

NOTICE

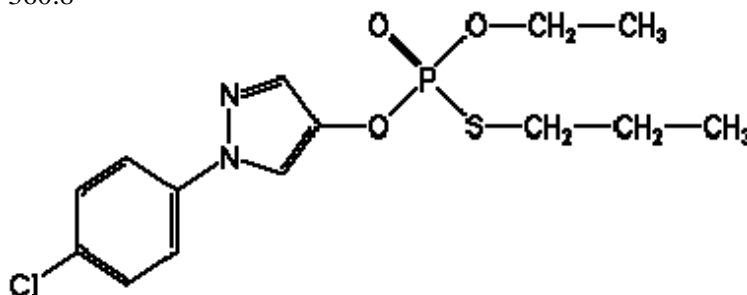
Pyraclofos

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, pyraclofos. Pyraclofos is an organophosphate insecticide developed for use as a broad spectrum anthelmintic in sheep.

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 pyraclofos 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:	Pyraclofos
IUPAC Name:	(<i>RS</i>)-[<i>O</i> -1-(4-chlorophenyl)pyrazol-4-yl <i>O</i> -ethyl <i>S</i> -propyl phosphorothioate]
CA Name:	(±)- <i>O</i> -[1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-4-yl] <i>O</i> -ethyl <i>S</i> -propyl phosphorothioate
CAS Number:	89784-60-1
Minimum Purity:	930 g/kg
Molecular Formula:	C ₁₄ H ₁₈ ClN ₂ O ₃ PS
Molecular Weight:	360.8
Structure:	



Chemical Family:	Organophosphate
Mode of Action:	Cholinesterase inhibitor

Summary of the APVMA's Evaluation of Pyraclofos Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of pyraclofos 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 pyraclofos active constituent:

Constituent	Specification	Level
Pyraclofos	Pyraclofos	Not less than 930 g/kg
	O,O-diethyl-S-n-propyl	Not more than 10 g/kg

Other compounds of toxicological significance are not expected to occur in pyraclofos 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 pyraclofos, and advised that there are no toxicological objections to the approval of this chemical.

An Acceptable Daily Intake (ADI) for pyraclofos is 0.001 mg/kg/day based on no observed adverse effect level (NOAEL) of 0.1 mg/kg/day using a safety factor of 100.

The National Drugs and Poisons Schedule Committee (NDPSC) has included pyraclofos into Appendix 6 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 pyraclofos 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 pyraclofos should be addressed in writing to:

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