

## Atropine Sulfate Formulation

Version 2.0      Revision Date: 22.12.2020      SDS Number: 7665458-00002      Date of last issue: 14.12.2020  
 Date of first issue: 14.12.2020

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Atropine Sulfate Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
 Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

#### Other hazards which do not result in classification

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name    | CAS-No.   | Classification  | Concentration (% w/w) |
|------------------|-----------|---|-----------------------|
| Benzyl alcohol   | 100-51-6  | Acute toxicity (Oral), Category 4<br>Acute toxicity (Inhalation), Category 4<br>Eye irritation, Category 2A         | >= 1 -< 5             |
| Sodium chloride  | 7647-14-5 | Acute toxicity (Oral), Category 5   | >= 1 -< 5             |
| Atropine Sulfate | 5908-99-6 | Acute toxicity (Oral), Category 4<br>Reproductive toxicity, Category 2<br>Specific target organ toxicity - repeated | >= 0,1 -< 1           |

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|  |  | exposure (Inhalation)<br>(Eye, Central nervous system), Category 1 |
|--|--|--|

### SECTION 4. FIRST AID MEASURES

|   |   |   |
|---|---|---|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.  |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention.  |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>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.   |

### SECTION 5. FIRE-FIGHTING MEASURES

|                                       |   |   |
|---------------------------------------|---|---|
| Suitable extinguishing media          | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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<br>Metal oxides<br>Chlorine compounds   |
| Specific extinguishing methods        | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment          | : | In the event of fire, wear self-contained breathing apparatus.  |



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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

| Components       | CAS-No.                  | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------|--------------------------|----------------------------------|--|-------|
| Atropine Sulfate | 5908-99-6                | TWA                              | 2 µg/m <sup>3</sup> (OEB 4)                    |       |
|                  | Further information: Eye |                                  |  |       |
|                  |                          | Wipe limit                       | 20 µg/100 cm <sup>2</sup>                      |       |

**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

**Appearance** : liquid

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

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|  |  |   |  |
|--|--|---|--|
|  | 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/cm <sup>3</sup>                          |
|  | Solubility(ies)<br>Water solubility              | : | No data available  |
|  | Partition coefficient: n-octanol/water           | : | Not applicable   |
|  | Autoignition temperature                         | : | No data available  |
|  | Decomposition temperature                        | : | No data available  |
|  | Viscosity<br>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   |

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### 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.

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### 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

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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)

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|                    |   |              |
|--------------------|---|--------------|
| Routes of exposure | : | 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)<br>Result: negative   |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

#### **Sodium chloride:**

|                                     |   |  |
|-------------------------------------|---|--|
| Genotoxicity in vitro               | : | Test Type: In vitro mammalian cell gene mutation test<br>Result: positive  |
|                                     |   | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative   |
|                                     |   | Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)<br>Result: positive  |
|                                     |   | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: positive  |
|                                     |   | Test Type: Chromosome aberration test in vitro<br>Result: positive   |
|                                     |   | Test Type: Chromosome aberration test in vitro<br>Result: negative   |
| Genotoxicity in vivo                | : | Test Type: In vivo micronucleus test<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative   |
|                                     |   | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Rat<br>Application Route: Intraperitoneal injection<br>Result: positive |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen.   |



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### 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

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 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
- 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 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

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### 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:

#### 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

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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

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**Atropine Sulfate:**  
Partition coefficient: n-octanol/water : log Pow: 1,83

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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.

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**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****ANTT**

Not regulated as a dangerous good

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

DSL : not determined

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AICS : not determined

IECSC : not determined

### SECTION 16. OTHER INFORMATION

#### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

#### 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 Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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