



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: ULTIMATE BRUSHWEED HERBICIDE
Applicant: ZELAM PTY LTD
Product number: 62431
Application number: 43106

Purpose of Application and Description of Use: Registration of a 75 g/L triclopyr and 28 g/L metsulfuron-methyl, oil dispersion product, for use in native pastures, rights of way, non-agricultural areas, commercial and industrial areas for the control of certain brush species.

Active Constituent(s): METSULFURON-METHYL
TRICLOPYR BUTOXYETHYL ESTER

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 http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml.

ADVICE

Australian Government Department Of Health And Ageing, Office Of Chemical Safety

ULTIMATE BRUSHWEED HERBICIDE, is a suspension concentrate formulation combining two currently registered active constituents; triclopyr butoxyethyl ester 75 g/L and metsulfuron-methyl 28 g/L intended for controlling certain brush weed and broad-leaved weed species in use in native pastures, rights of way, non-agricultural areas, commercial and industrial areas. No toxicological data on the active constituents or the proposed product were submitted. The existing toxicological database on the active constituents and excipients was relied on by the OCS.

Triclopyr is currently included in Schedule 6 of the SUSDP; this includes triclopyr butoxyethyl ester. Triclopyr (and triclopyr butoxyethyl ester) has an ADI of 0.005 mg/kg bw/day based on a NOEL of 0.5 mg/kg bw/day in a 1 year dietary study in dogs using a safety factor of 100 and remains appropriate. No acute reference dose (ARfD) was established for triclopyr butoxyethyl ester.

Metsulfuron-methyl is exempt from the requirements of scheduling and is included in Appendix B of the SUSDP. The existing ADI for metsulfuron-methyl remains appropriate at 0.01 mg/kg bw/day based on a NOEL of 1 mg/kg bw/day in a 2-year dietary study in rats using a safety factor of 100. No acute reference dose (ARfD) has been established for metsulfuron-methyl.

OCS estimated the formulated product toxicity from using the toxicology profile of its ingredients and the proposed product is anticipated to have an overall low level of toxicity for oral, dermal and inhalation exposure. The product is estimated to be a moderate skin irritant, a severe eye irritant and a possible skin sensitiser. In addition the excipients may be irritating to the respiratory tract. The proposed product, ULTIMATE BRUSHWEED HERBICIDE, is classified as a Schedule 6 poison.

The product is intended for use by professional operators and is not for use on food crops or in the home garden. Based on the proposed use situations for the product and seasonal growth and persistence of the target weeds, exposure to ULTIMATE BRUSHWEED HERBICIDE is likely to occur for between 3 to 6 months in duration and intermittent in frequency.

Worker exposure was estimated for hand held sprayer (backpack) use and while using vehicle-mounted hand held sprayers at low and high pressure. The following NOELs were used for the OH&S risk assessment: for Triclopyr butoxyethyl ester, a 13-week repeat dose rat dietary study gave a NOEL of 5 mg/kg/bw/day and for metsulfuron-methyl a 90-day dietary study in dogs gave a NOEL of 1.2 mg/kg bw/day.

A MOE of 100 or above was considered appropriate taking into account both interspecies extrapolation and intraspecies variability.

A dermal absorption factor of 1.65% was obtained from a human study of a triclopyr butoxyethyl ester 480 g/L product and was considered appropriate for the evaluation of triclopyr butoxyethyl ester in ULTIMATE BRUSHWEED HERBICIDE. No dermal studies were available for metsulfuron-methyl, however based on a high molecular weight and the log Kow value of -1.74, a 10% dermal absorption factor is considered appropriate in the evaluation of metsulfuron-methyl and the proposed product.

From the MOE estimates it is apparent that metsulfuron-methyl is the driving force for systemic toxicity for all scenarios and weed targets. The risk assessment for ULTIMATE BRUSHWEED HERBICIDE therefore only considered potential systemic toxicity from exposure to metsulfuron-methyl.

The POEM scenario with a hand held high pressure spray, with open mixing and loading, with a vehicle mounted spray tank size adjusted to 1000L for workers applying the product to gorse and cacti wearing a single layer of clothing and gloves produced a MOE that was below 100 and was therefore not acceptable. Adding cotton overalls buttoned to the neck and wrist affords an additional level of protection from dermal exposure of 90% and the resultant MOE's are acceptable.

Exposure post application was calculated for performing post-application scouting activities. The estimates were only calculated for metsulfuron-methyl because of the higher exposure estimates for metsulfuron-methyl than for triclopyr butoxyethyl ester as indicated in the worker exposure estimates, in combination with a lower NOEL for systemic toxicity (1.2 mg/kg/ bw/day vs 5 mg/kg bw/day). When undertaking a low exposure activity such as scouting, the risk to workers from re-entering treated areas once the spray has dried was acceptable at day zero. A re-entry period prior to the spray drying is recommended.

Safety directions including personal protective equipment are required to address the acute (eye and skin irritation and skin sensitisation) and chronic (systemic toxicity of metsulfuron-methyl) health risks. Excipients contained in the product may also cause respiratory tract irritation. A new safety directions entry is appropriate.

