

NOTICE

profoxydim

[in the product: *AURA HERBICIDE*]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from BASF Australia Limited for registration of a new product containing the active constituent profoxydim. The product, *AURA HERBICIDE*, is for the post-emergence control of barnyard grass and silvertop grass in rice.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Application

Proposed Product Name:	AURA HERBICIDE
Applicant Company:	BASF Australia Ltd.
Active Constituents:	Profoxydim
Poisons Sheduling:	Schedule 5
Statement of Claims:	For the control of barnyard & silvertop grass in rice Pack sizes: 5L, 20L
Withholding Period:	Rice: Harvest: Not required when used as directed. Grazing: Do not graze or cut for stock food for 28 days after application.

Summary of the APVMA's evaluation of *AURA HERBICIDE* in accordance with Section 14(3)(e) and (f) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of *AURA HERBICIDE* would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Department of Health and Ageing, Office of Chemical Safety (Occupational Health and Safety) [OCS (OHS)] section has conducted a risk assessment on *AURA HERBICIDE* and concluded that it can be used safely.

Profoxydim has displayed low acute oral, dermal and inhalational toxicity in mice, rats and rabbits and is a slight skin and eye irritant in rabbits, but not a skin sensitiser in guinea pigs.

The product, *AURA HERBICIDE*, was considered likely to exhibit low acute oral, dermal and inhalational toxicity but likely to be a moderate skin and eye irritant; it is not likely to cause skin-sensitisation.

Personal protective equipment statements for the Safety Directions of *AURA HERBICIDE* have been recommended by the OCS (OHS) section, and have been included on the draft label.

The APVMA having considered the findings and recommendations of the OCS (OHS) evaluation accepts these findings and recommendations.

- (ii) The APVMA is satisfied that the proposed use of *AURA HERBICIDE* will not be an undue hazard to the safety of people using anything containing its residues. Residue data were assessed by the APVMA and Maximum Residue Limits (MRLs) and associated Withholding Periods (WHPs) are recommended for *AURA HERBICIDE* when used on rice.

Based on the data provided, the following residue definition is considered appropriate: “Sum of profoxydim and all metabolites converted to dimethyl-3-(3-thianyl) glutarate-S-dioxide after oxidation and treatment with acidic methanol, expressed as profoxydim.”

The recommended WHPs for *AURA HERBICIDE* are stated on the draft label. Profoxydim MRLs are recommended for rice (0.05mg/kg), edible offal (mammalian) (0.5mg/kg), eggs (*0.05mg/kg), meat (mammalian) (*0.05mg/kg), milks (*0.01mg/kg), poultry meat (*0.05mg/kg), poultry, edible offal of (*0.05mg/kg).

- (iii) The APVMA is satisfied that the proposed use of the active constituent profoxydim in *AURA HERBICIDE* is not likely to be harmful to human beings if used according to the product label directions.

The APVMA has evaluated and proposes to approve the active constituent, profoxydim, and finds that the chemistry and manufacturing details of the product are acceptable. The proposed product has been assessed by the National Drugs and Poisons Scheduling Committee and has been included in Schedule 5 of the SUSDP. The appropriate Signal Heading appears on the label. First Aid and Safety Directions (hazard statements) for profoxydim and *AURA HERBICIDE* have been recommended by the Commonwealth Department of Health and Ageing, OCS (toxicology) section, and have been included on the label.

The product will be formulated overseas and imported ready to use in HDPE containers. *AURA HERBICIDE* is determined to be a hazardous substance, based on NOHSC hazard classification of active and non-active constituents and product toxicology information provided.

The APVMA has considered the findings of its advisers on this criterion and accepts their recommendations.

- (iv) The APVMA is satisfied that the proposed use of the new active constituent profoxydim in the product *AURA HERBICIDE* on rice is not likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

The Department of the Environment and Water Resources (DEW) has assessed the data submitted in support of the registration of *AURA HERBICIDE*, together with other relevant information. A full environmental fate and ecotoxicity data set was submitted. Laboratory studies indicate that profoxydim will degrade in the environment through aqueous oxidation, aqueous and soil photolysis and microbial processes. Field dissipation studies confirm that profoxydim and its initial oxidation metabolite dissipate rapidly in soil and water in rice crop application scenarios and do not move down the soil profile. Profoxydim is practically non-toxic to birds. As the active constituent or as a formulation, it varies in toxicity to terrestrial invertebrates and aquatic organisms, and the metabolites tested also range in toxicity.

The concentrations predicted in bird diet, in soils in sprayed crops, in water as a consequence of direct overspray, spray drift or from residues in newly sprayed soil, and on insects directly exposed, have been compared with the ecotoxicity test results. Based on these comparisons, which show an acceptable risk in all cases, DEW recommended that the APVMA be satisfied that use of *AURA HERBICIDE* as proposed and in accordance with good agricultural practice would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

The APVMA has considered the findings of DEW and accepts these conclusions.

- (v) The APVMA is satisfied that the proposed use of profoxydim in *AURA HERBICIDE* would not adversely affect trade between Australia and places outside Australia.

No detectable residues of profoxydim are expected to occur in harvested rice grain or in poultry fed on grain grown from treated rice crops. Residues in meat and milk from livestock fed on treated forage are expected to be below the limits of quantification (LOQ).

The overall risk to export trade in rice and animal commodities from the registration of *AURA HERBICIDE* is considered to be negligible.

In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:

- (vi) The APVMA is satisfied the data from trials supporting the efficacy of *AURA HERBICIDE* adequately demonstrates that under local conditions this product will be effective for the proposed uses.

Public Release Summary

A Public Release Summary of the evaluation is available by contacting Verity Scarlett on telephone (02) 62104748. Written submissions on the APVMA's proposal to grant the application for registration should be addressed in writing to:

Ranjit Gajanayake
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4760
Fax: (02) 6210 4776