Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: YATES PATHWEEDER KILLS WEEDS PREVENTS WEEDS UP TO 12 MONTHS

Applicant: DULUXGROUP (AUSTRALIA) PTY LTD

Product number: 68298

Application number: 57989

Purpose of Application and Description of Use: Registration of a 4.8g/L glyphosate, 4.8g/L oxyfluorfen and 0.29g/L diflufenican emulsion oil in water product, for control and prevention of germination of weeds and grasses in paths and driveways.

Active Constituent(s): DIFLUFENICAN
GLYPHOSATE
OXYFLUORFEN

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Agricultural products must meet Active Constituents Quality Assurance Requirements
3. Label must contain a Date of Manufacture and Batch Number

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

ADVICE

Australian Government Department of Health, Office of Chemical Safety

Toxicological information was provided by Dulux Group (Australia) Pty Ltd to register a new home garden product, YATES PATHWEEDER KILLS WEEDS PREVENTS WEEDS UP TO 12 MONTHS (RTU) containing 4.8 g/L glyphosate, 4.8 g/L oxyfluorfen and 0.29 g/L diflufenican. The product is intended for the control of existing weeds and the prevention of germination of weeds and grasses in paths and driveways in domestic situations.

The ADI for glyphosate is 0.3 mg/kg bw/d and was established in 1985 based on a NOEL of 30 mg/kg bw/d in a 3-generation reproduction dietary study in rats for no treatment-related effects at the highest dose and using a 100-fold safety factor. Glyphosate is in Schedule 5 of the SUSMP with no cut-offs or exceptions.

The ADI for oxyfluorfen is 0.025 mg/kg bw/d and was established in 1982 based on a NOEL of 2.5 mg/kg bw/d (40 ppm) in a 2-year dietary study in rats for slight reduction in thyroid weights and hepatocyte enlargement at the highest dose of 800 ppm and using a 100-fold safety factor. Oxyfluorfen is in Appendix B (substances considered not to require control by scheduling) of the SUSMP due to its low toxicity for agricultural use.

The ADI for diflufenican is 0.2 mg/kg bw/d and was established in 1988 based on a NOEL of 16.3 mg/kg bw/d (500 ppm) in a 2-year dietary study in rats for dose-related decrease of body weight gain and increase of liver weights in male animals at the next highest dose of 2500 ppm and using a 100-fold safety factor. Diflufenican is in Appendix B (substances considered not to require control by scheduling) of the SUSMP due to its low toxicity for agricultural use.

The proposed product contains 0.48 per cent of glyphosate and is therefore classified as a Schedule 5 poison. Based on the concentrations of active constituents and excipients in the product formulation, this classification is considered appropriate.

Based on the information evaluated the proposed product, is expected to be of low acute oral, acute dermal and acute inhalational toxicity. It is expected to be a non-skin and eye irritant and a non-skin sensitiser. Risk assessment concluded that acceptable margins of exposure were determined for users applying the product by handwand application (i.e. trigger spray) without the use of personal protective equipment (PPE) in the home garden/domestic setting. The toxicology data, the outcomes of the risk assessment on the product and other information on the product provided and considered in this assessment justify the recommendations made and the Safety Directions established in the present evaluation.

The APVMA is satisfied that the proposed use of YATES PATHWEEDER KILLS WEEDS PREVENTS WEEDS UP TO 12 MONTHS will not be an undue health hazard to humans according to the criteria stipulated in Section 14 of the Ag/Vet Code Act of 1994.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
98968	S	Intox PVT. LTD.	Yates Path Weeder Concentrate: Acute Dermal Toxicity Study in Rat (OECD Guideline No. 402), Report No: R/13531/ADR/13	24 July 2013	Toxicology	Acute dermal studies, product	Applicant	
98969	S	Intox PVT. LTD.	Yates Path Weeder Concentrate: Acute Eye Irritation / Corrosion Study in Rabbits (OECD Guideline No. 405), Report No: R/13419/AEI/13	4 July 2013	Toxicology	Acute eye irritation studies, product	Applicant	
98970	S	Intox PVT. LTD.	Yates Path Weeder Concentrate: Acute Oral Toxicity Study in Rat (OECD Guideline No. 423), Report No: R/13530/AOR/13	24 July 2013	Toxicology	Acute oral studies, product	Applicant	
98971	S	Intox PVT. LTD	Yates Path Weeder Concentrate: Acute Dermal Irritation / Corrosion Study in Rabbits (OECD Guideline No. 404), Report No: R/13418/ADI/13	4 July 2013	Toxicology	Acute skin irritation studies, product	Applicant	
98972	S	Toxikos Pty Ltd; Hugh Scobie (Ed.)	Toxicological evaluation: New Herbicide, Pathweed for Home Garden Use, Report No. TR14710_HS2	November 2012	Toxicology	Other information	Applicant	

