



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: BOBCAT I-MAXX HERBICIDE
Applicant: ADAMA AUSTRALIA PTY LIMITED
Product number: 69698
Application number: 61461

Purpose of Application and Description of Use: Registration of a 25 g/L Imazapic present as the ammonium salt and urea salt and 125 g/L Hexazinone, soluble concentrate product for the control of a wide range of annual and perennial grasses and broadleaf weeds in sugar cane.

Active Constituent(s): HEXAZINONE
IMAZAPIC

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 Bobcat i-Maxx Herbicide, containing hexazinone at 125 g/L and imazapic (as the ammonium salt) at 25 g/L in a soluble concentrate (SL) for the control of grasses and broadleaf weeds in sugarcane.

The applicant submitted six acute toxicology studies which were conducted in accordance with the Organisation for Economic Co-operation and Development (OECD) guidelines. The Office of Chemical Safety (OCS) has assessed the provided toxicity studies and other information on the product which were considered adequate to for risk assessment. 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 Acceptable Daily Intake (ADI) for hexazinone is 0.1 mg/kg bw/d and was established in 1987, based on a No Observed Effect Level (NOEL) of 10 mg/kg bw/d. from a two-year rat study where decreased body weight was observed at the next highest dose of 2500 ppm and using a 100-fold safety factor. The ADI for imazapic is 0.3 mg/kg bw/d and was established in 1996, based on a LOEL of 5000 ppm (137 mg/kg bw/d) from 1-year dog dietary study based on based on degeneration and necrosis of skeletal muscle at 5000 ppm and on reduced haematocrit, haemoglobin and RBC level at the next highest dose of 20000 ppm and applying a 500-fold safety factor. Acute Reference Dose (ARfD) values have not been established for either hexazinone or imazapic and no data were submitted to enable ARfD values to be set.

Hexazinone is listed in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) except when included in Schedule 5. Hexazinone is in Schedule 5 of the SUSMP in preparations containing 25 per cent or less hexazinone. Imazapic is listed in Schedule 5 of the SUSMP except in preparations containing 25 per cent or less imazapic. The acute toxicity profile and the concentration of the active constituents in the product therefore justifies this to be considered as a Schedule 5 poison.

Based on the findings of the toxicological studies evaluated, the product formulation was of low acute oral toxicity, low acute dermal and low acute inhalation toxicity in rats. The product was a moderate-irritant to the eyes of rabbits but was not a skin-irritant in rabbits. The product was not a skin sensitiser in guinea pigs.

The toxicology data and other information on the product provided and considered during this assessment justify the recommendations and the Safety Directions (SD) established.

The OCS therefore recommended to the APVMA that there are no objections on human health grounds to the registration of the product Bobcat i-Maxx Herbicide, containing 125 g/L hexazinone and 25 g/L imazapic. Furthermore, the proposed use of the Bobcat i-Maxx Herbicide will not be an undue health hazard to humans when applied for control of weeds in sugarcane when apply by groundboom application methods 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.

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.
82907	S	Kesavan, S. M.	Acute Dermal Toxicity Study with Farnoz Bobcat Imax SL in Wistar Rats.	18 July 2013	Toxicology	Acute dermal studies, product	Applicant	
82908	S	Kesavan, S. M.	Acute Eye Irritation/Corrosion of Farnoz Bobcat Imax SL in New Zealand White Rabbits.	18 July 2013	Toxicology	Acute eye irritation studies, product	Applicant	
82909	S	Srinivas, A.	Farnoz Bobcat Imax SL: Acute Inhalation Toxicity Study in Wistar Rats.	15 July 2013	Toxicology	Acute inhalation studies, product	Applicant	
82910	S	Kesavan, S. M.	Acute Oral Toxicity Study with Farnoz Bobcat Imax SL in Wistar Rats.	18 July 2013	Toxicology	Acute oral studies, product	Applicant	
82911	S	Kesavan, S. M.	Acute Dermal Irritation/Corrosion of Farnoz Bobcat Imax SL in New Zealand White Rabbits.	18 July 2013	Toxicology	Acute skin irritation studies, product	Applicant	
82912	S	Kesavan, S. M.	Skin Sensitization Potential of Farnoz Bobcat Imax SL in Guinea Pigs.	18 July 2013	Toxicology	Acute skin sensitisation studies, product	Applicant	

Australian Government Department of Environment

In support of the registration of a new combination product Bobcat i-Maxx Herbicide, containing two existing active constituents containing 125 g/L hexazinone and 25 g/L imazapic as the ammonium salt for use in the control of a wide range of annual and perennial grasses and broadleaf weeds in sugar cane, the applicant provided literature articles and international reports for the individual active constituents. The information provided, and the existing information from the Department's data holdings and current literature articles sourced by the Department of Environment for the two active constituents were to conduct the assessment.

