SAFETY DATA SHEET

Amoxicillin Trihydrate and Clavulanate Potassium Chewable Tablets

Section 1. Identification

Product identifier : Amoxicillin Trihydrate and Clavulanate Potassium Chewable Tablets

Other means of identification : Clavamox
Clavamox Chewable Tablets
Synulox
Synulox Chewable Tablets
Synulox Palatable Tablets

Product type : Solid.

Relevant identified uses of the substance or mixture and uses advised against

Identified uses
Veterinary product used as antibiotic agent

Uses advised against
Not for human use

Supplier's details : Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

1-800-461-0917
All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx

Emergency telephone number (with hours of operation) : CHEMTREC (24 hours): 1-800-424-9300

International CHEMTREC (24 hours): +1-703-527-3887

Rocky Mountain Poison & Drug Safety: 1-866-531-8896
Product support/Technical services: 1-888-963-8471

Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Section 2. Hazard identification

Classification of the substance or mixture : RESPIRATORY SENSITIZATION - Category 1
SKIN SENSITIZATION - Category 1
AQUATIC HAZARD (ACUTE) - Category 3
AQUATIC HAZARD (LONG-TERM) - Category 3

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Harmful to aquatic life with long lasting effects.

Section 2. Hazard identification

Precautionary statements

Prevention : Wear protective gloves. Wear respiratory protection. Avoid release to the environment. Avoid breathing dust. Contaminated work clothing should not be allowed out of the workplace.

Response : IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice or attention. Take off contaminated clothing and wash it before reuse.

Storage : Not applicable.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	Synonyms	% (w/w)	Identifiers	
Cellulose (paper fibers)	Cellulose (paper fibers)	≥10 - ≤30	CAS: 9004-34-6	
amoxicillin trihydrate	-	≥10 - ≤30	CAS: 61336-70-7	
potassium clavulanate	-	≥1 - ≤5	CAS: 61177-45-5	
silicon dioxide	-	≥1 - ≤5	CAS: 7631-86-9	
magnesium distearate	-	≥1 - ≤5	CAS: 557-04-0	

Ranges if listed above for hazardous ingredient(s) are prescribed ranges. The actual concentration(s) or actual concentration range(s) are being withheld as a trade secret.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. In the event of any complaints or symptoms, avoid further exposure.

Section 4. First-aid measures

Skin contact : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Rash. May cause allergic respiratory reaction. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Exposed individuals may experience eye tearing, redness, and discomfort. Difficulty in breathing.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Hazardous thermal decomposition products : Decomposition products may include the following materials:, carbon dioxide, carbon monoxide, nitrogen oxides, sulfur oxides, metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Keep unnecessary personnel away.

For emergency responders : Keep unnecessary personnel away. If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid release to the environment. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Do not store above the following temperature: 25°C (77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Section 8. Exposure controls/personal protection

Ingredient name	Exposure limits
Cellulose (paper fibers)	**CA Saskatchewan Provincial (Canada, 4/2021)** STEL 15 minutes: 20 mg/m³. Form: fibre. TWA 8 hours: 10 mg/m³. Form: fibre. **CA British Columbia Provincial (Canada, 4/2024)** Notes: The 8-hour TWA listed in the Table is for the total dust. The substance also has an 8-hour TWA of 3 mg/m3 for the respirable fraction. TWA 8 hours: 10 mg/m³. Form: Total dust. TWA 8 hours: 3 mg/m³. Form: respirable fraction. **CA Ontario Provincial (Canada, 6/2019)** TWA 8 hours: 10 mg/m³. **CA Quebec Provincial (Canada, 2/2024)** TWAEV 8 hours: 10 mg/m³. Form: total particulate matter. **CA Alberta Provincial (Canada, 3/2023)** OEL 8 hours: 10 mg/m³.
magnesium distearate	**CA Saskatchewan Provincial (Canada, 4/2021) [Stearates]** STEL 15 minutes: 20 mg/m³. TWA 8 hours: 10 mg/m³. **CA British Columbia Provincial (Canada, 4/2024) [stearates]** Notes: Does not include stearates of toxic metals. TWA 8 hours: 10 mg/m³. Form: Inhalable. TWA 8 hours: 3 mg/m³. Form: Respirable. **CA Ontario Provincial (Canada, 6/2019) [Stearates]** TWA 8 hours: 10 mg/m³. Form: Inhalable particulate matter.. TWA 8 hours: 3 mg/m³. Form: Respirable particulate matter.. **CA Quebec Provincial (Canada, 2/2024) [stearates]** TWAEV 8 hours: 10 mg/m³. Form: inhalable aerosol fraction. TWAEV 8 hours: 3 mg/m³. Form: respirable aerosol fraction. **CA Alberta Provincial (Canada, 3/2023) [Stearates, excludes stearates of toxic metals]** OEL 8 hours: 10 mg/m³.

Biological exposure indices

No exposure indices known.

Control Banding Approach

amoxicillin trihydrate: OEB 2 - Sensitizer (control exposure to the range of 100ug/m3 to < 1000ug/m3, provide additional precautions to protect from skin contact)
potassium clavulanate: OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

Section 8. Exposure controls/personal protection

Appropriate engineering controls : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. 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.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Solid. [Tablet.]

Color : Brown.

Odor : Not available.

Odor threshold : Not available.

pH : Not available.

Melting point/freezing point : Not available.

Section 9. Physical and chemical properties

Boiling point or initial boiling point and boiling range : Not available.

Flash point : Not applicable.

Evaporation rate : Not available.

Flammability : Not available.

Lower and upper explosion limit/flammability limit : Not applicable.

Vapor pressure : Not available.

Relative vapor density : Not applicable.

