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
- Product Support/Technical Services
- 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:


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.
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td></td>
<td>9004-34-6</td>
<td>15-40</td>
</tr>
<tr>
<td>Amoxicillin trihydrate</td>
<td></td>
<td>61336-70-7</td>
<td>15-55*</td>
</tr>
<tr>
<td>Potassium Clavulanate (Clavulanic Acid)</td>
<td></td>
<td>61177-45-5</td>
<td>4-20*</td>
</tr>
</tbody>
</table>

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.
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.

Ensure 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.

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.

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)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>PEL</td>
<td>5 mg/m3</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m3</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

### US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m3</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>5 mg/m3</td>
<td>Respirable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m3</td>
<td>Total</td>
</tr>
</tbody>
</table>

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

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)

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.

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

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

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

Respiratory protection

Thermal hazards

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

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

Eye contact
Microcrystalline cellulose
Direct contact with eyes may cause temporary irritation.
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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin trihydrate (CAS 61336-70-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>&gt; 25 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>&gt; 12 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 15 g/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subcutaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 8 g/kg</td>
</tr>
<tr>
<td>Clavulanic Acid/Amoxicillin Trihydrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>Rat</td>
<td>150 mg/kg/day, 28 weeks (Target organs: Liver, Gastrointestinal system)</td>
</tr>
<tr>
<td>Subacute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>Mouse</td>
<td>50 - 500 mg/kg/day, 4 weeks (Target organs: None identified)</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>50 - 500 mg/kg/day, 4 weeks (Target organs: None identified)</td>
</tr>
<tr>
<td>NOEL</td>
<td>Dog</td>
<td>90 mg/kg/day, 28 days (Target organs: Gastrointestinal system)</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rabbit</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 5000 mg/kg</td>
</tr>
</tbody>
</table>
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**
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.

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**
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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin trihydrate (CAS 61336-70-7)</td>
<td>Daphnia magna (Water Flea)</td>
<td>&gt; 2300 mg/L, 48 Hours</td>
</tr>
<tr>
<td></td>
<td>Microcystis aeruginosa (Blue-green Alga)</td>
<td>0.0037 mg/L, 48 Hours</td>
</tr>
<tr>
<td></td>
<td>Lepomis macrochirus (Bluegill Sunfish)</td>
<td>&gt; 930 mg/L, 96 Hours</td>
</tr>
<tr>
<td></td>
<td>Oncorhyncus mykiss (Rainbow Trout)</td>
<td>&gt; 1000 mg/L, 96 Hours</td>
</tr>
</tbody>
</table>
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.
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.
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
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

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

*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.