Section 1 - Identification of the Substance/Mixture and Supplier

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Rhodes NSW 2138 AUSTRALIA
Tel: 1800 814 883
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Product Identifier:	**DEPO MEDROL® Injectable Corticosteroid**
APVMA Approval No:	38678 (20mg/mL), 38689 (40mg/mL)
Other names:	None
Chemical family:	Injectable corticosteroid
Recommended Use:	Animal injectable for use as described on the product label
Restrictions on use	For veterinary use only
Emergency Phone:	**1800 814 883 (all hours)**

Section 2 - Hazards Identification

Appearance: Clear, colorless solution

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
Specific target organ systemic toxicity (repeated exposure): Category 2

Label Elements

Signal Word: Danger

Hazard Statements:

H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure (blood and blood forming organs, reproductive system, adrenal gland)

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
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

Short Term: Not a skin irritant. Not acutely toxic (based on animal data). May be harmful if absorbed through the skin. Accidental ingestion may cause effects similar to those seen in clinical use. May produce allergic reactions following skin contact.

Long Term: Animal studies indicate that this material may cause adverse effects on the developing fetus blood and blood forming organs.

Known Clinical Effects: Clinical use has resulted in hormonal alterations. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes.

Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning.

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.

Section 3 - Composition/Information on Ingredients

Hazardous

Ingredients	CAS No	Conc,%	GHS Classification
Methylprednisolone Acetate	53-36-1	2-4	Repr.1A (H360D) STOT RE.2 (H373)
Sodium chloride	7647-14-5	<1	Not Listed
Myristyl-gamma-picolinium chloride	2748-88-1	<0.1	Acute Tox.3 (H301)

Ingredients	CAS No	Conc,%	GHS Classification
Water	7732-18-5	*	Not Listed
Polyethylene glycol	25322-68-3	*	Not Listed

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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

Section 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

Section 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: May include oxides of carbon.

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.

Section 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 spill with absorbent material. 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.

Section 7 - Handling and Storage

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. 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

Section 8 - Exposure Controls and Personal Protection

Control Parameters

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

Methylprednisolone Acetate
Zoetis OEL TWA 8-hr 4µg/m³ Skin

Exposure Controls

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

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.

Section 9 - Physical and Chemical Properties:

Physical State:	Solution	**Color:**	Colorless
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
Myristyl-gamma-picolinium chloride
Predicted 7.4 Log D 1.30
Methylprednisolone
Predicted 7.4 Log D 1.99
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
Polymerization: Will not occur

Section 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

Section 11 - Toxicological Information

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of various forms of the active ingredients. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact, skin contact

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

Methylprednisolone Acetate

Rat	Oral	LD50	>10,000 mg/kg
Mouse	Sub-tenon injection (eye)	LD50	>1,409mg/kg
Rat	Subcutaneous	LD50	265mg/kg

Myristyl-gamma-picolinium chloride

Rat	Oral	LD 50	250 mg/kg
Rat	Para-periosteal	LD50	30mg/kg
Rat	Intraperitoneal	LD50	7500ug/kg
Rat	Subcutaneous	LD50	200mg/kg

Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Methylprednisolone

Rat	Oral	LD 50	> 2000 mg/kg
Mouse	Oral	LD 50	450mg/kg
Rat	Intraperitoneal	LD 50	1000mg/kg
Mouse	Intraperitoneal	LD 50	1409mg/kg
Rat	Subcutaneous	LD 50	>3000mg/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)

Polyethylene glycol

Eye Irritation	Rabbit	Mild
Skin Irritation	Rabbit	Mild

Methylprednisolone Acetate

Eye Irritation	Rabbit	No effect
Skin Irritation	Rabbit	No effect

Sodium chloride

Eye Irritation	Rabbit	Moderate

Skin Irritation Rabbit Mild

Methylprednisolone
Skin Irritation Rabbit No effect
Eye Irritation Rabbit No effect
Skin Sensitization - GPMT Guinea Pig No effect

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

Myristyl-gamma-picolinium chloride
60 Day(s) Rat Oral 2400 mg/kg Death

Methylprednisolone

42 Day(s)	Dog	Oral	167 µg/kg/day	LOAEL	Adrenal gland
6 Week(s)	Rat	Subcutaneous	500 µg/kg/day	LOAEL	None identified
14 Week(s)	Rat	Subcutaneous	0.4 µg/kg/day	NOAEL	Blood forming organs, Adrenal gland
52 Week(s)	Rat	Subcutaneous	4 µg/kg/day	NOAEL	Blood forming organs Adrenal gland

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

Methylprednisolone

Reproductive & Fertility	Rat	Subcutaneous	0.004 mg/kg/day	NOAEL	Paternal toxicity
Reproductive & Fertility	Rat	Subcutaneous	0.02 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Subcutaneous	1.0 mg/kg/day	LOAEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Mouse	Intramuscular	330 mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.1 mg/kg/day	LOAEL	Teratogenic

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

Methylprednisolone Acetate
Direct DNA Interaction Not applicable Negative
In Vitro Cytogenetics Not applicable Negative

Methylprednisolone
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Unscheduled DNA Synthesis Rat Hepatocyte Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
Direct DNA Interaction Negative

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

Section 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
Myristyl-gamma-picolinium chloride
Predicted 7.4 Log D 1.30
Methylprednisolone
Predicted 7.4 Log D 1.99

Mobility in Soil: No data available

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

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

Not regulated for transport under IATA, ADG or IMDG regulations.

Section 15 - Regulatory Information

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

Methylprednisolone Acetate
Australia (AICS): Present

Sodium chloride
Australia (AICS): Present

Myristyl-gamma-picolinium chloride
Australia (AICS): Present

Water
Australia (AICS): Present

Polyethylene glycol
Australia (AICS): Present

Poison Schedule: Schedule 4
AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.
The following ingredient:

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 (7th 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: 1 October 2016 and is valid for 5 years from this date
Supersedes: Revision issued 30 April 2015

Revision History:

Date of Revision	Reason
30 Apr 2015	Update to GHS
01 Oct 2016	Correction to GHS classification, hazard and precautionary statements.

Contact Points:

Zoetis	**1800 814 883**
Police and Fire Brigade:	**Dial 000**

If ineffective: **Dial Poisons Information Centre**
(13 11 26 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)

End of Safety Data Sheet