

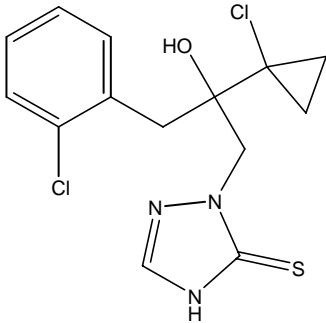
# NOTICE

## Prothioconazole

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, prothioconazole. Prothioconazole is a new class of fungicide which is proposed for use as a seed treatment to control common bunt in wheat crops.

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 prothioconazole 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:	Prothioconazole
IUPAC Name:	( <i>RS</i> )-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
CA Name:	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3 <i>H</i> -1,2,4-triazole-3-thione
CAS Number:	178928-70-6
Manufacturer's Codes:	JAU 6476
Minimum Purity:	970 g/kg
Molecular Formula:	C <sub>14</sub> H <sub>15</sub> Cl <sub>2</sub> N <sub>3</sub> OS
Molecular Weight:	344.26
Structure:	

Chemical Family:	triazolinthione
Mode of Action:	inhibition of demethylation of lanosterol or 24-methylene-dihydrolanosterol, which are precursors of fungi sterols

### Summary of the APVMA's Evaluation of Prothioconazole Active Constituent

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

<b>Constituent</b>	<b>Specification</b>	<b>Level</b>
Prothioconazole	Prothioconazole	Not less than 970 g/kg

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

The group acceptable daily intake (ADI) for prothioconazole and prothioconazole-desthio (major metabolite) is 0.01 mg/kg bw/d based on no observed adverse effect level (NOAEL) of 1.1 mg/kg bw/d in a chronic/carcinogenicity study in rats with prothioconazole-desthio (major metabolite), using a safety factor of 100, and a group acute reference dose (ARfD) is 0.03 mg/kg bw, based on a NOAEL of 3 mg/kg bw/d in a rat developmental toxicity study on prothioconazole-desthio, using a safety factor of 100.

The National Drugs and Poisons Schedule Committee (NDPSC) has included prothioconazole into Appendix B (Substances Considered not to Require Control by Scheduling) 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 prothioconazole 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 prothioconazole should be addressed in writing to:

Dr Paul Sethi  
 Chemistry Manager  
 Chemistry and Residues Program  
 Australian Pesticides and Veterinary Medicines Authority  
 PO Box E240  
 KINGSTON ACT 2604

Phone: (02) 6210 4821  
 Fax: (02) 6210 4840