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

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 productsupport.au@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

May form combustible dust concentrations in air.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Mixture</th>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amoxicillin trihydrate</td>
<td>61336-70-7</td>
<td>52 mg/ml</td>
</tr>
<tr>
<td></td>
<td>Other non-hazardous components</td>
<td>Proprietary</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Potassium Clavulanate (Clavulanic Acid)</td>
<td>61177-45-5</td>
<td>14 mg/ml</td>
</tr>
</tbody>
</table>

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. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

Personal protection for first-aid responders

Dusts may irritate the respiratory tract, skin and eyes. 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.

Symptoms caused by exposure

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.

Medical attention and special treatment

5. Fire-fighting measures

Extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Suitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Unsuitable extinguishing media

During fire, gases hazardous to health may be formed.

Specific hazards arising from the chemical

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

Special protective equipment and precautions for fire fighters

Use water spray to cool unopened containers.

Fire fighting equipment/instructions

None.

Hazchem code

None.

General fire hazards

May form combustible dust concentrations in air.

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

Wear appropriate protective equipment and clothing during clean-up. Keep people away from and upwind of spill/leak. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, fires, sparks or flames in immediate area). Do not breathe dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
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.

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.

Precautions for safe handling
Avoid dust formation. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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. 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 flammable.

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.
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: May cause discomfort if swallowed.

Symptoms related to exposure: Dusts may irritate the respiratory tract, skin and eyes. 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.

Acute toxicity: May cause an allergic skin reaction.
<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amoxicillin trihydrate (CAS 61336-70-7)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>&gt; 25 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>&gt; 12 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 15 g/kg</td>
</tr>
<tr>
<td><strong>Subcutaneous</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 8 g/kg</td>
</tr>
<tr>
<td><strong>Clavulanic Acid/Amoxicillin Trihydrate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>150 mg/kg/day, 28 weeks (Target organs: Liver, Gastrointestinal system)</td>
</tr>
<tr>
<td><strong>Subacute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>50 - 500 mg/kg/day, 4 weeks (Target organs: None identified)</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>50 - 500 mg/kg/day, 4 weeks (Target organs: None identified)</td>
</tr>
<tr>
<td>NOEL</td>
<td>Dog</td>
<td>90 mg/kg/day, 28 days (Target organs: Gastrointestinal system)</td>
</tr>
<tr>
<td><strong>Potassium Clavulanate (Clavulanic Acid) (CAS 61177-45-5)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>4526 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>7936 mg/kg</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous</td>
<td>Dog</td>
<td>20 mg/kg/day, 26 weeks (Target organ: Liver)</td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td>Prolonged skin contact may cause temporary irritation.</td>
<td></td>
</tr>
<tr>
<td><strong>Serious eye damage/irritation</strong></td>
<td>Direct contact with eyes may cause temporary irritation.</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory or skin sensitisation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory sensitisation</strong></td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
<td></td>
</tr>
<tr>
<td><strong>Skin sensitisation</strong></td>
<td>May cause an allergic skin reaction.</td>
<td></td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td>No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.</td>
<td></td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td>Due to partial or complete lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td><strong>Reproductive toxicity</strong></td>
<td>This product is not expected to cause reproductive or developmental effects. Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td><strong>Developmental effects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin trihydrate</td>
<td>600 mg/kg/day Embryo / Fetal Development, Not teratogenic</td>
<td></td>
</tr>
<tr>
<td>Result: NOEL</td>
<td>Species: Pig</td>
<td></td>
</tr>
<tr>
<td>Organ: Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Specific target organ toxicity - single exposure</strong></td>
<td>Not classified.</td>
<td></td>
</tr>
<tr>
<td><strong>Specific target organ toxicity - repeated exposure</strong></td>
<td>Not classified.</td>
<td></td>
</tr>
<tr>
<td><strong>Aspiration hazard</strong></td>
<td>Not an aspiration hazard.</td>
<td></td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>Symptoms may be delayed.</td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin trihydrate (CAS 61336-70-7)</td>
<td>Microcystis aeruginosa (Blue-green Alga)</td>
<td>EC50 0.0037 mg/l, 48 Hours</td>
</tr>
<tr>
<td></td>
<td>Selenastrum capricornutum (Green Alga)</td>
<td>NOEC 250 mg/l, 48 Hours</td>
</tr>
</tbody>
</table>

Aquatic

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crustacea</td>
<td>Daphnia magna (Water Flea)</td>
<td>EC50 &gt; 2300 mg/l, 48 Hours</td>
</tr>
<tr>
<td>Fish</td>
<td>Lepomis macrochirus (Bluegill Sunfish)</td>
<td>LC50 &gt; 930 mg/l, 96 Hours</td>
</tr>
<tr>
<td></td>
<td>Oncorhynchus mykiss (rainbow trout)</td>
<td>&gt; 1000 mg/l, 96 Hours</td>
</tr>
</tbody>
</table>

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 applicable.

15. Regulatory information

Safety, health and environmental 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 Number: 35843

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 Deleting 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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Industrial Chemicals (AICIS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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
Revision date 11-October-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 This document has undergone significant changes and should be reviewed in its entirety.