Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

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

Applicant: DULUXGROUP (AUSTRALIA) PTY LTD

Product number: 68412

Application number: 58310

Purpose of Application and Description of Use: Registration of a 25.6 g/L glyphosate, 25.6 g/L oxyfluorfen and 1.5 g/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 and Ageing, Office of Chemical Safety

Four acute toxicology studies on the proposed product were provided by Dulux Group (Australia) Pty Ltd to register YATES PATHWEEDER CONCENTRATE KILLS WEEDS PREVENTS WEEDS UP TO 12 MONTHS containing 25.6 g/L glyphosate, 25.6 g/L oxyfluorfen and 1.5 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 acute toxicology studies have been conducted in accordance with contemporary test guidelines. The acute toxicology data evaluated in this assessment along with previously evaluated information on the acute and repeat-dose toxicology of the active constituents were relied on by the OCS to establish the acute hazard profile for the proposed product.

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 findings of the toxicological studies evaluated, the product has low acute oral and low acute dermal toxicity. It is a non-skin or eye irritant. An acute inhalational toxicity study and a skin sensitisation study on the product were not provided in the current submission. Based on the individual acute toxicology profiles of the three active constituents and those of the product excipients, the product was estimated to have low acute inhalational toxicity and is not expected to exhibit sensitisation potential. 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 CONCENTRATE 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.
81118	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	
81119	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	
81120	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	
81121	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	
81125	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	

** S = Data submitted with the application*