# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078931420

**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 078931421 078931422 078944792 078944793 078944794 078944795

# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **Clavamox® Tablets**

**Other means of identification**

**Synonyms** Clavamox * Clavamox/Clavulox/Synulox tablets * Amoxicillin trihydrate and clavulanate potassium tablets

**Recommended use** Veterinary product used as antibiotic agent

**Recommended restrictions** Not for human use

**Manufacturer/Importer/Supplier/Distributor information**

**Company Name (US)** Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

**Rocky Mountain Poison and Drug Center** 1-866-531-8896

**Product Support/Technical Services** 1-800-366-5288

**Emergency telephone numbers** CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

**Company Name (EU)** Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

**Contact E-Mail** VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards**

| | |
|---|---|
| Sensitization, respiratory | Category 1 |
| Sensitization, skin | Category 1 |

**Environmental hazards** Not classified.

**OSHA defined hazards** Not classified.

**Label elements**



**Signal word** Danger

**Hazard statement** May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Precautionary statement**

**Prevention** Avoid breathing dust/fume/gas/mist/vapors/spray. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

**Response** If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. Wash contaminated clothing before reuse.

**Storage** Store away from incompatible materials.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.



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**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** 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* |

**Composition comments** * Dose-dependent
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## 4. First-aid measures

**Inhalation** Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. If breathing is difficult, trained personnel should give oxygen.

**Skin contact** 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.

**Eye contact** 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.

**Ingestion** Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control center 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.

**Most important symptoms/effects, acute and delayed** 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.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

**General information** 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

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical** During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions** Use water spray to cool unopened containers.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** 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.



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**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.

**Environmental precautions**

Avoid discharge into drains, water courses or onto the ground.

## 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. Minimize 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**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

| Components | Type | Value | Form |
|---|---|---|---|
| Microcrystalline cellulose (CAS 9004-34-6) | PEL | 5 mg/m3 | Respirable fraction. |
| | | 15 mg/m3 | Total dust. |

**US. ACGIH Threshold Limit Values**

| Components | Type | Value |
|---|---|---|
| Microcrystalline cellulose (CAS 9004-34-6) | TWA | 10 mg/m3 |

**US. NIOSH: Pocket Guide to Chemical Hazards**

| Components | Type | Value | Form |
|---|---|---|---|
| Microcrystalline cellulose (CAS 9004-34-6) | TWA | 5 mg/m3 | Respirable. |
| | | 10 mg/m3 | Total |

**Biological limit values**

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

**Control banding approach**

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)

**Appropriate engineering controls**

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.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

**Skin protection**

**Hand protection**

Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Other**

Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.



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| | |
|---|---|
| **Respiratory protection** | 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. |
| **Thermal hazards** | Not applicable. |
| **General hygiene considerations** | 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

| | |
|---|---|
| **Appearance** | Tablet. |
| **Physical state** | Solid. |
| **Form** | Solid. |
| **Color** | Not available. |
| **Odor** | Not available. |
| **Odor threshold** | Not available. |
| **pH** | Not available. |
| **Melting point/freezing point** | Not available. |
| **Initial boiling point and boiling range** | Not available. |
| **Flash point** | Not available. |
| **Evaporation rate** | Not available. |
| **Flammability (solid, gas)** | Not available. |
| **Upper/lower flammability or explosive limits** | |
| **Flammability limit - lower (%)** | Not available. |
| **Flammability limit - upper (%)** | Not available. |
| **Explosive limit - lower (%)** | Not available. |
| **Explosive limit - upper (%)** | Not available. |
| **Vapor pressure** | Not available. |
| **Vapor density** | Not available. |
| **Relative density** | Not available. |
| **Solubility(ies)** | |
| **Solubility (water)** | Not available. |
| **Partition coefficient (n-octanol/water)** | Not available. |
| **Auto-ignition temperature** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not available. |
| **Other information** | |
| **Explosive properties** | Not explosive. |
| **Oxidizing properties** | Not oxidizing. |

## 10. Stability and reactivity

| | |
|---|---|
| **Reactivity** | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| **Chemical stability** | Material is stable under normal conditions. |
| **Possibility of hazardous reactions** | No dangerous reaction known under conditions of normal use. |
| **Conditions to avoid** | Contact with incompatible materials. Avoid heat, sparks, open flames and other ignition sources. Protect from sunlight. |
| **Incompatible materials** | Strong oxidizing agents. |



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**Hazardous decomposition products** 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. Prolonged inhalation may be harmful.

**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) | | |
| **Acute** | | |
| **Oral** | | |
| LD50 | Mouse | > 25 g/kg |
| | Rabbit | > 12 g/kg |
| | Rat | > 15 g/kg |
| **Subcutaneous** | | |
| LD50 | Rat | > 8 g/kg |
| Clavulanic Acid/Amoxicillin Trihydrate | | |
| **Chronic** | | |
| **Oral** | | |
| NOAEL | Rat | 150 mg/kg/day, 28 weeks (Target organs: Liver, Gastrointestinal system) |
| **Subacute** | | |
| **Oral** | | |
| 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) | | |
| **Acute** | | |
| **Dermal** | | |
| LD50 | Rabbit | > 2000 mg/kg |
| **Oral** | | |
| LD50 | Rat | > 5000 mg/kg |



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| Components | Species | Test Results |
|---|---|---|
| Potassium Clavulanate (Clavulanic Acid) (CAS 61177-45-5) | | |
| **Acute** | | |
| **Oral** | | |
| LD50 | Mouse | 4526 mg/kg |
| | Rat | 7936 mg/kg |
| **Chronic** | | |
| **Intravenous** | | |
| NOAEL | Dog | 20 mg/kg/day, 26 weeks (Target organ: Liver) |

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.

**Eye Contact**

Microcrystalline cellulose — Species: Rabbit; Severity: Non-irritating

**Respiratory or skin sensitization**

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

**Skin sensitization** May cause an allergic skin reaction.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** 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%.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.

**Developmental effects**

Amoxicillin trihydrate — 600 mg/kg/day Embryo / Fetal Development, Not teratogenic
Result: NOEL
Species: Pig
Organ: Oral

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged inhalation may be harmful.

## 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 |



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| Components | | Species | Test Results |
|---|---|---|---|
| | 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

**DOT**

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

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.



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**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**
Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**
Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**
Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**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, including date of preparation or last revision

**Issue date** 06-10-2013

**Revision date** 04-21-2017

**Version #** 05

**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** This document has undergone significant changes and should be reviewed in its entirety.



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