

SAFETY DATA SHEET



Revision date: 28-Oct-2013

Version: 2.0

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

Product Identifier

Material Name: AMOXI-DROP® (amoxicillin)

Trade Name: AMOXI-DROP®
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: Off-white Powder

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Harmful

EU Symbol: Xn

EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

Label Elements

Signal Word: Danger

Hazard Statements: H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
May form combustible dust concentrations in air

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Precautionary Statements:

- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- 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
- P285 - In case of inadequate ventilation wear respiratory protection
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
- 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



Other Hazards

Short Term:

Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects:

May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Amoxicillin trihydrate	61336-70-7	Not Listed	Xn;R42/43	Skin Sens. 1,H317; Resp. Sens. 1,H334	14

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Non-hazardous ingredients	NOT APPLICABLE	Not Listed	Not Listed	Not Listed	*

Additional Information:

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

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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.
- 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 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:** Carbon dioxide, carbon monoxide
- Fire / Explosion Hazards:** During processing, dust may form explosive mixture in air. 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. Use caution in approaching fire.

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. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

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.

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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

Keep away from heat, sparks, flame and all other sources of ignition. Minimize dust generation and accumulation. Avoid breathing dust. 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 in a cool, dry, well-ventilated area.

Storage Temperature: <25°C (77°F)

Incompatible Materials: None known

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.

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.

Amoxicillin trihydrate

Zoetis OEB OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

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.

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 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	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:	None known
Incompatible Materials:	None known
Hazardous Decomposition Products:	May form toxic materials such as carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Amoxicillin trihydrate

Mouse Oral LD50 > 25 g/kg
Rat Oral LD50 > 15g/kg
Rabbit Oral LD50 > 12g/kg
Rat SC LD50 > 8g/kg

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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	No data available
Ingestion Acute Toxicity	See 'Acute toxicity' table, above. Dust may cause irritation
Skin Irritation / Sensitization	Dermal exposure to amoxicillin may cause allergic skin reaction. Amoxicillin is a semi-synthetic penicillin and has the potential for producing allergic reactions.
Chronic Effects/Carcinogenicity	No data available
Subchronic Effects	No data available

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Amoxicillin trihydrate

Embryo / Fetal Development Pig Oral 600 mg/kg/day NOEL Not teratogenic

Reproductive Effects

No adverse effects on fertility or reproduction were seen in rats treated with amoxicillin.

Teratogenicity

Amoxicillin was not teratogenic to pigs when administered by gavage at doses of 600 mg/kg on days 12-42.

Carcinogen Status:

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

At increase risk from exposure:

Allergy to penicillins

12. ECOLOGICAL INFORMATION

Environmental Overview:

Penicillins are susceptible to degradation by a number of microorganisms found in wastewater treatment plants and the general environment. Resulting degradation products are readily mineralized by environmental microorganisms.

Toxicity:

Amoxicillin trihydrate

<i>Daphnia magna</i> (Water Flea)	EC50	48 Hours	> 2300 mg/L
<i>Lepomis macrochirus</i> (Bluegill Sunfish)	EC50	96 Hours	> 930 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	EC50	96 Hours	> 1000 mg/L
<i>Microcystis aeruginosa</i> (Blue-green Alga)	EC50	48 Hours	0.0037 mg/L
<i>Selenastrum capricornutum</i> (Green Alga)	NOEC	48 Hours	250 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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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

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, Subdivision A



Amoxicillin trihydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Non-hazardous ingredients

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

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

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Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Xn - Harmful

R42/43 - May cause sensitization by inhalation and 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.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. 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