Public Release Summary on

Evaluation of the new active

IMAZAMOX

in the products

RAPTOR HERBICIDE & RAPTOR WG HERBICIDE

National Registration Authority for Agricultural and Veterinary Chemicals

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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 Family Services (Chemicals and Non-prescription Drug Branch), Environment Australia (Risk Assessment and Policy Section), the National Occupational Health and Safety Commission 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.

The information and technical data required by the NRA to assess the safety of new chemical products and the methods of assessment must be in accordance with 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 it 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
d	Day
EC50	concentration at which 50% of the test population are immobilised
Fo	original parent generation
h	Hour
HPLC	high pressure liquid chromatography or high performance liquid chromatography
id	Intradermal
ip	Intraperitoneal
im	Intramuscular
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
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
mg	Milligram
mL	Millilitre
MRL	maximum residue limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee
ng	Nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	no observable effect concentration/level
OC	Organic carbon
OM	Organic matter
ро	Oral
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
S	Second
sc	Subcutaneous
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
T-Value	a value used to determine the First Aid Instructions for chemical products that contain
	two or more poisons
TGAC	technical grade active constituent
WHP	withholding period

SUMMARY

This publication outlines the regulatory considerations and provides a summary of the data evaluated for the proposed registration of **Raptor Herbicide** and **Raptor WG Herbicide** (for brevity the two products together will be referred to as *Raptor* throughout this document). **Raptor Herbicide** is formulated as a aqueous concentrate containing 120 g/L imazamox as the ammonium salt. **Raptor WG Herbicide** is a water dispersible granule containing 700 g/kg imazamox as the free acid. It is proposed that the products will be used for post-emergence control of certain annual grass and broadleaf weeds in field peas, peanuts and soybeans.

The NRA has assessed the data submitted by the applicant in support of the proposed use of imazamox in *Raptor*. The following information is provided for public comment before the NRA determines whether to register the product in Australia. Comments should be submitted by **21 February 2000** to the NRA at the address indicated on page 1.

Public Health Aspects

Toxicology

Raptor and its active ingredient imazamox, have very low oral, inhalation and low dermal toxicity. They were not skin irritants and did not cause skin sensitisation. **Raptor Herbicide** was non-irritant to eyes and **Raptor WG Herbicide** and imazamox were moderate eye irritants.

There was no evidence of an increase in cancer incidence as a result of imazamox treatment for up to 2 years in mice or rats. Imazamox did not cause genetic damage in a range of genotoxicity tests. Even when imazamox was orally administered at very high doses (up to 1772mg/kg/day) the only treatment-related signs of toxicity were slight reductions in body weight gain, reductions in the levels of circulating white blood cells, and an increase in one liver enzyme concentration. Aside from a slight decrease in body weight gain, there were no treatment-related effects on fertility or reproductive performance and no evidence of embryo- or foetal toxicity was seen in developmental studies. Toxic effects were only seen at the highest doses tested and several studies had no treatment-related changes at all.

Conclusion

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the proposed use of imazamox as a component of the *Raptor* when used strictly in accordance with label directions.

Residues In Food

Imazamox residues in plants were found to decline rapidly following early post-emergent application. The metabolite profile in soybeans, field peas and wheat was qualitatively similar and no individual metabolite was quantitatively relevant. In animals imazamox was found to be rapidly eliminated with little biotransformation and negligible retention in tissue, eggs or milk.

As regards the residue definition it was considered appropriate to establish the parent compound (imazamox) as the residue definition in plant commodities. Validated analytical methods were capable of determining imazamox residues in the grain and forage of field peas, peanuts and soybeans down to 0.05 mg/kg.

Australian and overseas residue data support the proposed MRLs of *0.05 mg/kg for each of field pea (dry), peanut and soybean (dry). In all cases imazamox is applied early post-emergence and the product labels specifically prohibit application after the 4 node stage (field peas) or the 6 leaf stage (peanuts and soybeans). When the products are used as directed a harvest withholding period is not required.

Australian residue data support the proposed MRLs of *0.05 mg/kg for each of peanut forage (green), pea vines (green) and soybean forage (green). No quantifiable residues of imazamox were detected in forage commodities at the earliest sampling time after application. Grazing withholding periods of 4 weeks (peanuts and soybeans) and 6 weeks (field peas) are recommended to ensure that forage commodities do not contain quantifiable residues of imazamox.

No animal commodity MRLs were proposed by the applicant. Forage residues at or about the Limit of Quantitation are unlikely to result in detectable residues of imazamox in animals. Registration of *Raptor* does not pose a risk to human health or trade.

Compound	Food		MRL (mg/kg)
ADD:			
Imazamox	VD 0561	Field pea, dry	*0.05
	SO 0697	Peanut	*0.05
	VD 0541	Soybean, dry	*0.05
_		Table 3	
Compound		Residue	
ADD:			
Imazamox		imazamox	
		Table 4	
Compound	Animal Feed Commodity MRL (mg/kg)		
ADD:			
Imazamox	AL 1270	Peanut forage (green) [Fresh weight]	*0.05
	AL 0528	Pea vines (green) [Fresh weight]	*0.05
	AL 1265	Soybean forage (green) [Fresh weight]	*0.05

The following amendments to the *MRL Standard* are recommended: Table 1

The following withholding period statements are recommended in conjunction with the above MRLs:

Grazing

Field peas

DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 6 WEEKS AFTER APPLICATION

Х

Peanuts, Soybeans

DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION

Harvest

Field peas, Peanuts, Soybeans

NOT REQUIRED WHEN USED AS DIRECTED

Occupational Health and Safety Aspects

Raptor can be safely used by workers when handled in accordance with the control measures indicated in this assessment.

