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

Product Identifier

Material Name: Isoflupredone Acetate Sterile Aqueous Suspension
Trade Name: PREDEF; PREDEF 2X
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: VMIPSterecs@zoetis.com

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Aqueous solution
Classification of the Substance or Mixture
GHS - Classification
Reproductive Toxicity: Category 2

EU Classification:
EU Indication of danger: Not classified

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
SAFETY DATA SHEET

Material Name: Isoflupredone Acetate Sterile Aqueous Suspension
Revision date: 11-Feb-2015
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Other Hazards

Short Term: No data available however, direct contact may cause eye irritation.

Long Term: Due to its pharmacological action, exposure to this compound may produce adverse effects on fetal development.

Known Clinical Effects: Clinical use may cause an increase in blood pressure (hypertension). Ingestion of this material may cause effects similar to those seen in clinical use including gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. 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.


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>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>Isoflupredone Acetate</td>
<td>338-98-7</td>
<td>206-423-9</td>
<td>Repr.Cat.3;R63</td>
<td>Repr. 2 (H361d)</td>
<td>0.2</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>2748-68-1</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>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>6132-04-3</td>
<td>Not Listed</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>

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.

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
### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Eye Contact:</th>
<th>Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Contact:</td>
<td>Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.</td>
</tr>
<tr>
<td>Ingestion:</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation:</td>
<td>Remove to fresh air and keep patient at rest. Seek medical attention immediately.</td>
</tr>
</tbody>
</table>

**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.
- **Fire / Explosion Hazards:** Not flammable.

**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. Prevent discharge to drains.
  - **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**
7. HANDLING AND STORAGE

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

Isoflupredone Acetate

Zoetis OEL TWA 8-hr  1µg/m³, Contact Hazards Unknown

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. 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Clear</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
</tbody>
</table>
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Material Name: Isoflupredone Acetate Sterile Aqueous Suspension</th>
<th>Page 5 of 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date: 11-Feb-2015</td>
<td>Version: 2.1</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td></td>
</tr>
<tr>
<td>Isoflupredone Acetate</td>
<td>Predicted 7.4 Log D 2.46</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>Predicted 7.4 Log D 1.30</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density:</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability:</td>
<td></td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
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</table>

### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity:</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability:</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td>None</td>
</tr>
<tr>
<td>Oxidizing Properties:</td>
<td></td>
</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products:</td>
<td>Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on Toxicological Effects</td>
<td></td>
</tr>
<tr>
<td>General Information:</td>
<td>Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact, skin contact</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Route</th>
<th>LD50</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoflupredone Acetate</td>
<td>Mouse</td>
<td>IP</td>
<td>&gt; 1000 mg/kg</td>
</tr>
<tr>
<td>Povidone</td>
<td>Rat</td>
<td>Oral</td>
<td>100 g/kg</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>Rat</td>
<td>Oral</td>
<td>250 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Para-periosteal</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>7500 ug/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>200 mg/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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

Polyethylene glycol
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

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

Isoflupredone Acetate
21 Day(s)  Rat  Oral 10 mg/kg/day  LOAEL  Liver, Male reproductive system, Thymus
90 Day(s)  Rat  Oral 0.2 mg/kg/day  NOAEL  None identified

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

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Isoflupredone Acetate
Embryo / Fetal Development  Rat  Oral 0.1 mg/kg/day  NOAEL  Maternal toxicity, Fetotoxicity, Not teratogenic
2 Generation Reproductive Toxicity  Rat  Oral 1 mg/kg/day  NOAEL  Fetotoxicity
Reproductive & Fertility  Cow  Intramuscular 20 mg/kg/day  LOEL  Fetotoxicity

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

Povidone
IARC: Group 3 (Not Classifiable)

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:

Isoflupredone Acetate
Predicted  7.4  Log D  2.46

Myristyl-gamma-picolinium chloride
Predicted  7.4  Log D  1.30

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.

Isoflupredone Acetate
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List: 206-423-9

Myristyl-gamma-picolinium 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: 220-387-1

Povidone
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water, purified</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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.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 SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision:
Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information.