Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: NUFARM ELIMINAR C HERBICIDE

Applicant: NUFARM AUSTRALIA LIMITED

Product number: 69510

Application number: 60959

Purpose of Application and Description of Use: Registration of a 250 g/L Bromoxynil and 25 g/L Picolinafen emulsifiable concentrate product for the control of a range of broadleaf weeds in winter cereals.

Active Constituent(s): BROMOXYNIL OCTANOATE

PICOLINAFEN

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 a new herbicide product, Nufarm Eliminar C Herbicide (previously named as Nufarm Retro Herbicide), containing bromoxynil octanoate at 250 g/L and picolinafen at 25 g/L in an emulsifiable concentrate, for the control of a range of broadleaf weeds in winter cereals.

The data package provided in the present submission comprised six acute toxicology studies on the product which have been conducted in accordance with contemporary test guidelines and were considered to be adequate for the assessment of the toxicology profile of the product. The acute toxicology data along with previously evaluated information on the repeat-dose toxicology of the active constituents were relied on by the OCS to establish a hazard profile for the proposed product. 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. In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide (1998) was used to estimate exposure.

The ADI for bromoxynil octanoate is 0.003 mg/kg bw/d and was established in 1993 based on a NOEL of 0.3 mg/kg bw/d from a 1 year dog study for reduced bodyweight gain at the next highest dose of 1.5 mg/kg bw/d and using a 100-fold safety factor. The ADI for picolinafen is 0.007 mg/kg bw/d and was established in 2000 based on a LOEL of 1.4 mg/kg bw/d from a 1 year dog study for body weight gain reduction at this dose and using a 200-fold safety factor. No ARfD has been established for bromoxynil or picolinafen. Bromoxynil is in Schedule 6 of the SUSMP with no exceptions. Picolinafen is in Appendix B of the SUSMP for substances considered not to require control by scheduling. Nufarm Eliminar C Herbicide containing 250 g/L of bromoxynil is a Schedule 6 poison.

Based on the findings of the toxicological studies evaluated, the product has low acute oral, acute dermal and acute inhalational toxicity. It is a non-skin irritant, a moderate eye irritant and not a skin sensitiser. Taking into consideration the potential toxicological hazard, use pattern and likelihood of handler exposure, First Aid Instructions, Safety Directions, re-entry statements were established to appear on the product label.

The OCS therefore recommended to the APVMA that there are no objections on human health grounds to the registration of the product Nufarm Eliminar C Herbicide, containing 250 g/L of bromoxynil octanoate and 25 g/L of picolinafen. Furthermore the proposed use of “Nufarm Eliminar C Herbicide” 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 public and occupational health & safety.

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.
88803	S	R. Verma	Acute dermal toxicity study of NUL2730 in rats	8 June 2013	Toxicology	Acute dermal studies, product	Applicant	
88804	S	R.Verma	Acute eye irritation study of NUL2730 in rabbits	11 June 2013	Toxicology	Acute eye irritation studies, product	Applicant	
88797	S	R.Verma	Acute inhalational toxicity study of NUL2730 in rats	8 June 2013	Toxicology	Acute inhalation studies, product	Applicant	
88802	S	R. Verma	Acute oral toxicity study of NUL2730 in rats	5 June 2013	Toxicology	Acute oral studies, product	Applicant	
88822	S	R.Verma	Acute dermal irritation study of NUL2730 in rabbits	5 June 2013	Toxicology	Acute skin irritation studies, product	Applicant	
88798	S	R.Verma	Skin sensitisation study of NUL2730 in Guinea pigs (Guinea pig maximisation test)	8 June 2013	Toxicology	Acute skin sensitisation studies, product	Applicant	

External Environment Reviewer

In support of the proposed product Nufarm Eliminar C Herbicide, an emulsifiable concentrate (EC) herbicide containing 250 g/L bromoxynil (as the octanoate) and 25 g/L picolinafen intended for weed control and weed suppression via post emergence application for wheat, barley, triticale and cereal rye by applying once using ground boom equipment as a solo application or in two possible tank mixes (containing either MCPA or terbutryn) an environment risk assessment was conducted was conducted on combination toxicity of the actives- bromoxynil and picolinafen. No data on combination toxicity to non-target species were submitted; therefore, where relevant, combination toxicity in the appropriate ratios was estimated assuming additive toxicity.