Imazamox is not listed in the NOHSC List of Designated Hazardous Substances. NOHSC has determined imazamox and **Raptor WG Herbicide** to be hazardous substances according to NOHSC Approved Criteria for Classifying Hazardous Substances. This classification is based on the eye irritant effects, and the concentration of imazamox in **Raptor WG Herbicide**.

Raptor has low acute oral, dermal, and inhalation toxicity. **Raptor Herbicide** is not a skin and eye irritant, and has no skin sensitising properties. **Raptor WG Herbicide** is not a skin irritant and not a skin sensitiser, but is a moderate eye irritant.

Raptor will be imported fully formulated. The applicant anticipates that **Raptor Herbicide** will be formulated in Australia in future. **Raptor Herbicide** is packed in high-density polyethylene "Quadratainer" drums of 20L capacity with a neck diameter of 58 mm. **Raptor WG Herbicide** is packed in high-density polyethylene bottles of 2.5 and 5.0 kg capacity, both with neck diameters of 38 mm.

Formulators, store persons and forklift drivers will handle *Raptor* prior to use. Workers involved in transport, storage and retail will only be exposed to the products in the event of a packaging breach.

Raptor is to be applied to field peas, soybeans and peanuts by dry-ground application only. The maximum recommended application rate is 300 mL/ha **Raptor Herbicide** and 50 g/ha **Raptor WG Herbicide** with a maximum of 1 application per season. Application will be by boom spray equipment in a spray volume of 50 L/ha. A non-ionic surfactant (BS 1000 or similar at 200 mL/100 L water) is to be used in all three crops, while Boost liquid ammonium sulphate is to be used in peanuts and soybeans (2 L/100 L water). No re-entry period is specified on the draft labels. The withholding periods of 4 weeks for peanuts and soybeans and 6 weeks for field peas are specified for grazing, and cutting for stock feed.

No worker exposure data were available for imazamox or *Raptor*. The occupational health and safety risk assessment was based on estimates obtained from an exposure model.

Instructions and Safety Directions are provided on the product labels to minimise exposure to the products. No personal protective equipment is recommended for users of **Raptor Herbicide**. However, mixer/loaders using **Raptor WG Herbicide** need to wear face shield or goggles when opening the container and preparing spray. Additional information is available on the product material safety data sheet.

Environmental Aspects

Imazamox is stable to hydrolysis and the principal degradation pathway of imazamox is by photolysis and microbial breakdown in aerobic soils. There was little degradation via aquatic metabolism or under anaerobic conditions. While laboratory studies indicate a high potential for leaching, extensive field studies showed that residues were not detected below 45 cm at rates well above those proposed. Imazamox does not bioaccumulate.

Imazamox is non-toxic to birds, fish, and aquatic invertebrates and of low toxicity to algae when compared to the proposed use rates. However, imazamox is highly toxic to aquatic plants and to reduce the hazard to aquatic plants every care should be taken not to contaminate water with this product. Imazamox is expected to be toxic to some native vegetation and the draft labels include warning statements not to allow spray drift to contact desirable vegetation or other crops.

The hazard to birds, fish, aquatic invertebrates, bees, earthworms and soil microbes, even with the worst case assumptions, ie direct overspray, was determined to be insignificant. While there is a slight hazard to non-target terrestrial plants and aquatic plants using worst case scenarios, with more realistic assumptions for spray drift and taking into account the 50 metre buffer zone on the label, the hazard is acceptable. Similarly, the hazard to aquatic plants from runoff is determined to be acceptable.

Efficacy and Crop Safety Aspects

Imazamox has been evaluated by Cyanamid Australia (and more recently Cyanamid Agriculture) and other trial contractors since 1991. Since 1992, trials have concentrated on post-emergence timings in all major cropping areas of Australia, focusing particularly on field peas, peanuts and soybeans.

Data support the application of *Raptor* to control the weeds shown on the draft labels. Sufficient evidence was given to conclude that the rate range of 30g to 36g ac/ha imazamox, plus non-ionic surfactant (which equates approximately to 45g to 50g product per hectare of the 700g/kg wettable dispersible granule, or 250ml to 300ml product per hectare of the 120g/L aqueous concentrate) provides commercially acceptable control of these weeds providing they are sprayed at the correct stage, usually before the 3 leaf stage. This warning is shown appropriately on the draft labels.

Crop safety was shown to be generally satisfactory and although some transitory effects were reported there was no significant crop damage or yield penalties to field peas, soybeans and peanuts,.

Re-cropping investigations have also been conducted in a number of trial sites and no adverse re-cropping effects have been observed when the proposed plant-back intervals are observed.

INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of **Raptor Herbicide** and **Raptor WG Herbicide** (*Raptor*), which contain the new active ingredient, imazamox.

Responses to this Public Release Summary will be considered prior to registration of the product. They 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 imazamox, 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 **21 February 2000** and addressed to:

Malcolm Arney AgVet Chemicals Evaluation Section National Registration Authority PO Box E240 Kingston ACT 2604

Phone (02) 62723152 Fax (02) 62723218

Applicant

Cyanamid Agriculture Pty. Limited.

Product Details

It is proposed to register **Raptor Herbicide** containing imazamox at 120 g/L as the ammonium salt in an aqueous concentrate and **Raptor WG Herbicide** containing imazamox at 700 g/kg as the free acid in a water dispersible granule.

Both products will be imported fully formulated however Cyanamid Australia anticipates that **Raptor Herbicide** will be formulated in Australia in future.

Imazamox is a member of the Group B (imidazolinone) type of post-emergence herbicides, which includes imazapyr, imazethapyr, imazapic and imazaquin. Imidazolinones inhibit the plant enzyme acetolactate synthase/acetohydroxy acid synthase (ALS/AHAS), which interferes with DNA and protein synthesis and disrupts cell growth.

The proposed use of *Raptor* will be for the post-emergence control of a wide range of grasses and broadleaf weeds in field peas, peanuts and soybeans.

