

**Public Release Summary
on**

**Evaluation of the new active
ETHAMETSULFURON METHYL
in the product
BOUNTY SELECTIVE HERBICIDE**

**National Registration Authority
for Agricultural and Veterinary Chemicals**

March 2002

**Canberra
Australia**

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FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the NRA works in close cooperation with advisory agencies, including the Department of Health and Ageing (Chemicals and Non-prescription Medicines Branch), Environment Australia (Risk Assessment and Policy Section), the National Occupational Health and Safety Commission (NOHSC) and State departments of agriculture and environment.

The NRA has a policy of encouraging openness and transparency in its activities and of seeking community involvement in decision making. Part of that process is the publication of public release summaries for all products containing new active ingredients and for all proposed extensions of use for existing products.

The information and technical data required by the NRA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the NRA's publications *Ag Manual: The Requirements Manual for Agricultural Chemicals* and *Ag Requirements Series*.

This Public Release Summary is intended as a brief overview of the assessment that has been completed by the NRA and its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience thereby encouraging public comment.

More detailed technical assessment reports on all aspects of the evaluation of this chemical can be obtained by completing the order form in the back of this publication and submitting with payment to the NRA. Alternatively, the reports can be viewed at the NRA Library Ground Floor, 22 Brisbane Avenue, Barton, ACT.

The NRA welcomes comment on the usefulness of this publication and suggestions for further improvement. Comments should be submitted to the Executive Manager Registration, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box E240, Kingston ACT 2604.

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LIST OF ABBREVIATIONS AND ACRONYMS

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
BBA	Biologische Bundesanstalt für Land – und forstwirtschaft
bw	bodyweight
d	day
DAT	Days After Treatment
DT₅₀	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
ECD	Electron capture detection
E_bC₅₀	concentration at which the biomass of 50% of the test population is impacted
EC₅₀	concentration at which 50% of the test population are immobilised
EEC	Estimated Environmental Concentration
E_rC₅₀	concentration at which the rate of growth of 50% of the test population is impacted
ESI-MS	Electro spray ionisation mass selection
F₀	original parent generation
g	gram
GAP	Good Agricultural Practice
GC	Gas chromatography
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GVP	Good Veterinary Practice
h	hour
ha	hectare
Hct	Haematocrit
Hg	Haemoglobin
HPLC	High Pressure Liquid Chromatography <i>or</i> High Performance Liquid Chromatography
id	intradermal
im	intramuscular
ip	intraperitoneal
IPM	Integrated Pest Management
iv	intravenous
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
kg	kilogram
K_{oc}	Organic carbon partitioning coefficient
L	Litre
LC₅₀	concentration that kills 50% of the test population of organisms
LD₅₀	dosage of chemical that kills 50% of the test population of organisms
LOD	Limit of Detection – level at which residues can be detected
LOQ	Limit of Quantitation – level at which residues can be quantified
mg	milligram
mL	millilitre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee
NEDI	National Estimated Daily Intake
ng	nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	No Observable Effect Concentration/Level
OC	Organic Carbon

OM	Organic Matter
PHI	Pre-Harvest Interval
po	oral
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
Q-value	Quotient-value
RBC	Red Blood Cell Count
s	second
sc	subcutaneous
SC	Suspension Concentrate
SPE	Solid Phase Extraction
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration
TGAC	Technical grade active constituent
TRR	Total Radioactive Residues
T-Value	A value used to determine the First Aid Instructions for chemical products that contain two or more poisons
mg	microgram
uv	Ultra violet
vmd	volume median diameter
WG	Water Dispersible Granule
WHO	World Health Organisation
WHP	Withholding Period

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INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of BOUNTY SELECTIVE HERBICIDE which contains the new active ingredient, ethametsulfuron methyl, in combination with another currently approved active, diflufenican.

Responses to the Public Release Summary will be considered prior to registration of the product. These will be taken into account by the NRA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

Copies of full technical evaluation reports on ethametsulfuron-methyl, covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the NRA on request (see order form on last page). They can also be viewed at the NRA library located at the NRA offices, Ground Floor, 22 Brisbane Avenue, Barton ACT 2604.

Written comments should be submitted by 5 April 2002 and addressed to:

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National Registration Authority
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Kingston ACT 2604

Applicant

Aventis CropScience Pty Ltd

Product Details

It is proposed to register BOUNTY SELECTIVE HERBICIDE containing 270 g/kg ethametsulfuron methyl and 595 g/kg diflufenican as a water dispersible granule formulation for use on narrow leaf lupins in Western Australia. The active constituent ethametsulfuron methyl is manufactured overseas and will be imported into Australia. BOUNTY SELECTIVE HERBICIDE will be formulated and packaged in Australia. It will be packaged in 3, 5, 10 and 20 kg containers.

Ethametsulfuron methyl is a novel sulfonylurea herbicide which acts by inhibiting biosynthesis of essential amino acids valine and isoleucine (ALS inhibitor). It is exempt from poisons scheduling. Diflufenican is a nicotinanilide herbicide which acts by inhibiting carotenoid biosynthesis and is also exempt from poisons scheduling.

BOUNTY SELECTIVE HERBICIDE is a member of the sulfonylurea and nicotinanilide group of herbicides. For weed resistance management this product is a group **B** and **F** herbicide.

BOUNTY SELECTIVE HERBICIDE has been developed as a post-emergence selective herbicide for the control of a selected range of broadleaf weeds in narrow leaf lupins. This product will give the lupin growers a range of options for control of wild radish and their first ever option for post-emergence control of doublegee (spiny emex, three cornered jack). Ethametsulfuron methyl is currently registered for use on canola in Canada.

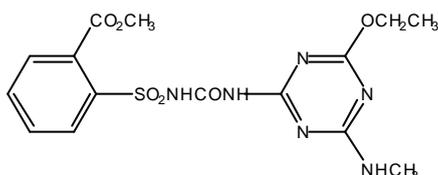
CHEMISTRY AND MANUFACTURE

ACTIVE CONSTITUENT

The active constituent ethametsulfuron methyl is manufactured at DuPont de Nemours (Flandre) SA, Route de pres fevrier, Loon-Plage, France and has been approved by the NRA (Approval Number 53546)

The active constituent has the following properties:

Common name:	Ethametsulfuron methyl (ASA)
Chemical name:	methyl 2-[[[[[4-ethoxy-6-(methylamino)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]benzoate
CAS Registry Number:	97780-06-08
Empirical formula:	C ₁₅ H ₁₈ N ₆ O ₆ S
Molecular weight:	410.4
Structural formula:	



Physical and Chemical Properties of Active Constituent

Physical form:	Crystalline solid
Colour:	White
Odour:	None
Melting point	194 ⁰ C
Density:	1.6 g/cc
Octanol/water partition: coefficient (K _{OW}):	38 at pH 5
Vapour pressure:	5.8 x 10 ⁻¹⁵ mm Hg
Solubility in water (25 ⁰ C)	350 mg/L @ pH 7

PRODUCT

Formulation type:	Water dispersible granule (WG)
Colour:	light brown
Physical form:	elongated granule
pH (0.5% dispersion):	7.5

Conclusion

Based on an assessment of the chemistry and manufacturing details provided by the applicant, the NRA is satisfied that BOUNTY SELECTIVE HERBICIDE will be manufactured to consistent specifications using sources of actives approved by the NRA and will be stable for a minimum of two years.