Given that the product is proposed to be used on sugarcane plantations in the vicinity of the Great Barrier Reef (GBR), there is considerable concern of the effects of pesticide run-off from treated fields to this sensitive ecosystem. Consequently, the impact of runoff waters on the Great Barrier Reef was considered as done in the APVMA's recent review of diuron. A runoff risk assessment was undertaken based on the updated toxicity data for aquatic organisms in the

freshwater and marine environment, and available monitoring data in the GBR regions. The assessment concluded that key GBR organisms are adequately protected since the runoff risk using conservative endpoints is acceptable.

The Department of Environment therefore recommended to the APVMA to be 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 under Section 14 subsection 1 of the Agvet Codes provided the product is applied according to 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.
82885	S	Lee-Steere, C.	Bobcat iMaxx Refined Runoff Risk Assessment for use in Sugar Cane.	08 August 2013	Environment fate	Modelling studies	Applicant	
82889	S	Thompson D.G., Holmes S.B., Wainio-Keizer K., MacDonald L., and Solomon K.R.	Impact of Hexazinone and Metsulfuron Methyl on the Zooplankton Community of a Boreal Forest Lake	1993	Environment toxicology	Other information	Public	
82892	S	Anon.	Imazapic Ecological Risk Assessment Final Report.	November 2005	Environment toxicology	Other information	Public	
82894	S	Flores, F., Collier, C. J., Mercurio, P. and Negri, A. P.	Phototoxicity of four photosystem II herbicides to tropical seagrasses.	2013	Environment toxicology	Other information	Public	
82895	S	Anon.	Water Quality Guidelines for the Great Barrier Reef Marine Park.	2010	Environment toxicology	Other information	Public	
82896	S	Jones, R. J., Muller, J., Haynes, D. and Schreiber, U.	Effects of Herbicides Diuron and Atrazine on Corals of the Great Barrier Reef, Australia.	11 April 2003	Environment toxicology	Other information	Public	
82898	S	Magnusson, M., Heimann, K., Quayle, P. and Negri, A. P.	Additive Toxicity of Herbicide Mixtures and Comparative Sensitivity of Tropical Benthic Microalgae.	2010	Environment toxicology	Other information	Public	
82899	S	Mayo-Bean, K., Moran, K., Meylan, B., and Ranslow, P.	Methodology Document for the ECOlogical Structure-Activity Relationship Model (ECOSAR) Class Program.	May 2012	Environment toxicology	Other information	Public	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
82900	S	Muller, R., Schreiber, U., Escher, B. I., Quayle, P., Nash, S. M. B. and Mueller, J. F.	Rapid Exposure Assessment of PSII Herbicides in Surface Water Using a Novel Chlorophyll a Fluorescence Imaging Assay.	27 May 2008	Environment toxicology	Other information	Public	
82901	S	Negri, A. P., Flores, F., Rothig, T. and Uthicke, S.	Herbicides Increase the Vulnerability of Corals to Rising Sea Surface Temperature.	2011	Environment toxicology	Other information	Public	
82902	S	Durkin, P. and Follansbee, M.	Imazapic - Human Health and Ecological Risk Assessment - Final Report.	23 December 2004	Environment toxicology	Other information	Public	
82903	S	Trevathan, W.	Hexazinone Pesticide Fact Sheet: Forestry Use.	November 2002	Environment toxicology	Other information	Public	
82904	S	Anon.	Reregistration Eligibility Decision (RED) Hexazinone.	September 1994	Environment toxicology	Other information	Public	
82905	S	Thompson D., Holmes S., Thomas D., MacDonald L. and Solomon K.	Impact of Hexazinone and Metsulfuron Methyl on the Phytoplankton Community of a Mixed-Weed/Boreal Forest Lake.	1993	Environment toxicology	Other information	Public	
82906	S	Durkin, P., King, C. and Klotzbach, J.	Hexazinone - Human Health and Ecological Risk Assessment - Final Report.	25 October 2005	Environment toxicology	Other information	Public	

State/External Efficacy Reviewer

The applicant has provided reports of six small-plot field trials in support of registration of the proposed product Bobcat i-Maxx Herbicide containing imazapic 25g/L + hexazinone 125g/L for the control of grasses and broadleaf weeds in sugarcane. The trials were conducted, in several sugarcane growing areas of Queensland, during 2011-12, 2012-13 and 2013. The six trials were all conducted as randomised complete block designs consisting of 10 to 15 treatments per trial with 3 or 4 replicates. In all trials Bobcat i-Maxx, tank mixture treatments of Imazapic + Bobcat SL were applied at similar doses to ensure bioequivalence. The registered standard products containing imazapic and hexazinone were also included in all trials. Results were analysed using standard statistical procedures (ANOVA, LSD).

The efficacy of Bobcat i-Maxx, in controlling a range of broad-leaf and grass weeds in sugar cane, was compared to several reference products, imazapic 240g/L SL, and diuron 468g/L+hexazinone132g/L WG. Target weeds were: Morning glory (*Ipomoea purpurea*); Sowthistle (*Sonchus oleraceus*); Blackberry nightshade (*Solanum* nigrum*); Cobblers peg (*Bidens pilosa*); Fleabane (*Conyza* sp.); Glycine (*Neonotonia wightii*); Guinea grass (*Panicum maximum*);

Nutgrass (*Cyperus rotundus*); Painted spurge (*Euphorbia cyanthophora*); Calopo vine (*Calopogonium mucunoides*); Square weed (*Spermacoce latifolia*); Ageratum, also called Bluetop, (*Ageratum houstonianum*); Green summer grass (*Urochloa* (syn *Bracharia*) *decumbens*); Crowsfoot grass (*Eleusine indica*); Red convolvulus (*Ipomoea hederifolia*); Phyllanthus (*Phyllanthus* spp.) and; Wild rose (*Cleome aculeate*).

Bobcat i-Maxx at 3840 mL/ha recorded full control of all weed species at 12 weeks after application. The data also provided evidence that Bobcat i-Maxx and tank mixture treatments applied at similar doses, are bioequivalent in control of the nominated weed spectrum.

In conclusion the reviewer recommended that the trial data support the registration of Bobcat i-Maxx Herbicide, for the control of a wide range of annual and perennial grasses and broadleaf weeds in sugarcane, at the rate specified in the label.

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.
82879	S	Pengelly, S.	Evaluation of New Pre-Emergent Herbicide for Residual Weed Control in Sugarcane. One Trial, Cordalba, Queensland, Australia, 2011/2012.	31 August 2012	Efficacy and safety	Efficacy	Applicant	
82880	S	Lewis, K.	Comparison of Impose 240 SL, Mayoral 350 SL and Mixtures of Impose or Mayoral with Soccer 750 WG for Pre Emergent Weed Control in Trash Blanket Sugarcane. Innisfail, Queensland, 2011/12.	27 July 2012	Efficacy and safety	Efficacy	Applicant	
82881	S	Themsen, C. and Bennett, K.	Evaluation of FMZ 1210 for the control of grasses and broadleaf weeds in sugarcane cv. Q208 when applied at the out of hand stage in a sugarcane plant crop. Abington, Queensland, 2012-13.	15 August 2013	Efficacy and safety	Efficacy	Applicant	
82882	S	Themsen, C. and Bennett, K.	Evaluation of FMZ 1210 and other pre-emergent herbicides for the control of grasses and broadleaf weeds in sugarcane cv. Q208 when applied over a green trash blanket. Abington, Queensland, 2012-13.	12 June 2013	Efficacy and safety	Efficacy	Applicant	
82883	S	Lewis, K.	Comparison of Impose 240 SL, Bobcat Combi 600 WG, Bobcat 250 SL and FMZ 1210 150 SL in mixture with Gramoxone 250 SL for weed control in plant sugarcane when applied at out of hand stage. Innisfail, Queensland, 2013.	26 June 2013	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
82884	S	Pengelly, S.	Evaluation of New Pre-Emergent Herbicide for Residual Weed Control in Sugarcane. One Trial, Bundaber, Queensland, Australia, 2011/2012.	3 September 2012	Efficacy and safety	Efficacy	Applicant	

* S = Data submitted with the application