SAFETY DATA SHEET

Albendazole Sulfoxide (10%) Formulation

Version 2.0  Revision Date: 2021/04/09  SDS Number: 3884319-00006  Date of last issue: 2020/10/10

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Albendazole Sulfoxide (10%) Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
Skin sensitisation: 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 vapours.
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.

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %

Other hazards which do not result in classification
None known.

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>
</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. 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.

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 (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 contain-
ment 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 absorb-
ent.
Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items
employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
certain local or national requirements.

7. HANDLING AND STORAGE

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

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
                        Do not breathe mist or 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 as-
                        sessment
                        Do not eat, drink or smoke when using this product.
                        Take care to prevent spills, waste and minimize release to the
                        environment.

Conditions for safe storage : Keep in properly labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>
</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., 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: 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.

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. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension

Colour: white

Odour: No data available

Odour 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
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Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour 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
Auto-ignition 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

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

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

Skin corrosion/irritation
Not classified based on available information.

Components:

Albendazole Sulfoxide:

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

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:
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

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
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 foetal development:
- Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity LOAEL: 10 mg/kg body weight
  - Result: Embryotoxic effects, Skeletal malformations
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<tbody>
<tr>
<td>2.0</td>
<td>2021/04/09</td>
<td>3884319-00006</td>
<td>2020/10/10</td>
<td>2018/11/30</td>
</tr>
</tbody>
</table>

### Reproductive toxicity - Assessment

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

- **Test Type:** Development  
- **Species:** Rat  
- **Application Route:** Oral  
- **Developmental Toxicity:** NOAEL: 5.8 mg/kg body weight  
- **Result:** Effects on postnatal development

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

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

### STOT - single exposure

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

#### Components:

<table>
<thead>
<tr>
<th>Albendazole Sulfoxide:</th>
<th></th>
</tr>
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<tbody>
<tr>
<td><strong>Exposure routes</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Gastrointestinal tract, Central nervous system</td>
</tr>
<tr>
<td><strong>Assessment</strong></td>
<td>May cause damage to organs.</td>
</tr>
</tbody>
</table>

### STOT - repeated exposure

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

#### Components:

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<td><strong>Assessment</strong></td>
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### Repeated dose toxicity

#### Components:

<table>
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<th>Albendazole Sulfoxide:</th>
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</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>168 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
</tbody>
</table>
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
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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

Persistence and degradability
No data available
Bioaccumulative potential

Components:

Albendazole Sulfoxide:
Partition coefficient: n-octanol/water : log Pow: 2.7
Mobility in soil
No data available
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.

### 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**
Hazardous substances approved for use : Glycerine
Prohibited substances : Not applicable
Restricted substances : Not applicable

**Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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**

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
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.