TOXICOLOGICAL ASSESSMENT

Evaluation of Toxicology

The toxicological database for ethametsulfuron-methyl, which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects might be generated in humans. From a conservative risk assessment perspective however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available. Where possible, considerations of the species specific mechanisms of adverse reactions weigh heavily in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels compared with those, usually many times higher, which produce effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

Toxicokinetics and Metabolism

Radiolabelled ethametsulfuron-methyl was administered in an acetone/corn oil mixture by gavage to rats as single repeat doses. The majority (>90%) of the administered dose was excreted within 48 hours with approximately equal proportions excreted in the faeces and urine. Ethametsulfuron-methyl was primarily excreted unchanged, but the metabolites N-demethyl and O-deethyl ethametsulfuron-methyl were also found in the excreta.

Acute Studies

Ethametsulfuron-methyl has low acute oral and inhalational toxicity in the rat ($LD_{50} >5000$ mg/kg bw with no deaths, $LC_{50} >5700$ mg/m³ with no deaths), low dermal toxicity in the rabbit ($LD_{50} >2000$ mg/kg bw with no deaths), is not a skin irritant in the rabbit on either intact or abraded skin, or a skin sensitiser in the guinea pig but is a moderate eye irritant in the rabbit. In studies designed to determine the approximate lethal dose in male rats and rabbits no animal died at doses up to 11000 and 5000 mg/kg bw respectively and clinical signs were limited to slight weight loss and, in the rat, wet perineum.

BOUNTY SELECTIVE HERBICIDE is expected to have low acute oral, dermal and inhalation toxicity. It is anticipated that it may cause slight skin and eye irritation.

Short-Term Studies

Male rats were treated with ethametsulfuron-methyl by gavage at 0 or 2200 mg/kg bw/day for 10 doses over 14 days with half the animals sacrificed 4 hours after the last dose and the remainder retained without treatment for a further 14 days before sacrifice. Histology revealed intracytoplasmic protein droplets in the epithelial cells of the proximal tubules of the kidneys of 2/3 animals killed after treatment and 1/3 killed after the recovery period. There were no other gross or histological findings.

Mice were treated with ethametsulfuron-methyl in the diet at 0, 50, 500, 2500 or 5000 ppm (approximately equal to 0, 7, 73, 350 and 690 mg/kg bw/day in males and 0, 10, 100, 500, and 920 mg/kg bw/day in females) for 90 days. There were no effects at the highest dose.

Rats were treated in the diet with ethametsulfuron-methyl at 0, 100, 1000, and 5000 ppm for 90 days. Actual approximate ethametsulfuron-methyl intake was 0, 7.5, 70, 365 mg/kg bw/day for males and 0, 9.5, 90, 450 mg/kg bw/day for females. Incidences of alopecia and coloured discharge from the eyes were increased in males at 5000 ppm. The NOEL was 1000 ppm (approximately 90 mg/kg bw/day).

Dogs were treated in the diet with ethametsulfuron-methyl at 0, 100, 3500, and 10000 ppm for 90 days to yield approximate actual ethametsulfuron-methyl intakes (m/f) 0, 3.5/4, 135/140, 390/380 mg/kg bw/day. There were no treatment related effects on any parameter examined at any dose and thus the no effect level was 10000 ppm in this study, the highest dose tested (approximately equal to 380 mg/kg bw/day).

Long-Term Studies

Mice were administered ethametsulfuron-methyl in the diet at levels of 0, 25, 500 and 5000 ppm for 18 months (approximate actual doses were (m/f) 3.5/4.6, 68/95, 700/930 mg/kg bw/day). The overall total number of mice with tumours was significantly and substantially *decreased* in both males and females at 5000 ppm, primarily due to a decrease in the number of animals with benign tumours, with the incidence of malignant tumours similar to control. There were no adverse or toxicologically significant effects at 5000 ppm (approx. 700 mg/kg bw/day), the highest dose tested.

Rats were administered ethametsulfuron-methyl in the diet at 0, 50, 500, or 5000 ppm for 2 years with an interim sacrifice at 12 months. Approximate actual ethametsulfuron-methyl intake was (m/f); 0, 2.1/2.6, 21/26, 210/270 mg/kg bw/day. Rats at 5000 ppm had slightly but significantly lower serum sodium levels at various times in the study. The incidence of enlarged mammary glands was significantly and substantially increased in females at 5000 ppm, although there were no differences between the groups in the histology of this tissue. There were no differences between groups in the incidences of benign or malignant neoplasms. The NOEL was 500 ppm (approximately equal to 21 mg/kg bw/day).

Dogs were treated with ethametsulfuron-methyl in the diet at 0, 250, 3000, and 15000 ppm for 12 months. Approximate actual achieved doses were (m/f) 0, 7.6/6.9, 87, 480 mg/kg bw/day. Effects were seen only at 15000 ppm and consisted of lower body weight gains accompanied by slightly lower food consumption, slightly but significantly decreased serum sodium and increased liver weights in both sexes with decreased thyroid/parathyroid weights in females. The NOEL was 3000 ppm (approximately equal to 87 mg/kg bw/day).

Reproduction and Developmental Studies

Rats were treated in the diet with ethametsulfuron-methyl at 0, 100, 1000, and 5000 ppm for 90 days then mated to produce a single generation. There were no effects at the highest dose tested (approximately equal to a dose of 450 mg/kg bw/day in adult females).

In a 2 generation reproduction study with 2 litters per generation, rats were treated in the diet at levels of 0, 250, 5000, or 20000 ppm. Parental body weights at 20000 ppm were slightly lower than control in both generations, but significant only in males. Food consumption was

slightly but significantly reduced in 20000 ppm F₁ parental males only. There were no effects on reproduction at the highest treatment level of 20000 ppm (approximately equal to 1000 mg/kg bw/day). The NOEL for parental toxicity was 5000 ppm (approximately equal to 250 mg/kg bw/day) based on reduced body weight gains at 20000 ppm in both generations.

Pregnant rats were treated by gavage with ethametsulfuron-methyl at 0, 60, 250, 1000 or 4000 mg/kg bw/day on gestation days 7 to 16 (the day of discovery of a copulation plug was designated day 1) and sacrificed on gestation day 22. Other than a slight reduction in body weight gain at 4000 mg/kg bw/day, probably reflecting GIT discomfort rather than systemic toxicity, accompanied by reduced food consumption, there were no maternal effects at any dose. The lower maternal weight gain may have contributed to the increase in skeletal variations, manifested primarily as delayed ossification of the sternbrae, seen in foetuses of this group. There was no maternal toxicity at 4000 mg/kg bw/day the highest dose tested. The NOEL for foetal development was 1000 mg/kg bw/day based on delayed ossification seen at 4000 mg/kg bw/day.

