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

MATERIAL SAFETY DATA SHEET

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

Product Identifier

Material Name: Temaril-P® Tablets

Trade Name: TEMARIL-P; VANECTYL-P
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as antitussive, anti-inflammatory, anti-itch treatment (antipruritus).
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

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

2. HAZARDS IDENTIFICATION

Appearance: Round, grey tablet

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

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.

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	GHS Classification	%
Prednisolone (anhydrous)	50-24-8	200-021-7	Xn;R22 Repr.Cat.3;R63	Acute Tox. 4 (H302) Repr. 2 (H361d)	4
Calcium sulfate	7778-18-9	231-900-3	Not Listed	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*
CELLULOSE (FIBRE DE PAPIER)	9004-34-6	232-674-9	Not Listed	Not Listed	*
Trimeprazine Tartrate	4330-99-8	224-368-9	Xn;R22	Acute Tox 3 (H301)	2
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Acacia	9000-01-5	232-519-5	Not Listed	Not Listed	*
Activated Charcoal	16291-96-6	240-383-3	Not Listed	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 and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling

7. HANDLING AND STORAGE

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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Prednisolone (anhydrous)

Zoetis OEL TWA 8-hr	5µg/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 4 mg/m^3
Hungary OEL - TWA	6 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
Latvia OEL - TWA	4 mg/m^3
OSHA - Final PELS - TWAs:	15 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
Switzerland OEL -TWAs	3 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
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs	3 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
Vietnam O EL - TWAs	10 mg/m^3 5 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 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

Exposure Controls

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.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious, disposable gloves (double suggested) 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 disposable 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
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: None
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
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 767mg/kg
Mouse Intraperitoneal LD 50 65mg/kg

Trimeprazine Tartrate
Rat Oral LD50 210 mg/kg
Mouse Oral LD50 300mg/kg
Rat Intravenous LD50 35mg/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 > 5000mg/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.

11. TOXICOLOGICAL INFORMATION

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 Oral10.1 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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

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

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.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Prednisolone (anhydrous)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-021-7

Calcium sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-900-3

Acacia

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-519-5

Corn Starch

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Trimeprazine Tartrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	224-368-9

Activated Charcoal

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	240-383-3

Magnesium Stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Toxic to Reproduction: Category 3
Xn - Harmful

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

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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End of Safety Data Sheet