# SAFETY DATA SHEET



1. Identification

Product identifier VALBAZEN® (Albendazole) suspension

Other means of identification

Synonyms VALBAZEN® \* Albendazole suspension \* Valbazen® For Cattle \* VALBAZEN® SUSPENSION \*

Valbazen® Ultra

Recommended use Veterinary product used as anti-worm agent (anthelmintic)

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA) Zoetis Inc.

10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

**Rocky Mountain Poison** 

and Drug Center

1-866-531-8896

Product Support/Technical

Services

1-800-366-5288

**Emergency telephone** 

numbers

CHEMTREC (24 hours): 1-800-424-9300

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

Company Name (CA) Zoetis Canada Inc.

16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7

**Emergency telephone** 

number

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

Contact E-Mail productsupport@zoetis.com

**Product Support** 1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at

https://www.zoetis.ca/sds/sds.aspx

Supplier Not available.

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Reproductive toxicity Category 1B

Specific target organ toxicity following repeated exposure Category 2 (Adrenal gland, blood forming organs, liver, Reproductive system)

Environmental hazards Hazardous to the aquatic environment, acute Category 1

hazard

Hazardous to the aquatic environment,

long-term hazard

Category 1

Label elements



Signal word Danger

Hazard statement May damage fertility or the unborn child. May cause damage to organs (Adrenal gland, blood

forming organs, liver, Reproductive system) through prolonged or repeated exposure. Very toxic

to aquatic life with long lasting effects.

Material name: VALBAZEN® (Albendazole) suspension

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe mist or vapour. Avoid release to the environment. Wear

protective gloves/protective clothing/eye protection/face protection.

IF exposed or concerned: Get medical advice/attention. Collect spillage. Response

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards None known.

Supplemental information May cause eye and skin irritation.

# 3. Composition/information on ingredients

#### **Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Albendazole		54965-21-8	7-12
Glycerol		56-81-5	<10
Potassium sorbate		590-00-1	<10
Benzoic acid		65-85-0	<u></u>

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

## 4. First-aid measures

Inhalation Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison

control centre immediately.

Wash off with soap and water. Remove contaminated clothing. If skin irritation or rash occurs: Get Skin contact

medical advice/attention. Wash contaminated clothing before reuse.

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Eye contact

Get medical attention immediately.

Ingestion Rinse mouth. Call a physician or poison control centre immediately. Do not induce vomiting without

advice from poison control center. Never give anything by mouth to a victim who is unconscious or

is having convulsions.

Most important

symptoms/effects, acute and

delayed

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Prolonged exposure may cause chronic effects. Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.

Indication of immediate medical attention and special

treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of General information

the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

## 5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

# Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.

# Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

#### **Environmental precautions**

Avoid discharge into drains, water courses or onto the ground.

# 7. Handling and storage

# Precautions for safe handling

Use this product with adequate ventilation. Wear appropriate personal protective equipment. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices.

# Conditions for safe storage, including any incompatibilities

Store locked up. Store in a well-ventilated place. @ 15-30°C (59-86°F). Protect from sunlight. Do not allow material to freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

# 8. Exposure controls/personal protection

# Occupational exposure limits

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Components	Туре	Value
Albendazole (CAS 54965-21-8)	TWA	200 μg/m³

# Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Туре	Value	Form	
Glycerol (CAS 56-81-5)	TWA	10 mg/m3	Mist.	

# Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Туре	Value	Form	
Glycerol (CAS 56-81-5)	TWA	3 mg/m3	Respirable mist.	
		10 mg/m3	Mist.	

#### Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Туре	Value	Form		
Glycerol (CAS 56-81-5)	TWA	10 mg/m3	Mist.		
Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)					

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)						
Components	Туре	Value	Form			
Glycerol (CAS 56-81-5)	TWA	10 mg/m3	Mist.			

## Biological limit values

No biological exposure limits noted for the ingredient(s).

# Control banding approach Appropriate engineering

controls

Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

### Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Not available.

#### Skin protection

Hand protection Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact

with drug product is possible and for bulk processing operations.

