SAFETY DATA SHEET

Albendazole Sulfoxide (10%) Formulation

SECTION 1. IDENTIFICATION

Product name : Albendazole Sulfoxide (10%) Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Skin sensitization : Sub-category 1B
Reproductive toxicity : Category 2
Specific target organ toxicity - single exposure (Oral) : Category 2 (Gastrointestinal tract, Central nervous system)
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Gastrointestinal tract, Central nervous system, Immune system, Liver)

GHS label elements
Hazard pictograms : ![Warning]![Exclamation]

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.
H361d Suspected of damaging the unborn child.
H371 May cause damage to organs (Gastrointestinal tract, Central nervous system) if swallowed.
H373 May cause damage to organs (Gastrointestinal tract, Central nervous system, Immune system, Liver) through prolonged or repeated exposure if swallowed.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTION 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>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret

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. Suspected of damaging the unborn child. May cause damage to organs if swallowed. May cause damage to organs through prolonged or repeated exposure if swallowed.

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.

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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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.
- Avoid inhalation of vapor or mist.
- Do not swallow.
- Avoid contact with eyes.
- 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 labeled containers.
- Store locked up.
- 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

Components

<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>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>TWA (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable mist)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA QC OEL</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**

**Hand protection Material**: Combined particulates and organic vapor type

**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**

**Hygiene measures**: 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. 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.

### 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**: Not applicable

**Evaporation rate**: No data available

**Flammability (solid, gas)**: Not applicable

**Flammability (liquids)**: No data available

**Upper explosion limit / Upper flammability limit**: No data available
SAFETY DATA SHEET

Albendazole Sulfoxide (10%) Formulation

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: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition 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: No data available

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.
SAFETY DATA SHEET

Albendazole Sulfoxide (10%) Formulation

Version Revision Date: SDS Number: Date of last issue: 08/01/2019
1.3 03/23/2020 3884315-00004 Date of first issue: 11/30/2018

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

Components:

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

Glycerine:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Guinea pig): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Albendazole Sulfoxide:
Species: Rabbit
Result: No skin irritation

Glycerine:
Species: Rabbit
Result: No skin irritation

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

Components:

Albendazole Sulfoxide:
Species: Rabbit
Result: No eye irritation

Glycerine:
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

Test Type: Maximization Test
Routes of exposure: Dermal
Result: Sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Glycerine:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: negative
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

Carcinogenicity
Not classified based on available information.
Components:

Albendazole Sulfoxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>400 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>20 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

Glycerine:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Albendazole Sulfoxide:

Effects on fertility:

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Fertility: NOAEL: 30 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No effects on fertility.</td>
</tr>
</tbody>
</table>

Effects on fetal development:

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 10 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryotoxic effects., Skeletal malformations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 30 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryotoxic effects., Skeletal malformations., Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 5.8 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Effects on postnatal development.</td>
</tr>
</tbody>
</table>
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.

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

STOT-single exposure
May cause damage to organs (Gastrointestinal tract, Central nervous system) if swallowed.

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

STOT-repeated exposure
May cause damage to organs (Gastrointestinal tract, Central nervous system, Immune system, Liver) through prolonged or repeated exposure if swallowed.

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:
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

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

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
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:

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

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

Persistence and degradability

Components:

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

Bioaccumulative potential

Components:

**Albendazole Sulfoxide:**
Partition coefficient: n-octanol/water: log Pow: 2.7

**Glycerine:**
Partition coefficient: n-octanol/water: log Pow: -1.75

**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

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**Domestic regulation**

**TDG**
Not regulated as a dangerous good

### SECTION 15. REGULATORY INFORMATION

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

- **AICS**: not determined
- **DSL**: not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

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.

CA / Z8