SAFETY DATA SHEET

Albendazole Sulfoxide (10%) Formulation

Section 1: Identification

Product name : Albendazole Sulfoxide (10%) Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
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

Section 2: Hazard 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 : ![Pictogram]
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
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.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substances / Mixture</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.

If swallowed:
If swallowed, DO NOT induce vomiting.
Get medical attention.
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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.

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 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.

Section 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.

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.

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.

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.

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

Section 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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
</tbody>
</table>

Further information: DSEN
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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.

Section 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
Lower explosion limit / Lower : 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

Exposure routes: 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

**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 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

Chronic toxicity

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
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Revision Date: 27.08.2021  
SDS Number: 3884324-00005  
Date of last issue: 10.10.2020  
Date of first issue: 30.11.2018

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

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

Test Type: Development  
Species: Rabbit  
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 foetal development**
  - Test Type: Embryo-foetal 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:**
  - Exposure routes: 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:**
  - Species: Rat
  - LOAEL: 168 mg/kg
  - Application Route: Oral
  - Exposure time: 4 Weeks
  - Target Organs: Gastrointestinal tract, Testis
  - Symptoms: Diarrhoea, Vomiting

**Repeated dose toxicity**

**Components:**

- **Albendazole Sulfoxide:**
  - Species: Dog
  - LOAEL: 48 mg/kg
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Date of last issue: 10.10.2020  
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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

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

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

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
UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR
UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Packing instruction (cargo aircraft) : Not applicable

IMDG-Code
UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
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Labels: Not applicable
EmS Code: Not applicable
Marine pollutant: Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
Hazchem Code: Not applicable

Special precautions for user
Not applicable

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
NZ OEL: New Zealand. Workplace Exposure Standards for Atmospher-
ic Contaminants

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AllC - 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; 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; TECI - Thailand Existing Chemicals 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; 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.

NZ / EN