Other Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact

with drug product is possible and for bulk processing operations.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination

(mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards Not applicable.

General hygiene considerations

Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

# 9. Physical and chemical properties

Liquid suspension **Appearance** 

Physical state Liquid. **Form** Liquid. White Colour

Odour Characteristic. Not available. Odour threshold

4 - 5.3 Hq

Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Flash point Not available. Not available. **Evaporation rate** Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Flammability limit - upper

Not available.

Explosive limit - lower (%) Not available. Explosive limit - upper Not available. (%)

Not available. Vapour pressure Vapour density Not available. Relative density Not available.

Solubility(ies)

0.53 mg/l (@ 25C/77F, pH 7) Solubility (water)

Not available.

Partition coefficient Not available.

(n-octanol/water)

Not available. Auto-ignition temperature **Decomposition temperature** Not available. Viscosity Not available.

Other information

Not explosive. **Explosive properties Oxidising properties** Not oxidising.

Specific gravity 1 - 1.4

# 10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions. Possibility of hazardous Hazardous polymerisation does not occur.

reactions

Conditions to avoid

Contact with incompatible materials. Heat, flames and sparks. Protect from freezing.

Incompatible materials Strong oxidising agents. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

# 11. Toxicological information

## Information on likely routes of exposure

**Inhalation** May cause damage to organs through prolonged or repeated exposure by inhalation.

**Skin contact** Prolonged skin contact may cause temporary irritation.

Benzoic acid Species: Rabbit

Severity: Mild

Glycerol Species: Rabbit

Severity: Mild

Albendazole Species: Rabbit

Severity: Non-irritating

**Eye contact** Direct contact with eyes may cause temporary irritation.

Glycerol Species: Rabbit

Severity: Mild

Albendazole Species: Rabbit

Severity: Non-irritating

Benzoic acid Species: Rabbit

Severity: Severe

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational

exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Prolonged exposure may cause chronic effects. Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and

headache.

### Information on toxicological effects

Acute toxicity May be harmful if inhaled. May be harmful if swallowed.

Components Species Test results

Albendazole (CAS 54965-21-8)

Acute

Oral

LD50 Mouse > 3000 mg/kg

Rat > 1320 mg/kg

Chronic

Oral

NOAEL Dog 5 mg/kg/day, 6 months (Target organs: Blood forming organs, Kidney, Liver.

Blood forming organs, Kidney, Liver, Female reproductive system, Male

reproductive system)

Mouse 400 mg/kg/day, 25 months (Not

carcinogenic)

Rat 20 mg/kg/day, 28 months (Not

carcinogenic)

<u>Subacute</u>

Oral

NOAEL Dog 4 mg/kg/day, 4 weeks (Target organs:

Adrenal gland, Blood forming organs, Bone

Marrow, Male reproductive system)

Rat 25 mg/kg/day, 4 weeks (Target organs:

Adrenal gland, Blood forming organs, Male

reproductive system, Spleen)

SDS CANADA

Components **Species** Test results Subchronic Oral NOAEL Mouse 20 - 40 mg/kg/day, 90 days M-F (Target organs: Liver) Rat 30 mg/kg/day, 3 months (No effects at maximum dose) Benzoic acid (CAS 65-85-0) Acute Inhalation LC50 Rat > 0.026 mg/l, 1 Hours Oral LD50 Rat 2350 mg/kg 1700 mg/kg Potassium sorbate (CAS 590-00-1) <u>Acute</u> Oral LD50 Mouse 3800 mg/kg Rat 4340 mg/kg Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. Corrosivity Albendazole Species: Rabbit Severity: Non-irritating Direct contact with eyes may cause temporary irritation. Serious eye damage/eye irritation Eye contact Glycerol Species: Rabbit Severity: Mild Albendazole Species: Rabbit Severity: Non-irritating Benzoic acid Species: Rabbit Severity: Severe Respiratory or skin sensitisation Canada - Alberta OELs: Irritant Glycerol (CAS 56-81-5) Irritant Respiratory sensitisation Not a respiratory sensitizer. Skin sensitisation This product is not expected to cause skin sensitisation. Skin sensitisation Albendazole Buehler Species: Guinea Pig Severity: negative No data available to indicate product or any components present at greater than 0.1% are Germ cell mutagenicity mutagenic or genotoxic. Mutagenicity Albendazole Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella Cell Transformation Assay Result: negative

Species: Mouse

Mutagenicity

Albendazole In Vitro Chromosome Aberration

Result: negative

Species: Chinese Hamster Ovary (CHO) cells

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**Reproductive toxicity** May damage fertility or the unborn child.

