Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: PYRESTA XTREME LV HERBICIDE

Applicant: SIPCAM PACIFIC AUSTRALIA PTY LTD

Product number: 69952

Application number: 62158

Purpose of Application and Description of Use: Registration of a 2.1 g/L Pyraflufen-ethyl and 600 g/L 2,4-D (present as the 2-ethyl hexyl ester), emulsifiable concentrate product for improvement in the brownout of a range of broadleaf and grass weeds and improved control of marshmallow, long storksbill (erodium) and wild radish, when used in tank mixtures with glyphosate based herbicides.

Active Constituent(s): 2,4-D-2-ETHYLHEXYL ESTER

PYRAFLUFEN-ETHYL

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 (OCS)

The OCS has conducted the toxicology & OHS assessment for the proposed registration of the new herbicide product, Pyresta Xtreme LV Herbicide, containing pyraflufen-ethyl at 2.1g/L and 600g/L 2, 4-D acid (present as the 2-ethylhexyl ester) in a emulsifiable concentrate intended for the improvement in the brownout of range of broadleaf and grass weeds, and improved control of marshmallow, long strorksbill and wild radish.

No acute toxicology studies on the product were submitted for evaluation. The OCS has estimated the acute toxicological profile of Pyresta Xtreme LV Herbicide based on data holdings on the active constituent, as well as from data on the excipients. An exposure assessment was conducted, and in conjunction with the hazard profile, used to determine whether the proposed use of the product would be an undue health hazard to humans. The Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide (1998) was used to estimate exposure.

The ADI for pyraflufen-ethyl is 0.2 mg/kg bw/d and was established in 2004 based on a NOEL of 20 mg/kg bw/d on an 18-month and a 24- month study in mice and rats respectively and a developmental study in rabbits, based on increased liver weight at the next highest dose of 1000 ppm (100mg/kg bw/d) in the mouse study; increased urinary volumes and relative kidney weight and decreased specific gravity of urine at the next highest dose of 2000 ppm (100 mg/kg bw/d) in the rat; and increased mortality at the next highest dose of 60 mg/kg bw/d in the rabbit study. The ARfD for pyraflufen-ethyl is also 0.2 mg/kg bw established in 2004 based on a NOEL of 20 in a developmental study in rabbits based on increased maternal mortality and morbidity at the next highest dose of 60 mg/kg bw/d. Pyraflufen-ethyl is listed in Schedule 5 of the SUSMP

The ADI for 2,4-D is 0.01 mg/kg bw/d established in 2006, is based on a NOEL of 1 mg/kg bw/d from a two-year rat study, based on abnormal renal morphology at the next highest dose of 5 mg/kg bw/d. No ARfD has been established for 2,4-D and there were no data submitted to establish an ARfD to be set. 2,4-D is in Schedule 6 of the SUSMP except when in Schedule 5. It is in Schedule 5 when in preparations containing 20 per cent or less. The product contains 2.1g/L pyraflufen-ethyl and 600g/L 2, 4-D and therefore classified as a Schedule 6 poison.

Based on the estimation, the product is considered to have moderate acute oral and low acute dermal toxicity, and low acute inhalational toxicity. It is considered to be a non-irritant to skin. It is likely to be a severe eye irritant, respiratory irritant and a skin sensitiser.

Based on the outcomes of the risk assessment, Restriction statements, First Aid Instructions and Safety Directions, including PPE and engineering controls were established. The risk assessment therefore concluded that the proposed use of “Pyresta Xtreme LV Herbicide” as per above restrictions 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.

Having considered the OCS advice, and the RLP being amended by incorporating the recommendations, the APVMA is satisfied of the toxicology and OH&S criteria.

State/External Efficacy Reviewer

Data from two replicated field trials in Shepparton, Victoria were provided to compare the new product Pyresta® Xtreme® LV Herbicide with the registered reference product to establish bioequivalence and efficacy for a range of weeds of fallow situations. This new product has the same level of pyraflufen-ethyl but an increased level of 2,4-D to 600 g/L present as the 2-ethylhexyl ester. The reference product and the proposed new product have similar label directions except for the level of active ingredient. Both products are only for use in fallows when applied with the Sipcam product Raze® or other registered glyphosate products.

Three rates (250, 500 and 750 ml of product per hectare) of the two products were tested on a range of weeds including -Caltrop *Tribulus terrestris,* Common storksbill *Erodium cicutarium,* Marshmallow *Malva parviflora,* Pigweed *Portulaca oleracea,* Shepherd's purse *Capsella bursa-pastoris,* Windmill grass *Chloris truncate,* Capeweed *Arctotheca calendula,* Chickweed *Stellaria media,* Fumitory *Fumaria muralis;* Mouse-ear chickweed *Cerastium glomeratum,* Rough poppy *Papaver hybridum and* Wild oats *Avena fatua.*

The trials used scientific methodology and appropriate assessment parameters. The weeds were appropriately identified and representative of fallow situations and the rates applied in the trials were equivalent to the proposed label rates with higher rates included on the label for some weeds. The trials incorporated 4 replicates, the reference product and untreated controls. Results were analysed using standard statistical procedures (ANOVA, LSD). Assessments were made at pre-spray and at intervals up to 29 days after application. Assessments included weed counts, weed control and regrowth assessment.

Pyresta® Xtreme® applied at 250 ml/ha performed as well as the standard reference product applied at the same rate and at the higher rates of 500ml/ha and 750 ml/ha Pyresta® Xtreme® LV + Raze® increased the level of knockdown. The increased level of active ingredient in the formulation provided quicker knockdown and improved the efficacy of the product.. At 7 or 8 days after application in respective trials, Pyresta® Xtreme® LV + Raze® provided equal or better knockdown than reference product + Raze®. At 28 or 29 days after application in respective trials, Pyresta® Xtreme® LV + Raze® provided equivalent control to reference product + Raze®. The product is only applied in fallow situations so there is no issue with phytotoxicity.

The reviewer therefore concluded that the results demonstrated efficacy of the proposed product for control of a range of weeds and established bioequivalence with the reference product.

Considering the efficacy reviewer’s advice, the APVMA is satisfied that the use of the product would be effective and safe when used in accordance with the proposed label instructions.

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.
84359	S	D. Landmeter	Evaluation of Raze in Combination with Pyresta LV Herbicide and Pyresta Xtreme for the control of grass and broadleaf weeds on pre-plant fallow situations - One trial Shepparton Vic	18 November 2013	Efficacy and safety	Efficacy	Applicant	
84357	S	D. Landmeter	Evaluation of Raze in Combination with Pyresta LV Herbicide and Pyresta Xtreme for the control of grass and broadleaf weeds on pre-plant fallow situations - One trial Shepparton Vic	14 November 2013	Efficacy and safety	Efficacy	Applicant	

** S = Data submitted with the application*