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.
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Version 3.1  Revision Date: 2020/10/10  SDS Number: 3903429-00005  Date of last issue: 2020/03/23  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>Mixture</td>
<td>Albendazole Sulfoxide</td>
</tr>
<tr>
<td></td>
<td>Polyethylene glycol sorbitan monolaurate</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.
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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 (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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety...
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.

Avoidance of contact:

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.

- 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 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>
</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 vapour type

Hand protection:

- 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 : Can react with strong oxidizing agents.
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
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

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
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<table>
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<td>3.1</td>
<td>2020/10/10</td>
<td>3903429-00005</td>
<td>2020/03/23</td>
<td>2018/12/10</td>
</tr>
</tbody>
</table>

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

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

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
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.

National Regulations
Refer to section 15 for specific national regulation.
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 dodecanoic acid) and alpha-hydro-omega-hydroxypoly(oxyethylene)</td>
<td>222</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  
Date format : yyyy/mm/dd  
Full text of other abbreviations  
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;
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.