**Developmental effects** 

Albendazole 30 mg/kg/day Prenatal & Postnatal Development, No effects

at maximum dose Result: NOAEL Species: Mouse Organ: Oral

5 mg/kg/day Prenatal & Postnatal Development,

Developmental toxicity Result: NOAEL Species: Rabbit Organ: Oral

6 mg/kg/day Prenatal & Postnatal Development,

Developmental toxicity

Result: NOAEL Species: Rat Organ: Oral

Reproductivity

Albendazole 1 mg/kg/day Reproductive & Fertility, negative

Result: NOAEL Species: Rat Organ: Oral

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Componente

May cause damage to organs (Adrenal gland, blood forming organs, liver, Reproductive system)

Toot requilte

through prolonged or repeated exposure.

**Aspiration hazard** Not an aspiration hazard.

Chronic effects May cause damage to organs through prolonged or repeated exposure. Prolonged inhalation may

be harmful.

## 12. Ecological information

**Ecotoxicity** Very toxic to aquatic life with long lasting effects. Avoid release to the environment.

Cnasica

Components		Species	lest results
Albendazole (CAS 54	965-21-8)		
	EC50	Daphnia magna (Water Flea)	0.024 mg/l, 48 Hours
		Pseudokirchneriella subcapitata (G Alga)	reen > 0.42 mg/l, 72 Hours
Benzoic acid (CAS 65	5-85-0)		
Aquatic			
Fish	LC50	Western mosquitofish (Gambusia at	ffinis) 180 mg/l, 96 hours
Glycerol (CAS 56-81-	5)		
Aquatic			
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	51000 - 57000 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Albendazole 3.06, Log D @ pH 7.4

Mobility in soil No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions** Avoid release to the environment. Do not allow this material to drain into sewers/water supplies.

Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container

in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

The waste code should be assigned in discussion between the user, the producer and the waste Hazardous waste code

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

## 14. Transport information

#### **TDG**

Not regulated as dangerous goods.

#### IATA

**UN number** UN3082

Environmentally hazardous substances, liquid, n.o.s. (Albendazole) UN proper shipping name

Transport hazard class(es)

9 Class Subsidiary risk Ш Packing group **Environmental hazards** Yes

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

**IMDG** 

**UN number** UN3082

UN proper shipping name Environmentally hazardous substances, liquid, n.o.s. (Albendazole), MARINE POLLUTANT

(Albendazole)

Transport hazard class(es)

9 Class Subsidiary risk Packing group Ш **Environmental hazards** 

Marine pollutant Yes F-A, S-F **EmS** 

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and

Not established.

the IBC Code



Material name: VALBAZEN® (Albendazole) suspension

## Marine pollutant



#### General information

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

## 15. Regulatory information

## Canadian regulations

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

## **Controlled Drugs and Substances Act**

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed

#### **Greenhouse Gases**

Not listed.

### **Precursor Control Regulations**

Not regulated.

#### International regulations

#### Stockholm Convention

Not applicable.

#### **Rotterdam Convention**

Not applicable.

### Kyoto protocol

Not applicable.

### **Montreal Protocol**

Not applicable.

#### **Basel Convention**

Not applicable.

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region Inventory name On inventory (yes/no)\*

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information

Issue date 28-April-2017

Version No. 01

Disclaimer 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. The information in the sheet was written based on the best knowledge and experience currently

available.

Revision information Composition / Information on Ingredients: Ingredients

Physical & Chemical Properties: Multiple Properties
Transport Information: Material Transportation Information

GHS: Qualifiers

Material name: VALBAZEN® (Albendazole) suspension