The formulations for both of the proposed products are registered in USA. Products which are comparable to *Raptor*, are registered in the following countries:

- Argentina
- Bolivia
- Brazil

- Canada
- Czech Republic
- Paraguay

- Slovakia
- South Africa
- USA

• Bulgaria

• Poland

• Zimbabwe

3.

CHEMISTRY AND MANUFACTURE

ACTIVE CONSTITUENT

The technical grade active constituent imazamox is manufactured in either the USA or Brazil. The manufacturers' details are as follows:

American Cyanamid Company Route 168 and JJ Spur Palmyra Missouri 63461USA

Cyanamid Quimica Do Brazil Rodovia Presidente Dutra KM 300.5 27500 Resende, R.J. BRAZIL

Imazamox TGAC manufactured at both sites has been approved by the NRA (TGAC Approval Numbers 51085 & 51086).

Chemical Characteristics of the Active Constituent

Common name (SA or ISO common name): imazamox Synonyms and code number: AC299, 263, CL299, 263 Chemical name

 $(IUPAC): ({\it RS})\mbox{-}2\mbox{-}(4\mbox{-}isopropyl\mbox{-}4\mbox{-}methyl\mbox{-}5\mbox{-}oxo\mbox{-}2\mbox{-}imidazolin\mbox{-}2\mbox{-}yl)\mbox{-}5\mbox{-}methylnicotinic acid$

(CA): 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid

Chemical Abstracts Service (CAS) Registry Number: [114311-32-9] Molecular formula: $C_{15}H_{19}N_3O_4$ Molecular weight: 305.3 Chemical structure:



Physical and Chemical Properties of Pure Active Constituent

Physical state: powdered solid Colour: white Odour: odourless Melting point or range: 165.5-167.2°C Solubility in water: 4160 ppm (deionised water at 20°C) Solubility in fat and various organic solvents (g/100 mL): hexane 0.0007, methanol 6.75, acetonitrile 1.90, toluene 0.22, acetone 3.09, dichloromethane 21.8, ethyl acetate 1.05, 1.05 Vapour pressure: $<1.0 \times 10^{-7}$ * Dissociation constant: pKa= 2.3, 3.3 and 10.8 * Octanol/water partition coefficient: Pow= 5.36 (log Pow= 0.73) * pH: 2.35 * (1% solution at 24.5°C) Storage stability: stable for at least 12 months when stored at 25°C * Chemical type: herbicide Chemical family: imidazolinone Mode of Action: ALS/AHAS inhibition

* When marked with an asterisk the property refers to that of the technical grade active constituent rather than the pure active constituent.

PRODUCTS

Distinguishing name: **Raptor Herbicide** Formulation type: aqueous concentrate Active constituent concentration: 120 g/L (present as the ammonium salt)

Distinguishing name: Raptor WG Herbicide

Formulation type: water dispersible granule Active constituent concentration: 700 g/kg

Physical and Chemical Properties of the Products

Raptor Herbicide

Physical state: liquid Colour: pale yellow Density: 1.0486 g/mL pH value: 6.05 Viscosity: 2.7 cps at 6 rpm, 2.75 cps at 12 rpm Explodability: not impact sensitive Corrosion characteristics: not corrosive to packaging materials Storage stability: Stability data provided by the applicant demonstrate that the product will be stable for 2 years when stored at ambient temperature in the marketing packaging.

Raptor WG Herbicide

Physical state: solid Colour: light tan pH value: 2.85 (2% dispersion) Explodability: not impact sensitive Corrosion characteristics: not corrosive to packaging materials Storage stability: stability data provided by the applicant demonstrate that the product will be stable for 2 years when stored at ambient temperature in the marketing packaging.

Recommendation

Based on a review of the details provided by the applicant and in relation to the Chemistry and Manufacture of **Raptor Herbicide** and **Raptor WG Herbicide**, registration is supported.

TOXICOLOGICAL ASSESSMENT

The toxicological database for imazamox, which consists primarily of toxicity tests conducted using animals, is extensive. In interpreting the data, it should be noted that toxicity tests generally use doses which are high compared to 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 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

In rats, imazamox is absorbed to around 70 to 80% after an oral dose and apart from 1-3% excreted in the bile, the remainder is excreted in the urine. Unabsorbed material was excreted in the faeces (11-18%). Distribution was widespread, with the kidney being the only organ showing higher levels of imazamox than in blood, presumably due to the high rate of elimination in the urine. The majority of a given dose was eliminated within 24 hours, predominantly as unchanged imazamox (90-97%), indicating little metabolic degradation.

Acute Studies

Imazamox and the *Raptor* showed very similar acute toxicity profiles, differing only in their irritancy to eyes. All three showed very low acute oral toxicity ($LD_{50}s >5000 \text{ mg/kg}$) in rats (and mice for imazamox) and low dermal toxicity ($LD_{50} >4000 \text{ mg/kg}$) in rats or rabbits. Inhalation toxicity was very low (LC_{50} ; imazamox >6300 mg/m³, *Raptor Herbicide* >5000 mg/m³, *Raptor WG Herbicide* >5800 mg/m³) in rats. All three were not irritant or sensitising to the skin. Imazamox and *Raptor WG Herbicide* were moderate eye irritants; *Raptor Herbicide* was non-irritant to eyes.

Short-Term Studies

No toxicity was observed in rats fed imazamox at doses of up to 2441 mg/kg/day in their daily diet for 28 days. Similarly, following skin applications of imazamox at up to 1000 mg/kg, no treatment-related changes were observed.

Long-Term Studies

In rats fed 0, 1000, 10000, or 20000 ppm (equivalent to ? /? 0/0, 76/81, 785/833, and 1550/1772 mg/kg/day) of imazamox in their daily diet for 13 weeks, males had a slight reduction in body weight gain, and both sexes had decreases in white blood cell and lymphocyte counts at

20000 ppm. Based on these effects, a NOEL was established at 10000 ppm (equivalent to 785 mg/kg/day).

