

SAFETY DATA SHEET



Revision date: 21-Jan-2014

Version: 2.0

Page 1 of 8

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

Product Identifier

Material Name: Cefoperazone Sodium Mastitis Suspension

Trade Name: PERACEF, Pathozone
Synonyms: CEFOTRON
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as antibiotic agent

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: White to yellowish homogenous oily suspension

Classification of the Substance or Mixture

GHS - Classification

Skin Corrosion/Irritation: Category 2
Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Harmful
Irritant

EU Symbol: Xn
EU Risk Phrases:

R42 - May cause sensitization by inhalation.
R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Danger
Hazard Statements: H315 - Causes skin irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction

SAFETY DATA SHEET

Material Name: Cefoperazone Sodium Mastitis Suspension
Revision date: 21-Jan-2014

Page 2 of 8
Version: 2.0

Precautionary Statements:

P264 - Wash hands thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P284 - Wear respiratory protection
P272 - Contaminated work clothing should not be allowed out of the workplace
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P321 - Specific treatment (see supplemental first aid instructions on this label)
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician



Other Hazards

Short Term:

Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Long Term:

Known Clinical Effects:

Occupational exposure to cefoperazone has resulted in allergic reactions. May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Concomitant administration of aminoglycosides and cephalosporins has caused nephrotoxicity. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

Australian Hazard Classification (NOHSC):

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 product or its ingredients 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Peanut Oil	8002-03-7	232-296-4	Not Listed	Skin Irrit. 2 (H315)	>50
Cefoperazone sodium	62893-20-3	263-751-5	Xn;R42 Xi;R43	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	3.6
Glyceryl monostearate	31566-31-1	250-705-4	Not Listed	Not Listed	*

SAFETY DATA SHEET

Material Name: Cefoperazone Sodium Mastitis Suspension
Revision date: 21-Jan-2014

Page 3 of 8
Version: 2.0

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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: None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

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

Material Name: Cefoperazone Sodium Mastitis Suspension
Revision date: 21-Jan-2014

Page 4 of 8
Version: 2.0

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

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

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.

Cefoperazone sodium

Zoetis OEL TWA 8-hr 1000 µg/m³, Sensitizer

Glyceryl monostearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³

Lithuania OEL - TWA 5 mg/m³

Sweden OEL - TWAs 5 mg/m³

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.

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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. 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:	Suspension	Color:	White to yellow
Odor:	Odorless	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
Solubility:	Soluble: Water		
pH:	4.5 - 6.5 (25% aqueous solution)		

SAFETY DATA SHEET

Material Name: Cefoperazone Sodium Mastitis Suspension
Revision date: 21-Jan-2014

Page 5 of 8
Version: 2.0

9. PHYSICAL AND CHEMICAL PROPERTIES

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: No data available
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

General Information: The information included in this section describes the potential hazards of the individual ingredients. Toxicological properties of the formulation have not been investigated.

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

Cefoperazone sodium

Rat Oral LD50 > 15 g/kg
Mouse Oral LD50 > 12g/kg

Glyceryl monostearate

Mouse IP LD50 200 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)

Peanut Oil

Skin Irritation Rabbit Moderate

SAFETY DATA SHEET

Material Name: Cefoperazone Sodium Mastitis Suspension
Revision date: 21-Jan-2014

Page 6 of 8
Version: 2.0

11. TOXICOLOGICAL INFORMATION

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

Cefoperazone sodium

3 Month(s)	Dog	Intravenous	200 mg/kg/day	NOAEL	Thymus, Blood
3 Month(s)	Dog	Intramuscular	125 mg/kg/day	NOAEL	Thymus, Blood

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Cefoperazone sodium

Embryo / Fetal Development	Monkey	Intravenous	50 mg/kg/day	LOEL	Maternal toxicity, Not teratogenic
Reproductive & Fertility-Males	Rat	Subcutaneous	1000 mg/kg/day	LOAEL	Fertility
2 Generation Reproductive Toxicity	Rat	No route specified	500 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Subcutaneous	1000 mg/kg/day	NOAEL	No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Cefoperazone sodium

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Dominant Lethal Assay	Mouse	Negative
Cytogenetics	Bone Marrow	Negative

Peanut Oil

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	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: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

SAFETY DATA SHEET

Material Name: Cefoperazone Sodium Mastitis Suspension
Revision date: 21-Jan-2014

Page 7 of 8
Version: 2.0

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

Class D, Division 2, Subdivision B



Peanut Oil

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	232-296-4

Cefoperazone sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	263-751-5

Glyceryl monostearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

SAFETY DATA SHEET

Material Name: Cefoperazone Sodium Mastitis Suspension
Revision date: 21-Jan-2014

Page 8 of 8
Version: 2.0

15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	250-705-4

REACH Authorizations: 2.0

16. OTHER INFORMATION

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

H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

R38 - Irritating to skin.
R42 - May cause sensitization by inhalation.
R43 - May cause sensitization by skin contact.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis 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