Section 1 - Identification of the Substance/Mixture and Supplier

Zoetis Australia Pty Ltd

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Tel: 1800 814 883
Fax: (02) 8876 0444
Email: productsupport.au@zoetis.com

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

<table>
<thead>
<tr>
<th>Hazardous Ingredients</th>
<th>CAS No</th>
<th>Conc, %</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylprednisolone Acetate</td>
<td>53-36-1</td>
<td>2-4</td>
<td>Repr.1A (H360D) STOT RE.2 (H373)</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>&lt;1</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>2748-88-1</td>
<td>&lt;0.1</td>
<td>Acute Tox.3 (H301)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS No</th>
<th>Conc, %</th>
<th>GHS Classification</th>
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<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>*</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>*</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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
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: May include oxides of carbon.

Products:

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.

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**Section 9 - Physical and Chemical Properties:**

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
<th>Color:</th>
<th>Colorless</th>
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<tr>
<td>Odor:</td>
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<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
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<tr>
<td>Water Solubility:</td>
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</tr>
<tr>
<td>pH:</td>
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<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
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<tr>
<td>Boiling Point (°C):</td>
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<td></td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<td></td>
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</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Evaporation Rate (Gram/s):</th>
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</thead>
<tbody>
<tr>
<td>Vapor Pressure (kPa):</td>
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</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density:</td>
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</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**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: No data available
Products:

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
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)

Methylprednisolone
60 Day(s) Rat Oral 2400 mg/kg Death

Myristyl-gamma-picolinium chloride
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: 21 September 2021 and is valid for 5 years from this date

Supersedes: Revision issued 1 Oct 2016

Revision History:

<table>
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<tr>
<th>Date of Revision</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Apr 2015</td>
<td>Update to GHS</td>
</tr>
<tr>
<td>01 Oct 2016</td>
<td>Correction to GHS classification, hazard and precautionary statements.</td>
</tr>
<tr>
<td>21 Sep 2021</td>
<td>Periodical revision</td>
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Contact Points:

<table>
<thead>
<tr>
<th>Zoetis</th>
<th>1800 814 883</th>
</tr>
</thead>
<tbody>
<tr>
<td>Police and Fire Brigade:</td>
<td>Dial 000</td>
</tr>
</tbody>
</table>

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)

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End of Safety Data Sheet