

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Clavamox® Tablets</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Clavamox * Clavamox/Clavulox/Synulox tablets * Amoxicillin trihydrate and clavulanate potassium tablets
<b>Recommended use</b>	Veterinary product used as antibiotic agent
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

**Supplier** Not available.

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
<b>Environmental hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Danger
<b>Hazard statement</b>	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Precautionary statement</b>	
<b>Prevention</b>	Avoid breathing dust/fume/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

<b>Response</b>	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE/doctor. Take off contaminated clothing and wash it before reuse.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Other hazards</b>	None known.
<b>Supplemental information</b>	Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Microcrystalline cellulose		9004-34-6	15-40
Amoxicillin trihydrate		61336-70-7	15-55*
Potassium Clavulanate (Clavulanic Acid)		61177-45-5	4-20*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

**Composition comments** \* Dose-dependent

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. If breathing is difficult, trained personnel should give oxygen.
<b>Skin contact</b>	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. May cause an allergic skin reaction. Dermatitis. Rash. Difficulty in breathing.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

### Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

### Environmental precautions

## 7. Handling and storage

### Precautions for safe handling

Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimise dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

### Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry, cool and well-ventilated place. @ ≤ 25C / 77F. Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>

#### Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>

#### Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	3 mg/m <sup>3</sup>	Respirable fraction.
		10 mg/m <sup>3</sup>	Total dust.

#### Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>

#### Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>

#### Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>	Total dust.

### Biological limit values

No biological exposure limits noted for the ingredient(s).

<b>Control banding approach</b>	Amoxicillin trihydrate: Zoetis OEB 2 - Sensitizer (control exposure to the range of 100ug/m3 to < 1000ug/m3, provide additional precautions to protect from skin contact)
	Potassium clavulanate: Zoetis OEB 2 - Sensitizer (control exposure to the range of 100ug/m3 to < 1000ug/m3, provide additional precautions to protect from skin contact)
<b>Appropriate engineering controls</b>	Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Other</b>	Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

## 9. Physical and chemical properties

<b>Appearance</b>	Tablet.
<b>Physical state</b>	Solid.
<b>Form</b>	Solid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.

<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Avoid heat, sparks, open flames and other ignition sources. Protect from sunlight.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin contact** May cause an allergic skin reaction.  
Microcrystalline cellulose Species: Rabbit  
Severity: Non-irritating

**Eye contact** Direct contact with eyes may cause temporary irritation.  
Microcrystalline cellulose Species: Rabbit  
Severity: Non-irritating

**Ingestion** Expected to be a low ingestion hazard.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. May cause an allergic skin reaction. Dermatitis. Rash. Difficulty in breathing. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

### Information on toxicological effects

**Acute toxicity** Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe.

Components	Species	Test results
Amoxicillin trihydrate (CAS 61336-70-7)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	> 25 g/kg
	Rabbit	> 12 g/kg
	Rat	> 15 g/kg
<b>Subcutaneous</b>		
LD50	Rat	> 8 g/kg
Clavulanic Acid/Amoxicillin Trihydrate		
<b>Chronic</b>		
<b>Oral</b>		
NOAEL	Rat	150 mg/kg/day, 28 weeks (Target organs: Liver, Gastrointestinal system)

Components	Species	Test results
<b><u>Subacute</u></b>		
<b>Oral</b>		
NOAEL	Mouse	50 - 500 mg/kg/day, 4 weeks (Target organs: None identified)
	Rat	50 - 500 mg/kg/day, 4 weeks (Target organs: None identified)
NOEL	Dog	90 mg/kg/day, 28 days (Target organs: Gastrointestinal system)
Microcrystalline cellulose (CAS 9004-34-6)		
<b><u>Acute</u></b>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg
Potassium Clavulanate (Clavulanic Acid) (CAS 61177-45-5)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Mouse	4526 mg/kg
	Rat	7936 mg/kg
<b><u>Chronic</u></b>		
<b>Intravenous</b>		
NOAEL	Dog	20 mg/kg/day, 26 weeks (Target organ: Liver)
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>		
Microcrystalline cellulose	Species: Rabbit	Severity: Non-irritating
<b>Respiratory or skin sensitisation</b>		
<b>Canada - Alberta OELs: Irritant</b>		
Microcrystalline cellulose (CAS 9004-34-6)	Irritant	
<b>Respiratory sensitisation</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
<b>Skin sensitisation</b>	May cause an allergic skin reaction.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known carcinogens are present at greater than 0.1%.	
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.	
<b>Developmental effects</b>		
Amoxicillin trihydrate	600 mg/kg/day Embryo / Fetal Development, Not teratogenic Result: NOEL Species: Pig Organ: Oral	
<b>Specific target organ toxicity - single exposure</b>	Not classified.	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Not an aspiration hazard.	

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test results
Amoxicillin trihydrate (CAS 61336-70-7)	EC50	Daphnia magna (Water Flea) > 2300 mg/l, 48 Hours
		Microcystis aeruginosa (Blue-green Alga) 0.0037 mg/l, 48 Hours
	LC50	Lepomis macrochirus (Bluegill Sunfish) > 930 mg/l, 96 Hours
		Oncorhynchus mykiss (Rainbow Trout) > 1000 mg/l, 96 Hours
	NOEC	Selenastrum capricornutum (Green Alga) 250 mg/l, 48 Hours

**Persistence and degradability** No data is available on the degradability of this product. 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.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions** Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** None known.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

**TDG**  
Not regulated as dangerous goods.

**IATA**  
Not regulated as dangerous goods.

**IMDG**  
Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

**Canadian regulations** This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

### Controlled Drugs and Substances Act

Not regulated.

### Export Control List (CEPA 1999, Schedule 3)

Not listed.

**Greenhouse Gases**

Not listed.

**Precursor Control Regulations**

Not regulated.

**International regulations****Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Not applicable.

**Kyoto protocol**

Not applicable.

**Montreal Protocol**

Not applicable.

**Basel Convention**

Not applicable.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information**

**Issue date** 21-April-2017

**Version No.** 01

**Disclaimer** Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information** Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties: Multiple Properties  
GHS: Classification