

SAFETY DATA SHEET



Revision date: 31-Oct-2013

Version: 2.0

Page 1 of 9

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

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 Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

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

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

SAFETY DATA SHEET

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

Revision date: 31-Oct-2013

Page 2 of 9

Version: 2.0

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):

Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Sulfadimethoxine	122-11-2	204-523-7	Xi;R43	Skin Sens. 1 (H317)	85.0

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Alginate acid	9005-32-7	232-680-1	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	Not Listed	*

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

SAFETY DATA SHEET

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g,
15g
Revision date: 31-Oct-2013

Page 3 of 9

Version: 2.0

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.

SAFETY DATA SHEET

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

Revision date: 31-Oct-2013

Page 4 of 9

Version: 2.0

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/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Sulfadimethoxine

Lithuania OEL - TWA	0.1 mg/m ³
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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

SAFETY DATA SHEET

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

Revision date: 31-Oct-2013

Page 5 of 9

Version: 2.0

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	Color:	White to off-white
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	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 .

SAFETY DATA SHEET

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

Revision date: 31-Oct-2013

Page 6 of 9

Version: 2.0

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)

Sulfadimethoxine

Mouse Oral LD50 > 16 g/kg

Mouse IP LD50 > 2g/kg

Rat Oral LD50 > 10g/kg

Alginic acid

Rat Oral LD50 > 5 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

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.

SAFETY DATA SHEET

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

15g

Revision date: 31-Oct-2013

Page 7 of 9

Version: 2.0

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

California Proposition 65

Not Listed

Not Listed

SAFETY DATA SHEET

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

Revision date: 31-Oct-2013

Page 8 of 9

Version: 2.0

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:	Present
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
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

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

Revision date: 31-Oct-2013

Page 9 of 9

Version: 2.0

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