Relative density : Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not applicable.

Auto-ignition temperature : Not applicable.

Decomposition temperature : Not available.

Viscosity : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): Not available.

Particle characteristics

Pmax : Not available.

Kst : Not available.

Min. Ignition Temperature (Dust) : Not available.

Minimum ignition energy (MIE) - dust cloud : Not available.

Median particle size : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : No specific data.

Remarks : Fluorine

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result
Cellulose (paper fibers)	**Rabbit - Dermal - LD50** >2000 mg/kg **Rat - Oral - LD50** >5000 mg/kg
amoxicillin trihydrate	**Mouse - Oral - LD50** >25 g/kg **Rabbit - Oral - LD50** >12 g/kg **Rat - Oral - LD50** >15 g/kg **Rat - Subcutaneous - LD50** >8 g/kg **Rat - Oral - LD50** >15 g/kg
potassium clavulanate	**Mouse - Oral - LD50** 4526 mg/kg **Rat - Oral - LD50** 7936 mg/kg **Rat - Oral - LD50** 7936 mg/kg Toxic effects: Behavioral - Somnolence (general depressed activity) Lung, Thorax, or Respiration - Dyspnea
magnesium distearate	**Rat - Oral - LD50** >2000 mg/kg

Conclusion/Summary [Product] : Not applicable.

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product] : Not applicable.

Serious eye damage/eye irritation

Product/ingredient name	Result
Cellulose (paper fibers)	**Rabbit - Eyes - Not irritant**
silicon dioxide	**Rabbit - Eyes - Mild irritant** Duration of treatment/exposure: 24 hours Amount/concentration applied: 25 mg

Conclusion/Summary [Product] : Not applicable.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] : Not applicable.

Respiratory or skin sensitization

Not available.

Section 11. Toxicological information

Skin

Conclusion/Summary [Product] : May cause an allergic skin reaction.

Respiratory

Conclusion/Summary [Product] : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Specific target organ toxicity (single exposure)

Not applicable.

Specific target organ toxicity (repeated exposure)

Not applicable.

Aspiration hazard

Not applicable.

Information on the likely routes of exposure

Not available.

Potential acute health effects

May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Rash. May cause allergic respiratory reaction. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Exposed individuals may experience eye tearing, redness, and discomfort. Difficulty in breathing.

Potential chronic health effects

Product/ingredient name	Result
potassium clavulanate	**Chronic - Dog - Intravenous - NOAEL** 20 mg/kg [26 weeks]

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Germ cell mutagenicity

Not available.

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Carcinogenicity

Not available.

Classification

Product/ingredient name	IARC	NTP	ACGIH
silicon dioxide	3	-	-
magnesium distearate	-	-	A4

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Reproductive toxicity

Product/ingredient name	Result

Section 11. Toxicological information

amoxicillin trihydrate

Pig - Oral
600 mg/kg [7 days per week]
Effects: NOEL No teratogenic effect.

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Cellulose (paper fibers)	N/A	2500	N/A	N/A	N/A
potassium clavulanate	7936	N/A	N/A	N/A	N/A
magnesium distearate	2500	N/A	N/A	N/A	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result
amoxicillin trihydrate	**Acute - NOEC** Algae - *Selenastrum capricornutum* 250 mg/l [48 hours] **Acute - EC50** Daphnia - *Daphnia magna* >2300 mg/l [48 hours] **Acute - LC50** Fish - *Lepomis macrochirus* >930 mg/l [96 hours] **Acute - LC50** Fish - *Oncorhynchus mykiss* >1000 mg/l [96 hours]
silicon dioxide	**Acute - EC50 - Fresh water** ISO Daphnia - Water flea - *Daphnia magna* - Neonate Age: 2 to 26 hours 2.2 g/l [48 hours] Effect: Intoxication **Chronic - NOEC - Fresh water** ISO Daphnia - Water flea - *Daphnia magna* - Neonate Age: 2 to 26 hours 12.5 mg/l [21 days] Effect: Reproduction

Conclusion/Summary [Product] : This material is harmful to aquatic life with long lasting effects.

Persistence and degradability

Not available.

Conclusion/Summary [Product] : Not available.

Section 12. Ecological information

Bioaccumulative potential

Not available.

Mobility in soil

Soil/Water partition coefficient : Not available.

Other adverse effects

No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : 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. The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Canadian lists

Canadian NPRI : None of the components are listed.

CEPA Toxic substances : None of the components are listed.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : Not determined.

Canada : Not determined.

China : Not determined.

Eurasian Economic Union : **Russian Federation inventory**: Not determined.

Japan : **Japan inventory (CSCL)**: Not determined.
Japan inventory (ISHL): Not determined.

New Zealand : Not determined.

Philippines : Not determined.

Republic of Korea : Not determined.

Taiwan : Not determined.

Thailand : Not determined.

Turkey : Not determined.

United States : Not determined.

Viet Nam : Not determined.

Section 16. Other information

History

Date of issue/Date of revision : 7/22/2025

Date of previous issue : 5/27/2025

Version : 1.01

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
DOT = Department of Transportation
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
HPR = Hazardous Products Regulations
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
IMO = International Maritime Organization
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available

Section 16. Other information

SGG = Segregation Group
TDG = Transportation of Dangerous Goods
UN = United Nations

Procedure used to derive the classification

Classification	Justification
RESPIRATORY SENSITIZATION - Category 1	Calculation method
SKIN SENSITIZATION - Category 1	Calculation method
AQUATIC HAZARD (ACUTE) - Category 3	Expert judgment
AQUATIC HAZARD (LONG-TERM) - Category 3	Expert judgment

References : Not available.

Notice to reader

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.