

SAFETY DATA SHEET



1. Identification

Product identifier Clavulox Palatable Drops Broad Spectrum Antibiotic

Other means of identification

Synonyms Amoxicillin trihydrate/potassium clavulanate drops * Clavulox/Clavamox/Synulox Drops

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

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

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 dust/fume/gas/mist/vapours/spray. 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 May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Product dust may be irritating to eyes, skin and respiratory system.

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 | 52 mg/ml |
| Other non-hazardous components | Proprietary | * |
| Potassium Clavulanate (Clavulanic Acid) | 61177-45-5 | 14 mg/ml |

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 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.

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 Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. 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 Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

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

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 Use water spray to cool unopened containers.

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 Do not breathe dust. Keep unnecessary personnel away. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not breathe dust. 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 Prevent product from entering drains.
Large Spills: Stop the flow of material, if this is without risk. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

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. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling Avoid dust formation. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wash contaminated clothing before reuse. Avoid release to the environment. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight.

Conditions for safe storage, including any incompatibilities Store below 25°C. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Keep away from heat, sparks and open flame. Keep away from food, drink and animal feeding stuffs. Use care in handling/storage.

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 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 suitable protective 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. 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.

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 Powder. Reconstitute with water for use.

| | |
|---|----------------|
| Physical state | Solid. |
| Form | Powder. |
| Colour | white |
| Odour | Bubble gum. |
| Odour threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | Decomposition. |
| 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 | |
| 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) | Dispersible. |
| 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. Direct sources of heat. Protect from sunlight. Avoid conditions which create dust. |
| Incompatible materials | Strong oxidising agents. Acids. Bases. |
| Hazardous decomposition products | 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. |

Acute toxicity 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) |
| 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) |
| 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/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. | |
| 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. | |

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 |

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 applicable.

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 Number: 35843

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

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 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 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 |
| 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**

16-September-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.