Dogs fed with 0, 1000, 10000, or 40000 ppm of imazamox (equivalent to ? /? 0/0, 34/36, 329/381, or 1333/1403 mg/kg/day) and mice fed with 0, 500, 3500, or 7000 ppm of imazamox (equivalent to ? /? 0/0, 73/96, 535/664, and 1053/1348 mg/kg/day) had no treatment-related changes.

Rats were fed 0, 1000, 10000, or 20000 ppm of imazamox (equivalent to ? /? 0/0, 52/63, 528/626, or 1068/1284 mg/kg/day) in their daily diet for 24 months. Female receiving 20000 ppm had slightly lower mean body weights at 20000 ppm from week 54, resulting in a 9% decrease in body weight gain after 24 months. This was used to establish a NOEL at 10000 ppm (equivalent to 626 mg/kg/day). No effects were seen in males.

Dogs who received 40000 ppm of imazamox (equivalent to ? /? 1174/1156 mg/kg/day) in their daily diet for between 369 and 375 days had an increase in a liver enzyme concentration. This appeared to be treatment-related and was used to establish a NOEL at the next lowest dose, namely 10000 ppm (equivalent to 282 mg/kg/day). There were no significant effects observed at the other concentrations tested, namely 1000 and 10000 ppm

Reproduction and Developmental Studies

In a two-generation study, parental rats received 0, 1000, 10000, or 20000 ppm (equivalent to ? /? 0/0, 53-76/78-143, 530-770/790-1487, or 1082-1554/1539-3129 mg/kg/day) of imazamox in their daily diet from 10 weeks prior to mating, through to delivery of their last litter (? 's 114-115 days, ? 's 134-135 days). Their offspring received the same dietary concentrations as their parents until males reached 121-122 days old and females 141-142 days old. Reductions in body weight gain were seen during the pre-mating period in parental and offspring females receiving 20000 ppm. This imazamox-related effect was used to establish a NOEL of 10000 ppm (equivalent to at least 790 mg/kg/day).

Imazamox, orally administered to pregnant female rats at doses of 0, 100, 500, or 1000 mg/kg/day, from day 6 to day 15 of gestation were killed on day 20. A reduction in body weight gain at 1000 mg/kg/day was used to establish a maternal NOEL of 500 mg/kg/day. Foetuses showed no treatment-related abnormalities at the highest dose, 1000 mg/kg/day.

Imazamox, orally administered to pregnant rabbits at doses of 0, 300, 600, or 900 mg/kg/day from day 7 to day 19 of gestation, were killed on day 29 and foetuses removed by Caesarean section. Maternal body weight gain was reduced at 900 mg/kg/day. The amount of food consumed decreased at =600 mg/kg/day and was used to establish a maternal NOEL at 300 mg/kg/day. Foetuses showed no treatment-related abnormalities at the highest dose, 900 mg/kg/day.

Genotoxicity studies

There were no increases in the incidence of gene mutation in a bacterial/microsome mutagenicity assay (Ames test), a *Bacillus subtilis* DNA repair test (Rec-Assay), and an *in vitro* mammalian cell CHO/HGPRT mutagenicity assay. An *in vitro* chromosome aberration assay in Chinese hamster

ovary cell cultures, and an *in vivo* micronucleus assay in mouse bone marrow cells showed no increases in the incidence of imazamox treatment-related chromosomal aberrations.

PUBLIC HEALTH STANDARDS

Poisons Scheduling

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

The NDPSC recommended that formulations containing imazamox be placed in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), except in preparations containing 25 per cent or less of imazamox. There are provisions for appropriate warning statements and first-aid directions on the product label.

NOEL/ADI

The most sensitive species tested was the dog with a NOEL of 282 mg/kg/day in a 12 month chronic toxicity study. In order to calculate an Acceptable Daily Intake (ADI) for humans, a safety factor is applied to the NOEL in the most sensitive species. The magnitude of the safety factor is selected to account for uncertainties in extrapolation from animal data to humans, variation within the human population, the quality of the experimental data, and the nature of the potential hazards. Using a safety factor of 100, an ADI of 2.8 mg/kg/day was established for imazamox.

RESIDUES ASSESSMENT

Data concerning residues in field peas, peanuts and soybeans, metabolism in plants and animals, environmental fate and chemistry were considered as part of the residue evaluation of the application.

Metabolism

In <u>rats</u> up to 99.6% of the administered dose (10 mg/kg bw, orally) was eliminated in the combined urine and faeces within 168 hours of dosing. In a separate study with rats dosed at 821 mg/kg bw the parent compound accounted for greater than 90% of the combined faecal and urinary radioactivity. Tissue residues were negligible except in rats dosed at highly exaggerated rates where the maximum residue at sacrifice (168 hours post-dose) was 0.38 mg/kg in the heart tissue.

In <u>laying hens</u> imazamox derived radioactivity was rapidly excreted without retention in eggs or poultry tissues. Up to 85.5% of the total administered dose was recovered in the animal excrement up until sacrifice at 22 hours after the final dose. No egg or tissue samples taken from any of the dose groups (2ppm or 10ppm daily in the feed) contained imazamox related residues at greater than 0.01 ppm (limit of quantitation).

In <u>lactating goats</u> imazamox derived radioactivity is rapidly eliminated without significant retention in milk or bodily tissues. Up to 106% of the total administered dose was recovered in the animal excrement up until sacrifice at 20 hours after the final dose. The only residue observed in any tissue was in kidney (0.02 ppm and 0.06 ppm for the 2 ppm and 10 ppm feeding levels respectively). Characterisation of the radioactivity in the urine and kidney of the high dose goat showed that 89% (kidney) and 91% (urine) of the radioactivity was due to the presence of the intact parent compound.

