SAFETY DATA SHEET

Albendazole Sulfoxide (1.9%) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Albendazole Sulfoxide (1.9%) Formulation

Supplier's company name, address and phone number
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Skin sensitisation: 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 vapours.
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.
SAFETY DATA SHEET

Albendazole Sulfoxide (1.9%) Formulation

Version 3.0  Revision Date: 2020/03/23  SDS Number: 3903429-00004  Date of last issue: 2019/08/02  Date of first issue: 2018/12/10

Additional Labelling
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
</tr>
<tr>
<td>Polyethylene glycol sorbitan monolaurate</td>
<td>9005-64-5</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical
Unsuitable extinguishing media: None known.
Specific hazards during firefighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)
- Sulphur 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 firefighters:
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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 dyeing or other appropriate containment to keep material from spreading. If dyed 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.

7. HANDLING AND STORAGE

Handling
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 vapour 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 as-
Avoidance of contact: Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- Oxidizing agents
- 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.

Storage

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

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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

Further information: DSEN

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 vapour 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: suspension

Colour: white

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: No data available

Decomposition temperature: No data available

pH: No data available

Evaporation rate: No data available

Auto-ignition temperature: No data available

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

Density and / or relative density

Relative density: No data available
Density: No data available
Relative vapour density: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle characteristics:
Particle size: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

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: > 2,000 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

Polyethylene glycol sorbitan monolaurate:
Acute inhalation toxicity:
LC50 (Rat): > 5.1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:
Albendazole Sulfoxide:
Species: Rabbit
Result: No skin irritation

Polyethylene glycol sorbitan monolaurate:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

Components:
Albendazole Sulfoxide:
Species: Rabbit
Result: No eye irritation

Polyethylene glycol sorbitan monolaurate:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation
Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:
Albendazole Sulfoxide:
Test Type: Maximisation Test
Exposure routes: Dermal
Assessment: Probability or evidence of low to moderate skin sensitisation rate in humans
Result: positive

: Maximisation Test
: Dermal
: Sensitiser
Polyethylene glycol sorbitan monolaurate:

- **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:

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

Polyethylene glycol sorbitan monolaurate:

- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  
  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.

Reproductive toxicity

Not classified based on available information.
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 foetal 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.

### Polyethylene glycol sorbitan monolaurate:

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

### STOT - single exposure

Not classified based on available information.

Components:

### Albendazole Sulfoxide:

- **Exposure routes**: 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:
Exposure routes: 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: Diarrhoea, Vomiting

Species: Dog
LOAEL: 48 mg/kg
Application Route: Oral
Exposure time: 4 Weeks
Target Organs: Gastrointestinal tract
Symptoms: Diarrhoea, 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

**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 sensitisation by skin contact.

**Ingestion**  
Target Organs: Gastrointestinal tract  
Symptoms: Gastrointestinal disturbance, Diarrhoea, 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

**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

**Polyethylene glycol sorbitan monolaurate:**

**Toxicity to fish**  
LL50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**  
NOEC (Daphnia magna (Water flea)): 10 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
Albendazole Sulfoxide (1.9%) Formulation

Ecotoxicology Assessment

Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

Persistence and degradability

Components:

Polyethylene glycol sorbitan monolaurate:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 60 %
Exposure time: 28 d

Bioaccumulative potential

Components:

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

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

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mono(or poly)ether of (mono ester of anhydro(or dianhydro)glucitol and</td>
<td>222</td>
</tr>
<tr>
<td>dodecanoic acid) and alpha-hydro-omega-hydroxypoly(oxyethylene)</td>
<td></td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable
Ordinance on Prevention of Organic Solvent Poisoning  
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)  
Not applicable

Poisonous and Deleterious Substances Control Law  
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof  
Not applicable

High Pressure Gas Safety Act  
Not applicable

Explosive Control Law  
Not applicable

Vessel Safety Law  
Not regulated as a dangerous good

Aviation Law  
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law  
Bulk transportation : Noxious liquid substance (Category Z)  
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act  
Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable

Waste Disposal and Public Cleansing Law  
Industrial waste

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

16. OTHER INFORMATION

Further information  
**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>
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<tr>
<td>3.0</td>
<td>2020/03/23</td>
<td>3903429-00004</td>
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<td>2018/12/10</td>
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</tbody>
</table>

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; IEC - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the 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.

JP / EN