Pregnant rabbits were administered ethametsulfuron-methyl by gavage at 0, 250, 1000, or 4000 mg/kg bw/day on gestation days 7 to 19 and sacrificed on day 29. The highly viscous nature of the dosing solution at 4000 mg/kg bw/day resulted in increased maternal mortality through GIT obstruction and increased the incidence of abortions and clinical signs (primarily related to discoloured faeces and reduced faeces size and number). Reduced body weight gains and food consumption during treatment were also likely to be related to the properties of the dosing solution. The incidence of early resorptions was increased at 4000 mg/kg bw/day. Increased liver weights at 1000 and 4000 mg/kg bw/day set the maternal NOEL at 250 mg/kg bw/day but there were no developmental effects on the foetuses at the highest dose, 4000 mg/kg bw/day. The NOEL for embryotoxicity was 1000 mg/kg bw/day based on increased early resorptions at 4000 mg/kg bw/day.

Genotoxicity

Ethametsulfuron-methyl was not genotoxic in; an Ames test, an *in vivo* bone marrow chromosome aberration study in rats, an *in vivo* bone marrow micronucleus assay in mice, a HPRT assay in Chinese Hamster Ovary (CHO) cells, or in an Unscheduled DNA Synthesis (UDS) study in primary rat hepatocytes.

Public Health Standards

Poisons Scheduling

The National Drugs and Poisons Schedule Committee (NDPSC) considered the toxicity of the product and its active ingredients and assessed the necessary controls to be implemented under States' poisons regulations to prevent the occurrence of poisoning.

On the basis of its toxicity, the NDPSC has recommended that ethametsulfuron-methyl need not be included in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

NOEL/ADI

The lowest NOEL obtained for ethametsulfuron-methyl was 21 mg/kg bw/day in a 12 month dietary rat study. Since the toxicology database was extensive, a safety factor of 100 was used to establish an ADI of 0.2 mg/kg bw/day.

Conclusion

Based on an assessment of toxicology, it was considered that there should be no adverse effects on human health from the use of this product when used in accordance with label directions.

RESIDUES ASSESSMENT

Data concerning residues in lupins (seed, forage and straw) and animals and metabolism in plants and animals were considered as part of the residue evaluation of the application.

Metabolism

Translocation of residues from leaves to seed occurred to a minor extent following application of ¹⁴C-ethametsulfuron methyl to canola seedlings. At the 2-3 leaf stage application at a rate equivalent to 30 g ai/ha resulted in ethametsulfuron methyl residues in seed of 0.012 mg/kg, and 0.02 mg/kg after application at 100 g ai/ha. Parent compound was the predominant residue in plants and comprised 89-96% TRR at day 0 after application, 68-71% TRR at day 10 and 18-34% at day 31. On day 60 after application only low levels of parent compound were detected, while the O-deethyl and O-deethyl-N-demethyl metabolites, polar material and bound residues were present at ≤0.002 mg equiv/kg.

Elimination of radioactivity was almost evenly distributed between urine and faeces of rats given single oral doses of ¹⁴C-triazine or ¹⁴C-phenyl labelled ethametsulfuron methyl at 10 or 1000 mg/kg bw. Urinary and faecal elimination, which peaked between 12 and 48 hours after dosing, each accounted for between approximately 40-60% of the administered dose. Tissue retention of radioactivity was low. Up to 0.13% of administered radioactivity was recovered in the bodies of rats. Overall, greater than 98% of the administered dose was recovered over the 5 day test period for males and 93% for females.

In rats administered ¹⁴C-ethametsulfuron methyl at 10 mg/kg bw, radioactivity was detected in kidneys (0.07 mg equiv/kg), liver (0.03 mg equiv/kg), muscle (0.01 mg equiv/kg) and fat (0.02 mg equiv/kg). In rats administered ethametsulfuron methyl at 1000 mg/kg, highest tissue residues were detected in kidneys (5.5 mg equiv/kg), liver (5.4 mg equiv/kg), muscle (1.0 mg equiv/kg) and fat (4.2 mg equiv/kg). Radioactivity in tissues was not characterised, however major metabolites in urine were identified as ethametsulfuron methyl (ca. 30 – 70% TRR), O-deethyl ethametsulfuron methyl (8 – 30% TRR) and N-demethyl ethametsulfuron methyl (12 – 30% TRR). In faeces, major metabolites were ethametsulfuron methyl (ca. 60 – 93% TRR), O-deethyl ethametsulfuron methyl (1 – 30% TRR) and N-demethyl ethametsulfuron methyl (3 – 13% TRR). Metabolism of ethametsulfuron methyl in rats proceeds via O-deethylation and N-demethylation.

The metabolism data for ethametsulfuron methyl are consistent with that of other sulfonyl urea herbicides evaluated previously by the NRA, where it was demonstrated that predominant residues are either parent compound or metabolites of low toxicological significance.

Diflufenican is an approved active constituent in several registered products and the metabolic pathways have been established previously. A new poultry metabolism study was provided with the application. The majority of administered radioactivity was recovered in excreta and cage wash. Very little tissue retention of radioactivity occurred. The predominant residue component identified was diflufenican.

Analytical methods

Validated analytical methods were provided for the determination of ethametsulfuron methyl in plant and animal commodities and diflufenican residues in animal commodities. The ethametsulfuron methyl methods involve solvent extraction of residues with polar solvents

(methanol, acetonitrile and water) followed by purification by SPE cartridge cleanup. Following solvent partitioning, chromatography and filtration, residues are quantified by HPLC with UV or ESI-MS detection. The Limit of Quantitation (LOQ) is 0.02 mg/kg for both plant and animal commodities.

The method for diflufenican involves solvent extraction and SPE cartridge cleanup followed by solvent partitioning. Residues are then quantified by GC with ECD detection. The method has a LOQ of 0.02 mg/kg in animal tissues, milk and eggs.

Storage stability

Samples of grain, straw and forage fortified with ethametsulfuron methyl at 0.1 mg/kg were stored for up to 22 months at -20°C. After 22 months storage recoveries ranged from 75 – 80%. The results obtained in the residue trials are considered an accurate reflection of the residues present at sampling.

Residue definition

The parent compound is adequate for the purpose of monitoring Good Agricultural Practice (GAP). The residue definition should be ethametsulfuron methyl.

Residue trials

Residue field trials conducted in Australia were provided for evaluation. All trials included treatments that were consistent with proposed Australian GAP. Ethametsulfuron methyl residues in lupin seed following application at approximately 23 g ai/ha were <0.02 mg/kg (n=7), and <0.02 mg/kg (n=7) following application at approximately 46 g ai/ha. A Maximum Residue Limit (MRL) at the LOQ of 0.02 mg/kg is appropriate.

No new residue data were provided for diflufenican. When present in BOUNTY SELECTIVE HERBICIDE, diflufenican will be applied in a manner consistent with the registered uses of other diflufenican products. No new residue data were required as part of this application.

Animal feed commodity MRLs

Ethametsulfuron methyl residues in lupin straw were below the LOQ of 0.02 mg/kg in all trials following application at up to twice the proposed maximum label rate for Bounty herbicide. An MRL at the LOQ of 0.02 mg/kg is appropriate.

Ethametsulfuron methyl residues in lupin forage decline to below the LOQ (0.02 mg/kg, fresh weight) 79-80 days after application of BOUNTY SELECTIVE HERBICIDE at up to twice the proposed maximum application rate. An MRL for lupin forage (fresh weight) at the LOQ of 0.02 mg/kg is appropriate.

