

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Albendazole / Closantel Sodium Formulation

Version 5.1 Revision Date: 30.09.2023 SDS Number: 10843123-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Albendazole / Closantel Sodium Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

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Hazard statements : H317 May cause an allergic skin reaction.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Albendazole Sulfoxide

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Closantel	57808-65-8 260-967-1	Acute Tox. 3; H301 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 2.5 - < 10

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		Acute toxicity estimate Acute oral toxicity: 262 mg/kg	
Albendazole Sulfoxide	54029-12-8	Acute Tox. 4; H302 Skin Sens. 1B; H317 Repr. 2; H361d STOT SE 2; H371 (Gastrointestinal tract, Central nervous system) STOT RE 2; H373 (Gastrointestinal tract, Central nervous system, Immune system, Liver) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 1 - < 2.5
Octamethylcyclotetrasiloxane	556-67-2 209-136-7 014-018-00-1	Flam. Liq. 3; H226 Repr. 2; H361f Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10	>= 0.025 - < 0.1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).

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- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides
Chlorine compounds
Iodine compounds
Metal oxides

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5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- 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.
-

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- 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.

6.3 Methods and material for containment and cleaning up

- Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

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- 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.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Gases

7.3 Specific end use(s)

- Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	OELV - 8 hrs (TWA) (particles)	10 mg/m ³	IE OEL
		OELV - 8 hrs (TWA) (total (vapour and particles))	150 ppm 470 mg/m ³	IE OEL
Closantel	57808-65-8	TWA	>= 10 < 100 µg/m ³ (OEB 3)	Internal
Albendazole Sulfoxide	54029-12-8	TWA	40 µg/m ³ (OEB 3)	Internal

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Further information: DSEN			
	Wipe limit	100 µg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	50 mg/m ³
Octamethylcyclotetra-siloxane	Workers	Inhalation	Long-term systemic effects	73 mg/m ³
	Workers	Inhalation	Long-term local effects	73 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	13 mg/m ³
	Consumers	Inhalation	Long-term local effects	13 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	3.7 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value	
Albendazole Sulfoxide	Water	0.00004 mg/l	
	Soil	0.54 mg/kg dry weight (d.w.)	
Propylene glycol	Fresh water	260 mg/l	
	Freshwater - intermittent	183 mg/l	
	Marine water	26 mg/l	
	Sewage treatment plant	20000 mg/l	
	Fresh water sediment	572 mg/kg dry weight (d.w.)	
	Marine sediment	57.2 mg/kg dry weight (d.w.)	
	Soil	50 mg/kg dry weight (d.w.)	
	Octamethylcyclotetrasiloxane	Fresh water	0.0015 mg/l
		Marine water	0.00015 mg/l
		Sewage treatment plant	10 mg/l
	Fresh water sediment	3 mg/kg dry weight (d.w.)	
	Marine sediment	0.3 mg/kg dry weight (d.w.)	
	Soil	0.54 mg/kg dry weight (d.w.)	
	Oral (Secondary Poisoning)	41 mg/kg food	

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8.2 Exposure controls

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 containment devices).

Minimize open handling.

Personal protective equipment

Eye/face 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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	white, off-white
Odour	:	odourless
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable

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Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 8.5 - 10.5

Viscosity

Viscosity, kinematic : 70 - 300 m²/s

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : 1.035 - 1.051

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : < 80 µm

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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:

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 administration) : LD50 (Rat): 265 mg/kg
Application Route: Intravenous

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Octamethylcyclotetrasiloxane:

- Acute oral toxicity : LD50 (Rat): > 4,800 mg/kg
Assessment: The substance or mixture has no acute oral toxicity
- Acute inhalation toxicity : LC50 (Rat): 36 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
- Acute dermal toxicity : LD50 (Rat): > 2,375 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Albendazole Sulfoxide:

- Species : Rabbit
Result : No skin irritation

Octamethylcyclotetrasiloxane:

- 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

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:

Albendazole Sulfoxide:

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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

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:

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)
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

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

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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:

Closantel:

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:

Closantel:

Effects on foetal development : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Albendazole Sulfoxide:

Effects on fertility : Test Type: Fertility
Species: Rat

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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.

