SAFETY DATA SHEET

Albendazole Sulfoxide (1.9%) Formulation

Version 1.2 Revision Date: 2019/08/02 SDS Number: 3903427-00003 Date of last issue: 2019/04/24
Date of first issue: 2018/12/10

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Albendazole Sulfoxide (1.9%) 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
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
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.

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>Glycerine</td>
<td>Chemical name: Glycerine</td>
</tr>
<tr>
<td>Albendazole Sulfoxide</td>
<td>Chemical name: Albendazole Sulfoxide</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)

Unsuitable extinguishing: None known.
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Specific hazards during firefighting
Hazardous combustion products
: Exposure to combustion products may be a hazard to health.
: 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 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

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-
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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

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>Glycerine</td>
<td>56-81-5</td>
<td>NAB (Mist)</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<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:
- Upper respiratory tract irritation
- DSEN
- Wipe limit 100 µg/100 cm²

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.

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,
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 : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
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
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Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
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:
Glycerine:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Guinea pig): > 5,000 mg/kg

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:
Glycerine:
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Species: Rabbit
Result: No skin irritation

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

**Components:**

**Glycerine:**
Species: Rabbit
Result: No eye irritation

**Albendazole Sulfoxide:**
Species: Rabbit
Result: No skin 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

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**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

**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:**

**Glycerine:**

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

**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:**

**Glycerine:**

- Effects on fertility: Test Type: Two-generation reproduction toxicity study
## Species: Rat
Application Route: Ingestion
Result: negative

### Effects on foetal development

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

### 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.

### 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:

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 yr

Species : Rabbit
NOAEL : 5,040 mg/kg
Application Route : Skin contact
Exposure time : 45 Weeks

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
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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:

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

**Albendazole Sulfoxide:**

**Ecotoxicology Assessment**

**Acute aquatic toxicity:**
- Toxic effects cannot be excluded

**Chronic aquatic toxicity:**
- Toxic effects cannot be excluded

**Persistence and degradability**

**Components:**

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

**Bioaccumulative potential**

**Components:**

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

**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**
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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
Sources of key data used to compile the Safety Data: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
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Date format: yyyy/mm/dd

Full text of other abbreviations

ID OEL: Indonesia. Occupational Exposure Limits
ID OEL / NAB: Long term exposure limit

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 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; 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.

ID / EN