Plant metabolism studies utilising ¹⁴C-labelled imazamox were provided for <u>soybeans</u>, <u>field peas</u>, <u>canola</u> and <u>wheat</u>. In foliage of soybeans, field peas and wheat, imazamox related residues declined rapidly with plant growth (dilution) following early post emergent application. Detectable residues of imazamox (and metabolites) were not observed in mature seed of soybeans, field peas, wheat and canola at harvest.

Characterisation of the radioactivity in field peas, soybeans and wheat identified 3 metabolites of the parent compound. In addition to the parent compound an *O*-demethylated metabolite (CL 263,284), a dicarboxylic acid (CL 312,622) and a glucose conjugate (CL 189,215) were observed. The contribution of the parent compound to the Total Radioactive Residues (TRR) was dependent on crop type and stage of growth. Up to 66.3% of the TRR was due to the parent compound in pea straw while as low as 1.5% of the TRR was attributed to the presence of parent compound in soybean foliage. Although the contribution of metabolites to the overall residue profile was significant on a percentage basis (% of TRR) the actual magnitude of the observed residues does not warrant their inclusion in the residue definition. In all cases the residue contribution of individual metabolites at sampling points after 0 DAT was ≤ 0.02 ppm parent compound equivalents.

In summary, imazamox residues in plants were found to decline rapidly following early post-emergent application. The metabolite profile in soybeans, field peas and wheat was found to be qualitatively similar and no individual metabolite was quantitatively relevant. In animals imazamox was found to rapidly eliminated with little biotransformation and minimal retention in tissue, eggs or milk.

Analytical Methods

A validated analytical method was used to determine imazamox residues in the Australian residue trials. The methodology involves extraction of residues from plant material with acidic aqueous methanol. The sample extract is concentrated and imazamox residues are partitioned into dichloromethane. The dichloromethane extract is evaporated and reconstituted in ethyl acetate and loaded onto a gel permeation chromatography column. The eluate is passed through a strong cation exchange SPE cartridge. The imazamox residues in the final extract are quantified by HPLC with comparison to an external standard. The method was validated for use in grain and green forage of field peas, peanuts and soybeans. In all matrices the LOQ of the method was determined to be 0.05 ppm imazamox. The methodology is considered adequate for determination of imazamox residues in or on grain and forage of the target crops.

An additional residue analytical method was provided for determination of imazamox residues based on quantitation by GC. Residues of imazamox and CL 263,284 (*O*-demethylated imazamox) are extracted with aqueous methanol. The extract is subjected to cleanup by solvent partitioning and solid phase extraction. Residues are quantified by GC with NPD following on-column methylation. The residue quantified is therefore the sum of the parent compound and the *O*-demethylated metabolite expressed as the parent compound. The LOQ of the GC method is 0.05 ppm (parent plus *O*-demethylated metabolite, expressed as parent).

Storage Stability

A storage stability study of imazamox residues in soybeans was presented in the application. Within the normal variability associated with the analytical method residues of imazamox in soybean seeds were shown to be stable for at least 2 years when stored frozen at -10° C

Residue Definition

The plant metabolism studies support a residue definition of "imazamox" as being appropriate. Such a definition is adequate for the purposes of monitoring good agricultural practice.

Residue Trials

Field peas

Two Australian residue trials were presented. In both trials imazamox was applied post-emergence at a rate of 2.4x the maximum Australian rate (30 g ai/ha). Samples of field pea (grain) were collected at normal commercial harvest, 101-112 days after treatment. In all cases residues in field peas were reported as <0.05 mg/kg. Supplementary Canadian data for field peas treated at 0.65x and 1.3x the proposed Australian application were also presented. Samples of field pea (grain) were collected at normal commercial harvest, 66-96 days after treatment. In all cases residues in field peas were reported as <0.05 mg/kg. Taken as a whole, the residue data support the applicant's proposed MRL of *0.05 mg/kg for imazamox in field peas. No harvest withholding period is considered necessary when the products are used as directed.

Peanuts

Three Australian residue trials were presented. In all trials imazamox was applied post-emergence at a rate of 2x the maximum Australian rate (36 g ai/ha). Samples of peanut (grain) were collected at normal commercial harvest, 130 to 171 days after treatment. In all cases residues in peanuts were reported as <0.05 mg/kg. The residue data support the applicant's proposed MRL of *0.05 mg/kg for imazamox in peanuts. No harvest withholding period is considered necessary when the products are used as directed.

Soybeans

Three Australian residue trials were presented. In all trials imazamox was applied post-emergence at a rate of 2x the maximum Australian rate (36 g ai/ha). Samples of soybean (grain) were collected at normal commercial harvest, 136-171 days after treatment. In all cases residues in soybeans were reported as <0.05 mg/kg. Supplementary US and Canadian data for soybeans treated at 1.3x to 2x the proposed Australian application rate were also presented. Samples of soybean (grain) were collected at harvest, 82-119 days after treatment. In all cases residues in soybean were reported as <0.05 mg/kg. Taken as a whole, the residue data support the applicant's proposed MRL of *0.05 mg/kg for imazamox in soybeans. No harvest withholding period is considered necessary when the products are used as directed.

Processing Studies

Since no detectable residues of imazamox were observed in raw agricultural commodities at harvest it was considered unnecessary to undertake detailed processing studies. Imazamox residues are not expected to be detectable in any processed commodities.

Animal Feed Commodity MRLs

Field pea, forage

The two Australian residue trials on field peas using a post-emergent application of imazamox were conducted at 2.3x the maximum Australian rate (31.5 g ai/ha). In all the trials the residues in field pea forage were <0.05 mg/kg at 42 days after treatment (1 trial) and 47 days after treatment (1 trial). Supplementary Canadian data for field peas treated at 0.65x and 1.3x the proposed Australian application rate were also presented. Samples of soybean forage were collected at 61 days after treatment. In all cases residues in field peas forage were reported as <0.05 mg/kg. Taken as a whole, the residue data support the applicant's proposed MRL of *0.05 mg/kg for field pea forage. The appropriate CODEX food classification group is AL 0528 pea vine (green) and in the present case the MRL should be established on a fresh weight basis. The following WHP statement is required for field peas treated with imazamox: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 6 WEEKS AFTER APPLICATION.

