



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Dec-2006

Version: 1.2

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health  
Pfizer Inc  
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Poison Control Center Phone: 1-866-531-8896  
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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, 15g**

**Trade Name:** ALBON® BOLUSES 5g, 15g  
**Synonyms:** Sulfadimethoxine Boluses 5g, 15g  
**Chemical Family:** Mixture  
**Intended Use:** Veterinary product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

| Ingredient             | CAS Number | EU EINECS List | %    |
|------------------------|------------|----------------|------|
| Starch, pregelatinized | 9005-25-8  | 232-679-6      | *    |
| Magnesium stearate     | 557-04-0   | 209-150-3      | *    |
| Sulfadimethoxine       | 122-11-2   | 204-523-7      | 85.0 |

| Ingredient    | CAS Number | EU EINECS List | % |
|---------------|------------|----------------|---|
| Alginate acid | 9005-32-7  | 232-680-1      | * |
| Gelatin       | 9000-70-8  | 232-554-6      | * |

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** White to off-white oblong, biconvex bolus tablet .  
**Signal Word:** WARNING

**Statement of Hazard:** May cause allergic reaction in individuals sensitive to sulfonamides.  
**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.

**EU Indication of danger:** Irritant

**EU Hazard Symbols:**

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### EU Risk Phrases:

### Australian Hazard Classification (NOHSC):

R43 - May cause sensitization by skin contact.  
Hazardous Substance.

### 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.

## 4. FIRST AID MEASURES

|                      |  |
|----------------------|--|
| <b>Eye Contact:</b>  | Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.  |
| <b>Skin Contact:</b> | 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. |
| <b>Ingestion:</b>    | Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.   |
| <b>Inhalation:</b>   | Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.   |

## 5. FIRE FIGHTING MEASURES

|                                       |  |
|---------------------------------------|--|
| <b>Extinguishing Media:</b>           | Water, dry powder or foam extinguishers are recommended.   |
| <b>Hazardous Combustion Products:</b> | Not known  |
| <b>Fire Fighting Procedures:</b>      | Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance |
| <b>Fire / Explosion Hazards:</b>      | Fine particles (such as dust and mists) may fuel fires/explosions.   |

## 6. ACCIDENTAL RELEASE MEASURES

|   |  |
|---|--|
| <b>Health and Safety Precautions:</b>             | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.   |
| <b>Measures for Cleaning / Collecting:</b>        | 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. |
| <b>Measures for Environmental Protections:</b>    | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.   |
| <b>Additional Consideration for Large Spills:</b> | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.   |

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### 7. HANDLING AND STORAGE

**General Handling:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Starch, pregelatinized

|                                   |                            |       |
|-----------------------------------|----------------------------|-------|
| OSHA - Final PELS - TWAs:         | = 15 mg/m <sup>3</sup> TWA | total |
|                                   | = 5 mg/m <sup>3</sup> TWA  |       |
| ACGIH Threshold Limit Value (TWA) | = 10 mg/m <sup>3</sup> TWA |       |
| Australia TWA                     | = 10 mg/m <sup>3</sup> TWA |       |

#### Magnesium stearate

|                                   |                            |                                  |
|-----------------------------------|----------------------------|----------------------------------|
| ACGIH Threshold Limit Value (TWA) | = 10 mg/m <sup>3</sup> TWA | except stearates of toxic metals |
| Australia TWA                     | = 10 mg/m <sup>3</sup> TWA |                                  |

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

**Pfizer Occupational Exposure Band (OEB):** OEB2 (control exposure to the range of >100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

**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 within the OEB range.

#### Personal Protective Equipment:

|                                |   |
|--------------------------------|---|
| <b>Hands:</b>                  | Not required for the normal use of this product. Wear protective gloves when working with large quantities.   |
| <b>Eyes:</b>                   | Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.   |
| <b>Skin:</b>                   | Not required for the normal use of this product. Wear protective clothing when working with large quantities.   |
| <b>Respiratory protection:</b> | Not required for the normal use of this product. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. |

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

|                           |                                      |                          |                    |
|---------------------------|--------------------------------------|--------------------------|--------------------|
| <b>Physical State:</b>    | Oblong, biconvex scored bolus tablet | <b>Color:</b>            | White to off-white |
| <b>Molecular Formula:</b> | Mixture                              | <b>Molecular Weight:</b> | Mixture            |

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### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** Direct sunlight, conditions that might generate heat and dispersion as a dust cloud .  
**Incompatible Materials:** Strong oxidizers .  
**Hazardous Decomposition Products:** No data available.  
**Polymerization:** Will not occur .

### 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient, except where noted.

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

##### **Sulfadimethoxine**

Mouse Oral LD50 > 16 g/kg

Mouse IP LD50 > 2 g/kg

Rat Oral LD50 > 10 g/kg

##### **Alginic acid**

Rat Oral LD50 > 5 g/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

**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

**Eye Irritation / Sensitization** Dust may cause irritation.

**Skin Irritation / Sensitization** Dermatitis may occur from contact of sulfonamides with the skin. Hypersensitivity reactions to sulfonamides have been reported.

**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.

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

**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

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

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

### 14. TRANSPORT INFORMATION

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

### 15. REGULATORY INFORMATION

**EU Symbol:** Xi  
**EU Indication of danger:** Irritant

**EU Risk Phrases:**  
R43 - May cause sensitization by skin contact.

**EU Safety Phrases:**  
S24 - Avoid contact with skin.  
S36 - Wear suitable protective clothing.  
S37 - Wear suitable gloves.

**OSHA Label:**  
WARNING  
May cause allergic reaction in individuals sensitive to sulfonamides.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, and Subdivision B.



Alginic acid

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS List

XU  
Present  
232-680-1

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### Starch, pregelatinized

|   |           |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | XU        |
| Australia (AICS):                           | Present   |
| EU EINECS List                              | 232-679-6 |

### Gelatin

|   |           |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | XU        |
| Australia (AICS):                           | Present   |
| EU EINECS List                              | 232-554-6 |

### Magnesium stearate

|   |           |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present   |
| Australia (AICS):                           | Present   |
| EU EINECS List                              | 209-150-3 |

### Sulfadimethoxine

|   |            |
|---|------------|
| Australia (AICS):   | Present    |
| Standard for the Uniform Scheduling<br>for Drugs and Poisons: | Schedule 4 |
| EU EINECS List  | 204-523-7  |

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information. Corrected Chemical Family and Intended Use.

### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**