For the proposed solo application of Nufarm Eliminar C Herbicide (1 L/ha (250 g bromoxynil + 25 g picolinafen per ha; 91:9 ratio), risks to terrestrial vertebrates, fish, aquatic invertebrates, bees & other non-target arthropods, earthworms and soil micro-organisms were considered to be no greater than the nominated reference products. Risk of spray drift to algae and aquatic plants are acceptable at ≥120m. Risks of spray drift to non-target terrestrial plants are acceptable at ≥10m.

For the tank mix with MCPA for control of wild radish, (125 g bromoxynil + 12 g picolinafen + 200 g MCPA per ha; 37:4:59 ratio), risks to birds and mammals were determined to be acceptable when considering a post-emergence timing of application when residues are expected to be lower than in earlier crop stages. Risks to aquatic organisms are no greater than the solo application of Nufarm Eliminar C Herbicide. Risks to bees and other non-target arthropods are considered to be no greater than the nominated reference products or tank mix partner. Risks to earthworms were determined to be acceptable. Risks of

spray drift to non-target terrestrial plants are acceptable at ≥10m.

For the tank mix with a terbutryn SC 500 g/l product for control of fumitory ((90 g bromoxynil + 9 g picolinafen + 100 g terbutryn per ha; 45:5:50 ratio), risks to birds, bees and other non-target arthropods are considered to be no greater than the nominated reference products or the tank mix partner. Risks to mammals were determined to be acceptable when considering a post-emergence timing of application when residues are expected to be lower than in earlier crop stages. Risks to aquatic organisms, earthworms and non-target terrestrial plants are considered to be no greater than the solo application of Nufarm Eliminar C Herbicide.

The reviewer therefore concluded that the environmental risks of solo application of Nufarm Eliminar C Herbicide or in tank mix with MCPA or Terbutryn at the proposed rates were determined to be acceptable with mitigation measures to minimise risk to aquatic species and non-target terrestrial plants (spray drift restrictions).

Having considered the advice, and the RLP being amended by incorporating the recommendations, the APVMA is satisfied that the proposed use of the product would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment provided the product is applied according to the proposed label instructions.

State/External Efficacy Reviewer

A series of 17 efficacy and crop tolerance trials have been conducted in winter cereals to support the registration of Nufarm Eliminar C Herbicide. The trials program consisted of 7 bioequivalence trials (comparing directly Retro and the reference product), a further 4 efficacy trials (assessing Retro alone and in tank mixes) and six crop tolerance trials. Trials were conducted under normal winter-like conditions experienced during July and August in southern Australia.

All trials were conducted as randomised complete blocks with four to five replicates. Individual plots were around 2.5 m wide by 10 m. Treatments were applied in a spray volume of 90 – 100 L/ha of water (majority 100 L/ha) as a coarse spray quality using hand held spray booms with 4 to 6 nozzles spaced 50 cm apart.

Assessments were undertaken with weed counts at application and at 8 weeks after application. Percent weed control was undertaken 2, 4 and 8 weeks after application. The bioequivalence trials assessed Nufarm Eliminar C Herbicide against the reference product at registered label rates and timings in the two major winter cereals wheat and barley, against the primary target weed species, Wild radish (*Raphanus raphanistrum*), as well as capeweed, Indian hedge mustard, paterson's curse and shepherd's purse. Data were analysed using an Analysis of Variance (ANOVA) to compare means.