Peanut, forage

The three Australian residue trials on peanuts using a post-emergent application of imazamox were conducted at 2x the maximum Australian rate (36 g ai/ha). In all the trials, the residues in peanut forage were <0.05 mg/kg at 29 days after treatment (1 trial) and 31 days after treatment (2 trials). The residue data support the applicant's proposed MRL of *0.05 mg/kg for peanut forage. The MRL should be established on a fresh weight basis. The following WHP statement is required for peanuts treated with imazamox:

DO NOT GRAZE OR CUT FOR STOCK FEED FOR 4 WEEKS AFTER APPLICATION.

Soybean, forage

The three Australian residue trials on soybeans using a post-emergent application of imazamox were conducted at 2x the maximum Australian rate (36 g ai/ha). In all the trials, the residues in soybean, forage were <0.05 mg/kg at 29 days after treatment (1 trial) and 35 days after treatment (2 trials). Overseas residue data for imazamox in soybean forage and straw did not contradict the results of the Australian residue trials. The residue data support the applicant's proposed MRL of *0.05 mg/kg for soybean forage. The MRL should be established on a fresh weight basis. The following WHP statement is required for soybeans treated with imazamox:

DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION.

Animal commodity MRLs

No animal commodity MRLs were proposed by the applicant. The magnitude of imazamox residues in forage crops (recommended MRLs are *0.05 mg/kg) are not expected to result in detectable residues of imazamox in animals.

In a lactating goat dosed at 10 ppm in the feed for 7 consecutive days the highest residue at sacrifice (20 hours after the last dose) was 0.06 mg/kg parent compound equivalents in the kidney. The feeding level of 10 ppm is a 200 fold exaggeration of the maximum imazamox residue expected in forage. Assuming that tissue residues scale proportionately with dose the expected residue of imazamox in the kidney, following consumption of forage containing imazamox at 0.05 mg/kg, would be 0.0003 mg/kg. This residue is significantly lower than the tissue LOD (0.01 mg/kg) which is based on the detection of radiolabelled residues.

No egg or tissue samples taken from laying hens dosed at up to 10 ppm in the feed contained imazamox related residues at greater than 0.01 ppm (limit of quantitation).

The applicant has confirmed that no residue analytical method is available for the determination of imazamox in animal tissues. No method was validated during product development due to the presence of sub-LOQ residues in crops at harvest and in green forage after specified withholding periods.

It is apparent from the above discussion that animal commodity MRLs for imazamox are not required. It is considered unlikely that detectable residues of imazamox would occur in animals as a result of the use of *Raptor* on peanuts, field peas and soybeans.

Estimated dietary intakes

The theoretical maximum daily intake of imazamox from the proposed use pattern is equivalent to less than 1% of the ADI of 2.8 mg/kg body wt/day.

Bioaccumulation potential

Imazamox is not expected to be fat soluble. The octanol/water partition (P_{ow}) coefficient was found to be 5.36 (log P_{ow} = 0.73). The FAO manual[#] designates compounds as fat soluble if they have log P_{ow} values greater than 4. Compounds with P_{ow} less than 3 are not designated fat soluble.

[#] FAO Manual on the Submission and Evaluation of Pesticide Residues Data, Food and Agriculture Organization of the United Nations, Rome, 1997, p 36.

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Recommendations

Imazamox

Registration of *Raptor* for use on field peas, peanuts and soybeans is supported on the basis of evaluation of the residue data.

Recommended amendments to the MRL Standard:

Table 1			
Compound	Food		MRL (mg/kg)
ADD:			
Imazamox	VD 0561	Field pea, dry	*0.05
	SO 0697	Peanut	*0.05
	VD 0541	Soybean, dry	*0.05
		Table 3	
Compound		Residue	
ADD:			

Та	hle	4

imazamox

Compound	Animal Feed Commodity		MRL (mg/kg)
ADD:			
Imazamox	AL 1270	Peanut forage (green) [Fresh weight]	*0.05
	AL 0528	Pea vines (green) [Fresh weight]	*0.05
	AL 1265	Soybean forage (green) [Fresh weight]	*0.05

The MRL recommendations indicated above will be conveyed to the Australia and New Zealand Food Authority (ANZFA) for consideration for incorporation into Standard A14 of the Food Standards Code and consequent adoption into the State/Territory food legislation. Withholding periods:

The following withholding period statements are recommended in conjunction with the above MRLs: Grazing

Field peas	DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 6 WEEKS AFTER APPLICATION
Peanuts, Soybeans	DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION
Harvest	
Field peas, Peanuts, Soybeans	NOT REQUIRED WHEN USED AS DIRECTED

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Overseas Registration Status

Imazamox is registered on various crops in Argentina, Bolivia, Brazil, Bulgaria, Canada, Czech Republic, Paraguay, Poland, Slovakia, South Africa, USA and Zimbabwe. Both formulations of imazamox are registered in the USA. Overseas residue definitions are based on the parent compound. The following MRLs have been established in overseas countries (residue definition is imazamox).

Country	Crop	MRL (mg/kg)
USA	Soybeans	0.1
Brazil	Soybeans	0.1
	Dry beans	0.1
Czech Republic	Beans	0.05
	Peas	0.05
Italy	Soybeans	0.05
	Peas	0.05
Costa Rica	Soybeans	0.1

CODEX Alimentarius Commission MRL

No submissions on imazamox have been made to CODEX.

Potential risk to Australian export trade

In assessing the potential risk to Australian export trade the volume of field pea, peanut and soybean exports and the Australian residue trials were considered.