Information for the individual active constituents were provided by Yates Australia for the registration of YATES PATHWEEDER KILLS WEEDS PREVENTS WEEDS UP TO 12 MONTHS containing the approved active constituents glyphosate, oxyfluorfen and diflufenican for long lasting control of weeds and grasses in paths, driveways, car parks and bare soils. It is claimed to control existing weeds (glyphosate) and also to prevent new weed seeds from germinating (oxyfluorfen and diflufenican).

Adequate information were available to conduct risk assessment and runoff modelling. Because the proposed product is applied by trigger spray directly to the weeds, the effect of spray drift, where combination product end points are used, will not be an environmental concern. The available data were considered as well as the proposed risk assessment of oxyfluorfen in determining the potential risk to aquatic organisms from runoff. The risk assessment determined that the proposed products are unlikely to pose an environmental risk as a result of runoff from the proposed use pattern when label warnings are followed.

The APVMA is satisfied that the proposed use would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment under Section 14 subsection 1 of the Agricultural and Veterinary Chemicals Code Act 1994.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
81103	S	European Food Safety Authority	Conclusion on the peer review of the pesticide risk assessment of the active substance oxyfluorfen	November 2010	Environment toxicology	Other information	Public	
81107	S	Pesticide Properties DataBase (PPDB)	Oxyfluorfen (Environmental Fate - Ecotoxicology-Human Health)	December 2011	Environment toxicology	Other information	Public	
81101	S	United States Environmental Protection Agency	Reregistration Eligibility Decision (RED) Oxyfluorfen	October 2002	Environment toxicology	Other information	Public	

External Efficacy Reviewer

Efficacy data from three trials conducted in NSW and Qld from 2012 to 2013 were provided for the registration of YATES PATHWEEDER KILLS WEEDS PREVENTS WEEDS UP TO 12 MONTHS, containing existing active ingredients (4.8 g/L glyphosate, 4.8 giL oxyfluorfen and 0.29 g/L diflufenican). The product was applied at ½ x, 1x and 2x the proposed label rate using the supplied trigger applicator and a watering can with a sprinkler bar. These treatments were compared with a reference standard. Weed control was assessed for 12 months after the treatments were applied.

The trials used sound scientific methodology suitable for efficacy and crop safety testing and they were conducted by suitably qualified personnel under conditions equivalent to those proposed on the label. The number of different weed species and their densities over different climatic zones and on different surfaces provide sufficient challenge to test the label claims. The trials used Randomised Complete Block design, with 3-4 replicates and, treated and untreated controls. Data were analysed using analysis of variance with means separated using least significant difference techniques.

It can be concluded from the results of three field trials that product, when applied according to label directions, will provide knockdown and residual control of common broadleaf and grass weeds on hard standing areas for up to 12 months. The sprayed surfaces in the three trials were assessed for any adverse effects and none were found at up to 2x the proposed use rate.

The APVMA is satisfied that the product, if used as proposed and approved, would be effective according to criteria determined by the APVMA, and would not be likely to have an unintended effect that is harmful to the crop or host animals

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
81097	S	Greg Murdoch (PM), Agrisearch Services Pty Ltd	Determination of the paver safety, knockdown and long-term residual efficacy of proposed new path weeder products against a range of grass and broadleaf weeds one trial, Peats Ridge, New South Wales, report no.: YATESAUS/11/16-1	15 July 2013	Efficacy and safety	Efficacy	Applicant	
81098	S	Greg Murdoch (PM), Agrisearch Services Pty Ltd	Determination of the paver safety, knockdown and long-term residual efficacy of proposed new path weeder products against a range of grass and broadleaf weeds one trial, Berkeley Vale, New South Wales, Australia, 2012, report no.: YATESAUS/11/16-2	15 July 2013	Efficacy and safety	Efficacy	Applicant	
81099	S	Greg Murdoch (PM), Agrisearch Services Pty Ltd	Determination of the paver safety, knockdown and long-term residual efficacy of proposed new path weeder products against a range of grass and broadleaf weeds, one trial, Bundaberg, Queensland, Report No.: YATESAUS/11/16-4	Aug 2013	Efficacy and safety	Efficacy	Applicant	

** S = Data submitted with the application*