SAFETY DATA SHEET

Albendazole Sulfoxide (1.9%) Formulation

SECTION 1. IDENTIFICATION

Product name: Albendazole Sulfoxide (1.9%) Formulation

Manufacturer or supplier's details

Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
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

Skin sensitization: Category 1

GHS label elements

Hazard pictograms: 

Signal Word: Warning

Hazard Statements: H317 May cause an allergic skin reaction.

Precautionary Statements:

Prevention: P261 Avoid breathing mist or vapors. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves.

Response: P302 + P352 IF ON SKIN: Wash with plenty of water. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.
Additional Labeling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 1.9%

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: May cause an allergic skin reaction.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.
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Albendazole Sulfoxide (1.9%) Formulation

Specific hazards during fire fighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)
- Sulfur oxides

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

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapors.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety standards.
practice, based on the results of the workplace exposure assessment.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>CMP (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN

Wipe limit 100 µg/100 cm² Internal

Engineering measures:
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

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

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.
- 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.
- Contaminated work clothing should not be allowed out of the workplace.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of
**SAFETY DATA SHEET**

**Albendazole Sulfoxide (1.9%) 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>1.5</td>
<td>27.08.2021</td>
<td>3903423-00006</td>
<td>10.10.2020</td>
<td>10.12.2018</td>
</tr>
</tbody>
</table>

Engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: suspension
- **Color**: white
- **Odor**: No data available
- **Odor Threshold**: No data available
- **pH**: No data available
- **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**: No data available
- **Solubility(ies)**: Water solubility
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**: Viscosity, kinematic
  - **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

SECTION 10. STABILITY AND REACTIVITY

Reactivity

Not classified as a reactivity hazard.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

Can react with strong oxidizing agents.

Conditions to avoid

None known.

Incompatible materials

Oxidizing agents

Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation

Skin contact

Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity

Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Glycerine:

Acute oral toxicity

LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity

LD50 (Guinea pig): > 5,000 mg/kg

Albendazole Sulfoxide:

Acute oral toxicity

LD50 (Mouse): 1,500 mg/kg
LD50 (Rat): 2,400 mg/kg

Acute toxicity (other routes of administration)

LD50 (Rat): 265 mg/kg
Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.
Components:

Glycerine:
Species: Rabbit
Result: No skin irritation

Albendazole Sulfoxide:
Species: Rabbit
Result: No skin irritation

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

Components:

Glycerine:
Species: Rabbit
Result: No eye irritation

Albendazole Sulfoxide:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.

Components:

Albendazole Sulfoxide:
Test Type: Maximization Test
Routes of exposure: Dermal
Assessment: Probability or evidence of low to moderate skin sensitization rate in humans
Result: positive

Germ cell mutagenicity
Not classified based on available information.

Components:

Glycerine:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative
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Albendazole Sulfoxide (1.9%) Formulation

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Albendazole Sulfoxide:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Result: negative

Carcinogenicity:
Not classified based on available information.

Components:

Glycerine:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Albendazole Sulfoxide:
Species: Mouse
Application Route: Oral
Exposure time: 2 Years
NOAEL: 400 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 20 mg/kg body weight
Result: negative

Carcinogenicity - Assessment: No evidence of carcinogenicity in animal studies.

Reproductive toxicity:
Not classified based on available information.
Components:

Glycerine:
- Effects on fertility: Test Type: Two-generation reproduction toxicity study
  Species: Rat
  Application Route: Ingestion
  Result: negative

- Effects on fetal development: Test Type: Embryo-fetal development
  Species: Rat
  Application Route: Ingestion
  Result: negative

Albendazole Sulfoxide:
- Effects on fertility: Test Type: Fertility
  Species: Rat
  Application Route: Oral
  Fertility: NOAEL: 30 mg/kg body weight
  Result: No effects on fertility.

- Effects on fetal development: Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: LOAEL: 10 mg/kg body weight
  Result: Embryotoxic effects, Skeletal malformations.

