

SAFETY DATA SHEET



1. Identification

Product identifier Amoxicillin Trihydrate and Clavulanate Potassium Chewable Tablets

Other means of identification

Synonyms Clavamox * Synulox * Clavamox Chewable Tablets * Synulox Chewable Tablets

Recommended use Veterinary product used as antibiotic agent

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

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

Rocky Mountain Poison & Drug Safety 1-866-531-8896

Product Support/Technical Services 1-888-963-8471

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

Company Name (CA) Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

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

Contact E-Mail productsupport@zoetis.com

Product Support 1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard identification

Physical hazards Not classified.

Health hazards Sensitization, respiratory Category 1
Sensitization, skin Category 1

Environmental hazards Hazardous to the aquatic environment, acute hazard Category 3
Hazardous to the aquatic environment, long-term hazard Category 3

Label elements



Signal word Danger

Hazard statement 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.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves.

Response	IF ON SKIN: Wash with plenty of water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTRE/doctor. Take off contaminated clothing and wash it before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Supplemental information	Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe.
Other hazards	None known.

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
Potassium Clavulanate (Clavulanic Acid)		61177-45-5	4
Colloidal silicon dioxide		7631-86-9	<2
Magnesium stearate		557-04-0	<2

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The exact percentage composition of this mixture has been withheld as a trade secret. Other components below reportable levels

4. First-aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. 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. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Exposed individuals may experience eye tearing, redness, and discomfort. Difficulty in breathing. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. May cause allergic respiratory reaction.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.
General information	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. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse. For personal protection, see section 8 of the SDS.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. Avoid contact with eyes, skin, and clothing.

Methods and materials for containment and cleaning up

Remove sources of ignition. Ensure adequate ventilation. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike far ahead of spill for later disposal. Shovel the material into waste container. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. Put material in suitable, covered, labeled containers. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid dust formation. Ensure adequate ventilation. Do not taste or swallow. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Conditions for safe storage, including any incompatibilities

Keep away from heat and sources of ignition. Store in tightly closed container. Keep tightly closed in a dry, cool and well-ventilated place. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Storage Temperature: ≤ 25C / 77F.

8. Exposure controls/personal protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Inhalable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	3 mg/m ³	Respirable particles.
		10 mg/m ³	Total
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Total dust.
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m ³	Respirable.
		10 mg/m ³	Inhalable

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Total dust.

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Inhalable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	

Canada. New Brunswick OELs: Threshold Limit Values (TLVs) Based on the 1991 and 1997 ACGIH TLVs and BEIs Publication (New Brunswick Regulation 91-191)

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	3 mg/m ³	Respirable.
		10 mg/m ³	Inhalable
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m ³	Respirable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	10 mg/m ³	Total dust.
Magnesium stearate (CAS 557-04-0)	TWA	10 ppm	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Total dust.

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	15 minute	6 mg/m ³	Respirable fraction.
		20 mg/m ³	Inhalable fraction.
Magnesium stearate (CAS 557-04-0)	15 minute	20 mg/m ³	
Microcrystalline cellulose (CAS 9004-34-6)	15 minute	20 mg/m ³	Fiber.

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

Good general ventilation 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. 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.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Other	Wear appropriate chemical resistant clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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. 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.
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.
Colour	Brown.
Odour	Not available.
Odour 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	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour 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.
Oxidising properties	Not oxidising.

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	Avoid dispersion as a dust cloud. Avoid heat, sparks, open flames and other ignition sources. Protect from sunlight. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents. Fluorine.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

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. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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 Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics Exposed individuals may experience eye tearing, redness, and discomfort. Direct contact with eyes may cause temporary irritation. Difficulty in breathing. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. 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 Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

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)
Colloidal silicon dioxide (CAS 7631-86-9)		
Acute		
Oral		
LD50	Rat	> 22500 mg/kg

Components	Species	Test Results
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	> 2000 mg/kg
Microcrystalline cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
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 sensitisation		
Canada - Alberta OELs: Irritant		
Colloidal silicon dioxide (CAS 7631-86-9)	Irritant	
Magnesium stearate (CAS 557-04-0)	Irritant	
Microcrystalline cellulose (CAS 9004-34-6)	Irritant	
Respiratory sensitisation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitisation	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	None of the other components of this mixture are listed as a carcinogen by IARC, NTP or OSHA.	
ACGIH Carcinogens		
Magnesium stearate (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.	
Canada - Manitoba OELs: carcinogenicity		
Magnesium stearate (CAS 557-04-0)	Not classifiable as a human carcinogen.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Colloidal silicon dioxide (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.	
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	Based on available data, the classification criteria are not met.	

Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	Prolonged inhalation may be harmful.
Further information	May cause allergic respiratory and skin reactions. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe.

12. Ecological information

Ecotoxicity Avoid release to the environment. Harmful to aquatic life with long lasting effects.

Components	Species	Test Results
Amoxicillin trihydrate (CAS 61336-70-7)		
	EC50	Microcystis aeruginosa (Blue-green Alga) 0.0037 mg/l, 48 Hours
Aquatic		
Algae	NOEC	Selenastrum capricornutum (Green Alga) 250 mg/l, 48 Hours
Crustacea	EC50	Daphnia magna (Water Flea) > 2300 mg/l, 48 Hours
Fish	LC50	Lepomis macrochirus (Bluegill Sunfish) > 930 mg/l, 96 Hours Oncorhynchus mykiss (rainbow trout) > 1000 mg/l, 96 Hours

Persistence and degradability No data available for this product.

Bioaccumulative potential No data available for this product.

Mobility in soil No data available for this product.

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 discharge into drains, water courses or onto the ground. 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 The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

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

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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**Issue date** 04-September-2019**Revision date** 30-May-2023**Version No.** 02**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.