

SAFETY DATA SHEET



1. Identification

Product identifier Clavulox LC Broad Spectrum Intramammary Antibiotic For Lactating Cows (APVMA No: 47115)

Other means of identification

Synonyms Amoxicillin trihydrate/potassium clavulanate * Clavamox * Clavulox * Synulox LC

Recommended use of the chemical and restrictions on use

Recommended use Veterinary antibiotic for intramammary infusion

Restrictions on use Not for human use

Details of manufacturer or importer

Manufacturer

Company Name (AU) Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard
Rhodes NSW 2138 AUSTRALIA

Tel 1800 814 883
Fax (02) 8876 0444
Email australia.animalhealth@zoetis.com
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
Aspiration hazard Category 1

Environmental hazards Not classified.

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word Danger

Hazard Statement(s) May be fatal if swallowed and enters airways. 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 SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Do NOT induce vomiting. 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 locked up.

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 None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Amoxicillin trihydrate	61336-70-7	56 g/L
Light mineral oil (liquid paraffin)	8042-47-5	<20*
Potassium Clavulanate (Clavulanic Acid)	61177-45-5	15 g/L
White petroleum	8009-03-8	<0.1*

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 If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. Get medical attention if symptoms persist.

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.

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 If swallowed, do NOT induce vomiting. Call a physician or poison control centre immediately. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Never give anything by mouth to a victim who is unconscious or is having convulsions.

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 Aspiration may cause pulmonary oedema and pneumonitis. Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media Foam. Dry chemicals. Carbon dioxide (CO₂). Water spray.

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 Cool containers exposed to heat with water spray and remove container, if no risk is involved.

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 Ensure adequate ventilation. Keep unnecessary personnel away. Do not breathe mist or vapour. Local authorities should be advised if significant spillages cannot be contained.

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. 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.

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. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
Light mineral oil (liquid paraffin) (CAS 8042-47-5)	TWA	5 mg/m ³
White petroleum (CAS 8009-03-8)	TWA	5 mg/m ³

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
Light mineral oil (liquid paraffin) (CAS 8042-47-5)	TWA	5 mg/m ³	Mist.
White petroleum (CAS 8009-03-8)	TWA	5 mg/m ³	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Light mineral oil (liquid paraffin) (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.
White petroleum (CAS 8009-03-8)	TWA	5 mg/m ³	Inhalable fraction.

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Light mineral oil (liquid paraffin) (CAS 8042-47-5)	TWA	5 mg/m ³	Respirable fraction.

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. 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. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. 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 emulsion
Physical state	Liquid.
Form	Liquid.
Colour	Off-white.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	194 °C (381.2 °F) estimated
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.

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	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.

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.	
Light mineral oil (liquid paraffin)	Species: Rabbit	Severity: Non-irritating
Eye contact	Direct contact with eyes may cause temporary irritation.	
Light mineral oil (liquid paraffin)	Species: Rabbit	Severity: Non-irritating
Ingestion	Droplets of the product aspirated into the lungs through ingestion or vomiting may cause a serious chemical pneumonia.	

Symptoms related to exposure Aspiration may cause pulmonary oedema and pneumonitis. Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.

Acute toxicity May be fatal if swallowed and enters airways. May cause an allergic skin reaction.

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)

Components	Species	Test results
<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)
Light mineral oil (liquid paraffin) (CAS 8042-47-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
<u>Chronic</u>		
Oral		
NOAEL	Rat	1800 mg/kg/day, 90 days Liver
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)
White petroleum (CAS 8009-03-8)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	3600 mg/kg
Other		
LD50	Mouse	> 50 g/kg Sub-tenon injection (eye)
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Light mineral oil (liquid paraffin)	Species: Rabbit	Severity: Non-irritating
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.	
Skin sensitisation		
Light mineral oil (liquid paraffin)	Species: Guinea Pig	Severity: negative
White petroleum	Species: Guinea Pig	Severity: negative
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Light mineral oil (liquid paraffin)	In Vitro Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella	

Mutagenicity

Light mineral oil (liquid paraffin)

In Vitro Mammalian Cell Mutagenicity

Result: negative

Species: Mouse Lymphoma

Carcinogenicity

Due to partial or complete lack of data the classification is not possible.

ACGIH Carcinogens

Light mineral oil (liquid paraffin) (CAS 8042-47-5)

A4 Not classifiable as a human carcinogen.

White petroleum (CAS 8009-03-8)

A2 Suspected human carcinogen.

A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Light mineral oil (liquid paraffin) (CAS 8042-47-5)

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

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard

May be fatal if swallowed and enters airways.

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

Daphnia magna (Water Flea)

> 2300 mg/l, 48 Hours

Microcystis aeruginosa (Blue-green Alga)

0.0037 mg/l, 48 Hours

LC50

Lepomis macrochirus (Bluegill Sunfish)

> 930 mg/l, 96 Hours

Oncorhynchus mykiss (Rainbow Trout)

> 1000 mg/l, 96 Hours

NOEC

Selenastrum capricornutum (Green Alga)

250 mg/l, 48 Hours

Light mineral oil (liquid paraffin) (CAS 8042-47-5)

LC50

Lepomis macrochirus (Bluegill Sunfish)

> 10000 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. Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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 (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal

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 Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 47115

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued October 2015

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Light mineral oil (liquid paraffin) (CAS 8042-47-5)

White petroleum (CAS 8009-03-8)

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting.

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting.

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 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

Light mineral oil (liquid paraffin) (CAS 8042-47-5)

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

White petroleum (CAS 8009-03-8)

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

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)

Light mineral oil (liquid paraffin) (CAS 8042-47-5)

1000 - 9999 TONNES See the regulation for additional information.

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 Chemical Substances (AICS)	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

Country(s) or region	Inventory name	On inventory (yes/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	31-August-2016
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.