

SAFETY DATA SHEET



Revision date: 16-Jun-2015

Version: 2.7

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Valbazen™ Suspension

Trade Name: Valbazen, Valbantel

Synonyms: Valbantel 1.9% Suspension; Albendazole/Closantel; Valbazen 1.9% Suspension

Chemical Family: Benzimidazole

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as anti-worm agent (anthelmintic)

Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Clear Pale Brown Liquid

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Specific target organ systemic toxicity (repeated exposure): Category 2

Acute aquatic toxicity: Category 2

Chronic aquatic toxicity: Category 2

EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2
Dangerous for the Environment

EU Symbol: T N

EU Risk Phrases:

R61 - May cause harm to the unborn child.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Label Elements

Signal Word: Danger

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2. HAZARDS IDENTIFICATION

Hazard Statements: H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure (liver , reproductive system , adrenal gland , blood forming organs)
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P273 - Avoid release to the environment
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term: May produce slight eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain. May cause slight skin irritation. Signs and symptoms might include skin rash, itching, redness or swelling.

Long Term: May cause damage to organs; may have the potential to produce effects on the developing fetus.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	10
Closantel sodium	57808-65-8	260-967-1	Xn; R22 Repr. 3; R62/63 Xn; R48/22 N; R51/53	Acute tox. 3 (H301) Repr. 2 (H361) STOT RE 2 (H373) Aq. Acute 2 (H401) Aq. Chronic 2 (H411)	3.0

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Albendazole	54965-21-8	259-414-7	Xn;R48/22 Repr.Cat.2;R61 N;R50/53	STOT RE2 (H373) Repr. 1B (H360D) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	1.9
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	<1.0
Sodium Lauryl Sulfate	151-21-3	205-788-1	Xn R22 T R24	Acute Tox 4 (H302) Acute Tox 3 (H311)	<1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water, purified	7732-18-5	231-791-2	Not Listed	Not Listed	*
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid dust and mist generation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Place waste in an appropriate container for disposal.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use proper personal protective equipment as specified in Section 8. Avoid inhalation and contact with skin, eye, and clothing. Wash hands and any exposed skin after removal of PPE. Avoid open handling. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Propylene glycol

Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
Ireland OEL - TWAs	150 ppm 470 mg/m ³ 10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³

Albendazole

Zoetis OEL TWA 8-hr	200µg/m ³
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Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³

Sodium Lauryl Sulfate	
Zoetis OEL TWA 8-hr	300µg/m ³

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Pale brown
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	8.5 - 10		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Albendazole			
Predicted	7.4	Log D	3.06
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		

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Relative Density: 1.02 - 1.04 g/ml
Viscosity: 70 - 150 cPs at 20C/68F

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

Albendazole

Mouse Oral LD50 > 3000 mg/kg
Rat Oral LD50 > 1320 mg/kg

Closantel sodium

Rat Oral LD50 262 mg/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/kg

Carboxymethylcellulose sodium

Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

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11. TOXICOLOGICAL INFORMATION

Sodium Lauryl Sulfate

Rat Oral LD50 977 mg/kg
Rabbit Dermal LD50 580mg/kg
Rat Inhalation LC50 > 3900mg/m³ 1 h

Irritation / Sensitization: (Study Type, Species, Severity)

Albendazole

Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating
Skin Sensitization - Beuhler Guinea Pig Negative

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Albendazole

4 Week(s) Rat Oral 25 mg/kg/day NOEL Adrenal gland, Blood forming organs, Male reproductive system, Spleen
3 Month(s) Rat Oral 30 mg/kg/day NOEL No effects at maximum dose
90 Day(s) Mouse Oral 20 (M); 40 (F) mg/kg/day NOEL Liver
4 Week(s) Dog Oral 4 mg/kg/day NOEL Adrenal gland, Blood forming organs, Bone Marrow, Male reproductive system
6 Month(s) Dog Oral 5 mg/kg/day NOEL Blood forming organs, Kidney, Liver, Female reproductive system, Male reproductive system

Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOEL Liver, Kidney, Ureter, Bladder

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Albendazole

Prenatal & Postnatal Development Rat Oral 6 mg/kg/day NOEL Developmental toxicity
Prenatal & Postnatal Development Mouse Oral 30 mg/kg/day NOEL No effects at maximum dose
Reproductive & Fertility Rat Oral 1 mg/kg/day NOEL Negative
Prenatal & Postnatal Development Rabbit Oral 5 mg/kg/day NOEL Developmental toxicity,

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Albendazole

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
Cell Transformation Assay Mouse Negative

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11. TOXICOLOGICAL INFORMATION

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Albendazole

25 Month(s) Mouse Oral 400 mg/kg/day NOAEL Not carcinogenic
28 Month(s) Rat Oral 20 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Product Level Toxicity Data

Acute Toxicity Estimate (ATE), oral > 5000 mg/kg
Acute Toxicity Estimate (ATE), dermal > 5000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Albendazole

Daphnia magna (Water Flea) TAD 4.08 EC50 48 Hours 0.024 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD 201 EC50 72 Hours > 0.42 mg/L

Persistence and Degradability:

Albendazole Not Ready

Bio-accumulative Potential: No data available

Albendazole

Predicted 7.4 Log D 3.06

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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14. TRANSPORT INFORMATION

As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375.

UN number: UN 3082
UN proper shipping name: Environmentally hazardous substances, liquid, n.o.s. (albendazole)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

DOT / ANTT: Not regulated for transportation

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

Closantel sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List	260-967-1
Albendazole	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	259-414-7
Microcrystalline cellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9
Sodium Lauryl Sulfate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1
Water, purified	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Carboxymethylcellulose sodium	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

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Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, dermal-Cat.3; H311 - Toxic in contact with skin

Xn - Harmful
N - Dangerous for the environment
Toxic to Reproduction: Category 2
Toxic to Reproduction: Category 3
T - Toxic

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R24 - Toxic in contact with skin.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 14 - Transport Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet