

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Vanectyl™-P</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	VANECTYL P * VANECTYL * TEMARIL-P * TEMARIL * Trimeprazine tartrate and prednisolone tablets
<b>Recommended use</b>	Veterinary product used as anti-itch treatment (antipruritus), antitussive, anti-inflammatory
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

**Supplier** Not available.

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Sensitization, respiratory	Category 1
	Reproductive toxicity (the unborn child)	Category 1B
	Specific target organ toxicity following single exposure	Category 1 (heart)
	Specific target organ toxicity following repeated exposure	Category 1 (nervous system)
<b>Environmental hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage the unborn child. Causes damage to organs (heart). Causes damage to organs (nervous system) through prolonged or repeated exposure.

## Precautionary statement

### Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.

### Response

IF exposed or concerned: Call a POISON CENTRE/doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE/doctor.

### Storage

Store locked up.

### Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

### Other hazards

None known.

### Supplemental information

Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Acacia		9000-01-5	<5
Prednisolone (Anhydrous)		50-24-8	2 mg
Trimeprazine Tartrate		4330-99-8	5 mg

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

## 4. First-aid measures

### Inhalation

Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. If breathing is difficult, trained personnel should give oxygen.

### Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

### Eye contact

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

### Ingestion

Rinse mouth. Get medical advice/attention if you feel unwell. 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.

### Most important symptoms/effects, acute and delayed

Fatigue. Dizziness. Narcosis. Behavioural changes. Decrease in motor functions. Difficulty in breathing. May cause decreases in blood pressure and other cardiac effects. Prolonged exposure may cause chronic effects. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances.

### Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Monitor respiratory, cardiac and central nervous system. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes.

### General information

For personal protection, see section 8 of the SDS. 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. Show this safety data sheet to the doctor in attendance.

## 5. Fire-fighting measures

### Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

### 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 firefighters

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.

### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

### General fire hazards

No unusual fire or explosion hazards noted.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

### Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition. Wear appropriate protective equipment and clothing during clean-up.

Large Spills: Stop the flow of material, if this is without risk. 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. Avoid discharge into drains, water courses or onto the ground.

### Environmental precautions

## 7. Handling and storage

### Precautions for safe handling

Use this product with adequate ventilation. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimise dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

### Conditions for safe storage, including any incompatibilities

Store locked up. Keep tightly closed in a dry, cool and well-ventilated place. @ 15 - 25°C (59 - 77°F). Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### Zoetis

#### Components

#### Type

#### Value

Prednisolone (Anhydrous)  
(CAS 50-24-8)

TWA

5 µg/m<sup>3</sup>

### Biological limit values

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

### Exposure guidelines

OEL Additional Information: Skin ( May be absorbed through the skin and cause systemic effects. )

### Control banding approach

Trimeprazine tartrate: Zoetis OEB 3 (control exposure to the range of 10ug/m3 to < 100ug/m3)

### Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

##### Hand protection

Impervious gloves. Wear impervious, disposable gloves as minimum protection (double recommended).

##### Other

Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

#### Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment. Respirator must be worn if exposed to dust. 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. 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

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

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

<b>Appearance</b>	Tablet.
<b>Physical state</b>	Solid.
<b>Form</b>	Solid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Avoid heat, sparks, open flames and other ignition sources.
<b>Incompatible materials</b>	Aluminium. Phosphorus. Strong oxidising agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation. May be absorbed through the skin and cause systemic effects.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.

**Eye contact**

Acacia

Species: Rabbit

Severity: Severe

**Ingestion**

Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.

**Symptoms related to the physical, chemical and toxicological characteristics**

Fatigue. Dizziness. Narcosis. Behavioural changes. Decrease in motor functions. Difficulty in breathing. May cause decreases in blood pressure and other cardiac effects. Prolonged exposure may cause chronic effects. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances.

**Information on toxicological effects****Acute toxicity**

Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

**Product****Species****Test results**

Vanectyl™-P

**Acute****Oral**

ATE

5000 mg/kg

**Components****Species****Test results**

Prednisolone (Anhydrous) (CAS 50-24-8)

**Acute****Intraperitoneal**

LD50

Mouse

65 mg/kg

**Oral**

LD50

Mouse

1680 mg/kg

**Chronic****Oral**

LOAEL

Guinea Pig

1 mg/kg/day, 24 weeks (Target organs: Bone, Blood)

**Subacute****Oral**

LOAEL

Dog

2.5 mg/kg/day, 6 weeks (Target organs: Adrenal gland, Liver)

Rat

10.1 mg/kg, 4 days (Target organs: None identified)

Trimeprazine Tartrate (CAS 4330-99-8)

**Acute****Intravenous**

LD50

Rat

35 mg/kg

**Oral**

LD50

Mouse

300 mg/kg

Rat

210 mg/kg

**Skin corrosion/irritation**

Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation**

Direct contact with eyes may cause temporary irritation.

**Eye contact**

Acacia

Species: Rabbit

Severity: Severe

**Respiratory or skin sensitisation****Respiratory sensitisation**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin sensitisation**

This product is not expected to cause skin sensitisation.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Mutagenicity**

Prednisolone (Anhydrous)

Cytogenetics  
Result: negative  
Species: Human lymphocytes

In Vivo Mammalian Cell Mutagenicity  
Result: negative  
Species: Mouse Lymphoma

Sister Chromatid Exchange  
Result: negative  
Species: Human lymphocytes

**Carcinogenicity** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**Reproductive toxicity** May damage the unborn child.

**Developmental effects**

Prednisolone (Anhydrous)

0.5 mg/day Embryo / Fetal Development, teratogenic  
Result: LOEL  
Species: Mouse  
Organ: No route specified

2.5 mg/kg Embryo / Fetal Development, teratogenic  
Result: LOEL  
Species: Rat  
Organ: Subcutaneous

**Reproductivity**

Prednisolone (Anhydrous)

250 - 600 mg/kg/day Reproductive & Fertility, teratogenic  
Result: LOAEL  
Species: Rat  
Organ: Oral

**Specific target organ toxicity - single exposure** Causes damage to organs (heart).

**Specific target organ toxicity - repeated exposure** Causes damage to organs (nervous system) through prolonged or repeated exposure.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged exposure may cause chronic effects.

## 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.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**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 instructions** Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** None known.

<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### TDG

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

**Canadian regulations** This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

### Controlled Drugs and Substances Act

Not regulated.

### Export Control List (CEPA 1999, Schedule 3)

Not listed.

### Greenhouse Gases

Not listed.

### Precursor Control Regulations

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)	Yes
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)	Yes
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** 04-May-2017

**Version No.** 01

**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** Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients  
Toxicological Information: Toxicological Data  
GHS: Classification