Animal commodity MRLs

No animal transfer studies were provided, however ethametsulfuron methyl residues above the LOQ are not expected in lupin seed, straw and forage when the product is used as directed. Given that quantifiable residues are not expected to occur in animal feed commodities it is appropriate to set MRLs at the LOQ (0.02 mg/kg) for mammalian and poultry meat and offal, milk and eggs.

Lupins and other commodities such as cereal grains and pulses may be fed to poultry. The diflufenican poultry metabolism study provided indicates quantifiable residues should not occur in poultry commodities as a result of consumption of diflufenican-treated produce.

MRLs set at the LOQ (0.02 mg/kg) are therefore recommended for diflufenican in poultry meat, offal and eggs.

Estimated dietary intakes

The chronic dietary risk is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and dietary intake data from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with accepted guidelines.^Φ

The NEDI for ethametsulfuron methyl is equivalent to 0.1% of the ADI. It is concluded that the chronic dietary exposure is small and the risk is acceptable. An acute reference dose was not considered necessary therefore the acute dietary exposure has not been considered here.

Bioaccumulation potential

Ethametsulfuron methyl has a calculated log P value of 0.89 indicating that it is unlikely to preferentially concentrate in fat.

Recommended amendments to the MRL Standard:

Table 1

Compound	Food	MRL (mg/kg)	
ADD			
Ethametsulfuron methyl	VD 0545	Lupin (dry)	*0.02
	MM 0095	Meat [mammalian]	*0.02
	MO 0105	Edible offal (mammalian)	*0.02
	ML 0106	Milks	*0.02
	PO 0111	Poultry, Edible offal of	*0.02
	PM 0110	Poultry meat	*0.02
	PE 0112	Eggs	*0.02
Diflufenican	PO 0111	Poultry, Edible offal of	*0.02
	PM 0110	Poultry meat	*0.02
	PE 0112	Eggs	*0.02

* Denotes MRL set at or about the limit of analytical quantitation

Table 3

Compound	Residue
Ethametsulfuron methyl	
ADD:	Ethametsulfuron methyl

^Φ Guidelines for predicting dietary intake of pesticide residues (revised), World Health Organisation, 1997.

Table 4

Compound	Food	MRL (mg/kg)	
ADD			
Ethametsulfuron methyl	AL 0545	Lupin forage [fresh weight]	*0.02 mg/kg
		Lupin straw	*0.02 mg/kg

Withholding Periods

The following Withholding Periods are recommended in relation to the above MRLs:

Harvest

NOT REQUIRED WHEN USED AS DIRECTED

Grazing

DO NOT GRAZE OR CUT FOR STOCK FEED FOR 12 WEEKS AFTER APPLICATION

Conclusion

The NRA is satisfied that the proposed use of BOUNTY SELECTIVE HERBICIDE will not be an undue hazard to the safety of people consuming anything containing their residues. Maximum Residue Limits (MRLs) have been proposed for ethametsulfuron methyl (including MRLs for animal feed commodities), and Withholding Periods proposed for BOUNTY SELECTIVE HERBICIDE when used in lupins.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Commodities exported and main destinations

Lupin grain and animal commodities may be exported. During the 1999/2000 period production of lupins totalled 1990 kt, of which approximately 1220 kt was exported. The value of Australia's lupin exports was \$214 m (ABARE commodity Statistics 2000). The destinations of Australian lupins during the 1999/2000 period are summarised below.

Destination	Volume, tonnes
South Korea	348,000
Spain and Portugal	336,000
Netherlands	300,000
Thailand	84,000
Japan	60,000
Taiwan	48,000
Italy	24,000
UK	1,200

Overseas registration status

The applicant stated that ethametsulfuron methyl is registered for use only in Canada, on canola. Neither diflufenican or ethametsulfuron methyl are used on lupins grown in the export market countries above.

CODEX Alimentarius Commission MRL

Ethametsulfuron methyl and diflufenican have not been considered by CODEX. Please note that Codex does not consider chemicals unless it can be demonstrated that there are finite residues in produce moving in trade.

Potential risk to Australian export trade

Residues of ethametsulfuron methyl in lupin grain were non-detectable or below the Limit of Quantitation (0.02 mg/kg) following application at up to twice the proposed maximum label rate of BOUNTY SELECTIVE HERBICIDE. Detection of ethametsulfuron methyl residues in grain by importing countries is unlikely to occur. Since diflufenican is already registered for use on lupins at the same rate the trade risk from diflufenican residues is unchanged. It is concluded that the proposed use should not unduly prejudice trade in lupin grain.

Quantifiable ethametsulfuron methyl residues are unlikely to occur in animals fed treated lupin seed, straw or forage because quantifiable residues are not expected in the crop commodities. The likelihood of quantifiable residues occurring in animal commodities derived from animals consuming treated produce is negligible and the use therefore should not unduly prejudice Australia's trade in animal commodities.

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

National Occupational Health and Safety Commission (NOHSC) has conducted a risk assessment on BOUNTY SELECTIVE HERBICIDE containing diflufenican and ethametsulfuron methyl at 595 g/kg and 270 g/kg respectively, as a water dispersible granule formulation. Ethametsulfuron methyl is a new active constituent. BOUNTY SELECTIVE HERBICIDE can be safely used by workers when handled in accordance with the control measures indicated in this assessment.

Ethametsulfuron methyl is not on the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999a). The applicant has classified ethametsulfuron methyl and BOUNTY SELECTIVE HERBICIDE as non-hazardous. Based on the available information, NOHSC has determined that neither, ethametsulfuron methyl or Bounty Selective Herbicide meet the *Approved Criteria* (NOHSC, 1999b) for classification as hazardous substances.

Ethametsulfuron methyl is a white crystalline solid. It has low acute oral, dermal and inhalation toxicity in rats. It is not a skin irritant in rabbits or a skin sensitiser in guinea pigs, but is a moderate eye irritant in rabbits.

Formulation, repackaging, transport, storage and retailing

The active constituent ethametsulfuron methyl will be manufactured overseas and will be imported into Australia in 50 kg rigid fibreboard containers. The product will be formulated in Australia from the imported active constituent and will be packed in 5, 10 and 20 kg plastic / foil bags in cardboard cartons or in 3, 5 and 10 kg high-density polyethylene bottles with 63 mm openings.

Storemen, transport workers, laboratory staff, formulators and packers will handle the active constituent and the product. Worker exposure relating to manufacturing of BOUNTY SELECTIVE HERBICIDE has been evaluated by the DuPont manufacturing assessment team (acceptable to NOHSC) and is expected to be minimal. Australian manufacturers / formulators have Commonwealth / State / Territory occupational health and safety legislative requirements to follow good work practices and have adequate quality control and monitoring facilities.

Use and exposure

BOUNTY SELECTIVE HERBICIDE is indicated for the control of broadleaf weeds in narrowleaf lupins in Western Australia. It will be applied once per season, by ground boom spraying at the 4 – 8 leaf stage of the crop (approximately 4 – 6 weeks after sowing). The recommended application rate is 85 g/ha, with a minimum spray volume of 50 L/ha (0.17% formulated product (w/v), 0.1% diflufenican and 0.05% ethametsulfuron methyl (w/v)).

