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

Product Identifier

Material Name: Methylprednisolone Acetate Suspension, USP, Animal Health Product
Trade Name: Depo-medrol (R) Sterile Aqueous Suspension (Animal Health Product)
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

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

EU Classification:
EU Indication of danger: Toxic to reproduction: Category 1
EU Symbol: T
EU Risk Phrases:
  R61 - May cause harm to the unborn child.

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.

Australian Hazard Classification (NOHSC):


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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylprednisolone Acetate</td>
<td>53-36-1</td>
<td>200-171-3</td>
<td>T;48/22-R61</td>
<td>Repr.1A (H360D) STOT RE.2 (H373)</td>
<td>2-4</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>2748-88-1</td>
<td>220-387-1</td>
<td>Xn;R22</td>
<td>Acute Tox.3 (H301)</td>
<td>&lt;0.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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: 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.

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.
SAFETY DATA SHEET

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
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

8. EXPOSURE CONTROLS / 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
Sodium chloride
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³
Polyethylene glycol
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL -TWAs 1000 ppm

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.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Odor: No data available.
Molecular Formula: 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

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

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
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
### 11. TOXICOLOGICAL INFORMATION

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

**Methylprednisolone Acetate**
- **Rat** Oral LD$_{50}$ >10,000 mg/kg
- **Mouse** Sub-tenon injection (eye) LD$_{50}$ >1,409 mg/kg
- **Rat** Subcutaneous LD$_{50}$ 265 mg/kg

**Myristyl-gamma-picolinium chloride**
- **Rat** Oral LD$_{50}$ 250 mg/kg
- **Rat** Para-periosteal LD$_{50}$ 30 mg/kg
- **Rat** Intraperitoneal LD$_{50}$ 7500 mg/kg
- **Rat** Subcutaneous LD$_{50}$ 200 mg/kg

**Sodium chloride**
- **Rat** Oral LD$_{50}$ 3000 mg/kg
- **Mouse** Oral LD$_{50}$ 4000 mg/kg

**Methylprednisolone**
- **Rat** Oral LD$_{50}$ > 2000 mg/kg
- **Mouse** Oral LD$_{50}$ 450 mg/kg
- **Rat** Intraperitoneal LD$_{50}$ 1000 mg/kg
- **Mouse** Intraperitoneal LD$_{50}$ 1409 mg/kg
- **Rat** Subcutaneous LD$_{50}$ >3000 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)

**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**
### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Time(s)</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>Dog</td>
<td>Oral</td>
<td>167 µg/kg</td>
<td>LOAEL</td>
<td>Adrenal gland</td>
</tr>
<tr>
<td>6</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>500 µg/kg</td>
<td>LOAEL</td>
<td>None identified</td>
</tr>
<tr>
<td>14</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>0.4 µg/kg</td>
<td>NOAEL</td>
<td>Blood forming organs, Adrenal gland</td>
</tr>
<tr>
<td>52</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>4 µg/kg</td>
<td>NOAEL</td>
<td>Blood forming organs, Adrenal gland</td>
</tr>
</tbody>
</table>

#### 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.

### 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:
**Myristyl-gamma-picolinium chloride**
- Predicted: Log D 1.30

**Methylprednisolone**
- Predicted: Log D 1.99

#### 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
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Methylprednisolone Acetate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List 200-171-3

Sodium chloride
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 231-598-3

Myristyl-gamma-picolininium chloride

ZT00479
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               | 220-387-1 |

Water

| 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               | 231-791-2 |

Polyethylene glycol

| 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 3 |
| EU EINECS/ELINCS List               | Not Listed |

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

T - Toxic
Xn - Harmful
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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