The OCS has no objections on human health grounds to the registration of the product ULTIMATE BRUSHWEED HERBICIDE, containing Triclopyr Butoxyethyl Ester 75 g/L and Metsulfuron-Methyl 28 g/L. The proposed use of ULTIMATE BRUSHWEED HERBICIDE by knapsack and vehicle mounted hand held applications 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.

External Efficacy Reviewer

A total of 25 trials were conducted over 5 years at sites in New South Wales, Victoria & Tasmania. Trials targeted blackberries (*Rubus fruticosus*), bracken (*Pteridium aquilinum*, also known as *Pteridium esculentum*), hawthorn (*Crataegus monogyna*), sweet briar (*Rosa rubiginosa*) and gorse (*Ulex europaeus*). The weeds were spot sprayed until run-off from 50-100L tank mixes. Trials compared the effectiveness of ULTIMATE BRUSHWEED HERBICIDE with industry standards and included Triclopyr Butoxyethyl Ester alone, metsulfuron-methyl alone and Triclopyr Butoxyethyl Ester + picloram.

Rates of desiccation were visually assessed 24-83 days after application (DAA) using a rating system of 0% for no effect to 100% for complete desiccation and leaf loss. Regrowth was visually assessed from 273 to 730 DAA. The reviewer considered the data analysis (ANOVA) appropriate.

Trials for ULTIMATE BRUSHWEED HERBICIDE on blackberries demonstrated 78% desiccation (regrowth = 7.3% \geq 284 DAA, 43% \geq 601 DAA) at 125 mL/100L to 95% (regrowth = 0%) at 750 mL/100L. At the proposed label rates of 250 mL/100L and 375 mL/100L desiccation was assessed at 82% and 89% respectively (regrowth at 2 years = 0-30% for 250 mL and 0-12.5% for 375 mL/100L). For the control of blackberries the proposed product at and above label rates is as effective as the Triclopyr Butoxyethyl Ester industry standards and more efficacious than metsulfuron-methyl.

When treating bracken, metsulfuron-methyl caused 86.6 % desiccation with 0.6% regrowth (\geq 284 DAA). The proposed product produced similar results to metsulfuron-methyl ranging from 92 to 99% desiccation for rates from 350 to 750 mL/100L with no regrowth. The proposed product was as effective as the industry standard. Trials for ULTIMATE BRUSHWEED HERBICIDE on hawthorn demonstrated 98.5 – 100% desiccation and 0-02% regrowth for rates ranging from 125 – 1000 mL/100L. All treatments and rates except for the proposed product at 125 mL/100L resulted in 100% desiccation of sweet briar with no subsequent regrowth (\geq 369 DAA) therefore the efficacy was the same as the industry standards.

Gorse was much slower to desiccate than the other weeds treated under dry conditions. Trials for ULTIMATE BRUSHWEED HERBICIDE on gorse demonstrated 70% desiccation at 500 mL/100L (44% regrowth \geq 273 DAA) and 96% desiccation at 750mL/100L (30% regrowth). Metsulfuron-methyl alone demonstrated 42% desiccation (66% regrowth), Triclopyr Butoxyethyl Ester alone demonstrated 63% desiccation (66% regrowth) and Triclopyr Butoxyethyl Ester + picloram demonstrated 74% desiccation (8% regrowth).

The trial data demonstrate that ULTIMATE BRUSHWEED HERBICIDE gives control of these five weeds at label rates and is equivalent to industry standards.

The APVMA accepts the advice of the reviewer that the trial data support the specific label claims and the directions for use for ULTIMATE BRUSHWEED HERBICIDE.

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.
19639	S	Kerry Webb	Summary Report - ULTIMATE HERBICIDE for the CONTROL of Sweet briar (<i>Rosa rubiginosa</i>) AUSTRALIA 2000 to 2005.	2007	Efficacy and Safety	Efficacy	Applicant	
19640	S	Kerry Webb	Summary Report - ULTIMATE HERBICIDE for the CONTROL of Gorse (<i>Ulex europeans</i>),AUSTRALIA 2000 to 2005.	2007	Efficacy and Safety	Efficacy	Applicant	
19638	S	Kerry Webb	Summary Report - ULTIMATE HERBICIDE for the CONTROL of Hawthorn (<i>Crataegus monogyna</i>) AUSTRALIA 2000 to 2005.	2007	Efficacy and Safety	Efficacy	Applicant	
19636	S	Kerry Webb	ULTIMATE HERBICIDE for the CONTROL of Blackberry (<i>Rubus fruticosus</i>), AUSTRALIA 2000 to 2005.	2007	Efficacy and Safety	Efficacy	Applicant	
19637	S	Kerry Webb	Summary Report - ULTIMATE HERBICIDE for the CONTROL of Bracken (<i>Pteridium aquilinum</i>) AUSTRALIA 2000 to 2005.	2007	Efficacy and Safety	Efficacy	Applicant	
19641	S	Kerry Webb	Summary Report - ULTIMATE HERBICIDE for the CONTROL of Blackberry (<i>Rubus fruticosus</i>), TASMANIA 2000 to 2005.	2007	Efficacy and Safety	Efficacy	Applicant	
19635	S	Kerry Webb	Ultimate Summary Report	2/8/07	Efficacy and Safety	Efficacy	Applicant	

* S = Data submitted with the application

I = Data inherited (that is, referenced) from another application