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

Product Identifier

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, 15g
Trade Name: ALBON® BOLUSES 5g, 15g
Synonyms: Sulfadimethoxine Boluses 5g, 15g
Chemical Family: Mixture

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

Intended Use: Veterinary product used as antibiotic agent
Restrictions on Use: Not for human use

2. HAZARDS IDENTIFICATION

Appearance: White to off-white oblong, biconvex bolus tablet.

Classification of the Substance or Mixture

GHS - Classification
Skin Sensitization: Category 1

EU Classification:
EU Indication of danger: Irritant
EU Symbol: Xi
EU Risk Phrases: R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Warning
Hazard Statements: H317 - May cause an allergic skin reaction
Precautionary Statements:
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Short Term:
Contact with sulfonamides may cause dermatitis. Allergic skin reaction may occur based on effects of other sulfonamides. Dust may cause irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects:
As in all sulfonamide therapy, the following reactions may occur including nausea, vomiting, diarrhea, inflammation of the liver and pancreas, blood disorder, drug fever, skin rash, infection of the conjunctiva and sclera, blood in the urine and crystalluria.

Australian Hazard Classification (NOHSC):

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>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sulfadimethoxine</td>
<td>122-11-2</td>
<td>204-523-7</td>
<td>Xi;R43</td>
<td>Skin Sens. 1 (H317)</td>
<td>85.0</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alginic acid</td>
<td>9005-32-7</td>
<td>232-680-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</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.

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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and shoes. Wash skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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: Water, dry powder or foam extinguishers are recommended.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Not known

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. Evacuate area and fight fire from a safe distance

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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. Store as directed by product packaging.
Incompatible Materials: Strong oxidizers.
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.

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
France OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Sulfadimethoxine
Lithuania OEL - TWA 0.1 mg/m³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sulfadimethoxine
Zoetis OEB OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Exposure Controls
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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 air contamination levels below the exposure limits or within the OEB range 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:**
Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:**
Oblong, biconvex scored bolus tablet

**Odor:**
No data available.

**Molecular Formula:**
Mixture

**Solvent Solubility:**
No data available

**Water Solubility:**
No data available

**pH:**
No data available

**Melting/Freezing Point (°C):**
No data available

**Boiling Point (°C):**
No data available

**Partition Coefficient: (Method, pH, Endpoint, Value):**
No data available

**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:**
No data available

**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

**Possibility of Hazardous Reactions**
Oxidizing Properties: None
Conditions to Avoid: Direct sunlight, conditions that might generate heat and dispersion as a dust cloud.
Incompatible Materials: Strong oxidizers.
10. STABILITY AND REACTIVITY

Hazardous Decomposition Products:
No data available.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The following information is available for the individual ingredients.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadimethoxine</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 16 g/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>IP</td>
<td>LD50</td>
<td>&gt; 2 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 10 g/kg</td>
</tr>
<tr>
<td>Alginic acid</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5 g/kg</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Inhalation</td>
<td>LC50</td>
<td>&gt; 2000 mg/m³</td>
</tr>
</tbody>
</table>

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.

Inhalation Acute Toxicity See Acute toxicity table
Ingestion Acute Toxicity See Acute toxicity table Dust may cause irritation.
Skin Irritation / Sensitization Dermatitis may occur from contact of sulfonamides with the skin. Hypersensitivity reactions to sulfonamides have been reported.

Chronic Effects/Carcinogenicity Studies to evaluate the carcinogenic potential of sulfadimethoxine were not available. Other sulfonamide drugs which have been evaluated are not carcinogenic.

Subchronic Effects In rats, oral dosing of 9,100 mg/kg sulfadimethoxine for 13 weeks caused changes in thyroid weight (goitrogenic effect) and decreased weight gain. Sulfonamides are known to be goitrogenic, but not in primates or humans. Dogs given daily oral doses of 160 mg/kg sulfadimethoxine for 13 weeks showed no signs of toxicity.

Reproductive Effects Not determined

Teratogenicity In humans, sulfonamides administered prior to delivery can cause jaundice and hemolytic anemia in the offspring. Studies in pregnant laboratory animals administered sulfadimethoxine have shown developmental effects, but retrospective studies in humans with other sulfonamides have not been conclusive.

Mutagenicity Other sulfonamide drugs which have been evaluated are not mutagenic.

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

At increase risk from exposure: Like other sulfonamides, this material can produce hypersensitivity reactions in some individuals.
12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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, and Subdivision B.

Alginic acid
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)  Present
Australia (AICS):  Present
EU EINECS/ELINCS List  232-680-1

Starch, pregelatinized
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:
EU EINECS/ELINCS List  232-679-6

Magnesium stearate
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  209-150-3

Gelatin
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  232-554-6

Sulfadimethoxine
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 4
EU EINECS/ELINCS List  204-523-7

16. OTHER INFORMATION

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

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Xi - Irritant
R43 - May cause sensitization by skin contact.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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