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 development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Inhalation
Result: negative

Reproductive toxicity - Assessment : 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 system, 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 : Dog
LOAEL : 48 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Gastrointestinal tract
Symptoms : Diarrhoea, Vomiting

Species : Mouse
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Blood, Liver, Nose
Symptoms : Hematologic effects, Liver effects

Species : Rat
LOAEL : ≥ 30 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Blood
Symptoms : Hematologic effects

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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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Albendazole Sulfoxide:

General Information : Symptoms: Allergic reactions, hair loss, Gastrointestinal disturbance, Headache, Dizziness
Skin contact : Target Organs: Skin
Symptoms: Allergic reactions
Remarks: May cause sensitisation by skin contact.
Ingestion : Target Organs: Gastrointestinal tract
Symptoms: Gastrointestinal disturbance, Diarrhoea, Abdominal pain

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Target Organs: Central nervous system
Symptoms: Headache, Dizziness
Target Organs: Liver
Symptoms: liver function change
Target Organs: Immune system
Symptoms: immune system effects

SECTION 12: Ecological information

12.1 Toxicity

Components:

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 toxicity) : 10

M-Factor (Chronic aquatic toxicity) : 10

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

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): 0.024 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10

M-Factor (Chronic aquatic toxicity) : 10

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

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Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 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 toxicity) : NOEC: 0.0044 mg/l
Exposure time: 14 d
Species: Oncorhynchus mykiss (rainbow trout)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.0079 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 10

12.2 Persistence and degradability

Components:

Octamethylcyclotetrasiloxane:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 3.7 %
Exposure time: 29 d
Method: OECD Test Guideline 310

12.3 Bioaccumulative potential

Components:

Closantel:

Partition coefficient: n-octanol/water : log Pow: > 4
Remarks: Expert judgement

Albendazole Sulfoxide:

Partition coefficient: n-octanol/water : log Pow: 1.27
pH: 7

Octamethylcyclotetrasiloxane:

Bioaccumulation : Species: Pimephales promelas (fathead minnow)
Bioconcentration factor (BCF): 12,400
Method: OPPTS 850.1730

Partition coefficient: n-octanol/water : log Pow: 6.488
Method: OECD Test Guideline 123

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12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Components:

Octamethylcyclotetrasiloxane:

Assessment : This substance is considered to be persistent, bioaccumulating and toxic (PBT).
: This substance is considered to be very persistent and very bioaccumulating (vPvB).

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

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

14.1 UN number or ID number

ADN : UN 3082

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ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Closantel, Albendazole Sulfoxide)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Closantel, Albendazole Sulfoxide)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Closantel, Albendazole Sulfoxide)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Closantel, Albendazole Sulfoxide)
IATA : Environmentally hazardous substance, liquid, n.o.s.
(Closantel, Albendazole Sulfoxide)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M6

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Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on : Conditions of restriction for the fol-

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the market and use of certain dangerous substances,
mixtures and articles (Annex XVII)

lowing entries should be considered:
Number on list 75, 3

If you intend to use this product as
tattoo ink, please contact your ven-
dor.

Substance(s) or mixture(s) are listed
here according to their appearance
in the regulation, irrespective of their
use/purpose or the conditions of the
restriction. Please refer to the condi-
tions in corresponding Regulation to
determine whether an entry is appli-
cable to the placing on the market or
not.

REACH - Candidate List of Substances of Very High
Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that de-
plete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-
tants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parlia-
ment and the Council concerning the export and import
of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation
(Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of
major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national
regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

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Full text of H-Statements

H226 : Flammable liquid and vapour.
H301 : Toxic if swallowed.
H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H361d : Suspected of damaging the unborn child.
H361f : Suspected of damaging fertility.
H371 : May cause damage to organs if swallowed.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
IE OEL : List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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

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Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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 Agency, <http://echa.europa.eu/>

Classification of the mixture:

Skin Sens. 1	H317
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method

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.

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