  Test Type: Development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: LOAEL: 30 mg/kg body weight
  Result: Embryotoxic effects, Skeletal malformations,
  Maternal toxicity observed.

  Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: NOAEL: 5,8 mg/kg body weight
  Result: Effects on postnatal development.

  Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: LOAEL: 7 mg/kg body weight
  Result: Embryotoxic effects and adverse effects on the offspring were detected.

Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

STOT-single exposure
Not classified based on available information.
Components:

**Albendazole Sulfoxide:**
- Routes of exposure: Oral
- Target Organs: Gastrointestinal tract, Central nervous system
- Assessment: May cause damage to organs.

**STOT-repeated exposure**
Not classified based on available information.

Components:

**Albendazole Sulfoxide:**
- Routes of exposure: Oral
- Target Organs: Gastrointestinal tract, Central nervous system, Immune system, Liver
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

**Glycerine:**
- Species: Rat
- NOAEL: 0.167 mg/l
- LOAEL: 0.622 mg/l
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 13 Weeks

Species: Rat
- NOAEL: 8.000 - 10.000 mg/kg
- Application Route: Ingestion
- Exposure time: 2 y

Species: Rabbit
- NOAEL: 5.040 mg/kg
- Application Route: Skin contact
- Exposure time: 45 Weeks

**Albendazole Sulfoxide:**
- Species: Rat
- LOAEL: 168 mg/kg
- Application Route: Oral
- Exposure time: 4 Weeks
- Target Organs: Gastrointestinal tract, Testis
- Symptoms: Diarrhea, Vomiting

Species: Dog
- LOAEL: 48 mg/kg
- Application Route: Oral
- Exposure time: 4 Weeks
- Target Organs: Gastrointestinal tract
- Symptoms: Diarrhea, Vomiting
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Albendazole Sulfoxide (1.9%) Formulation

Version: 1.5
Revision Date: 27.08.2021
SDS Number: 3903423-00006
Date of last issue: 10.10.2020
Date of first issue: 10.12.2018

Species: Mouse
LOAEL: 40 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Blood, Liver, Nose
Symptoms: Hematologic effects, Liver effects

Species: Rat
LOAEL: >= 30 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Blood
Symptoms: Hematologic effects

Species: Dog
LOAEL: 40 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Blood, Liver
Symptoms: Hematologic effects, Liver effects

Species: Rat
NOAEL: 7 mg/kg
Application Route: Oral
Exposure time: 60 d
Target Organs: Liver, Testis
Symptoms: Liver effects, male reproductive effects

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Albendazole Sulfoxide:

General Information: Symptoms: Allergic reactions, hair loss, Gastrointestinal disturbance, Headache, Dizziness
Skin contact: Target Organs: Skin
Symptoms: Allergic reactions
Remarks: May cause sensitization by skin contact.

Ingestion: Target Organs: Gastrointestinal tract
Symptoms: Gastrointestinal disturbance, Diarrhea, Abdominal pain
Target Organs: Central nervous system
Symptoms: Headache, Dizziness
Target Organs: Liver
Symptoms: liver function change
Target Organs: Immune system
Symptoms: immune system effects
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Glycerine:
Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.955 mg/l
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10.000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

Albendazole Sulfoxide:
Ecotoxicology Assessment
Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Persistence and degradability

Components:
Glycerine:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:
Glycerine:
Partition coefficient: n-octanol/water : log Pow: -1,75

Albendazole Sulfoxide:
Partition coefficient: n-octanol/water : log Pow: 2,7

Mobility in soil
No data available

Other adverse effects
No data available
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations
- UNRTDG: Not regulated as a dangerous good
- IATA-DGR: Not regulated as a dangerous good
- IMDG-Code: Not regulated as a dangerous good

Special precautions for user
- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable for product as supplied.
- Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
- Argentina. Carcinogenic Substances and Agents Registry: Not applicable
- Control of precursors and essential chemicals for the preparation of drugs: Not applicable

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information
Full text of other abbreviations

AR OEL : Argentina. Occupational Exposure Limits

AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - 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; 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 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; 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; 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 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.

AR / Z8