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

Product Identifier

Material Name: Amoxicillin Trihydrate and Clavulanate Potassium Chewable Tablets

Trade Name: Clavamox, Synulox
Synonyms: Clavamox Chewable Tablets; Synulox Chewable Tablets
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
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Brown tablets

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

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
Precautionary Statements: P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P285 - In case of inadequate ventilation wear respiratory protection  
P272 - Contaminated work clothing should not be allowed out of the workplace  
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  
P501 - Dispose of contents/container in accordance with all local and national regulations

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.  

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>15 - 40</td>
</tr>
<tr>
<td>Amoxicillin trihydrate</td>
<td>61336-70-7</td>
<td>Not Listed</td>
<td>Xn;R42/43</td>
<td>Skin Sens. 1 (H317) Resp. Sens. 1 (H334)</td>
<td>15</td>
</tr>
<tr>
<td>Potassium clavulanate</td>
<td>61177-45-5</td>
<td>262-640-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>4</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;2</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;2</td>
</tr>
</tbody>
</table>

Additional Information: 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: 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. If irritation occurs or persists, get 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: People allergic to penicillins may exhibit cross reaction sensitivity.

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

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.

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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
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/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWA 10 mg/m³
Latvia OEL - TWA 2 mg/m³
Vietnam OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWA 3 mg/m³

Colloidal silicon dioxide
Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
Latvia OEL - TWA 1 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed
Slovakia OEL - TWA 4.0 mg/m³
SAFETY DATA SHEET

Material Name: Amoxicillin Trihydrate and Clavulanate
Potassium Chewable Tablets
Revision date: 07-Aug-2014

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls:

- Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. 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:

- Not required for the normal use of this product. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

- Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin:

- Not required for the normal use of this product. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

- Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. 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
Odor: No data available.
Molecular Formula: Mixture

Color: Brown, mottled
Odor Threshold: No data available.
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.
9. PHYSICAL AND CHEMICAL PROPERTIES

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 under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid:
- Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions. Keep away from heat, spark, flames and all other sources of ignition.

Incompatible Materials:
- As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products:
- Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:
Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

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

**Amoxicillin trihydrate**
- Mouse Oral LD50 > 25 g/kg
- Rat Oral LD50 > 15g/kg
- Rabbit Oral LD50 > 12g/kg
- Rat SC LD50 > 8g/kg

**Microcrystalline cellulose**
- Rat Oral LD50 > 5000 mg/kg
11. TOXICOLOGICAL INFORMATION

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 Intravenous 20 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.

Colloidal silicon dioxide
IARC: Group 3 (Not Classifiable)
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)

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (Water Flea)</td>
<td>EC50</td>
<td>48 Hours</td>
<td>&gt; 2300 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Lepomis macrochirus</em> (Bluegill Sunfish)</td>
<td>EC50</td>
<td>96 Hours</td>
<td>&gt; 930 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Oncorhynchus mykiss</em> (Rainbow Trout)</td>
<td>EC50</td>
<td>96 Hours</td>
<td>&gt; 1000 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Microcystis aeruginosa</em> (Blue-green Alga)</td>
<td>EC50</td>
<td>48 Hours</td>
<td>0.0037 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Selenastrum capricornutum</em> (Green Alga)</td>
<td>NOEC</td>
<td>48 Hours</td>
<td>250 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

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
15. REGULATORY INFORMATION

WHMIS hazard class:
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Microcrystalline cellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS):
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: EU EINECS/ELINCS List 232-674-9

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

Potassium clavulanate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List 262-640-9

Colloidal silicon dioxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS):
- EU EINECS/ELINCS List 231-545-4

Magnesium stearate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS):
- EU EINECS/ELINCS List 209-150-3

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
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 SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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.

End of Safety Data Sheet