

SAFETY DATA SHEET



1. Identification

Product identifier Clavulox Ready To Use Broad Spectrum Antibiotic Injectable Suspension

Other means of identification

Synonyms SYNULOX Ready-To-Use Injection * Clavamox/Clavulox/Synulox RTU

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product used as antibiotic agent

Restrictions on use Not for human use

Details of manufacturer or importer

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Emergency Phone 1800 814 883 (all hours)

Police and Fire Brigade Dial 000

If ineffective Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards Not classified.

Health hazards Sensitization, respiratory Category 1

Sensitization, skin Category 1

Environmental hazards Not classified.

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word Danger

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

Precautionary statement(s)

Prevention Avoid breathing mist or vapour. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

Response IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Storage Store away from incompatible materials.

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

Other hazards which do not result in classification 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

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Amoxicillin trihydrate	61336-70-7	12-18
Potassium Clavulanate (Clavulanic Acid)	61177-45-5	2-6
Coconut oil, fractionated	Mixture	*

Composition comments *Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. For breathing difficulties, oxygen may be necessary.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Personal protection for first-aid responders Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

Symptoms caused by exposure Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash. Direct contact with eyes may cause temporary irritation.

Medical attention and special treatment Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

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 fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem code None.

General fire hazards No unusual fire or explosion hazards noted.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away.

For emergency responders Use personal protection recommended in Section 8 of the SDS. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ventilate the contaminated area. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

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.

Methods and materials for containment and cleaning up ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid release to the environment. Ensure adequate ventilation. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Clean surface thoroughly to remove residual contamination.

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.

7. Handling and storage

Precautions for safe handling Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Observe good industrial hygiene practices. Provide adequate ventilation. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Avoid accidental injection. Avoid release to the environment. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Wash contaminated clothing before reuse.

Conditions for safe storage, including any incompatibilities Store locked up. Store in a well-ventilated place. Protect from sunlight. Keep away from heat, sparks and open flame. Store below 25°C. Do not freeze. Keep away from food, drink and animal feeding stuffs.

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits No exposure limits noted for ingredient(s).

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 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. 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. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other

Wear appropriate chemical resistant clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. If ventilation is insufficient, suitable respiratory protection must be provided. 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. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards Not applicable.

Hygiene measures 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 Oily. Suspension.

Material name: Clavulox Ready To Use Broad Spectrum Antibiotic Injectable Suspension

Physical state	Liquid.
Form	Liquid.
Colour	Off-white to pale buff-colored
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 applicable.
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.
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 physical and chemical parameters	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
Specific gravity	0.98 - 1.02 @ 25C/77F

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. Protect from sunlight. Keep away from heat, sparks, flame and all other sources of ignition.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

11. Toxicological information

Information on possible routes of exposure

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.

Symptoms related to exposure Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash. Direct contact with eyes may cause temporary irritation. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

Acute toxicity May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components	Species	Test Results
Amoxicillin trihydrate (CAS 61336-70-7)		
<u>Acute</u>		
Oral		
LD50	Mouse	> 25 g/kg
	Rabbit	> 12 g/kg
	Rat	> 15 g/kg
Subcutaneous		
LD50	Rat	> 8 g/kg
Clavulanic Acid/Amoxicillin Trihydrate		
<u>Chronic</u>		
Oral		
NOAEL	Rat	150 mg/kg/day, 28 weeks (Target organs: Liver, Gastrointestinal system)
<u>Subacute</u>		
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)
Potassium Clavulanate (Clavulanic Acid) (CAS 61177-45-5)		
<u>Acute</u>		
Oral		
LD50	Mouse	4526 mg/kg
	Rat	7936 mg/kg
<u>Chronic</u>		
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/irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitisation		
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	Due to partial or complete lack of data the classification is not possible.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects. Based on available data, the classification criteria are not met.	
Developmental effects		
Amoxicillin trihydrate	600 mg/kg/day Embryo / Fetal Development, Not teratogenic Result: NOEL Species: Pig Organ: Oral	

Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Other information	Symptoms may be delayed.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test Results
Amoxicillin trihydrate (CAS 61336-70-7)	EC50	Microcystis aeruginosa (Blue-green Alga) 0.0037 mg/l, 48 Hours
	NOEC	Selenastrum capricornutum (Green Alga) 250 mg/l, 48 Hours
Aquatic		
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 is available on the degradability of this product.
Bioaccumulative potential	No data available.
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 methods	Avoid release to the environment. 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.
Residual waste	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

ADG	Not regulated as dangerous goods.
RID	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 established.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

APVMA No. 40271

Poison Schedule (Product) - Schedule 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

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	30-October-2016
Revision date	01-November-2021
Further information	None known.
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	Identification: Restrictions on use Composition/information on ingredients: Component information Accidental release measures: Methods and materials for containment and cleaning up Accidental release measures: For non-emergency personnel Toxicological information: Acute toxicity Toxicological information: Other information Toxicological information: Reproductivity Disposal considerations: Disposal methods Regulatory information: National regulations Other information: References Other information: Further information