

Section 1 - Identification of the Substance/Mixture and Supplier

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Product Identifier: SOLU-DELTA-CORTEF® Prednisolone 10mg/mL Injectable Solution

APVMA Approval No: 47994

Other names: None.

Chemical family: Injectable corticosteroid in a saline solution.

Recommended Use: For intravenous use in horses, dogs and cats requiring rapid and intense glucocorticoid and/or anti-inflammatory effect.

Restrictions on use: For veterinary use only.

Emergency Phone: 1800 814 883 (all hours)

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Not classified as hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

Risk Phrases: Not Hazardous - No criteria found.

Safety Phrases: S25, S36. Avoid contact with eyes. Wear suitable protective clothing.

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

GHS Label Elements: None

GHS Signal word: NONE. Not hazardous.

PREVENTION

P102: Keep out of reach of children.

P262: Do not get in eyes, on skin, or on clothing.

P281: Use personal protective equipment as required.

RESPONSE

P353: Rinse skin or shower with water.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P402+P404: Store in a dry place. Store in a closed container.

P411+P235: Store at temperatures not exceeding 25°C. Keep cool.

DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Other/supplementary hazards. None known.

Emergency Overview

Physical Description & colour: Powder in 10ml Act-O-Vial® System. (Powder and water are separated until mixed prior to injection).

Odour: No data re odour.

Major Health Hazards: no significant risk factors have been found for this product.

No specific medical attention is advised. Treat symptomatically.

SAFETY DATA SHEET

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Prednisolone Sodium Succinate	1715-33-9	10mg/mL	not set	not set
Other non hazardous ingredients		<3	not set	not set
Water	7732-18-5	to 100	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia and is available at all times. Have this SDS with you when you call.

Self Injection: Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

Eye Contact: No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.

Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: None known.

Medical Conditions Aggravated by Exposure: None known.

Indication of the Immediate Medical Attention and Special Treatment Needed: None known.

Notes to Physician: None.

Section 5 - Fire Fighting Measures

Hazards arising from the product: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Only small quantities of decomposition products are expected from this product at temperatures normally achieved in a fire. This will only occur after heating to dryness.

Fire decomposition products from this product are not expected to be hazardous or harmful.

Suitable Extinguishing Media: Not combustible. Use extinguishing media suited to burning materials.

Special Protective Equipment and Precautions for Firefighters: If a significant quantity of this product is involved in a fire, call the fire brigade.

Hazchem Code: None.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

SAFETY DATA SHEET

Environmental Precautions: None.

Methods and Material for Containment and Cleaning Up. This product is sold in small packages. No special measures are usually necessary following spills.

Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labelled container for disposal.

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.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

Control Parameters:

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure limits **TWA (mg/m³)** **STEL (mg/m³)**

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

Engineering Controls: No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when skin contact is likely.

Protective Material Types: We suggest that protective clothing be made from the following materials: rubber.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

Section 9 - Physical and Chemical Properties:

Physical Description & colour:	Powder in 10ml Act-O-Vial® System. (Powder and water are separated until mixed prior to injection).
Odour:	No data re odour.
Odour Threshold:	No data.
pH:	3.5-7.0 (as supplied)
Freezing/Melting Point:	Approximately 0°C.
Boiling Point:	Approximately 100°C at 100kPa.
Flash point:	Does not burn.
Upper Flammability Limit:	Does not burn.
Lower Flammability Limit:	Does not burn.
Autoignition temperature:	Not applicable - does not burn.
Flammability Class:	Does not burn.
Upper Flammability Limit:	Does not burn.

SAFETY DATA SHEET

Lower Flammability Limit:	Does not burn.
Autoignition temperature:	Not applicable - does not burn.
Flammability (solid, gas):	Not applicable.
Flammability Class:	Does not burn.
Decomposition Temperature:	No data.
Volatiles:	Water component.
Vapour Pressure:	2.37 kPa at 20°C (water vapour pressure).
Vapour Density:	As for water.
Relative Density:	1.006-1.026
Water Solubility:	Completely soluble in water.
Solvent Solubility:	No data.
Volatility:	No data.
Evaporation Rate:	As for water.
Partition Coefficient (n-octanol/water):	No data
Autoignition temp:	Not applicable - does not burn.
Viscosity:	Not applicable.

