SAFETY DATA SHEET

1. Identification

Product identifier
Vanectyl™-P

Other means of identification
Synonyms
VANECTYL P * VANECTYL * TEMARIL-P * TEMARIL * Trimeprazine tartrate and prednisolone tablets

Recommended use
Veterinary product used as anti-itch treatment (antipruritus), antitussive, anti-inflammatory

Recommended restrictions
Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA)
Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)
1-866-531-8896

Rocky Mountain Poison and Drug Center
1-800-366-5288

Emergency telephone numbers
CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

Company Name (CA)
Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

Emergency telephone number
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail
productsupport@zoetis.com

Product Support
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

Physical hazards
Not classified.

Health hazards
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)

Environmental hazards
Not classified.

Label elements

Signal word
Danger

Hazard statement
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acacia</td>
<td></td>
<td>9000-01-5</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Prednisolone (Anhydrous)</td>
<td></td>
<td>50-24-8</td>
<td>2</td>
</tr>
<tr>
<td>Trimeprazine Tartrate</td>
<td></td>
<td>4330-99-8</td>
<td>5</td>
</tr>
</tbody>
</table>

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, acme, 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 (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 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.

**Environmental precautions**
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**
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**

<table>
<thead>
<tr>
<th>Zoetis Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone (Anhydrous) (CAS 50-24-8)</td>
<td>TWA</td>
<td>5 µg/m³</td>
</tr>
</tbody>
</table>

| Biological limit values                  | No biological exposure limits noted for the ingredient(s). |
| Biological exposure limits               | 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

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

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. Avoid heat, sparks, open flames and other ignition sources.


Hazardous decomposition products: Irritating and/or toxic fumes and gases may be emitted upon the product’s decomposition.

11. Toxicological information

Information on likely routes of exposure

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanectyl™-P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATE</td>
<td></td>
<td>5000 mg/kg</td>
</tr>
<tr>
<td>Components</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisolone (Anhydrous) (CAS 50-24-8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraperitoneal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>65 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>1680 mg/kg</td>
</tr>
<tr>
<td>Chronic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>Guinea Pig</td>
<td>1 mg/kg/day, 24 weeks (Target organs: Bone, Blood)</td>
</tr>
<tr>
<td>Subacute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>Dog</td>
<td>2.5 mg/kg/day, 6 weeks (Target organs: Adrenal gland, Liver)</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>10.1 mg/kg, 4 days (Target organs: None identified)</td>
</tr>
<tr>
<td>Trimeprazine Tartrate (CAS 4330-99-8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>35 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>300 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>210 mg/kg</td>
</tr>
</tbody>
</table>

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 releases. 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.
Waste from residues / unused products
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.

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