SAFETY DATA SHEET

1. Identification

Product identifier Vibravet 50 mg and 100 mg Tablets

Other means of identification

- Synonyms Vibravet 50 Tablets for Cats & Dogs (APVMA No. 37879) * Vibravet 100 Tablets for Large Dogs (APVMA No. 46161)

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 Reproductive toxicity (the unborn child) Category 1A
- Environmental hazards Not classified.

Label elements, including precautionary statements

Hazard symbol(s)

- Health hazard

Signal word Danger

Hazard Statement(s) May damage the unborn child.

Precautionary Statement(s)

- Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
- Response IF exposed or concerned: Get medical advice/attention.
- 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

May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
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>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Doxycycline monohydrate</td>
<td>17086-28-1</td>
<td>50 or 100 mg/tab</td>
</tr>
<tr>
<td></td>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>*</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. Call a physician if symptoms develop or persist.

Skin contact
Wash off with soap and water. Get medical attention if irritation develops and persists.

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

Ingestion
If swallowed, do NOT induce vomiting. Rinse mouth thoroughly. Call a physician or poison control centre immediately. Never give anything by mouth to an unconscious person.

Personal protection for first-aid responders
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.

Symptoms caused by exposure
Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. 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
Treat symptomatically.

5. Fire-fighting measures
Extinguishing media
- Suitable extinguishing media
  Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.
- 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. May emit toxic fumes of oxides of carbon and nitrogen.

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
In case of fire and/or explosion do not breathe fumes. Use water spray to cool unopened containers. Move containers from fire area if you can do so without risk. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Hazchem Code
None.

General fire hazards
During processing, dust may form explosive mixture in air. Fine particles (such as mists) may fuel fires/explosions.

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 of the SDS.
For emergency responders

Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Keep people away from and upward 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

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with skin. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. 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 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

<table>
<thead>
<tr>
<th>Component Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxycycline monohydrate (CAS 17086-28-1) TWA</td>
<td>250 µg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate (CAS 557-04-0) TWA</td>
<td>10 mg/m³ Inhalable dust.</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6) TWA</td>
<td>10 mg/m³ Inhalable fibers.</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF (CAS 7631-86-9) TWA</td>
<td>2 mg/m³ Respirable dust.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate (CAS 557-04-0) TWA</td>
<td>10 mg/m³ Inspirable dust.</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6) TWA</td>
<td>10 mg/m³ Inspirable dust.</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF (CAS 7631-86-9) TWA</td>
<td>2 mg/m³ Respirable fraction.</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Component Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate (CAS 557-04-0) TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6) TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
Material name: Vibravet 50 mg and 100 mg Tablets

UK. EH40 Workplace Exposure Limits (WELs)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>STEL</td>
<td>20 mg/m³</td>
<td>Inhalable dust.</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>4 mg/m³</td>
<td>Respirable dust.</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF (CAS 7631-86-9)</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>Inhalable dust.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 mg/m³</td>
<td>Inhalable dust.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.4 mg/m³</td>
<td>Respirable dust.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide, colloidal NF (CAS 7631-86-9)</td>
<td>TWA</td>
<td>4 mg/m³</td>
<td>Inhalable fraction.</td>
</tr>
</tbody>
</table>

Biological limit values

Appropriate engineering controls

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 impervious gloves if skin contact is possible.

Other

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 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.

Hygiene measures

Observe any medical surveillance requirements. 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.

9. Physical and chemical properties

Appearance

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Form</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid.</td>
<td>Solid.</td>
<td>Light green</td>
</tr>
</tbody>
</table>

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

| 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) Soluble
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 Heat, flames and sparks. Contact with incompatible materials. Avoid dispersion as a dust cloud. Protect from sunlight.
Incompatible materials Strong oxidising agents.
Hazardous decomposition products Carbon dioxide, carbon monoxide, and oxides of nitrogen.

11. Toxicological information
Information on possible routes of exposure
Inhalation Health injuries are not known or expected under normal use.
  Skin contact No adverse effects due to skin contact are expected.
    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 Expected to be a low ingestion hazard.
Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Acute toxicity
Components Species Test results
Carboxymethylcellulose sodium (CAS 9004-32-4)
  Acute
  Dermal
    LD50 Rabbit > 2000 mg/kg
  Oral
    LD50 Mouse > 27000 mg/kg
    Rat 27000 mg/kg
## Components

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>Rat</td>
<td>227 g/kg, 13 weeks Liver Kidney Ureter Bladder</td>
</tr>
</tbody>
</table>

Doxycycline monohydrate (CAS 17086-28-1)

| **Acute**     |         |              |
| **Oral**      |         |              |
| LD50          | Rat     | 1700 mg/kg (by analogy) |

| **Chronic** |         |              |
| **Oral**    |         |              |
| LOEL        | Dog     | 100 mg/kg/day, 1 years (Target organ(s): Liver) |
| NOAEL       | Rat     | 500 mg/kg/day, 18 months (Target organ(s): None identified) |

| **Subacute** |         |              |
| **Oral**     |         |              |
| NOEL         | Rat     | 500 mg/kg/day, 30 days (Target organ(s): No effects at maximum dose) |

Magnesium Stearate (CAS 557-04-0)

| ** Chronic** |         |              |
| **Oral**     |         |              |
| LOAEL        | Rat     | 1092 g/kg, 13 weeks Liver |

Microcrystalline cellulose (CAS 9004-34-6)

| **Acute** |         |              |
| **Dermal** |         |              |
| LD50       | Rabbit  | > 2000 mg/kg |
| **Oral**   |         |              |
| LD50       | Rat     | > 5000 mg/kg |

| Skin corrosion/irritation | Prolonged skin contact may cause temporary irritation. |
| Serious eye damage/irritation | Direct contact with eyes may cause temporary irritation. |

**Eye contact**

| Microcrystalline cellulose | Species: Rabbit |
|                           | Severity: Non-irritating |

Respiratory or skin sensitisation

- **Respiratory sensitisation** Not a respiratory sensitizer.
- **Skin sensitisation** This product is not expected to cause skin sensitisation. Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.
- **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.

**ACGIH Carcinogens**

- Magnesium Stearate (CAS 557-04-0)
  - A4 Not classifiable as a human carcinogen.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

- Silicon dioxide, colloidal NF (CAS 7631-86-9)
  - 3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity**

- **Developmental effects** May damage the unborn child.
  - Doxycycline monohydrate
    - 50 mg/kg/day Embryo / Fetal Development, Not Teratogenic
      - Result: NOAEL
      - Species: Monkey
      - Organ: Oral
Reproductivity
Doxycycline monohydrate 250 mg/kg/day Reproductive & Fertility, No effects at maximum dose
Result: NOAEL
Species: Rat
Organ: Oral

Specific target organ toxicity
- single exposure
Not classified.
- repeated exposure
Not classified.
Aspiration hazard
Not an aspiration hazard.
Chronic effects
Based on available data, the classification criteria are not met. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain.

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
--- | --- | ---
Carboxymethylcellulose sodium (CAS 9004-32-4) | Aquatic |  
Crustacea | EC50 | Water flea (Ceriodaphnia dubia) 46.04 - 165.37 mg/l, 48 hours
Fish | LC50 | Crucian carp (Carassius carassius) > 20000 mg/l, 96 hours
Persistence and degradability
No data available on the degradability of this product.
Bioaccumulative potential
No data available.
Mobility in soil
This product is miscible in water.
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. Do not discharge into drains, water courses or onto the ground. Do not allow this material to remain in sewers/water supplies. 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. 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

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. VIBRAVET 50 TABLETS FOR CATS AND DOGS 37879
VIBRAVET 100 TABLETS FOR LARGE DOGS 46161

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued December 2016

High Volume Industrial Chemicals (HVIC)
Silicon dioxide, colloidal NF (CAS 7631-86-9) 10000 - 99999 TONNES See the regulation for additional information.

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.

Base 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 Chemical Substances (AICS)</td>
<td>Yes</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>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Country(s) or region</td>
<td>Inventory name</td>
<td>On inventory (yes/no)</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>-----------------------</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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>05-December-2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>14-October-2021</td>
</tr>
</tbody>
</table>

**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**

Periodical revision