The trial data shows that Retro provides equivalent levels of weed control across a range of weeds when compared to the commercial standard Minder. Data provided also showed that in tank mixes, grass herbicides did not impact broadleaf weed control by Nufarm Eliminar C Herbicide and that Nufarm Eliminar C Herbicide did not impact grass control by these grass herbicides. These data also indicate that the inclusion of oils to assist the activity of grass herbicides did not significantly increase crop effects.

Field crop tolerance data from a range of trials demonstrated that the effect of Nufarm Eliminar C Herbicide was equivalent to that of the reference product on wheat and barley. Whilst some phytotoxic symptoms were observed with the use of each product, these were generally transient and commercially acceptable. However some significant reduction in yields of wheat and barley were observed in weed free situations.

Assessments were undertaken for crop phytotoxicity. In a number of trials the product was applied at double label (2X) rates, with no crop phytotoxicity observed. It was concluded that the application of Nufarm Eliminar C Herbicide at proposed label rates is safe to the crop.

In conclusion, the reviewer recommended that the trial data supports the registration of Nufarm Eliminar C Herbicide. 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.
88821	S	R.Devlin, A.Wherrett	Assessing the effectiveness of NUL2730 in crop in comparison to Minder	24 January 2013	Efficacy and safety	Efficacy	Applicant	
88820	S	S.Tilbrook	Develop NUL2730: Tank mix compatibility	6 February 2013	Efficacy and safety	Efficacy	Applicant	
88813	S	R.Porter	Evaluation of NUL 2730 275 EC in various tank mixtures for the control of annual grass and broadleaf weeds in wheat cv. Mace	15 March 2013	Efficacy and safety	Efficacy	Applicant	
88812	S	N.Whittaker	Evaluation of NUL2730 tank mixes for control of Annual Ryegrass (Lolium rigidum) in wheat cv. Gregory	13 February 2013	Efficacy and safety	Efficacy	Applicant	
88811	S	N.Whittaker	Evaluation of NUL2730 tank mixes for control of wild radish (Raphanus raphanistrum) in wheat cv. Livingston	13 February 2013	Efficacy and safety	Efficacy	Applicant	
88805	S	S.Tilbrook	NUL2730: Develop Timing and rates	23 January 2013	Efficacy and safety	Efficacy	Applicant	
88806	S	S.Tilbrook	NUL2730: Develop Timing and rates	23 January 2013	Efficacy and safety	Efficacy	Applicant	
88807	S	A.Wherrett	Assessing the effectiveness of NUL2730 in crop in comparison to Minder	24 January 2013	Efficacy and safety	Efficacy	Applicant	
88808	S	B.Frost	Develop NUL2730 - Timing and Rates	27 March 2013	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
88809	S	N.Whittaker	Evaluation of NUL2730 for the control of shepherd's purse (Capsella bursa-pastoris) and Indian hedge mustard (Sisymbrium orientale) in wheat cv. Gregory	18 March 2013	Efficacy and safety	Efficacy	Applicant	
88810	S	D.Lonsdale	Develop NUL2730 - timing and rates	7 February 2013	Efficacy and safety	Efficacy	Applicant	
88818	S	H.Dhammu, V.Lambert	Herbicide tolerance of barley varieties (Katanning)	2 April 2013	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	
88819	S	S.Tilbrook	NUL2730-Crop Tolerance, Timing and Rates	21 February 2013	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	
88814	S	S.Tilbrook	NUL2730 - Crop Tolerance, Timing and Rates	5 February 2013	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	
88815	S	H.Wu, P.Lockley, P.Shephard	Differential Herbicide Tolerance of Winter Crops in S.E Australia - Stage 3. Nufarm Australia Ltd 2012 Report	2013	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	
88816	S	H.Dhammu, D.Nicholson	Herbicide tolerance of wheat varieties (Mullewa)	2 April 2013	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	
88817	S	H.Dhammu, V.Lambert	Herbicide tolerance of wheat varieties (Katanning)	2 April 2013	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	

** S = Data submitted with the application*