according to the Globally Harmonized System



# Albendazole Sulfoxide (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 4.0
 28.09.2024
 3884320-00020
 Date of first issue: 30.11.2018

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Albendazole Sulfoxide (10%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

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 Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**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)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

### **GHS** label elements

according to the Globally Harmonized System



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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 pro-

longed or repeated exposure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use.

P260 Do not breathe mist or vapours.

P264 Wash hands 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.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P308 + P316 IF exposed or concerned: Get emergency medi-

cal help immediately.

P333 + P317 If skin irritation or rash occurs: Get medical help. P362 + P364 Take off contaminated clothing and wash it before

reuse

P391 Collect spillage.

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.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (%	
		w/w)	
Albendazole Sulfoxide	54029-12-8	>= 10 - < 20	

according to the Globally Harmonized System



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4. FIRST AID MEASURES

In the case of accident or if you feel unwell, seek medical ad-General advice

vice 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. 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

In case of eye contact

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.

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulphur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

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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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 absor-

bent.

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 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 Advice on safe handling Use only with adequate ventilation. 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

according to the Globally Harmonized System



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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Albendazole Sulfoxide	54029-12-8	TWA	45 μg/m3 (OEB	Internal	
			3)		
	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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face contain-

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Combined particulates and organic vapour type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

vorkplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of

according to the Globally Harmonized System



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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

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

according to the Globally Harmonized System



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Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle characteristics

Particle size No data available

### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac- :

tions

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: > 5,000 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 : LD50 (Rat): 265 mg/kg

administration)

Application Route: Intravenous

#### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

### Albendazole Sulfoxide:

Species Rabbit

according to the Globally Harmonized System



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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:**

### Albendazole Sulfoxide:

Test Type : Maximisation Test

Exposure routes : Dermal

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Result : positive

Test Type : Maximisation Test

Exposure routes : Dermal Result : Sensitiser

### 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.

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### **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 - Assess-

ment

: 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 develop-

ment

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 off-

spring were detected.

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Reproductive toxicity - As-

: Suspected of damaging the unborn child.

sessment

### 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:

Exposure routes : Oral

Target Organs : Gastrointestinal tract, Central nervous system, Immune sys-

tem, 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: DogLOAEL: 48 mg/kgApplication Route: OralExposure time: 4 Weeks

Target Organs : Gastrointestinal tract Symptoms : Diarrhoea, Vomiting

Species: MouseLOAEL: 40 mg/kgApplication Route: OralExposure time: 3 Months

Target Organs : Blood, Liver, Nose

Symptoms : Hematologic effects, Liver effects

Species : Rat

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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: RatNOAEL: 7 mg/kgApplication Route: OralExposure 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 dis-

turbance, 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, Ab-

dominal 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:

Toxicity to fish : EC50 (Brachydanio rerio (zebrafish)): 0.042 mg/l

Exposure time: 144 hrs

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0.068 mg/l

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aquatic invertebrates Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 ( Raphidocelis subcapitata (freshwater green alga)):

plants 0.024 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 10

icity)

M-Factor (Chronic aquatic

toxicity)

: 10

Persistence and degradability

No data available

Bioaccumulative potential

**Components:** 

Albendazole Sulfoxide:

Partition coefficient: n- : log Pow: 1.27

octanol/water pH: 7

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

**International Regulations** 

**UNRTDG** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Albendazole Sulfoxide)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

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**IATA-DGR** 

UN/ID No. UN 3082

Environmentally hazardous substance, liquid, n.o.s. Proper shipping name

(Albendazole Sulfoxide)

Class 9 Ш Packing group

Miscellaneous Labels

Packing instruction (cargo

aircraft)

Packing instruction (passen-964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

**UN** number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(Albendazole Sulfoxide)

Class 9 Packing group Ш Labels **EmS Code** 

F-A, S-F Marine pollutant yes

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

**AICS** not determined

DSL not determined

**IECSC** not determined

### **16. OTHER INFORMATION**

**Revision Date** 28.09.2024

**Further information** 

Sources of key data used to

compile the Safety Data eChem Portal search results and European Chemicals Agen-Sheet

Internal technical data, data from raw material SDSs, OECD

cy, http://echa.europa.eu/

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

Date format : dd.mm.yyyy

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; 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.

IN / EN