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)

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem, Belgium

Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Belgium

Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number (North America): CHEMTREC (24 hours): 1-800-424-9300

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

Contact E-Mail: VMIPSrecords@zoetis.com

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
Other Hazards

Short Term: May cause eye and skin irritation (based on components). May cause allergic skin reaction.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes and the developing fetus.

Known Clinical Effects: Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.


Note: 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole</td>
<td>54965-21-8</td>
<td>259-414-7</td>
<td>STOT RE2 (H373) Repr. 1B (H360D) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)</td>
<td>&lt;12</td>
</tr>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Benzoic Acid</td>
<td>65-85-0</td>
<td>200-618-2</td>
<td>Not Listed</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Potassium sorbate</td>
<td>950-00-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Simethicone</td>
<td>8050-81-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>1327-43-1</td>
<td>215-478-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitan monolaurate</td>
<td>1338-39-2</td>
<td>215-663-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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
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
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/m³
Belgium OEL - TWA 10 mg/m³
Czech Republic OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
Finland OEL - TWA 20 mg/m³
France OEL - TWA 10 mg/m³
Germany (DFG) - MAK 50 mg/m³
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 50 mg/m³

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.
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid suspension</td>
</tr>
<tr>
<td>Odor</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>0.53 mg/L (at 25°C and pH 7)</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Insoluble</td>
</tr>
<tr>
<td>pH</td>
<td>4.0 - 5.25</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Albendazole</td>
<td>Predicted 7.4 Log D 3.06</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>1.0 - 1.04</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>Will not occur</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

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

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
11. TOXICOLOGICAL INFORMATION

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)

Repeatead Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

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

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

Material Name: VALBAZEN® (Albendazole) suspension
Revision date: 22-Sep-2015
Version: 3.2
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)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species/Method</th>
<th>EC50</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole</td>
<td>Daphnia magna (Water Flea)</td>
<td>EC50</td>
<td>48 Hours</td>
<td>0.024 mg/L</td>
</tr>
<tr>
<td>Albendazole</td>
<td>Pseudokirchneriella subcapitata (Green Alga)</td>
<td>OECD 201</td>
<td>EC50</td>
<td>72 Hours</td>
</tr>
</tbody>
</table>

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 Log D 7.4

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.

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing group</th>
<th>Environmental Hazard(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3082</td>
<td>Environmentally hazardous substances, liquid, n.o.s. (contains Albendazole)</td>
<td>9</td>
<td>III</td>
<td>Marine Pollutant</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA</th>
<th>SARA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic Acid</td>
<td>5000 lb</td>
<td>2270 kg</td>
</tr>
</tbody>
</table>

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
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic Acid</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Potassium sorbate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Simethicone</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>215-478-8</td>
</tr>
<tr>
<td>Sorbitan monolaurate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>215-663-3</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>
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