1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Atropine Sulfate Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
          Pandaan, Jawa Timur - Indonesia
Telephone: 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

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>&lt; 10</td>
</tr>
<tr>
<td>Atropine Sulfate</td>
<td>5908-99-6</td>
<td>&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.
### 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 spills cannot be contained.  
| Methods and materials for | Soak up with inert absorbent material.  

Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.  
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.  
None known.  
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).  
Treat symptomatically and supportively.
containment and cleaning up

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>Further information: Eye</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
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.

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.

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

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): Not applicable
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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: > 2,000 mg/kg
  - Method: Calculation method
- **Acute inhalation toxicity:** Acute toxicity estimate: > 5 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 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

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
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

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

Effects on foetal 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

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

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

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
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

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:
SAFETY DATA SHEET
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Partition coefficient: n-octanol/water  
\[ \text{log Pow: 1.83} \]

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 Annex II of MARPOL 73/78 and the IBC Code  
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health  
Hazardous substances that must be registered  
Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances  
Hazardous substances approved for use  
Not applicable
Prohibited substances  
Not applicable
Restricted substances  
Not applicable
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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
Sources of key data used to compile the Safety Data Sheet:

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

Date format: yyyy/mm/dd

Full text of other abbreviations

AIIIC - 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 Tem-
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Atropine Sulfate Formulation

Version 2.0  Revision Date: 2020/12/22  SDS Number: 7665463-00002  Date of last issue: 2020/12/14

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.

ID / EN