While peanuts and soybeans are important domestic crops in Australia they are not major export commodities. Field peas are a major export commodity with greater than 200 000 tonnes exported in 1995/6. However, since detectable residues of imazamox are not expected at harvest in any of the target crops the risk to trade is not considered to be significant.

The risk to Australian trade posed by the use of *Raptor* on field peas, peanuts and soybeans is considered to be small and consequently, from a trade perspective, registration of the products is supported.

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OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Imazamox is not listed in the NOHSC List of Designated Hazardous Substances. NOHSC has determined imazamox to be a hazardous substance according to NOHSC Approved Criteria for Classifying Hazardous Substances. This classification is based at least on its eye irritant effects.

The following risk phrase is assigned:

R36 Irritating to eyes

Substances containing imazamox at concentrations equal to or greater than 20% are classified as hazardous.

Imazamox is an off-white powdered solid with no odour. Imazamox is of low acute toxicity by all routes. It was not a skin irritant in rabbits and not a skin sensitiser in guinea pigs, but was a moderate eye irritant in rabbits.

Raptor Herbicide was not determined to be a hazardous substance, based on NOHSC criteria. It is an aqueous concentrate and of low acute toxicity by all routes. **Raptor Herbicide** was not irritating to the skin and eyes of rabbits, and non sensitising to guinea pigs skin.

Raptor WG Herbicide was determined to be a hazardous substance based on its acute eye irritancy and the concentration of imazamox in the formulation, in accordance with NOHSC Approved Criteria for Classifying Hazardous Substances. **Raptor WG Herbicide** is a water dispersible granule formulation and of low acute toxicity by all routes. It is not a skin irritant in rabbits and has no skin sensitising properties in guinea pigs, but is a moderate eye irritant in rabbits.

The products will be imported fully formulated. The applicant anticipates that **Raptor Herbicide** will be formulated in Australia in future. **Raptor Herbicide** is packed in high-density polyethylene "Quadratainer" drums of 20 L capacity with neck diameter of 58 mm. **Raptor WG Herbicide** is packed in high-density polyethylene bottles of 2.5 and 5.0 kg capacity, both with neck diameters of 38 mm.

Transport, storage and retailing

Formulators, store persons and forklift drivers will handle *Raptor* prior to use. Workers involved in transport, storage and retail will only be exposed to the products in the event of a packaging breach.

Advice on safe handling of the products during routine use is provided in the product Material Safety Data Sheet (MSDS).

Product Use

Raptor is to be applied to field peas, soybeans and peanuts by dry-ground application only. The maximum recommended application rate is 300 mL/ha **Raptor Herbicide** and 50 g/ha **Raptor WG Herbicide** with a maximum of 1 application per season. Application will be by boom spray equipment in a spray volume of 50 L/ha (max 0.07% imazamox).

For field peas, the products are to be applied to actively growing broadleaved weeds in the cotyledon stage to 3 leaf stage, and to grass weeds up to the 2 tiller stage. For peanuts and soybeans, the products are to be applied to actively growing weeds in the cotyledon to 2 leaf stage, and to grass weeds up to the 2 litter stage. A non-ionic surfactant (BS 100 or similar at 200 mL/100 L water) is to be used in all three crops, while Boost liquid ammonium sulphate is to be used in peanuts and soybeans (2 L/100 L water). A re-entry period is not specified on the draft labels. The withholding periods of 4 weeks in peanuts and soybeans and 6 weeks in field peas are specified for grazing, and cutting for stock feed. Workers likely to use the products are farmers and contract applicators.

Exposure of users will be predominantly through the dermal route during mixing/loading, application and clean-up procedures. Inhalation exposure to spray mist or dust may occur. Given that the products are of low acute inhalation toxicity and imazamox is non-volatile, exposure to product mist is not expected to contribute significantly to adverse effects. **Raptor WG Herbicide** is a moderate eye irritant. Considering the dilution of the product in the working strength solution (0.1 % w/v), the prepared spray is not expected to be irritating to the eyes. Therefore, eye protection is warranted only for workers handling the undiluted product (**Raptor WG Herbicide**).

No worker exposure data were available for imazamox or the products. The risk assessment was based on exposure estimates from the UK Predictive Operator Exposure Model. Calculated margins of exposure showed that the risk was acceptable for mixer/loaders and applicators not wearing gloves.

The risk assessment indicated that no personal protective equipment is recommended for users of **Raptor Herbicide**; however, for **Raptor WG Herbicide**, face shield or goggles are recommended when opening the container and preparing spray.

Entry into treated areas or handling treated crops

Foliar dissipation studies were not available. Harvesting of field peas, soybeans and peanuts is likely to be mechanical. Considering the low toxicity of the products, the dilution in the final spray (0.6% **Raptor Herbicide**, 0.1% **Raptor WG Herbicide**), and that re-entry is expected to be minimal, a re-entry period is not recommended.

Recommendations for safe use

Workers involved in transport, storage, and retailing should be protected by safe work practices and training. Users should follow the instructions and Safety Directions on the product labels. No personal protective equipment is recommended for **Raptor Herbicide**. Safety Directions for **Raptor WG Herbicide** include the use of face shield or goggles when opening the container and preparing spray.

The personal protective equipment recommended should meet the relevant Standards Australia standards specified below:

AS 1337-1992 Eye Protection for Industrial Applications.

Manufacturers and importers should produce a MSDS for hazardous products containing imazamox. These should contain information relevant to Australian workers, as outlined in the NOHSC National Code of Practice for the Preparation of Material Safety Data Sheets. Employers should obtain the MSDS from the supplier and ensure that their employees have ready access to it.

Conclusions

Raptor can be used safely if handled in accordance with the instructions on the product labels. Additional information is available on the MSDS for both products.