Categories of workers that can be potentially exposed to the product are mixer / loaders, ground applicators, clean-up personnel and re-entry workers. The main routes of exposure will be dermal and ocular, though inhalation exposure to product dust and spray mist can also occur.

Worker exposure studies on ethametsulfuron methyl or BOUNTY SELECTIVE HERBICIDE are not available. Therefore, NOHSC used UK Predictive Operator Exposure Model to

estimate mixer/loader/applicator exposure to the product. These estimates indicated that the use of gloves during mixing and loading is necessary to reduce risks from repeated exposure.

In order to protect workers during repeated exposure to BOUNTY SELECTIVE HERBICIDE, elbow-length PVC or nitrile gloves should be worn when opening the container and preparing spray.

Entry into treated areas

In the absence of re-entry data, NOHSC estimated re-entry exposure, using the US Occupational Post-Application Risk Assessment Calculator (US EPA Policy 003.1) and recommends that re-entry to treated areas not occur until the spray has dried. Chemical resistant gloves should be used if re-entry is necessary before the spray has dried.

Recommendations for safe use

Users should follow the instructions and Safety Directions on the product label. Safety Directions include the use of elbow-length PVC or nitrile gloves when mixing and loading and when opening container and preparing the spray.

The PPE recommended should meet the relevant *Australian Standards*.

Re-entry statement

“Do not allow entry into treated areas until the spray has dried. If prior entry is necessary, wear chemical resistant gloves.”

Conclusion

BOUNTY SELECTIVE HERBICIDE can be used safely if handled in accordance with the instructions on the product label and other control measures described above. Additional information is available in the MSDS of the product.

ENVIRONMENTAL ASSESSMENT

Environmental Exposure

Aventis CropScience Pty Ltd has applied for the registration of the end use product BOUNTY SELECTIVE HERBICIDE, containing the active constituents diflufenican (595 g/kg and ethametsulfuron methyl (270 g/kg). This product will be used to control a range of broad leaf weeds in narrow leaf lupins.

Registration is sought in Western Australia only. Ethametsulfuron methyl has not been previously registered in Australia. Diflufenican formulations are currently registered in Argentina, Belgium, Denmark, France, Germany, Italy, Japan, Luxembourg, Netherlands and Spain.

Environment Australia evaluated diflufenican in 1990 for the then Rhone-Poulenc products Brodal Selective Herbicide and Tigrex Selective Herbicide. This included use in lupins, and the maximum application rate of diflufenican was 100 g/ha. In the product forming the basis of this submission, diflufenican is present at a concentration of 595 g/kg, and the application rate to lupins will be at around 50 g/ha. The company does not expect the use of this proposed mixture will increase the quantities of diflufenican used and this chemical was not considered further in the assessment.

Environmental Chemistry and Fate

Hydrolysis

Ethametsulfuron methyl hydrolyses faster under acidic conditions. At pH 5 the hydrolysis half life was in the order of 41 days, but only limited hydrolysis observed after 30 days at pH 7 and 9. Hydrolysis is rapid (half life of 0.5 days) under extreme acidic (pH 2) or basic (pH 12) conditions.

Photolysis

Soil: One test using two radiolabelled forms of ethametsulfuron methyl was provided. One soil type (black loam) was tested. Degradation occurred approximately three times faster in samples exposed to sunlight with an estimated half life of 81-86 days compared with 262-289 days in the dark control samples. Parent compound accounted for 70-74% of remaining radioactivity after 31 days.

Water: One test using two radiolabelled forms of ethametsulfuron methyl was provided. Neither radiolabels showed significant photodegradation with only 2-9% decomposition after 30 days exposure to natural sunlight. Carbon dioxide was only a very minor decomposition product. While no half life was determined, the minimal decomposition after 30 days suggests a first order half life greater than 150 days.

Degradation in Soil and Water

Soils aerobic: One poorly described test was provided covering 8 soil types. No half lives were determined. However, Environment Australia estimates based on raw data that they appear to fall in the range of between 15 and 100 days. All soils exhibited a substantial microbial degradation component, however, data suggested that in some sterile acidic soils, chemical hydrolysis may significantly influence the overall degradation of parent compound.

Water aerobic: One aerobic experiment was submitted with ethametsulfuron labelled in alternate rings. The test system consisted of one water system with no sediment component, tested at two temperatures, 29 and 5°C. Temperature appeared to be a major factor with degradation in the higher temperature system resulting in a half life of around 6 months. This compared with around 86 months in the colder experiment. Degradation pathways and metabolite distribution pattern were nearly identical in sterile and nonsterile samples. Major degradation products were triazine amine and saccharin.

Water anaerobic: One anaerobic aquatic degradation study was provided in pond water/sediment systems. Two water/sediment systems were used. Radioactivity tended to remain in the water column throughout the experiment. Half lives of the parent compound were 2-9 months, dependent on sediment pH, with major metabolites being the same as those identified in the aerobic study. The half life in the water column alone could not be determined.

Mobility

Volatility: The very low vapour pressure of ethametsulfuron methyl precludes significant volatilisation of the active substance from soil under practical conditions of use. Further, the Henry's law constant is very low again suggesting little potential for volatilisation from water bodies.

TLC studies: One soil mobility study using TLC was provided using 4 soil types. Reference chemicals were diuron and terbacil. Ethametsulfuron methyl exhibited low to intermediate soil mobility based on its R_f values which were somewhat lower than the hydrophilic standard terbacil, and significantly higher than those of the hydrophobic standard, diuron.

Adsorption/desorption: One batch equilibrium experiment in the same 4 soils was provided. Ethametsulfuron methyl was weakly adsorbed compared to the hydrophilic standard. However, K_{om} values ranging from 38-87, which is indicative of slight mobility. Adsorbed radioactivity was moderately desorbed in all test soils. A further test using 8 different soil types showed the chemical to be moderately mobile to immobile. Sorptivity was greater in acidic soils or those higher in organic matter.

Column leaching: One residue column leaching study was provided using two sandy loams, a clay loam and a loam soil under aerobic conditions. Results were varied. In one soil, parent and the two main metabolites (which were applied to separate columns) were strongly retained in the soil column with less than 4% found in the eluate. In the other three soils, the amount of radioactivity found in the eluate varied from around 48% to over 80%, with the remainder of the radioactivity found distributed throughout the soil column. This study demonstrated the leaching capacity of ethametsulfuron methyl although reasons for the variability in results are unclear.

Field Dissipation

Soils: One field dissipation study was provided. Ethametsulfuron methyl was applied to bare ground on five different soil types at slightly higher rates than proposed in Australia. Most of the recovered radioactivity in cylinders from all sites remained in the upper 0-7.5 cm soil segment throughout the study. The major metabolites were again triazine amine and saccharin. The chemical degraded at a moderate rate with a calculated half life of between 4 to 8 weeks with an outlier of 23 weeks. Results were consistent with laboratory environmental fate studies.

Accumulation/Bioaccumulation

Ethametsulfuron methyl is not expected to accumulate in soils under the proposed use pattern. Environment Australia modelling predicts maximum concentrations in soil around 0.022 mg/kg soil immediately following applications, but worst case levels are expected to be only around 0.002 mg/kg at further applications (assuming annual spraying). No bioaccumulation study was provided. However, given the moderate water solubility and low lipid solubility ($K_{ow} = 0.89$), the chemical would not be expected to bioaccumulate.

