

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078414840

N/A



## MATERIAL SAFETY DATA SHEET

Revision date: 26-Jan-2011

Version: 1.4

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### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288  
Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: [pfizer-MSDS@pfizer.com](mailto:pfizer-MSDS@pfizer.com)

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Isoflupredone Acetate Sterile Aqueous Suspension**

Trade Name:	PREDEF; PREDEF 2X
Chemical Family:	Mixture
Intended Use:	Veterinary product used as anti-inflammatory

### 2. HAZARDS IDENTIFICATION

Appearance: Aqueous solution  
Signal Word: WARNING

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

**Additional Hazard Information:**

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: 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. Clinical use may cause an increase in blood pressure (hypertension).

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

ISOFLUPREDONE ACETATE 2X STERILE AQUEOUS SOLUTION

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Xn;R22	*
Isoflupredone Acetate	338-98-7	206-423-9	Repr.Cat.3;R63	0.2

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Povidone	9003-39-8	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Sodium Citrate	6132-04-3	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. 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.
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.

### 5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	None known or expected.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.

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### Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### 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

### General Handling:

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

### Storage Conditions:

Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

### Isoflupredone Acetate

Pfizer OEL TWA-8 Hr:

1µg/m<sup>3</sup>, Contact Hazards Unknown

### Polyethylene glycol

Austria OEL - MAKs

Listed

Germany - TRGS 900 - TWAs

1000 mg/m<sup>3</sup>

Germany (DFG) - MAK

1000 mg/m<sup>3</sup> MAK

Slovenia OEL - TWA

Listed

### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

### Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

### Hands:

Impervious gloves 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 protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

### Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Physical State:

Aqueous solution

### Color:

Clear

### Molecular Formula:

Mixture

### Molecular Weight:

Mixture

ISOFLUPREDONE ACETATE 2X STERILE AQUEOUS SOLUTION

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

### 10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.  
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

### 11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

##### **Isoflupredone Acetate**

Mouse IP LD50 > 1000 mg/kg

##### **Povidone**

Rat Oral LD50 100 g/kg

##### **Myristyl-gamma-picolinium chloride**

Rat Oral LD 50 250 mg/kg

Rat Para-periosteal LD50 30 mg/kg

Rat Intraperitoneal LD50 7500 ug/kg

Rat Subcutaneous LD50 200 mg/kg

#### 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

ISOFLUPREDONE ACETATE 2X STERILE AQUEOUS SOLUTION

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### 11. TOXICOLOGICAL INFORMATION

Povidone

IARC:

Group 3

### 12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been investigated. Releases to the environment should be avoided.

### 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

EU Indication of danger: Not classified

OSHA Label:

WARNING

Non-hazardous in accordance with international standards for workplace safety.

#### Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



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### 15. REGULATORY INFORMATION

#### Povidone

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

#### Myristyl-gamma-picolinium chloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	220-387-1

#### Isoflupredone Acetate

Australia (AICS):	Listed
EU EINECS/ELINCS List	206-423-9

#### Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

#### Water, purified

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

#### Sodium Citrate

Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Prepared by: Product Stewardship Hazard Communications  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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

ISOFLUPREDONE ACETATE 2X STERILE AQUEOUS SOLUTION

# SAFETY DATA SHEET



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## 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:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**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



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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.  
Hazardous Substance. Non-Dangerous Goods.

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Isoflupredone Acetate	338-98-7	206-423-9	Repr.Cat.3;R63	Repr. 2 (H361d)	0.2
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Xn;R22	Acute Tox.3 (H301)	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	Not Listed	*
Sodium Citrate	6132-04-3	Not Listed	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	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.

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

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### 4. 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:** 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

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### 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/m<sup>3</sup>, Contact Hazards Unknown

#### Polyethylene glycol

Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>
Switzerland OEL -TWAs	1000 ppm

#### Exposure Controls

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Aqueous solution	<b>Color:</b>	Clear
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Isoflupredone Acetate**

Predicted 7.4 Log D 2.46

**Myristyl-gamma-picolinium chloride**

Predicted 7.4 Log D 1.30

**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

### 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:** Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** 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

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

**Isoflupredone Acetate**

Mouse IP LD50 > 1000 mg/kg

**Povidone**

Rat Oral LD50 100 g/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

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### 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

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### 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**

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### 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	Not Listed

#### Water, purified

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

#### Sodium Citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### 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.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.

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**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**



# SAFETY DATA SHEET



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## 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: VMIPSrecords@zoetis.com

#### Emergency telephone number:

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

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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. Hazardous Substance. Non-Dangerous Goods.

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Isoflupredone Acetate	338-98-7	206-423-9	Repr.Cat.3;R63	Repr. 2 (H361d)	0.2
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Xn;R22	Acute Tox.3 (H301)	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	Not Listed	*
Sodium Citrate	6132-04-3	Not Listed	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	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.

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

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### 4. FIRST AID MEASURES

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

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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### 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

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### 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/m<sup>3</sup>, Contact Hazards Unknown

#### Polyethylene glycol

Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>
Switzerland OEL - TWAs	1000 ppm

#### Exposure Controls

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Aqueous solution	<b>Color:</b>	Clear
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)

**Isoflupredone Acetate**

Predicted 7.4 Log D 2.46

**Myristyl-gamma-picolinium chloride**

Predicted 7.4 Log D 1.30

**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

### 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:** Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** 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

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

**Isoflupredone Acetate**

Mouse IP LD50 > 1000 mg/kg

**Povidone**

Rat Oral LD50 100 g/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

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### 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

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### 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**

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### 15. REGULATORY INFORMATION

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California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Water, purified

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

#### Sodium Citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### 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.2; H361d - Suspected of damaging the unborn child

Toxic to Reproduction: Category 3  
Xn - Harmful

R22 - Harmful if swallowed.  
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#### Reasons for Revision:

Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information.



## SAFETY DATA SHEET

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**End of Safety Data Sheet**