SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Atropine Sulfate Formulation

1.1 Product identifier
Trade name: Atropine Sulfate Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone: 353-51-601000
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

Additional Labelling
EUH210 Safety data sheet available on request.

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>
| Benzyl alcohol      | 100-51-6       | 202-859-9       | 603-057-00-5    |                    | Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319  
                      & Acute toxicity estimate & Acute oral toxicity: 1.620 mg/kg | 1 - < 10 |  
| Atropine Sulfate    | 5908-99-6      |                 |                 |                    | Acute Tox. 4; H302 Repr. 2; H361 STOT RE 1; H372 (Eye, Central nervous system)  
                      & Acute toxicity estimate & Acute oral toxicity: 500 mg/kg | 0,1 - < 1 |  

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures**

### 4.1 Description of 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.

**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).

**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.

4.2 Most important symptoms and effects, both acute and delayed
None known.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides
Chlorine compounds

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

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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.
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
</tbody>
</table>

**Further information:** Eye

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Wipe limit</th>
<th>20 µg/100 cm²</th>
<th></th>
</tr>
</thead>
</table>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5,4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>27 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Atropine Sulfate Formulation

Version 2.2
Revision Date: 27.08.2021
SDS Number: 7683465-00004
Date of last issue: 09.04.2021
Date of first issue: 14.12.2020

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Ingestion</th>
<th>Acute systemic effects</th>
<th>20 mg/kg bw/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>2068.62 mg/m3</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>443.28 mg/m3</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>443.28 mg/m3</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Fresh water</td>
<td>1 mg/l</td>
</tr>
<tr>
<td>Marine water</td>
<td>0.1 mg/l</td>
<td></td>
</tr>
<tr>
<td>Intermittent use/release</td>
<td>2.3 mg/l</td>
<td></td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td>39 mg/l</td>
<td></td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>5.27 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Marine sediment</td>
<td>0.527 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>0.456 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Fresh water</td>
<td>5 mg/l</td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td>500 mg/l</td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>4.86 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Atropine Sulfate Formulation

Version 2.2 Revision Date: 27.08.2021
SDS Number: 7683465-00004 Date of last issue: 09.04.2021
Date of first issue: 14.12.2020

Hand protection

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

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.

Respiratory protection

Material: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387
Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: liquid
Colour: Translucent-colorless to pale yellow
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: 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
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: 3.0 - 6.5
Viscosity
Viscosity, kinematic: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : No data available
Relative density : No data available
Density : 0.900 - 1.100 g/cm³
Relative vapour density : No data available
Particle characteristics
   Particle size : Not applicable

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
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 toxicity estimate: 1.620 mg/kg
    - Method: Calculation method
  - **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
    - Acute toxicity estimate: 500 mg/kg
    - Method: Calculation method

**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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Atropine Sulfate Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>27.08.2021</td>
<td>7683465-00004</td>
<td>09.04.2021</td>
<td>14.12.2020</td>
</tr>
</tbody>
</table>

**Components:**

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

**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
Atropine Sulfate Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>27.08.2021</td>
<td>7683465-00004</td>
<td>09.04.2021</td>
<td>14.12.2020</td>
</tr>
</tbody>
</table>

**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:**

**Benzyalcohol:**

- **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
assessment of 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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

12.1 Toxicity

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 (Chron-...
Atropine Sulfate Formulation

12.2 Persistence and degradability

Components:

Benzyl alcohol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

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

12.3 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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available
SECTION 13: Disposal considerations

13.1 Waste treatment methods
   Product : Dispose of in accordance with local regulations.
   According to the European Waste Catalogue, Waste Codes
   are not product specific, but application specific.
   Waste codes should be assigned by the user, preferably in
   discussion with the waste disposal authorities.
   Contaminated packaging : Empty containers should be taken to an approved waste han-
   dling site for recycling or disposal.
   If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number
   Not regulated as a dangerous good

14.2 UN proper shipping name
   Not regulated as a dangerous good

14.3 Transport hazard class(es)
   Not regulated as a dangerous good

14.4 Packing group
   Not regulated as a dangerous good

14.5 Environmental hazards
   Not regulated as a dangerous good

14.6 Special precautions for user
   Not applicable

14.7 Maritime transport in bulk according to IMO instruments
   Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

   REACH - Restrictions on the manufacture, placing on
   the market and use of certain dangerous substances,
   preparations and articles (Annex XVII)
   : Not applicable
   REACH - Candidate List of Substances of Very High
   Concern for Authorisation (Article 59).
   : Not applicable
   REACH - List of substances subject to authorisation
   (Annex XIV)
   : Not applicable
   Regulation (EC) No 1005/2009 on substances that de-
   plete the ozone layer
   : Not applicable
   Regulation (EU) 2019/1021 on persistent organic pollu-
   tants (recast)
   : Not applicable
   Regulation (EC) No 649/2012 of the European Parlia-
   ment and the Council concerning the export and import
   of dangerous chemicals
   : Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Atropine Sulfate Formulation

Version 2.2
Revision Date: 27.08.2021
SDS Number: 7683465-00004
Date of last issue: 09.04.2021
Date of first issue: 14.12.2020


Not applicable

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

- DSL: not determined
- AICS: not determined
- IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: 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 H-Statements

- **H302**: Harmful if swallowed.
- **H319**: Causes serious eye irritation.
- **H332**: Harmful if inhaled.
- **H361**: Suspected of damaging fertility or the unborn child.
- **H372**: Causes damage to organs through prolonged or repeated exposure if inhaled.

Full text of other abbreviations

- **Acute Tox.**: Acute toxicity
- **Eye Irrit.**: Eye irritation
- **Repr.**: Reproductive toxicity
- **STOT RE**: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; KECLI - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Atropine Sulfate Formulation

Version 2.2  Revision Date: 27.08.2021  SDS Number: 7683465-00004  Date of last issue: 09.04.2021

Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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

Further information

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.

NO / EN