

SAFETY DATA SHEET



Revision date: 22-Sep-2015

Version: 3.2

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

Product Identifier

Material Name: VALBAZEN® (Albendazole) suspension

Trade Name: VALBAZEN®

Synonyms: Albendazole suspension , VALBAZEN® SUSPENSION, Valbazen® Ultra, Valbazen® For Cattle

Chemical Family: Mixture

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

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

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

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

2. HAZARDS IDENTIFICATION

Appearance: White suspension

Classification of the Substance or Mixture

Reproductive Toxicity: Category 1B

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

Acute aquatic toxicity: Category 1

Chronic aquatic toxicity: Category 1

Label Elements

Signal Word: Danger

Hazard Statements: H360D - May damage the unborn child H373 - May cause damage to organs through prolonged or repeated exposure (adrenal gland , blood forming organs , reproductive system , liver)
H410 - Very 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
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P273 - Avoid release to the environment
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

Short Term:

Long Term:

Known Clinical Effects:

Australian Hazard Classification (NOHSC):

Note:

May cause eye and skin irritation (based on components) . May cause allergic skin reaction . Repeat-dose studies in animals have shown a potential to cause adverse effects on testes and the developing fetus.

Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.

Hazardous Substance. Non-Dangerous Goods.

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings 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	GHS Classification	%
Albendazole	54965-21-8	259-414-7	STOT RE2 (H373) Repr. 1B (H360D) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	<12
Glycerol	56-81-5	200-289-5	Not Listed	<10
Benzoic Acid	65-85-0	200-618-2	Not Listed	<10
Potassium sorbate	590-00-1	Not Listed	Not Listed	<10

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Simethicone	8050-81-5	Not Listed	Not Listed	*
Magnesium aluminum silicate	1327-43-1	215-478-8	Not Listed	*
Sorbitan monolaurate	1338-39-2	215-663-3	Not Listed	*
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	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 CLP/GHS abbreviations mentioned in this Section, see Section 16

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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: Use water, carbon dioxide, foam or dry chemical extinguishers.

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.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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.
- 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

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7. HANDLING AND STORAGE

When handling, use appropriate personal protective equipment (see Section 8). Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. 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 as directed by product packaging.
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.

Albendazole

Zoetis OEL TWA 8-hr 200 µg/m³

Glycerol

Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Czech Republic OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
Finland OEL - TWA	20 mg/m ³
France OEL - TWA	10 mg/m ³
Germany (DFG) - MAK	50 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	50 mg/m ³

Benzoic Acid

Latvia OEL - TWA 5 mg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid suspension	Color:	White
Odor:	Characteristic	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water solubility:	0.53 mg/L (at 25°C and pH 7)		
Water Solubility:	Insoluble		
pH:	4.0 - 5.25		
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		
Relative Density:	1.0 - 1.04		
Viscosity:	No data available		
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	
Polymerization:		Will not occur	

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)

Sorbitan monolaurate

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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 = 33600 mg/kg

Carboxymethylcellulose sodium

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

Polysorbate 80

Rat Oral LD50 25 g/kg

Benzoic Acid

Rat Oral LD50 1700 mg/kg
Rat Oral LD50 2350 mg/kg

Albendazole

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

Potassium sorbate

Mouse Oral LD50 3800 mg/kg
Rat Oral LD50 4340 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Benzoic Acid

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Severe

Albendazole

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

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

Sorbitan monolaurate

13 Week(s) Rat Oral =112 g/kg LOAEL Liver, Kidney, Bladder, Ureter

Carboxymethylcellulose sodium

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

Albendazole

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

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11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, 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)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Cell Transformation Assay	Mouse	Negative

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

Albendazole

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

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12. ECOLOGICAL INFORMATION

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

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

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability:

Albendazole Not Ready

Bio-accumulative Potential:

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.

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. (contains Albendazole)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

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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

U.S. DOT Reportable Quantity (RQ), 49 CFR 172.101 Appendix A:

Benzoic Acid

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
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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

Class D, Division 2, Subdivision B

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.



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

Glycerol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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15. REGULATORY INFORMATION

<p>REACH - Annex V - Exemptions from the obligations of Register:</p>	<p>Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern</p>
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<p>EU EINECS/ELINCS List</p>	<p>200-289-5</p>
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Benzoic Acid

<p>CERCLA/SARA 313 Emission reporting</p>	<p>Not Listed</p>
<p>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</p>	<p>5000 lb 2270 kg</p>
<p>California Proposition 65</p>	<p>Not Listed</p>
<p>Inventory - United States TSCA - Sect. 8(b)</p>	<p>Present</p>
<p>Australia (AICS):</p>	<p>Present</p>
<p>EU EINECS/ELINCS List</p>	<p>200-618-2</p>

Potassium sorbate

<p>CERCLA/SARA 313 Emission reporting</p>	<p>Not Listed</p>
<p>California Proposition 65</p>	<p>Not Listed</p>
<p>Inventory - United States TSCA - Sect. 8(b)</p>	<p>Present</p>
<p>EU EINECS/ELINCS List</p>	<p>Not Listed</p>

Simethicone

<p>CERCLA/SARA 313 Emission reporting</p>	<p>Not Listed</p>
<p>California Proposition 65</p>	<p>Not Listed</p>
<p>Australia (AICS):</p>	<p>Present</p>
<p>EU EINECS/ELINCS List</p>	<p>Not Listed</p>

Magnesium aluminum silicate

<p>CERCLA/SARA 313 Emission reporting</p>	<p>Not Listed</p>
<p>California Proposition 65</p>	<p>Not Listed</p>
<p>Inventory - United States TSCA - Sect. 8(b)</p>	<p>Present</p>
<p>Australia (AICS):</p>	<p>Present</p>
<p>EU EINECS/ELINCS List</p>	<p>215-478-8</p>

Sorbitan monolaurate

<p>CERCLA/SARA 313 Emission reporting</p>	<p>Not Listed</p>
<p>California Proposition 65</p>	<p>Not Listed</p>
<p>Inventory - United States TSCA - Sect. 8(b)</p>	<p>Present</p>
<p>Australia (AICS):</p>	<p>Present</p>
<p>EU EINECS/ELINCS List</p>	<p>215-663-3</p>

Carboxymethylcellulose sodium

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

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15. REGULATORY INFORMATION

Polysorbate 80

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 CLP/GHS Classification abbreviations mentioned in Section 3

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child 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

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 2 - Hazard Identification. Updated Section 11 - Toxicology Information.
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