Conclusion

Ethametsulfuron methyl is stable to hydrolysis. On soil, photolysis is relatively slow (half lives 81-86 days), while in water, the chemical is resistant to photolysis with half lives >150 days. Ethametsulfuron methyl is fairly to slightly degradable in viable aerobic soils (laboratory half life 15-100 days). Major metabolites are the triazine amine, and saccharin. Small amounts of CO₂ are formed. Anaerobic conditions resulted in the same major metabolites. Half lives for aerobic and anaerobic aquatic metabolism were between 2 and 9 months. Radioactivity tended to remain in the water column throughout the course of the anaerobic study, with less than 20% generally being found in the sediments.

Environmental Toxicology

Avian

Ethametsulfuron methyl, administered as a single dose (acute oral) or for five days mixed in the diet, was shown to be practically non-toxic to bobwhite quail and mallard duck. There were no overt signs of toxicity at any treatment level in any of the studies.

Aquatic

Two freshwater fish were tested with technical ethametsulfuron methyl. The chemical was tested up to 600 ppm on both species. While mortality of up to 80% was observed, these were not at the highest level tested, and no dose response curve could be determined. The authors attributed the random mortalities to aggressive behaviour, possibly as a result of exposure to the test substance. Consequently, LC₅₀ values were determined to be higher than 600 ppm. No chronic studies were provided.

Invertebrates also did not appear sensitive to ethametsulfuron methyl, although only *Daphnia magna* was tested. Ethametsulfuron methyl is practically non-toxic to *Daphnia magna* when tested in the milled form or when the test organisms are fed during the study. The decomposition products, the triazine urea and the triazine amine were at worst moderately toxic to *Daphnia magna*. However, ethametsulfuron methyl is slightly toxic to *Daphnia magna* when the test organism is not fed during an acute study and on chronic exposure.

While tests on algae were only indicative of moderate toxicity, aquatic plants were shown to be very sensitive to ethametsulfuron methyl. The aquatic macrophyte test results should be treated with caution due to omission of key data. However, the information provided suggests toxicity is far greater when exposure is through the roots than via foliage. Two aquatic plants showed EC₅₀ values in the range of 0.5-5 ppb, although the actual value could not be calculated due to raw data not being available.

Two tests on non-target plants were provided. Ethametsulfuron methyl was shown to be moderately to highly phytotoxic at around twice the maximum field rate in one test using 10 different crop plants. Germination of most species did not appear to be significantly affected.

In comparing these laboratory results with field results, it was determined that greenhouse plants have a far wider spectrum of susceptibility to the chemical than plants in the field. In a field study using terrestrial plants considered to be of importance to wildlife in Canada, plant biomass was found to be the most sensitive indicator with cultivated lentil the most sensitive plant. The study determined that 26.4 g/ha (approximately the maximum field rate) would cause a 25% biomass reduction in species with the sensitivity of the lentil. The ability of plants to recover was not investigated in either test.

Environmental Hazard

The label prohibits application by air, so this scenario is not investigated in this report.

Ethametsulfuron methyl will be applied using hydraulic boom sprayers with 85 g/ha product (23 g ai/ha) in 50-100 L/ha water. Recommended label pressure ranges from 210-240 kPa. Two exposure situations to water bodies will be considered, namely exposure through spray drift and exposure through run-off.

Ethametsulfuron methyl is to be applied to early post emergence to lupins for control of broadleaf weeds. There is one application a season between May and July. Application will be by ground equipment only.

Ethametsulfuron is moderately soluble in water with negligible vapour pressure.

Birds

Birds did not prove sensitive to ethametsulfuron methyl with no acute effects noticed at exposure through direct oral route of >2250 mg/kg bodyweight for bobwhite quail or mallard duck; or from exposure levels >5620 ppm in the diet to both these species.

Dietary Q values for application of the herbicide at 23 g ai/ha (maximum annual application rate in Australia) have been determined. This nomogram is based on a review of the highest levels of pesticide residues reported from spray application and represents an upper limit to residues likely to be found on various substrates. Based on the application and diet described here, the Kenaga nomogram predicts residues in quail and mallard duck of 2.41 and 0.89 mg/kg bodyweight respectively. With dietary LC50s >5620 ppm, these residue values represent Q values of >>0.01 for both species, supporting a conclusion of a negligible hazard to birds.

Bees

The maximum application rate of 23 g ai/ha equates to 0.23 $\mu\text{g}/\text{cm}^2$. Ethametsulfuron methyl was shown to cause 10% mortality to bees at the highest tested rate of 12.5 $\mu\text{g}/\text{bee}$. Therefore, the potential hazard to bees is expected to be low.

Soil-dwelling invertebrates

No effect was seen on earthworms at a concentration of 1000 mg/kg soil, or on soil microorganisms at a concentrations tested up to 0.31 mg/kg soil (10 times the recommended field application rate). Therefore, ethametsulfuron methyl is expected to have a negligible potential for adverse impacts on populations of these organisms.

The potential environmental hazard to soil dwelling invertebrates is predicted to be low.

Aquatic organisms

Use of ethametsulfuron is likely to pose a risk to aquatic plants and algae. The most sensitive EC50 of 0.5 ppb was found for aquatic macrophytes during toxicity testing. This level is chosen as the most sensitive EC50 as data were not sufficient from the test to calculate an accurate EC50. At best, the value could only be stated as being in the range of 0.5-5 ppb, hence the lowest part of this range was chosen for the hazard calculations.

Spray drift

A total of 50 drift trials were carried out on both bare ground and cereals during late growth stages. Calculations show there may be a hazard to aquatic plants where application occurs at 23 g ai/ha within 10 m or less of a water body. Where application is at 10 m or less, the potential hazard is not considered unacceptable, and control measures may be used to lower the risk.

The most apparent mitigating measure is the buffer zone. The calculations indicate a buffer of 15 metres would be sufficient to reduce drift to levels where Q equals or falls below 0.1. Environment Australia recommends a statement be included on the label to allow for a buffer zone of 15 metres between application and adjacent waterways.

Run-Off

Ethametsulfuron is proposed to be used in the lupin growing region in Western Australia. The proposed use pattern is for a single spray using ground application techniques. The chemical has been shown to be relatively stable in soils with a field half life between 4 and 23 weeks. In aquatic systems, the chemical would be expected to largely remain in the water column, where it is expected to persist with a half life of several months. Due to the infrequency of application, repeated exposure from the chemical may not be a problem, but its persistence in water is of concern. Restrictions on buffer strips have been shown as necessary in order to derive an acceptable hazard to algae and aquatic plants resulting from spray drift, but the potential hazard from runoff is uncertain. The necessary data to adequately assess this aspect are unavailable, and adverse impacts to aquatic plants from surface runoff cannot be discounted.

Non-Target Vegetation

Being a herbicide, non target vegetation may be at risk from exposure. In a test on non target plants it was calculated that 26.4 g/ha would cause a 25% biomass reduction in the most sensitive plant. The expected concentration resulting from spray drift is some 190 times lower than this, and using the most sensitive result as a surrogate for non-target Australian plants, it can be predicted that the potential for adverse effects on non-target terrestrial plants is low.

Therefore, the use of ethametsulfuron methyl in accordance with the proposed pattern is not expected to result in lasting adverse impacts on non-target vegetation.

Groundwater

Leaching studies suggest ethametsulfuron methyl will leach to groundwater given the right soil conditions. However, movement to groundwater is not expected based on field data showing limited movement through the soil horizon after a study period of around two years.

The product will not be aerially applied, and to try and minimise risks to aquatic plants from spray drift and runoff, it is recommended a buffer zone of 15 metres should be maintained between application sites and adjacent waterways, and application should not occur where heavy rain is expected within 48 hours.

Conclusions and Recommendations

Environment Australia has considered the available data, and is satisfied that the proposed use of the chemical will generally not lead to lasting adverse impacts on the environment at the proposed rate and following Good Agricultural Practice. However, there is clearly the potential for short term risks to aquatic plants. Environment Australia has determined the risk to be acceptable in the case of spray drift provided a buffer of 15m is maintained. However, no firm conclusion could be reached in the event of exposure to aquatic plants through runoff, therefore precautionary label statements have been incorporated to limit any hazard which may occur through runoff events.

EFFICACY AND SAFETY ASSESSMENT

Justification for Use

BOUNTY SELECTIVE HERBICIDE will offer lupin growers a greater range of options for control of radish in lupins, and their first ever option for post-emergence control of doublegee (spiny emex, three cornered jack) in lupins. The product is to be applied with non-ionic wetting agent following a pre-emergence application of simazine

Adequacy of Efficacy Data

Trial designs are good with adequate number of trials, correctly designed and analysed, covering a range of lupin varieties to substantiate the claims for registration.

Some of the trials were affected by lupin diseases, and this affected some results. These were noted, and no unwarranted conclusions were drawn. The label specifically warns against treating crop affected by such disease.

The experimental conditions were adequately recorded and relevant details supplied. The trials were conducted in main lupin growing areas in Western Australia.

The trials appear to have been conducted by qualified personnel and reports have been well presented and easy to interpret.

Claims

The trial data fully supports the weed control claimed on the label.

Directions for Use

The application rates are adequately supported by trial data. Application by boom spray alone is sought, and all trials have been done in this way. The directions for application are complete and detailed, and include crop status, weather conditions and timing. Scientific names have also been included for all target weed species.

Safety to Target and Non Target Species

Several restraints are listed on the product label in order to increase the effectiveness of the product and to minimise off target damage.

Conclusion

BOUNTY SELECTIVE HERBICIDE is most likely to fulfil its claims on the label and would fill a niche in weed control for Western Australian lupin growers. As long as the product is used according to label instructions and Good Agricultural Practice it should be suitable for the proposed uses.

LABELLING REQUIREMENTS

MAIN PANEL

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Bounty^â

SELECTIVE HERBICIDE

**Active Constituents: 595 g/kg DIFLUFENICAN
270 g/kg ETHAMETSULFURON METHYL**

GROUP	B	F	HERBICIDE
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* kg Net

For the control of certain weeds in narrow leaf lupins (*Lupinus angustifolius*) as specified in the DIRECTIONS FOR USE table.

**IMPORTANT: READ THE ATTACHED BOOKLET
BEFORE USE.**



(Label code)

* 3, 5, 10 or 20 kg

REAR PANEL (attached to container)

BOUNTY SELECTIVE HERBICIDE

**Active Constituents: 595 g/kg DIFLUFENICAN
270 g/kg ETHAMETSULFURON METHYL**

STORAGE AND DISPOSAL

Keep out of reach of children. Store in the closed, original container in a dry, cool, well-ventilated area, out of direct sunlight.

Plastic/foil bag (in a carton)

Single rinse before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. Puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

Plastic bottle

Triple or preferably pressure rinse containers before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

SAFETY DIRECTIONS

May irritate the eyes and skin. Avoid contact with eyes and skin. When opening the container and preparing the spray wear elbow-length PVC or nitrile gloves. Wash hands after use. After each day's use, wash gloves.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre (telephone 13 11 26).

MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet available from Aventis CropScience Pty Ltd.

EXCLUSION OF LIABILITY

This product as supplied is of a high grade and suitable for the purpose for which it is expressly intended and must be used in accordance with the directions. The user must monitor the performance of any product as climatic, geographical or biological variables and/or developed resistance may affect the results obtained. No responsibility is accepted in respect of this product, save for those non-excludable conditions implied by the Trade Practices Act or any State or Federal legislation.

NRA Approval No.: 53546/

Bounty® is a Registered Trademark of Aventis.

IMPORTANT: READ THE ATTACHED BOOKLET BEFORE USE

REAR PANEL (attached to container) - continued

Aventis CropScience Pty Ltd
A.B.N. 87 000 226 022
391-393 Tooronga Rd.
East Hawthorn Vic. 3123
Phone: 03 9248 6888
Fax: 03 9248 6800
Website: www.aventis.com.au

IN A TRANSPORT EMERGENCY DIAL 000 POLICE OR FIRE BRIGADE
FOR 24 HOUR SPECIALIST ADVICE IN EMERGENCY ONLY PHONE 1800 033 111

Bar code



Batch Number:
Date of Manufacture:

(Label code)

* drummuster logo required for plastic bottle packs only

FRONT PAGE OF BOOKLET

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

BOUNTY SELECTIVE HERBICIDE

Active Constituents: 595 g/kg DIFLUFENICAN

270 g/kg ETHAMETSULFURON METHYL

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NRA Approval No.: 53546/

Bounty® is a Registered Trademark of Aventis.

IMPORTANT: READ THIS BOOKLET BEFORE USE

BOOKLET CONTENTS

DIRECTIONS FOR USE (Western Australia only)

Restraints

DO NOT apply before the 4 leaf stage of the crop.

DO NOT apply to Albus/white lupin (*Lupinus albus*) eg Kiev Mutant.

DO NOT apply to lupins affected by disease eg. Rhizoctonia, brown leaf spot.

DO NOT apply if weeds are stressed due to dry or excessively moist conditions.

DO NOT apply to crops under stress due to previous herbicide treatment, root disease, physical damage (eg. insect, hail, wind damage), nutrient deficiency, excessively moist or dry conditions or extremes of pH.

DO NOT apply to frost-affected crops or if frosts are imminent.

DO NOT apply if rainfall is expected within 6 hours.

DO NOT apply within 15 metres of entry points for runoff into streams and watercourses.

DO NOT apply if heavy rain is expected within at least 48 hours.

