



MATERIAL SAFETY DATA SHEET

Revision date: 13-Sep-2007

Version: 2.2

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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

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Material Name: Cefovecin Sodium for Injection

Trade Name:	CONVENIA
Chemical Family:	Mixture
Intended Use:	Veterinary product used as antibiotic agent
Restrictions on Use:	Not for human use

2. HAZARDS IDENTIFICATION

Appearance: Off-white to yellow freeze-dried powder
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:

Short Term: May cause skin irritation. May cause eye irritation (based on components) .
Known Clinical Effects: 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. Additionally, kidney toxicity (nephrotoxicity) and Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

EU Indication of danger: Irritant

EU Hazard Symbols:



EU Risk Phrases:

R43 - May cause sensitization by skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Cefovecin sodium	141195-77-9	Not listed	Xi;R43	20
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**
Citric acid monohydrate	5949-29-1	Not listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium citrate, dihydrate	6132-04-3	Not listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

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. Delayed effects may occur. 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: No data available

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: No data available

6. ACCIDENTAL RELEASE MEASURES

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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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
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:	Minimize dust generation and accumulation. Avoid breathing dust. 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.
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.

Cefovecin sodium

Pfizer OEL TWA-8 Hr: 1000µg/m³, Sensitizer

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m ³ Ceiling
Australia PEAK	= 2 mg/m ³ Peak
Austria OEL - MAKs	= 2 mg/m ³ MAK
Belgium OEL - TWA	= 2 mg/m ³ TWA
Bulgaria OEL - TWA	= 2.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 1 mg/m ³ TWA
Finland OEL - TWA	= 2 mg/m ³ TWA
France OEL - TWA	= 2 mg/m ³ VME
Greece OEL - TWA	= 2 mg/m ³ TWA
Hungary OEL - TWA	= 2 mg/m ³ TWA
Latvia OEL - TWA	= 0.5 mg/m ³ TWA
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	= 0.5 mg/m ³ NDS
Slovakia OEL - TWA	= 2 mg/m ³ TWA
Slovenia OEL - TWA	= 2 mg/m ³ TWA
Sweden OEL - TWAs	= 1 mg/m ³ LLV

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	= 2 ppm Ceiling
Australia PEAK	= 5 ppm Peak
	= 7.5 mg/m ³ Peak
Austria OEL - MAKs	= 5 ppm MAK
	= 8 mg/m ³ MAK
Belgium OEL - TWA	= 5 ppm TWA
	= 8 mg/m ³ TWA
Bulgaria OEL - TWA	= 8.0 mg/m ³ TWA

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Cyprus OEL - TWA		= 5.0 ppm TWA = 8.0 mg/m ³ TWA
Czech Republic OEL - TWA		= 8 mg/m ³ TWA
Estonia OEL - TWA		= 5 ppm TWA = 8 mg/m ³ TWA
Germany - TRGS 900 - TWAs		= 2 ppm TWA = 3 mg/m ³ TWA
Greece OEL - TWA		= 5 ppm TWA = 7 mg/m ³ TWA
Hungary OEL - TWA		= 8 mg/m ³ TWA
Ireland OEL - TWAs		= 5 ppm TWA = 7 mg/m ³ TWA
Italy OEL - TWA		= 5 ppm TWA = 8 mg/m ³ TWA
Latvia OEL - TWA		= 5 ppm TWA = 8 mg/m ³ TWA
Lithuania OEL - TWA		= 5 ppm IPRV = 8 mg/m ³ IPRV
Luxembourg OEL - TWA		= 5 ppm TWA = 8 mg/m ³ TWA
Malta OEL - TWA	= 5 ppm TWA = 8 mg/m ³ TWA	
Netherlands OEL - TWA		= 5 ppm MAC = 8 mg/m ³ MAC
Poland OEL - TWA		= 5 mg/m ³ NDS
Romania OEL - TWA		= 5 ppm TWA = 8 mg/m ³ TWA
Slovakia OEL - TWA		= 5 ppm TWA = 8.0 mg/m ³ TWA
Slovenia OEL - TWA		= 5 ppm TWA anhydrous = 8 mg/m ³ TWA anhydrous
Spain OEL - TWA		= 5 ppm VLA-ED = 7.6 mg/m ³ VLA-ED

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for Cefovecin. Contact Pfizer Inc for further information.

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:

- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

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Physical State:	Freeze-dried	Color:	Off-white to yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	6.2 - 7.5 (reconstituted)		

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: No data available
Incompatible Materials: No data available

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)

Methylparaben

Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Intraperitoneal LD 50 200 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Cefovecin sodium

Rat Oral LD50 >2000 mg/kg
Rat Dermal LD50 >2000 mg/kg
Dog Oral Maximally Tolerated Dose 1000 mg/kg
Dog Subcutaneous Maximally Tolerated Dose >2000 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)

Citric acid monohydrate

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Cefovecin sodium

Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Non-irritating
Skin Sensitization - LLNA Mouse Positive

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

Propylparaben

3 Week(s)	Rat	Oral	27.1 g/kg	LOAEL	Endocrine system
4 Week(s)	Rat	Oral	347.2 mg/kg	LOAEL	Male reproductive system

Cefovecin sodium

5 Week(s)	Dog	Subcutaneous	60 mg/kg/day	NOAEL	No effects at maximum dose
5 Week(s)	Cat	Subcutaneous	60 mg/kg/day	NOAEL	No effects at maximum dose
16 Week(s)	Dog	Subcutaneous	40 mg/kg/day	NOAEL	No effects at maximum dose
16 Week(s)	Cat	Subcutaneous	40 mg/kg/day	NOAEL	Gastrointestinal system

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

Cefovecin sodium

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Micronucleus	Rat Bone Marrow	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Equivocal without activation

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

Hydrochloric Acid

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Cefovecin sodium

<i>Daphnia magna</i> (Water Flea)	NPDES	EC50	48 Hours	> 1000 mg/L
<i>Mysidopsis bahia</i> (Mysid Shrimp)	NPDES	LC50	48 Hours	580 mg/L
<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	NPDES	LC50	48 Hours	770 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Cefovecin sodium

Polytox Surrogate	IC50	4 Hours	10.31 mg/L
Polytox Surrogate	MIC	4 Hours	1.85 mg/L

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases: R43 - May cause sensitization by skin contact.

EU Safety Phrases: S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2b toxic materials



Sodium citrate, dihydrate	
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6

Methylparaben	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

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Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Water for injection

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

Citric acid monohydrate

Australia (AICS):	Present
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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R23 - Toxic by inhalation.
R35 - Causes severe burns.
R43 - May cause sensitization by skin contact.

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

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 12 - Ecological Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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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