

MATERIAL SAFETY DATA SHEET



Revision date: 12-Sep-2013

Version: 2.0

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

Product Identifier

Material Name: Prednisolone Sodium Succinate Sterile Powder

Trade Name: Solu-delta-cortef (R) Sterile Powder
Chemical Family: Mixture

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

Intended Use: Veterinary product used as anti-inflammatory
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: Powder

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Harmful

EU Symbol: Xn

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

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

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Other Hazards

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical 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.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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 sodium succinate	1715-33-9	216-995-1	Repr. 3;R63	Repr 2 (H361d)	1-5
Tyloxapol	25301-02-4	Not Listed	Not Listed	Not Listed	*
Chlorobutanol	57-15-8	200-317-6	Xn;R22	Acute Tox 4(H302)	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	Not Listed	*
Lactose hydrous	64044-51-5	Not Listed	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.

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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: Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of chlorine

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

Minimize dust generation and accumulation. Avoid breathing dust. 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 at controlled room temperature. Protect from light. Keep out of reach of children.

Storage Temperature: 15-30°C

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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 sodium succinate

Zoetis OEL TWA 8-hr

4µg/m³, Skin

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:

Powder

Color:

No data available.

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

Solubility:

Soluble: Water

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

Flammability:

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

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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 various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

Prednisolone sodium succinate

Rat Intravenous LD50 770 mg/kg

Mouse IV LD50 1125mg/kg

Sodium phosphate, monobasic

Rat Oral LD 50 8290 mg/kg

Sodium phosphate, dibasic

Rat Oral LD 50 17 g/kg

Chlorobutanol

Rat Oral LD50 510 mg/kg

Prednisolone (anhydrous)

Mouse Oral LD50 1680 mg/kg

Rat Sub-tenon injection (eye) LD50 767mg/kg

Mouse Intraperitoneal LD 50 65mg/kg

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

Sodium phosphate, dibasic

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Chlorobutanol

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

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

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11. TOXICOLOGICAL INFORMATION

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 & Development Toxicity: (Duration, 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)

Chlorobutanol

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Positive
In Vitro Micronucleus Mouse Bone Marrow Negative

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: Environmental properties have not been investigated. 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.

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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 sodium succinate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	216-995-1

Tyloxapol

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

Sodium phosphate, monobasic

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	231-449-2

Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-448-7

Lactose hydrous

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

Chlorobutanol

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 2
	Schedule 3
EU EINECS/ELINCS List	200-317-6

16. OTHER INFORMATION

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

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 4 - First Aid Measures. Updated Section 7 - Handling and Storage.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis 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