

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

SECTION 1. IDENTIFICATION

Product name : Albendazole / Closantel Sodium Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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


SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Skin sensitization : 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 vapors.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
 Date of first issue: 26.08.2022

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.
 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Closantel	57808-65-8	>= 2,5 -< 5
Albendazole Sulfoxide	54029-12-8	>= 1 -< 2,5
Octamethylcyclotetrasiloxane	556-67-2	>= 0,025 -< 0,1

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
 Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
 Remove contaminated clothing and shoes.
 Get medical attention.
 Wash clothing before reuse.
 Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
 Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
 Get medical attention.
 Rinse mouth thoroughly with water.
 Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

Albendazole / Closantel Sodium Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.8	30.09.2023	10843094-00011	Date of first issue: 26.08.2022

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Sulfur oxides
Chlorine compounds
Iodine compounds
Metal oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
 Date of first issue: 26.08.2022

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.
 Do not breathe mist or vapors.
 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.
- Conditions for safe storage : Keep in properly labeled containers.
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
 Strong oxidizing agents
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
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
Further information: DSEN				
		Wipe limit	100 µg/100 cm ²	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 containment devices).
 Minimize open handling.

Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

Hand protection

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 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Color : white, off-white

Odor : odorless

Odor Threshold : No data available

pH : 8,5 - 10,5

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Albendazole / Closantel Sodium Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.8	30.09.2023	10843094-00011	Date of first issue: 26.08.2022

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1,035 - 1,051
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	70 - 300 m ² /s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	< 80 µm

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 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

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.

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

Components:**Albendazole Sulfoxide:**

Species : Rabbit
Result : No eye irritation

Octamethylcyclotetrasiloxane:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization**Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:**Albendazole Sulfoxide:**

Test Type : Maximization Test
Routes of exposure : Dermal
Assessment : Probability or evidence of low to moderate skin sensitization rate in humans
Result : positive

Test Type : Maximization Test
Routes of exposure : Dermal
Result : Sensitizer

Octamethylcyclotetrasiloxane:

Test Type : Maximization Test
Routes of exposure : 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:

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

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
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

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

Carcinogenicity - Assessment : No evidence of carcinogenicity in animal studies.

Reproductive toxicity

Not classified based on available information.

Components:**Closantel:**

Effects on fetal 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
Application Route: Oral
Fertility: NOAEL: 30 mg/kg body weight
Result: No effects on fertility.

Effects on fetal 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

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
Date of first issue: 26.08.2022

Result: positive

Effects on fetal development : Test Type: Embryo-fetal 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.

Components:**Albendazole Sulfoxide:**

Routes of exposure : 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:**

Routes of exposure : 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 : Diarrhea, Vomiting

Species : Dog
LOAEL : 48 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Gastrointestinal tract
Symptoms : Diarrhea, Vomiting

Species : Mouse
LOAEL : 40 mg/kg
Application Route : Oral

Albendazole / Closantel Sodium Formulation

Version 3.8 Revision Date: 30.09.2023 SDS Number: 10843094-00011 Date of last issue: 04.04.2023
 Date of first issue: 26.08.2022

Exposure time : 3 Months
 Target Organs : Blood, Liver, Nose
 Symptoms : Hematologic effects, Liver effects

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

Species : Dog
 LOAEL : 40 mg/kg
 Application Route : Oral
 Exposure time : 6 Months
 Target Organs : Blood, Liver
 Symptoms : Hematologic effects, Liver effects

Species : Rat
 NOAEL : 7 mg/kg
 Application Route : Oral
 Exposure time : 60 d
 Target Organs : Liver, Testis
 Symptoms : Liver effects, male reproductive effects

Octamethylcyclotetrasiloxane:

Species : Rat
 NOAEL : 1,82 mg/l
 Application Route : inhalation (vapor)
 Exposure time : 2 y

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 disturbance, Headache, Dizziness
 Skin contact : Target Organs: Skin
 Symptoms: Allergic reactions
 Remarks: May cause sensitization by skin contact.
 Ingestion : Target Organs: Gastrointestinal tract
 Symptoms: Gastrointestinal disturbance, Diarrhea, Abdominal pain
 Target Organs: Central nervous system
 Symptoms: Headache, Dizziness

Albendazole / Closantel Sodium Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.8	30.09.2023	10843094-00011	Date of first issue: 26.08.2022

Target Organs: Liver
 Symptoms: liver function change
 Target Organs: Immune system
 Symptoms: immune system effects

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****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.

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.

Albendazole / Closantel Sodium Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.8	30.09.2023	10843094-00011	Date of first issue: 26.08.2022

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 (Oncorhynchus mykiss (rainbow trout)): 0,0044 mg/l
Exposure time: 14 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,0079 mg/l
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability**Components:****Octamethylcyclotetrasiloxane:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 3,7 %
Exposure time: 29 d
Method: OECD Test Guideline 310

Bioaccumulative potential**Components:****Closantel:**

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

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

Mobility in soil

No data available

Other adverse effects

No data available

Albendazole / Closantel Sodium Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.8	30.09.2023	10843094-00011	Date of first issue: 26.08.2022

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Full text of other abbreviations

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - 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 Develop-

Albendazole / Closantel Sodium Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.8	30.09.2023	10843094-00011	Date of first issue: 26.08.2022

ment; 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; TECl - 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.

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