SAFETY DATA SHEET
Albendazole Sulfoxide (10%) Formulation

SECTION 1. IDENTIFICATION

Product name : Albendazole Sulfoxide (10%) Formulation

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 29 CFR 1910.1200
Skin sensitization : Category 1
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 :

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.
Section 3. Composition/Information on Ingredients

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

Actual concentration 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.
## 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

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>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>Wipe limit</td>
<td>100 µg/100 cm² Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN

Engineering measures : Use appropriate engineering controls and manufacturing
technologies to control airborne concentrations (e.g., drip-less 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 : General and local exhaust ventilation is recommended to
maintain vapor exposures below recommended limits. Where
concentrations are above recommended limits or are
unknown, appropriate respiratory protection should be worn.
Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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.

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.

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: No data available
SAFETY DATA SHEET

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flammmability limit

Lower explosion limit / Lower flammmability 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.

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:
- 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.

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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

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.

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
Symptoms : Diarrhea, Vomiting

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.
SAFETY DATA SHEET

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Section 15. Regulatory Information

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic acid</td>
<td>65-85-0</td>
<td>5000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Respiratory or skin sensitization
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Water 7732-18-5
- Albendazole Sulfoxide 54029-12-8
- Glycerine 56-81-5
- Benzoic acid 65-85-0

California Permissible Exposure Limits for Chemical Contaminants
- Glycerine 56-81-5

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
SAFETY DATA SHEET

Albendazole Sulfoxide (10%) Formulation

Version: 1.3  Revision Date: 03/23/2020  SDS Number: 3884326-00004  Date of last issue: 08/01/2019  Date of first issue: 11/30/2018

**NFPA 704:**

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Instability</th>
<th>Health</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

**HMIS® IV:**

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SAR - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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
Sources of key data used to compile the Material Safety Data Sheet:


Revision Date: 03/23/2020

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.

US / Z8