

SAFETY DATA SHEET




1. Identification

Product identifier	Cefovecin Sodium for Injection	
Other means of identification		
Synonyms	CONVENIA * Convenia® * Convenia® Antibiotic Injection	
Recommended use of the chemical and restrictions on use		
Recommended use	Veterinary product used as antibiotic agent	
Restrictions on use	Not for human use	
Details of manufacturer or importer		
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA	
Tel	1800 814 883	
Fax	(02) 8876 0444	
Email	australia.animalhealth@zoetis.com	
Emergency Phone	1800 814 883 (all hours)	
Police and Fire Brigade	Dial 000	
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)	

2. Hazard(s) identification

Classification of the hazardous chemical		
Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)	 <p>Exclamation mark</p>	
Signal word	Warning	
Hazard statement(s)	May cause an allergic skin reaction.	
Precautionary statement(s)		
Prevention	Avoid breathing dust/fume/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves.	
Response	IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.	
Storage	Store away from incompatible materials.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Other hazards which do not result in classification	None known.	
Supplemental information	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.	

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Cefovecin sodium	141195-77-9	20
Methylparaben	99-76-3	<1
Propylparaben	94-13-3	<1

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Personal protection for first-aid responders For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. May cause an allergic skin reaction. Dermatitis. Rash.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. 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.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use water spray to cool unopened containers.

Hazchem Code None.

General fire hazards No unusual fire or explosion hazards noted.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Ensure adequate ventilation. Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Ventilate the contaminated area. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid the generation of dusts during clean-up. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid accidental injection. Avoid prolonged exposure. Observe good industrial hygiene practices. Wash thoroughly after handling. Wash contaminated clothing before reuse. When using, do not eat, drink or smoke. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a cool, well-ventilated place. @ 2 - 8°C (36 - 46°F). Do not store in direct sunlight. Protect from light. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components

Cefovecin sodium (CAS 141195-77-9)

Type

TWA

Value

1000 µg/m³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

OEL Additional Information: Sensitizer

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

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

Other

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

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.

Thermal hazards

Not applicable.

Hygiene measures

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Freeze-dried Powder for reconstitution

Physical state

Solid.

Form

Solid.

Colour

Off-white to yellow

Odour

Not available.

Odour threshold	Not available.
pH	6.2 - 7.5 (reconstituted)
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.

Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.

Solubility(ies)

Solubility (water)	Not available.
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Partition coefficient (n-octanol/water)	Not available.
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Auto-ignition temperature	Not available.
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Decomposition temperature	Not available.
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Viscosity	Not available.
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Other physical and chemical parameters

Explosive properties	Not explosive.
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Oxidising properties	Not oxidising.
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10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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Chemical stability	Material is stable under normal conditions.
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Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
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Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Sunlight.
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Incompatible materials	Strong oxidising agents.
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Hazardous decomposition products	No hazardous decomposition products are known.
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11. Toxicological information

Information on possible routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. 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.
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Skin contact	May cause an allergic skin reaction.
Cefovecin sodium	Species: Rabbit Severity: Non-irritating

Eye contact	Direct contact with eyes may cause temporary irritation.
Cefovecin sodium	Species: Rabbit Severity: Minimal

Ingestion	Ingestion of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhoea. However, ingestion is not likely to be a primary route of occupational exposure.
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Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. May cause an allergic skin reaction. Dermatitis. Rash.

Acute toxicity Allergic reactions are possible.

Components	Species	Test results
Cefovecin sodium (CAS 141195-77-9)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
MTD	Dog	1000 mg/kg
Subcutaneous		
MTD	Dog	> 2000 mg/kg
Subacute		
Subcutaneous		
NOAEL	Cat	60 mg/kg/day, 5 weeks No effects at maximum dose
	Dog	60 mg/kg/day, 5 weeks No effects at maximum dose
Subchronic		
Subcutaneous		
NOAEL	Cat	40 mg/kg/day, 16 weeks [Target organ(s): Gastrointestinal system]
	Dog	40 mg/kg/day, 16 weeks No effects at maximum dose

Propylparaben (CAS 94-13-3)

Acute

Oral

LD50

Mouse

6332 mg/kg

Other

LD50

Mouse

200 mg/kg Sub-tenon injection (eye)

Chronic

Oral

LOAEL

Rat

347.2 mg/kg, 4 weeks Male reproductive system

27.1 g/kg, 3 weeks Endocrine system

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Cefovecin sodium

Species: Rabbit

Severity: Non-irritating

Serious eye damage/irritation Direct contact with eyes may cause temporary irritation.

Eye contact

Cefovecin sodium

Species: Rabbit

Severity: Minimal

Respiratory or skin sensitisation

Respiratory sensitisation

Not a respiratory sensitizer.

Skin sensitisation

May cause an allergic skin reaction.

Skin sensitisation

Cefovecin sodium

LLNA

Species: Mouse

Severity: positive

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
Cefovecin sodium

Bacterial Mutagenicity (Ames)
Result: negative
Species: Salmonella , E. coli

In Vivo Micronucleus
Result: negative
Species: Rat Bone Marrow

Mammalian Cell Mutagenicity
Result: Equivocal without activation
Species: Mouse Lymphoma

Carcinogenicity Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible. This product may affect Kidneys. through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Other information Caution - Pharmaceutical agent. 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. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test results
Cefovecin sodium (CAS 141195-77-9)		
EC50	Daphnia magna (Water Flea)	> 1000 mg/l, 48 Hours
IC50	Polytox	10.31 mg/l
LC50	Cyprinodon variegatus (Sheepshead Minnow)	770 mg/l, 48 Hours
	Mysidopsis bahia (Mysid Shrimp)	580 mg/l, 48 Hours
MIC	Polytox	1.85 mg/l

Persistence and degradability No data is available on the degradability of this product. Cephalosporins are susceptible to degradation by a number of microorganisms found in waste water treatment plants and the general environment. Resulting degradation products are readily mineralised by environmental microorganisms.

Bioaccumulative potential No data available.

Mobility in soil No data available for this product.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal methods Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

ADG

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

Poison Schedule (Product) - Schedule 4

APVMA Registration Number: 60461

This SDS replaces version: Issued October 2016

Australia Medicines & Poisons Appendix B

METHYL P-HYDROXYBENZOATE (CAS 99-76-3)

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date

16-May-2017

Disclaimer

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. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties