SAFETY DATA SHEETS

This SDS packet was issued with item:

078925759

N/A

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Temaril-P® Tablets

Trade Name: TEMARIL; VANECTYL-P
Chemical Family: Mixture
Intended Use: Veterinary product used as antitussive, anti-inflammatory, anti-itch treatment (antipruritus).

2. HAZARDS IDENTIFICATION

Appearance: Round, grey tablet

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. 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. Drowsiness, fatigue, or headache are also possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. While this compound causes birth defects in animal studies, experience in humans has not shown increased birth defects in infants born to mothers treated with this compound during pregnancy.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%

3. COMPOSITION/INFORMATION ON INGREDIENTS

Prednisolone (anhydrous)	50-24-8	200-021-7	Xn;R22 Repr.Cat.3;R63	4
Calcium sulfate	7778-18-9	231-900-3	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
CELLULOSE (FIBRE DE PAPIER)	9004-34-6	232-674-9	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Trimeprazine Tartrate	4330-99-8	224-368-9	Not Listed	2

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Acacia	9000-01-5	232-519-5	Not Listed	*
Activated Charcoal	16291-96-6	240-383-3	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Toxic or corrosive gases are expected in fires involving this mixture.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Prednisolone (anhydrous)

Pfizer OEL TWA-8 Hr:	5 µg/m^3, Skin

Calcium sulfate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Austria OEL - MAKs	5 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
France OEL - TWA	10 mg/m^3
Germany - TRGS 900 - TWAs	6 mg/m^3
Germany (DFG) - MAK	1.5 mg/m^3 respirable fraction 4 mg/m^3 inhalable fraction
Hungary OEL - TWA	6 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Poland OEL - TWA	10.0 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	6 mg/m^3
Slovenia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3

Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Czech Republic OEL - TWA	4.0 mg/m^3
Greece OEL - TWA	10 mg/m^3 5 mg/m^3
Ireland OEL - TWAs	10 mg/m^3 4 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	4 mg/m^3
Spain OEL - TWA	10 mg/m^3

CELLULOSE (FIBRE DE PAPIER)

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3 4 mg/m^3
Latvia OEL - TWA	2 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Analytical Method: Analytical method available for Prednisolone. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

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

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Round tablet	**Color:**	Gray
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

10. STABILITY AND REACTIVITY

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Prednisolone (anhydrous)
Mouse Oral LD50 1680 mg/kg
Rat Sub-tenon injection (eye) LD50 767 mg/kg
Mouse Intraperitoneal LD 50 65 mg/kg

Trimeprazine Tartrate
Rat Oral LD50 210 mg/kg
Mouse Oral LD50 300 mg/kg
Rat Intravenous LD50 35 mg/kg

Magnesium Stearate
Rat Oral LD 50 1092 gm/kg/13 weeks

CELLULOSE (FIBRE DE PAPIER)
Rabbit Dermal LD 50 > 2000 mg/kg
Rat Inhalation LC 50 > 5.05 mg/L/4 hours
Rat Oral LD 50 > 5000 mg/kg
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Acacia
Eye Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Prednisolone (anhydrous)
4 Day(s) Rat Oral 10.1 mg/kg LOAEL None identified
6 Week(s) Dog Oral 2.5 mg/kg/day LOAEL Adrenal gland, Liver
24 Week(s) Guinea Pig Oral 1 mg/kg/day LOAEL Bone, Blood

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Prednisolone (anhydrous)
Embryo / Fetal Development Mouse No route specified 0.5 mg/day LOEL Teratogenic
Embryo / Fetal Development Rat Subcutaneous 2.5 mg/kg LOEL Teratogenic
Reproductive & Fertility Rat Oral 250 - 600 mg/kg/day LOAEL Teratogenic

Prednisolone (anhydrous)
In Vivo Mammalian Cell Mutagenicity Mouse Lymphoma Negative
Sister Chromatid Exchange Human Lymphocytes Negative
Cytogenetics Human Lymphocytes Negative

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Prednisolone (anhydrous)
Inventory - United States TSCA - Sect. 8(b) Present

15. REGULATORY INFORMATION

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-021-7

Calcium sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-900-3

Acacia

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-519-5

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

CELLULOSE (FIBRE DE PAPIER)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Magnesium Stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Trimeprazine Tartrate

Australia (AICS):	Present
EU EINECS/ELINCS List	224-368-9

Activated Charcoal

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	240-383-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 7 - Handling and Storage. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

End of Safety Data Sheet

SAFETY DATA SHEET

1. Identification

Product identifier **Temaril-P® Tablets**

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 (US) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison and Drug Center 1-866-531-8896

Product Support/Technical Services 1-800-366-5288

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

Company Name (EU) Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

Contact E-Mail VMIPSrecords@zoetis.com

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, single exposure	Category 1 (heart)
Specific target organ toxicity, repeated exposure	Category 1 (nervous system)

Environmental hazards Not classified.

OSHA defined 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: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	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
Cellulose		9004-34-6	<5
Magnesium stearate		557-04-0	<1
Calcium sulfate		7778-18-9	
Corn Starch		9005-25-8	
Prednisolone (Anhydrous)		50-24-8	2 mg
Trimeprazine Tartrate		4330-99-8	5 mg

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER 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 center 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. Behavioral 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 (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.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

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. Minimize 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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis

Components	Type	Value
Prednisolone (Anhydrous) (CAS 50-24-8)	TWA	5 µg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Calcium sulfate (CAS 7778-18-9)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
Cellulose (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
Corn Starch (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Calcium sulfate (CAS 7778-18-9)	TWA	10 mg/m3	Inhalable fraction.
Cellulose (CAS 9004-34-6)	TWA	10 mg/m3	
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m3	
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Calcium sulfate (CAS 7778-18-9)	TWA	5 mg/m3	Respirable.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
		10 mg/m3	Total
Cellulose (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
Corn Starch (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

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

Appearance Tablet.

Physical state Solid.

Form Solid.

Color Not available.

Odor Not available.

Odor 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.

Vapor pressure Not available.

Vapor density Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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.
Incompatible materials	Aluminum. Phosphorus. Strong oxidizing agents.
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.
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. Behavioral 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
Temaril-P® Tablets		
Acute		
Oral		
ATE		5000 mg/kg

Components	Species	Test Results
Cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 5.05 mg/l/4h

Components	Species	Test Results
Oral		
LD50	Rat	> 5000 mg/kg
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	> 2000 mg/kg
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 sensitization

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

Skin sensitization This product is not expected to cause skin sensitization.

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

Mutagenicity

Prednisolone (Anhydrous)	Sister Chromatid Exchange Result: Negative Species: Human Lymphocytes

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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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.

Components	Species	Test Results
Calcium sulfate (CAS 7778-18-9)		
Aquatic		
Fish	LC50	Fathead minnow (Pimephales promelas) > 1970 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 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.
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

DOT

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

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
US state regulations	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

Country(s) or region	Inventory name	On inventory (yes/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, including date of preparation or last revision

Issue date 09-04-2013

Revision date 05-04-2017

Version # 03

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.