CROP	WEEDS	WEED STAGE	RATE	CRITICAL COMMENTS
Narrow leaf lupin (<i>Lupinus angustifolius</i>)	Doublegee (<i>Emex australis</i>)	2-4 leaf	85 g/ha	Apply post-emergence from the 4 leaf to the 8 leaf stage of the crop. Apply when weeds are actively growing. For optimum results apply 4 to 6 weeks after sowing.
	Wild radish (<i>Raphanus raphanistrum</i>), hedge mustard (<i>Sisymbrium officinale</i>), Indian hedge mustard (<i>Sisymbrium orientale</i>), wild turnip (<i>Brassica tournefortii</i>)	Up to 2 leaf stage and not more than 60 mm in diameter		Apply following a pre-emergence application of simazine . Bounty must be applied with a non-ionic wetting agent (e.g. BS1000 [®] at 0.1% v/v). Bounty will not effectively control : * regrowth of suppressed weeds, * transplanted weeds, * regrowth from rhizomes or roots, * weeds growing under stress from previous herbicide applications. Good spray coverage of the weeds is important. Apply before weeds are obscured by the crop canopy. Weed control may be reduced in areas where trash or burnt straw from previous harvest is dense, such as in header trails. Best results will be obtained if good soil moisture exists at and after application.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

WITHHOLDING PERIOD

Harvest: NOT REQUIRED WHEN USED AS DIRECTED

Grazing: DO NOT GRAZE OR CUT FOR STOCK FEED FOR 12 WEEKS AFTER APPLICATION

GENERAL INSTRUCTIONS

For use as an early post-emergence spray in lupins, for control of the weeds specified.

This product also provides residual activity against wild radish. The level of effective residual control may be reduced where dry conditions prevail, where poor coverage of the soil surface is achieved, or soils are non-wetting sands or have a high content of clay or organic matter.

After application, some transient crop discoloration may occur. This usually appears as yellow or white banding on the leaves. Some crop height reduction may also occur.

Provided the crop is not under stress from pre-emergent herbicide, disease, insect damage, nutrient deficiency, frost, extremes of pH, dry or excessively moist conditions, the development of the crop and all subsequent growth will not be affected.

Some pre-emergence herbicides, such as atrazine, can cause stress, resulting in an increase in crop damage when using this product. Variety Myallie appears particularly sensitive to such an atrazine/Bounty interaction.

Resistant Weeds Warning

GROUP	B	F	HERBICIDE
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Bounty Selective Herbicide is a member of the sulfonylurea and nicotinanalide group of herbicides, and acts by inhibiting ALS and carotenoid biosynthesis. For weed resistance management Bounty is a group **B** and **F** herbicide.

Some naturally occurring weed biotypes resistant to Bounty and other group **B** and **F** herbicides may exist through normal genetic variability in any weed population. The resistant individuals can eventually dominate the weed population if these herbicides are used repeatedly. These resistant weeds will not be controlled by Bounty or other Group B and F herbicides.

Since the occurrence of resistant weeds is difficult to detect prior to use, Aventis CropScience Pty Ltd accepts no liability for any losses that may result from the failure of Bounty to control resistant weeds.

Where radish has developed resistance to Group B or to Group F herbicides efficacy will be reduced. If resistance has developed to both Group B and to Group F herbicides, this product will not give adequate control.

Export of treated produce

Growers should note that MRLs or import tolerances do not exist in all markets for produce from crops treated with Bounty Selective Herbicide. If you are growing for export, please check with Aventis CropScience for the latest information on MRLs and import tolerances BEFORE using Bounty.

Crop Rotation Recommendations

Minimum recropping intervals apply for all crops following Bounty application.

Use on soils with a pH greater than 8.0 (soil in water) has not been extensively tested and is not recommended.

For advice on crops not listed below, contact the manufacturer, Aventis CropScience Pty. Ltd.

Crop	Minimum recropping interval
wheat	10 months

Mixing

To ensure even mixing, half fill the spray tank with clean water and add the required amount of product. Agitate thoroughly then add the remainder of the water. Agitate continuously while carrying out spray operations. Reseal part-used container immediately after use.

Application

Ground

A minimum of 50 litres of water per ha should be used, however, for optimum results water rates of 70-100 L/ha are recommended. Increase the water volume where weed infestation is heavy or the crop cover is dense. Complete coverage of weeds is essential. Higher water volumes (up to 100 L/ha)

will ensure improved activity of the product on the weeds but may increase the symptoms of crop damage.

The following settings are examples that will ensure excellent coverage of exposed weeds:

WATER RATE	50 L/ha	75 L/ha	75 L/ha
NOZZLE	Hardi No. 10 or equivalent	Hardi No. 12 or equivalent	Hardi No. 14 or equivalent
SPEED	10 kph	10 kph	12 kph
PRESSURE	240 kPa (2.4 bar)	220 kPa (2.2 bar)	210 kPa (2.1 bar)

Aerial

Do not apply Bounty by air.

Sprayer Clean Up

The sprayer must be decontaminated before being used to spray crops other than lupins.

Ensure that the following operation is carried out in an area that is clear of waterways, desirable vegetation and tree roots, and preferably in an area where drainings can be contained.

1. Drain sprayer completely and wash out tank, boom and hoses with clean water.
2. Drain again.
3. Fill the tank with clean water and add 300 mL of chlorine bleach (containing 4% chlorine) per 100 L of water with agitation running.
4. Flush some bleach solution through booms and hoses and allow remainder to agitate in tank for 10 minutes.
5. Remove nozzles and filters and leave to soak in a bleach solution of 500 mL per 10 L of water while tank cleaning is in progress.
6. Briefly run the pump at periodic intervals to refresh chlorine solution in spray lines.
7. Drain tank and repeat the procedure of flushing with bleach solution.
8. Flush the tank, boom and hoses with clean water.

Compatibility

For details of herbicides and insecticides compatible with Bounty, contact the manufacturer, Aventis CropScience Pty Ltd.

PRECAUTIONS

Re-entry

DO NOT allow entry into treated areas until the spray has dried. When prior entry is necessary, wear chemical resistant gloves.

PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS

DO NOT apply under weather conditions, or from spraying equipment, that may cause spray to drift onto nearby susceptible plants/crops, cropping lands or pastures.

PROTECTION OF WILDLIFE, FISH, CRUSTACEA AND ENVIRONMENT

This product is very highly toxic to aquatic plants. DO NOT contaminate streams, rivers or waterways with the chemical or used containers.

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GLOSSARY

Active constituent	The substance that is primarily responsible for the effect produced by a chemical product.
Acute	Having rapid onset and of short duration.
Carcinogenicity	The ability to cause cancer.
Chronic	Of long duration.
Codex MRL	Internationally published standard maximum residue limit.
Desorption	Removal of an absorbed material from a surface.
Efficacy	Production of the desired effect.
Formulation	A combination of both active and inactive constituents to form the end use product.
Genotoxicity	The ability to damage genetic material
Hydrophobic	Water repelling
Leaching	Removal of a compound by use of a solvent.
Log P_{ow}	Log to base 10 of octanol water partitioning co-efficient.
Metabolism	The conversion of food into energy
Photodegradation	Breakdown of chemicals due to the action of light.
Photolysis	Breakdown of chemicals due to the action of light.
Subcutaneous	Under the skin
Toxicokinetics	The study of the movement of toxins through the body.
Toxicology	The study of the nature and effects of poisons.

References

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Footnote:

Updated versions of these documents are available on the NRA website <http://www.nra.gov.au>.

NRA PUBLICATIONS ORDER FORM

To receive a copy of the full technical report for the evaluation of ethametsulfuron methyl in the product Bounty Selective Herbicide, please fill in this form and send it, along with payment of \$30 to:

David Hutchison
Agricultural Chemicals Evaluation Section
National Registration Authority for Agricultural and Veterinary Chemicals
PO Box E240
Kingston ACT 2604

Alternatively, fax this form, along with your credit card details, to the above contact person:
(06) 6272 3218.

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