

NOTICE

pyrasulfotole

in the product: *PRECEPT SELECTIVE HERBICIDE*

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropSciences Pty Ltd for registration of a new product containing the active constituent pyrasulfotole in combination with another currently approved active MCPA. The product, *PRECEPT SELECTIVE HERBICIDE*, is for the post-emergence control of certain broadleaf weeds in wheat, barley, oats, cereal rye and triticale.

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:	PRECEPT SELECTIVE HERBICIDE
Applicant Company:	Bayer CropScience Pty Ltd.
Active Constituents:	Pyrasulfotole and MCPA
Poisons Sheduling:	Schedule 5
Statement of Claims:	For the control of broadleaf weeds in wheat, barley, oats, cereal rye and triticale
Pack sizes:	20L, 110L
Withholding Period:	Barley, wheat, oats, cereal rye and triticale: Harvest: Not required when used as directed. Grazing/Stockfood: wheat, oats, cereal rye and triticale: Do not graze or cut for stockfood for 2 weeks after application. Barley: Do not graze or cut for stockfood for 4 weeks after application

Summary of the APVMA's evaluation of *PRECEPT SELECTIVE 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 *PRECEPT SELECTIVE 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 *PRECEPT SELECTIVE HERBICIDE* and concluded that it can be used safely.

Pyrasulfotole has displayed low acute oral, dermal and inhalational toxicity in male and female rats. It is not a skin irritant in rabbits or a skin sensitiser in guinea pigs. It was however a moderate eye irritant in rabbits.

The product, *PRECEPT SELECTIVE HERBICIDE*, was considered likely to exhibit low acute oral, dermal and inhalational toxicity in male and female rats. It is a moderate skin irritant in rabbits but was not found to be a skin sensitiser. It was however a severe eye irritant in rabbits.

Personal protective equipment statements for the Safety Directions of *PRECEPT SELECTIVE 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 *PRECEPT SELECTIVE 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 *PRECEPT SELECTIVE HERBICIDE* when used on barley, cereal rye, oats, triticale and wheat.

Based on the data provided, the following residue definition is considered appropriate:

The sum of pyrasulfotole and (5-hydroxy-1H-pyrazol-4-yl)[2-mesyl-4-(trifluoromethyl)phenyl]methanone, expressed as pyrasulfotole.

The recommended WHPs for *PRECEPT SELECTIVE HERBICIDE* are stated on the draft label. Pyrasulfotole MRLs are recommended for cereal grains (*0.02mg/kg), edible offal (mammalian) (0.5mg/kg), eggs (*0.01mg/kg), meat (mammalian) (*0.01mg/kg), milks (*0.01mg/kg), poultry meat (*0.01mg/kg), poultry, edible offal (*0.01mg/kg), bran, unprocessed of cereal grains (0.03), fodder and straw of cereal grain 0.02 mg/kg, forage of cereal grain 0.5 mg/kg. [* Denotes that the MRL has been set at the limit of quantitation (LOQ).]

- (iii) The APVMA is satisfied that the proposed use of the active constituent pyrasulfotole in *PRECEPT SELECTIVE 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, pyrasulfotole, 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 pyrasulfotole and *PRECEPT SELECTIVE HERBICIDE* have been recommended by the Commonwealth Department of Health and Ageing, OCS (toxicology) section, and have been included on the label.

The product is formulated in Australia and will be packed in HDPE containers. *PRECEPT SELECTIVE 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 product *PRECEPT SELECTIVE HERBICIDE* containing the new active constituent pyrasulfotole, would not be 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 data in support of the proposed use and has concluded that the risks to the environment from the proposed use are acceptable.

Pyrasulfotole is expected to be persistent in soils and particularly water/sediment systems but is not considered to be bioaccumulative. Soil metabolism and field dissipation studies show a considerable slowing in the degradation rate over time with one major metabolite generated.

Pyrasulfotole is not toxic to birds, mammals, earthworms, bees, fish and daphnia but slightly harmful to parasitic wasps and predatory mites, slightly toxic to algae, moderately toxic to mysid shrimp, and very highly toxic to duckweed. It has no effect on the seedling emergence of monocot species but survival was significantly affected in dicot species. Significant effects were observed in the vegetative vigour of monocot and dicot seedlings.

There is unlikely to be an aquatic risk as a result of spray drift from ground and aerial application or from run-off as an amended label drift warning statement would suffice for the proposed use pattern. The main environmental risk is from aerial spray drift impacting non-target vegetation where buffers are required depending on droplet sizes, if *PRECEPT SELECTIVE HERBICIDE* is to be allowed to be aerially applied.

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

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

The APVMA has determined that the use of product in accordance with the required instructions could potentially unduly prejudice trade and commerce between Australia and places outside Australia as per section 14(3)(e)(iv) of the Agvet Codes.

Quantifiable residues are not anticipated in cereal grains, fodder or any poultry commodity, thus it is unlikely the use of pyrasulfotole would unduly prejudice the trade of these commodities.

Residues in meat (mammalian) and milk are also expected to be below the LOQ, however detectable residues may be present in edible offal. Accordingly, a determination of undue

prejudice to trade or commerce should be made following the completion of the trade consultation process. Areas of potential concern and possible management strategies have been outlined in the draft Public Release Summary.

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

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

Public Release Summary

A Public Release Summary (PRS) of the evaluation is available by contacting Verity Scarlett on telephone (02) 6210 4748. 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 6182
KINGSTON ACT 2604

Phone: (02) 6210 4760
Fax: (02) 6210 4776
Email: ranjit.gajanayake@apvma.gov.au