

NOTICE

Cefovecin sodium

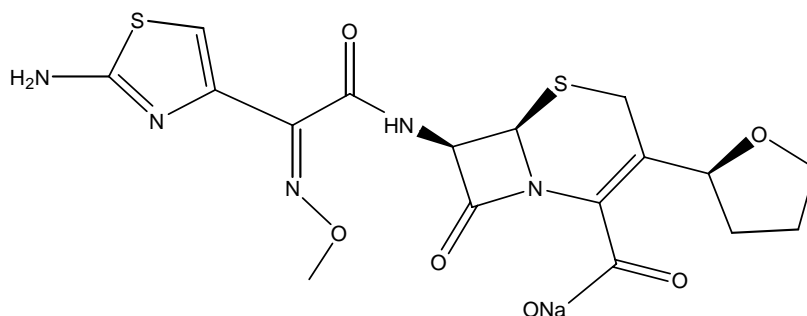
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent cefovecin sodium. Cefovecin sodium is a semi-synthetic broad-spectrum cephalosporin antibiotic.

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of cefovecin sodium should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to the matters that the APVMA is required to take into account in deciding whether to grant the approval. Comments must be received by the APVMA within 28 days of the date of this Gazette.

Particulars of the Active Constituent

Common Name:	Cefovecin sodium
IUPAC Name:	(6 <i>R</i> , 7 <i>R</i>) -7-[[2 <i>Z</i>)-(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-3[(2 <i>S</i>)-tetrahydro-2-furanyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2 carboxylic acid, monosodium salt.
CA Name	5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[2 <i>Z</i>)-2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-3-[(2 <i>S</i>)-tetrahydrofuranyl]=monosodium salt , (6 <i>R</i> ,7 <i>R</i>)-
CAS Number:	141195-77-9
Manufacturer's Codes:	UK-287-074-02
Minimum Purity:	950 g/kg
Molecular Formula:	C ₁₇ H ₁₈ N ₅ NaO ₆ S ₂
Molecular Weight:	475.48

Structure:



Chemical Family:	β -Lactam antibiotic
Mode of Action:	Cefovecin sodium interferes with bacterial cell wall synthesis by covalently binding to the penicillin binding proteins

Summary of the APVMA's Evaluation Cefovecin sodium Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of cefovecin sodium active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

Other compounds of toxicological significance are not expected to occur in cefovecin sodium as a result of the raw materials and the synthetic route used.

On the basis of the data provided, it is proposed that the following APVMA Active Constituent Standard be established for cefovecin sodium active constituent:

Constituent	Specification	Level
Cefovecin sodium	Cefovecin sodium	Not less than 950 g/kg (anhydrous, solvent free basis)

The Office of Chemical Safety of the Therapeutic Goods Administration has considered the toxicological aspects of cefovecin sodium, and advised that there are no toxicological objections to the approval of this chemical.

As the product is intended to be used by veterinary professionals or under their supervision, in non-food producing animals, and establishment of an ADI or ARfD for cefovecin sodium was not considered necessary.

The National Drugs and Poisons Schedule Committee (NDPSC) has included cefovecin sodium into Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

The APVMA accepts the findings and recommendations of its advisers on these criteria.

The APVMA is satisfied that the proposed importation and use of cefovecin sodium would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

Written submissions on the APVMA's proposal to grant approval for cefovecin sodium should be addressed in writing to:

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