

# Albendazole / Closantel Sodium Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 6.0 2023/09/30 10843103-00011 Date of first issue: 2022/08/26

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Albendazole / Closantel Sodium Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Skin sensitisation : Category 1

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms :





Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of

the workplace.



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P273 Avoid release to the environment.

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 ad-

vice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

P391 Collect spillage.

## 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)	ENCS No.
Propylene glycol	57-55-6	>= 20 - < 30	2-234
Closantel	57808-65-8	3.87	
Albendazole Sulfoxide	54029-12-8	>= 1 - < 2.5	
Alcohols, C10-16, ethoxylated,	68585-34-2	>= 0.025 - < 0.1	7-120 / 7-155
sulfates, sodium salts			
Octamethylcyclotetrasiloxane	556-67-2	>= 0.025 - < 0.1	7-475

#### 4. FIRST AID MEASURES

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

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.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.



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Get medical attention.

Rinse mouth thoroughly with water.

May cause an allergic skin reaction.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

delaved

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).

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

Carbon oxides

Hazardous combustion prod-

ucts

Nitrogen oxides (NOx)

Sulphur oxides Chlorine compounds lodine compounds Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

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.

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, protec- :

tive 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 contain-



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> 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 absor-

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

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Avoidance of contact

Oxidizing agents

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.

Storage

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.



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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Closantel	57808-65-8	TWA	>= 10 < 100 µg/m3 (OEB 3)	Internal
Albendazole Sulfoxide	54029-12-8	TWA	40 μg/m3 (OEB 3)	Internal
	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 con-

tainment 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

Particulates 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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.



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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state suspension

Colour white, off-white

Odour odourless

Odour Threshold No data available

No data available Melting point/freezing point

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available

Decomposition temperature No data available

8.5 - 10.5 pΗ

Evaporation rate No data available

Auto-ignition temperature No data available

Viscosity

Viscosity, kinematic 70 - 300 m2/s

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Vapour pressure

Density and / or relative density

Relative density 1.035 - 1.051

Density No data available



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Relative vapour density No data available

Explosive properties Not explosive

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

Molecular weight No data available

Particle characteristics

Particle size  $< 80 \mu m$ 

#### 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

None known. Conditions to avoid 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:**

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity LC50 (Rat): > 44.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

LD50 (Rabbit): > 2,000 mg/kg Acute dermal toxicity

Assessment: The substance or mixture has no acute dermal

toxicity



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Closantel:

Acute oral toxicity : LD50 (Rat, female): 262 mg/kg

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

Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

Acute oral toxicity LD50 (Rat): > 2,000 - 5,000 mg/kg

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Octamethylcyclotetrasiloxane:

Acute oral toxicity LD50 (Rat): > 4,800 mg/kg

Assessment: The substance or mixture has no acute oral tox-

icity

LC50 (Rat): 36 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

LD50 (Rat): > 2,375 mg/kg Acute dermal toxicity

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Propylene glycol:

**Species** Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Albendazole Sulfoxide:

Species Rabbit

Result No skin irritation



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#### Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Skin irritation

Remarks : Based on data from similar materials

## Octamethylcyclotetrasiloxane:

Species : Rabbit

Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

#### Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

#### Albendazole Sulfoxide:

Species : Rabbit

Result : No eye irritation

## Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

Species : Rabbit

Result : Irreversible effects on the eye

Remarks : Based on data from similar materials

## Octamethylcyclotetrasiloxane:

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:

# Propylene glycol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative



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#### 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

#### Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

Test Type : Maximisation Test

Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

## Octamethylcyclotetrasiloxane:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

## Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Closantel:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)



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Species: Mouse

Application Route: Ingestion

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

Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Octamethylcyclotetrasiloxane:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Inhalation

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Propylene glycol:

Species: RatApplication Route: IngestionExposure time: 2 YearsResult: negative



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#### Closantel:

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

#### Albendazole Sulfoxide:

Species : Mouse : Oral Application Route : 2 Years Exposure time

NOAEL : 400 mg/kg body weight

Result : negative

: Rat Species Application Route : Oral : 2 Years Exposure time

NOAEL : 20 mg/kg body weight

Result : negative

Carcinogenicity - Assess-

ment

: No evidence of carcinogenicity in animal studies.

# Reproductive toxicity

Not classified based on available information.

#### **Components:**

# Propylene glycol:

Effects on fertility Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

## Closantel:

Effects on foetal develop-Test Type: Three-generation reproduction toxicity study ment

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



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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.

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

#### Octamethylcyclotetrasiloxane:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Inhalation Method: OPPTS 870.3800

Result: positive

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Inhalation

Result: negative

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, based on animal experiments.

#### STOT - single exposure

Not classified based on available information.



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#### **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 sys-

tem, Liver

Assessment : May cause damage to organs through prolonged or repeated

exposure.

## Repeated dose toxicity

# Components:

## Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 yr

#### 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: MouseLOAEL: 40 mg/kgApplication Route: OralExposure 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

## Octamethylcyclotetrasiloxane:

Species : Rat NOAEL : 1.82 mg/l

Application Route : inhalation (vapour)

Exposure time : 2 yr

Species : Rabbit
NOAEL : >= 960 mg/kg
Application Route : Skin contact
Exposure time : 3 Weeks

## **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



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Symptoms: Headache, Dizziness

Target Organs: Liver

Symptoms: liver function change

Target Organs: Immune system Symptoms: immune system effects

#### 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

## **Components:**

# Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pse

NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

## Closantel:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.01 - 0.1

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox- :

icity)

: 10

M-Factor (Chronic aquatic

: 10

toxicity)

## Albendazole Sulfoxide:

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

Exposure time: 144 hrs

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.068 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202



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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

icitv)

M-Factor (Chronic aquatic

10

toxicity)

Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

LC50 (Danio rerio (zebra fish)): > 1 - 10 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 10 - 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): > 0.10 - 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): > 0.1 - 1 mg/l

Exposure time: 28 d

Remarks: Based on data from similar materials

EC10 (Pseudomonas putida): > 10,000 mg/l Toxicity to microorganisms

> Exposure time: 16 h Method: DIN 38 412 Part 8

Remarks: Based on data from similar materials

Octamethylcyclotetrasiloxane:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.022 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 0.015 mg/l

Exposure time: 48 h

Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic ErC50 (Pseudokirchneriella subcapitata (green algae)): >



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plants 0.022 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility

EC10 (Pseudokirchneriella subcapitata (green algae)): >=

0.022 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): 0.0044 mg/l

Exposure time: 14 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.0079 mg/l

Exposure time: 21 d

M-Factor (Chronic aquatic

toxicity)

: 10

## Persistence and degradability

#### **Components:**

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Octamethylcyclotetrasiloxane:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 3.7 % Exposure time: 29 d

Method: OECD Test Guideline 310

**Bioaccumulative potential** 

**Components:** 

Propylene glycol:

Partition coefficient: n- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

Closantel:

Partition coefficient: n-

octanol/water

log Pow: > 4

Remarks: Expert judgement



# Albendazole / Closantel Sodium Formulation

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Albendazole Sulfoxide:

Partition coefficient: n- : log Pow: 1.27

octanol/water pH: 7

Alcohols, C10-16, ethoxylated, sulfates, sodium salts:

Partition coefficient: n- :

octanol/water

log Pow: < 3

Octamethylcyclotetrasiloxane:

Bioaccumulation : Species: Pimephales promelas (fathead minnow)

Bioconcentration factor (BCF): 12,400

Method: OPPTS 850.1730

Partition coefficient: n- : log Pow: 6.488

octanol/water Method: OECD Test Guideline 123

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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.

(Closantel, Albendazole Sulfoxide)

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

**IATA-DGR** 

UN/ID No. : UN 3082

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



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(Closantel, Albendazole Sulfoxide)

Class : 9 Packing group : III

Labels : Miscellaneous

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

(Closantel, Albendazole Sulfoxide)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

# Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

## **National Regulations**

Refer to section 15 for specific national regulation.

#### 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.

ERG Code : 171

#### 15. REGULATORY INFORMATION

#### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

**Priority Assessment Chemical Substance** 

Chemical name	Number
Propane-1,2-diol	106
Salts of alpha-(alkyl(C=10-16))-omega-(sulfoxy)poly[(oxyethylene)(or	223
oxyethylene/oxy(methylethylene))] (It is limited that the average of re-	
peating number of the repeating unit is 1-4.)	

Monitoring Chemical Substance

Chemical name	Number
2,2,4,4,6,6,8,8-Octamethylcyclotetrasiloxane	40



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#### **Industrial Safety and Health Law**

#### Harmful Substances Prohibited from Manufacture

Not applicable

## **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

## **Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
propane-1,2-diol	>=20 - <30	From April 1st, 2025

## **Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	9	Remarks
propane-1,2-did	ol	From April 1st, 2025

## Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

#### **Ordinance on Prevention of Lead Poisoning**

Not applicable

## Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

#### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

# Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

## **Poisonous and Deleterious Substances Control Law**

Deleterious substance

Chemical name	Cabinet Order Number
Organic cyanide compounds and preparations	32

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof



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## Not applicable

## **High Pressure Gas Safety Act**

Not applicable

## **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

#### **Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

#### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

#### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

#### Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **16. OTHER INFORMATION**

#### **Further information**

Sources of key data used to : compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

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

#### Full text of other abbreviations



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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.

JP / EN