

## NOTICE

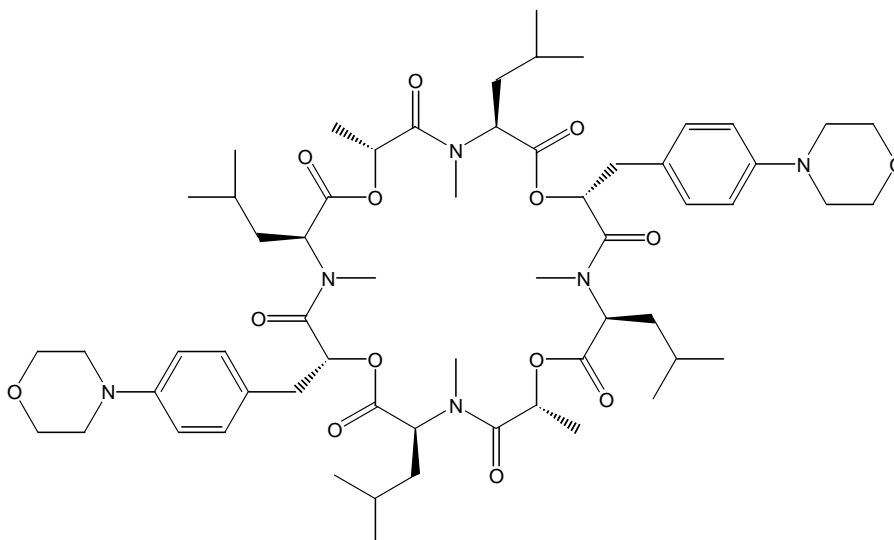
### Emodepside

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, emodepside for use in veterinary chemical products. Emodepside is a bis-morpholino cyclic octadepsipeptide with 8 chiral centres of fixed stereochemistry and thus emodepside is optically active. Emodepside is an anthelmintic effective against ascarids and hookworms as it acts by stimulation of the presynaptic latrophilin receptor causing paralysis and death of the parasite.

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 emodepside 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: Emodepside  
IUPAC Name: cyclo[(*R*)-2-hydroxypropanoyl-(*N*-méthyl-L-leucyl)-[(*R*)-3-[4-(morpholin-4-yl)phényl]-2-hydroxypropanoyl]-(*N*-méthyl-L-leucyl)-(*R*)-2-hydroxypropanoyl-(*N*-méthyl-L-leucyl)-[(*R*)-3-[4-(morpholin-4-yl)phényl]-2-hydroxypropanoyl]-(*N*-méthyl-L-leucyl)]  
CAS Number: 155030-63-0  
Manufacturer's Codes: BAY44-4400, BAY44-8, PF1022-221, FR156742;  
Minimum Purity: 950 g/kg  
Molecular Formula: C<sub>60</sub>H<sub>90</sub>N<sub>6</sub>O<sub>14</sub>  
Molecular Weight: 1119.42  
Structure:



Polymorphism: Emodepside may exist in any of four polymorphs and in the

amorphous form. The thermodynamically stable polymorph of emodepside is used.

Chemical: Cyclic octadepsipeptide

Family:

Mode of Action: Acts at the neuromuscular junction by stimulating presynaptic receptors belonging to the secretin receptor family, resulting in paralysis and death of parasite.

### **Summary of the APVMA's Evaluation of Emodepside Active Constituent**

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

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

<b>Constituent</b>	<b>Specification</b>	<b>Level</b>
Emodepside	Emodepside	Not less than 950 g/kg

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

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

Since emodepside is not intended for use in food production, an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ArfD) are not considered necessary.

The National Drugs and Poisons Schedule Committee (NDPSC) has included emodepside into Schedule 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) except when in preparations containing 2.5 percent or less where it is included in Schedule 5.

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

The APVMA is satisfied that the proposed importation and use of emodepside 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 emodepside should be addressed in writing to:

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