

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	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	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.
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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.
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3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Carboxymethylcellulose sodium	9004-32-4	*
Doxycycline monohydrate	17086-28-1	50 or 100 mg/tab
Magnesium Stearate	557-04-0	*
Microcrystalline cellulose	9004-34-6	*
Silicon dioxide, colloidal NF	7631-86-9	*

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 (CO ₂). 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.
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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 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

Zoetis

Components	Type	Value
Doxycycline monohydrate (CAS 17086-28-1)	TWA	250 µg/m ³

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

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inhalable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Inhalable fibers.
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	2 mg/m ³	Respirable dust.

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

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inspirable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Inspirable dust.
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	2 mg/m ³	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	STEL	20 mg/m ³	Inhalable dust.
	TWA	4 mg/m ³	Respirable dust.
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	10 mg/m ³	Inhalable dust.
		6 mg/m ³	Inhalable dust.
		2.4 mg/m ³	Respirable dust.

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
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	4 mg/m ³	Inhalable fraction.

Biological limit values

No biological exposure limits noted for the ingredient(s).

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 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**

tablet

Physical state

Solid.

Form

Solid.

Colour

Light green

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.
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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.
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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	Species	Test results
Chronic		
Oral		
LOAEL	Rat	227 g/kg, 13 weeks Liver Kidney Ureter Bladder
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	May damage the unborn child.	
Developmental effects		
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.

Specific target organ toxicity - 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 (<i>Ceriodaphnia dubia</i>)	46.04 - 165.37 mg/l, 48 hours
Fish	LC50	Crucian carp (<i>Carassius carassius</i>)	> 20000 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 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 drain into 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 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).

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued October 2015

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 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)	Yes
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	Yes
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 05-December-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.