This SDS packet was issued with item:

078912900

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078912901 078912913 078949244 078949246



Revision date: 05-Dec-2006 Version: 1.2 Page 1 of 6

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health
Pfizer Inc
Street
Pfizer Ltd,
Kent
CT13 9NJ
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Technical Services Phone: 1-800-366-5288

Emergency telephone number: Emergency telephone number:

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	%
Alginic 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:

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 2 of 6

15g

Revision date: 05-Dec-2006 Version: 1.2

×

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

Australian Hazard Classification

(NOHSC):

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

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Water, dry powder or foam extinguishers are recommended.

Hazardous Combustion Products: Not known

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn

out gear. Evacuate area and fight fire from a safe distance

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

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.

Measures for Environmental

Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to

avoid environmental release.

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.

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 3 of 6

15g

Revision date: 05-Dec-2006 Version: 1.2

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

ACGIH Threshold Limit Value (TWA)

Starch, pregelatinized

OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total

= 5 mg/m³ TWA = 10 mg/m³ TWA = 10 mg/m³ TWA

Magnesium stearate

Australia TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals

Australia TWA = $10 \text{ mg/m}^3 \text{ TWA}$

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 OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

Band (OEB):

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:

Hands: Not required for the normal use of this product. Wear protective gloves when working with

large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is

possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with

large quantities.

Respiratory protection: 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:

Physical State: Oblong, biconvex scored bolus tablet Color: White to off-white

Molecular Formula: Mixture Molecular Weight: Mixture

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 4 of 6

15g

Revision date: 05-Dec-2006 Version: 1.2

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/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 ToxicitySee Acute toxicity tableIngestion Acute ToxicitySee Acute toxicity tableEye Irritation / SensitizationDust 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

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 5 of 6

15g

Revision date: 05-Dec-2006 Version: 1.2

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

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 6 of 6

15g

Revision date: 05-Dec-2006 Version: 1.2

Starch, pregelatinized

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

XU

Present
232-679-6

Gelatin

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

XU

Present
232-554-6

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present
209-150-3

Sulfadimethoxine

Australia (AICS): Present
Standard for the Uniform Scheduling Schedule 4
for Drugs and Poisons:

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

Pfizer 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 a warranty of any kind, expressed or implied.

End of 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

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 2 of 9

15g

Revision date: 31-Oct-2013 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 includ

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	%
Alginic 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

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 3 of 9

15q

Revision date: 31-Oct-2013 Version: 2.0

4. FIRST AID MEASURES

Description of First Aid Measures

Eve 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.

Get medical attention. Do not induce vomiting unless directed by medical personnel. Never Ingestion:

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

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Symptoms and Effects of

Exposure: Identification and/or Section 11 - Toxicological Information. None known

Medical Conditions

Aggravated by Exposure:

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 / 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 Collecting:

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.

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 4 of 9

15g

Revision date: 31-Oct-2013 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

 10 mg/m^3

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Starch, pregelatinized

ACGIH I nresnoid Limit Value (I WA)	ro mg/m ^s
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/m³
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/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

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 5 of 9

15g

Revision date: 31-Oct-2013 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

room ventilation is adequate unless the process generates dust, mist or tumes. Keep air contamination levels below the exposure limits or within the OEB range listed above in this

section.

Personal Protective Refer to applicable national standards and regulations in the selection and use of personal

Equipment: 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 tabletColor:White to off-whiteOdor:No data available.Odor Threshold:No data available.

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility:
Water Solubility:
PH:
No data available
No data available
No data available.
No data available.
No data available.
No data available
No data available
No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

Polymerization:

No data available
No data available
No data available
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 .

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 6 of 9

15g

Revision date: 31-Oct-2013 Version: 2.0

10. STABILITY AND REACTIVITY

Hazardous Decomposition

No data available.

Products:

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 IΡ 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 $> 2000 \text{ mg/m}^3$

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable **Acute Toxicity Comments:**

at the highest dose used in the test. See Acute toxicity table

Inhalation Acute Toxicity

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.

Studies to evaluate the carcinogenic potential of sulfadimethoxine were not available. Other Chronic Effects/Carcinogenicity

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

In humans, sulfonamides administered prior to delivery can cause jaundice and hemolytic **Teratogenicity**

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.

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 7 of 9

15g

Revision date: 31-Oct-2013 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

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 8 of 9

15g

Revision date: 31-Oct-2013 Version: 2.0

15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

232-680-1

Starch, pregelatinized

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed
Present
Present

obligations of Register:

EU EINECS/ELINCS List 232-679-6

Magnesium stearate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Present

209-150-3

Gelatin

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

232-554-6

Sulfadimethoxine

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling

Not Listed

Not Listed

Present

Schedule 4

for Drugs and Poisons:

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.

Material Name: ALBON® (sulfadimethoxine) BOLUSES 5g, Page 9 of 9

15g

Revision date: 31-Oct-2013 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