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Stability: Stable if stored under normal conditions.

Conditions to Avoid: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: No particular Incompatibilities.

Hazardous decomposition products: Only small quantities of decomposition products are expected from this product at temperatures normally achieved in a fire. This will only occur after heating to dryness. Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. May form hydrogen chloride gas, other compounds of chlorine. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Symptoms caused by Exposure

General Information: No data.

Routes of exposure: No data.

Symptoms of exposure:

Prednisolone may cause suppression of adrenal gland secretion; Cushing's syndrome; water retention; electrolyte imbalance; hyperglycaemia.

Overexposure to corticosteroids may increase susceptibility to infection or mask some signs of infections. Recent immunisation procedures may result in a lack of antibody response and neurological disorders.

Inhalation:

Short term exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

Long Term exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short term exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. In addition product is unlikely to cause any discomfort in normal use.

Long Term exposure: No data for health effects associated with long term skin exposure.

SAFETY DATA SHEET

Eye Contact:

Short term exposure: This product may be mildly irritating to eyes, but is unlikely to cause anything more than mild discomfort which should disappear once product is removed.

Long Term exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short term exposure: Significant oral exposure is considered to be unlikely. However, this product may be mildly irritating to mucous membranes but is unlikely to cause anything more than mild transient discomfort.

Long Term exposure: No data for health effects associated with long term ingestion.

Specific Target Organ Toxicity (STOT) – single exposure: No data.

Specific Target Organ Toxicity (STOT) – repeated exposure: No data.

Aspiration Hazard: No data.

Early Onset Symptoms Related to Exposure: No data.

Delayed Health Effects from Exposure: No data.

Exposure Levels and Health Effects: No data.

Interactive Effects: No data.

Classification of Hazardous Ingredients

Ingredient	Risk Phrases
No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.	
Prednisolone sodium succinate:	LD ₅₀ (rat, intravenous): 770 mg/kg
LD ₅₀ (mouse, intravenous):	1,125 mg/kg
TDL ₀ (mouse, subcutaneous):	96 mg/kg (11D preg, post-implantation mortality)
TDL ₀ (mouse, subcutaneous):	96 mg/kg (11-14D preg, foetotoxicity)
TDL ₀ (mouse, intravenous):	96 mg/kg (11-14D preg, post-implantation mortality, developmental abnormalities - craniofacial).

There is no data to hand indicating any particular target organs.

Respiratory or Skin Sensitisation: No data.

Germ Cell Mutagenicity: No data.

Carcinogenicity: No data.

Reproductive Toxicity: No data.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA.

NTP: No significant ingredient is classified as carcinogenic by NTP.

IARC: No significant ingredient is classified as carcinogenic by IARC.

Section 12 - Ecological Information

This product is biodegradable. It will not accumulate in the soil or water or cause long term problems. Expected to not be an environmental hazard.

Toxicity information:	No data.
Persistence and degradability:	No data.
Bioaccumulative potential:	No data.
Mobility in soil:	No data.
Other adverse effects:	No data.

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

SAFETY DATA SHEET

Special precaution for user: None known.

Additional Information: None known.

Environmental Hazard: None known.

Section 15 - Regulatory Information

Poison Schedule: S4

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

The following ingredient: Prednisolone, is mentioned in the SUSMP.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

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

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

This version issued: 30 April 2015 and is valid for 5 years from this date.

Supersedes:

Revision History:

Date of Revision	Reason

Contact Points:

Zoetis	1800 814 883
Police and Fire Brigade:	Dial 000

If ineffective:

**Dial Poisons Information Centre
(13 1126 from anywhere in Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

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Prepared by Kilford & Kilford Pty Ltd

End of Safety Data Sheet

SAFETY DATA SHEET