# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078944792

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

078564110 078564128 078564136 078564144 078931419 078931420 078931421 078931422 078944793 078944794 078944795

# MATERIAL SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Clavamox® Tablets**

**Trade Name:** Clavamox
**Chemical Family:** Mixture

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**

**Intended Use:** Veterinary product used as antibiotic agent

**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:** Tablets

**Classification of the Substance or Mixture**

**GHS - Classification**

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

**EU Classification:**

EU Indication of danger: Irritant
Harmful

EU Symbol: Xn
EU Risk Phrases:
R42/43 - May cause sensitization by inhalation and skin contact.

**Label Elements**

**Signal Word:** Danger
**Hazard Statements:** H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction

**Precautionary Statements:**

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P285 - In case of inadequate ventilation wear respiratory protection
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P304 + P341 - IF INHALED: If breathing is difficult, remove 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
P321 - Specific treatment (see supplemental first aid instructions on this label)
P363 - Wash contaminated clothing 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. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

**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.

**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 | % |
|---|---|---|---|---|---|
| Potassium clavulanate | 61177-45-5 | 262-640-9 | Not Listed | Not Listed | 13.5 |
| Amoxicillin trihydrate | 61336-70-7 | Not Listed | Xn;R42/43 | Skin Sens. 1,H317; Resp. Sens. 1,H334 | 53 |
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | Not Listed | Not Listed | * |

| 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.

**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:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek 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:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

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

**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 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.

## 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 as directed by product packaging.

**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.**

**Microcrystalline cellulose**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 mg/m$^3$ |
| **Australia TWA** | 10 mg/m$^3$ |
| **Belgium OEL - TWA** | 10 mg/m$^3$ |
| **Estonia OEL - TWA** | 10 mg/m$^3$ |
| **France OEL - TWA** | 10 mg/m$^3$ |
| **Ireland OEL - TWAs** | 10 mg/m$^3$<br>4 mg/m$^3$ |
| **Latvia OEL - TWA** | 2 mg/m$^3$ |
| **Vietnam O EL - TWAs** | 10 mg/m$^3$<br>5 mg/m$^3$ |
| **OSHA - Final PELS - TWAs:** | 15 mg/m$^3$ |
| **Portugal OEL - TWA** | 10 mg/m$^3$ |
| **Spain OEL - TWA** | 10 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 3 mg/m$^3$ |

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/m$^3$ to < 1000ug/m$^3$, provide additional precautions to protect from skin contact)

**Analytical Method:** Analytical method available for Amoxicillin. Contact Pfizer Inc for further information.

**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. Keep airborne contamination levels below the exposure limits 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).

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Tablet
**Color:** No data available.
**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

**Flammablity:**
**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 under normal conditions of use.
**Possibility of Hazardous Reactions**
**Oxidizing Properties:** No data available
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
**Hazardous Decomposition Products:** No data available

# 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**
**General Information:** 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

**Potassium clavulanate**
Mouse Oral LD50 4526 mg/kg
Rat Oral LD50 7936mg/kg

**Microcrystalline cellulose**
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg
**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.

**Irritation / Sensitization: (Study Type, Species, Severity)**

**Microcrystalline cellulose**
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Potassium clavulanate**
26 Week(s) Dog Intravenous20 mg/kg/day NOAEL Liver

**Clavulanic Acid/Amoxicillin Trihydrate**
4 Week(s) Mouse Oral 50/500 mg/kg/day NOAEL None identified
4 Week(s) Rat Oral 50/500 mg/kg/day NOAEL None identified
28 Day(s) Dog Oral 90 mg/kg/day NOEL Gastrointestinal system
28 Week(s) Rat Oral 150 mg/kg/day NOAEL Liver, Gastrointestinal system

**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

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

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:**
**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

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

## 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

## 15. REGULATORY INFORMATION

**Potassium clavulanate**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **EU EINECS/ELINCS List** | 262-640-9 |

**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 |

**Microcrystalline cellulose**

| | |
|---|---|
| **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** | 232-674-9 |

## 16. OTHER INFORMATION

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

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

Xn - Harmful
Xi - Irritant

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.

**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**