

SAFETY DATA SHEET



Revision date: 11-Feb-2015

Version: 2.1

Page 1 of 9

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

SAFETY DATA SHEET

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

Page 2 of 9

Version: 2.1



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

SAFETY DATA SHEET

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

Page 3 of 9

Version: 2.1

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

SAFETY DATA SHEET

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

Page 4 of 9

Version: 2.1

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/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³
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

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

SAFETY DATA SHEET

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

Page 5 of 9

Version: 2.1

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

SAFETY DATA SHEET

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

Page 6 of 9

Version: 2.1

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

SAFETY DATA SHEET

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

Page 7 of 9

Version: 2.1

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

SAFETY DATA SHEET

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

Page 8 of 9

Version: 2.1

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.

SAFETY DATA SHEET

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

Page 9 of 9

Version: 2.1

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