
Relative vapour 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
Auto-ignition 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
Particle size : Not applicable

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.
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

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

**Components:**

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

**Sodium chloride:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Benzyl alcohol:**
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

**Sodium chloride:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Benzyl alcohol:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
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<table>
<thead>
<tr>
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<th>Revision Date</th>
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<th>Date of last issue: 14.12.2020</th>
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<tr>
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</tr>
</tbody>
</table>

**Genotoxicity in vivo**

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

**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.
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Atropine Sulfate Formulation

<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
</table>

**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**
Not classified based on available information.

**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 foetal development:**
- Test Type: Embryo-foetal 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 foetal 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:
Exposure routes: 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
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 yr

Atropine Sulfate:
Species: Rabbit
LOAEL: 59 mg/kg
Application Route: Subcutaneous
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Atropine Sulfate Formulation

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>100 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Convulsions, respiratory depression</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Eye</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Dilatation of the pupil</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Eye</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Dilatation of the pupil</td>
</tr>
</tbody>
</table>

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

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: 51 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- 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 microorganisms: EC10: > 1,000 mg/l
- Toxicity to fish (Chronic toxicity):
  - NOEC: 252 mg/l
  - Exposure time: 33 d
  - Species: Pimephales promelas (fathead minnow)
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
  - NOEC: 314 mg/l
  - Exposure time: 21 d
  - Species: Daphnia pulex (Water flea)

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
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Mobility in soil
No data available

Other adverse effects
No data available

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.

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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

DSL : not determined

AICS : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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.