ENVIRONMENTAL ASSESSMENT

Introduction

Cyanamid Australia Pty Limited has applied for approval of a new technical grade active constituent, imazamox, and registration of the products **Raptor Herbicide** and **Raptor WG Herbicide**. This active is of the imidazolinone type and its proposed use is for the post-emergent control of a wide range of grasses and broadleaf weeds in field peas, peanuts and soybeans.

Environmental Fate

Hydrolysis

In a study conducted according to EC and OECD Guidelines, hydrolysis at pH 9 was slow, with no hydrolysis at pH 4 and 7. The half-life at pH 9 and 25 °C was determined by extrapolation as 192 days. Hydrolysis is not expected under normal environmental conditions.

The hydrolysis of two soil metabolites of imazamox, CL 312622 and CL 354825 were studied as above. CL 354825 was stable at pH 4, 7 and 9 and CL 312622 was stable at pH 4 and 7 under the same conditions. At pH 9, the half-life of CL 312622 was determined by extrapolation as 222 days at 25 °C. These metabolites are not expected to hydrolyse under environmental conditions.

Photolysis

In studies conducted to meet US EPA Guidelines, photolytic half lives were 6.75, 6.67 and 7.09 hours for buffered solution of pH 5, 7 and 9 respectively. In soil the degradation was slower and after 30 days only 20% degradation occurred. The half-life was calculated as 65 days. The lamp used for both studies used was similar to natural sunlight in New Jersey during September.

In another study, performed to meet German Guidelines, the quantum yield of imazamox was determined and from this the environmental half-life in a small lake was calculated as 2.0 days in summer (16.5 hours of sunlight per day, 20 °C) and 6.5 days in winter (7.6 hours sunlight, 3 °C).

Photolysis in water under Australian conditions could be a significant route of degradation, unless the water is turbid, while photolysis on soil is expected to be slow.

Metabolism

In two aerobic soil degradation studies, conducted to meet USEPA Guidelines, the half-lives in sandy loam soils were 28 and 65 days. There were two principle metabolites identified, CL 312,622 which reached approximately 45% of applied in both studies and CL 354,825 which was only significant in one study and reached 54% of applied material after 1 year.

An aquatic aerobic metabolism was performed to meet Canadian and USEPA Guidelines using sandy loam sediment. There was approximately 30% degradation during the one year study and a half-life at 25 °C was calculated as 975 days. Imazamox is rated as very slightly degradable.

A soil anaerobic study conducted to satisfy to USEPA requirements there was no detectable degradation of imazamox after 56 days of anaerobic incubation using the same sandy loam soil used for the aerobic study above. Imazamox does not readily degrade in anaerobic soil.

In an anaerobic aquatic degradation study, conducted to satisfy Canadian and USEPA requirements using the same sandy loam soil, there was limited degradation at 25 °C, with approximately 24% degradation after 12 months and a half-life of 764 days was calculated. Imazamox does not readily degrade in aquatic anaerobic conditions. However, it is unlikely to go to sediment due to the high water solubility and low Koc.

Mobility

In batch adsorption/desorption studies performed to meet USEPA requirements using 10 different soils, 4 from Japan and 6 from the USA, the Koc was low except in low pH and possible some clayey soils where the Koc was slightly higher but not > than 150. Imazamox was rated as very mobile in most soils except at low pH or some clay soils, where it is rated as having high mobility. Soil TLCs showed that imazamox was rated as highly mobile in most soils except one soil with low pH, were it was rated as mobile. However, in the field dissipation studies there was no leaching detected.

In batch adsorption/desorption studies on the principal soil metabolites CL 312,622 and CL 354,825 in 6 USA soils (as above), showed that the metabolite CL 312,622 was poorly absorbed which was confirmed by soil TLC studies. In contrast the other metabolite was moderately to strongly adsorbed.

Field Studies

There were 13 field studies performed, 6 in Canada and 7 in the USA, and the first order half lives were calculated as between <7 to 52 days, except for one outlier with a half life of 130 days. Imazamox was not detected in any soil below 22.5-30 cm and the principal metabolite, CL 312,622, was detected to a depth of 45 cm at 5 times proposed rates for Australia. Imazamox may range from readily degradable to slightly degradable in soils.

Environmental Toxicity

Avian

In acute oral and dietary toxicity tests on mallards and Bobwhite quail conducted to meet USEPA requirements there were no treatment related effects at the maximum doses used, approximately 2000 mg/kg bw and 5000 mg/kg (in feed) respectively. There were no effects in the long term reproductive studies at 2000 mg/kg in the feed. Imazamox is practically non-toxic to birds.

Aquatic

The acute studies on fish and daphnia, conducted to meet USEPA and EEC requirements, showed no effects at the maximum concentrations used, 120 mg/L nominal. Similarly, the chronic studies for fish and daphnia also showed no effects at these levels. Imazamox is rated as practically non-toxic to fish and daphnia, based on these studies. In a chronic study, early life stage fish, there was no effect at 11.8 mg/L, the maximum concentration tested, and is rated as very slightly toxic.

In USEPA Tier 1 level studies there were no effects on freshwater or salt water algae or diatoms at 40 μ g/L nominal, corresponding to direct overspray at twice the proposed Australian rate. In a test conducted to USEPA requirements, imazamox was toxic to duckweed, with IC50 (biomass) of 11 μ g/L. For emerged rooted aquatic plants, imazamox was toxic to *Monochoria vaginalis*, with

20.

100% mortality at 35 g/ha (maximum Australian rate) and significant effects at 19 g/ha, but non-toxic to *Sagittaria pygmaea* and *Cyperus serotinus*. This test did not follow any recognised protocol.

Non-target invertebrates

In studies conducted to USEPA and OECD requirements, imazamox was not toxic to bees and earthworms and rated as practically non-toxic to both organisms. It did not affect the respiration or nitrification of soil microbes at 150 g ai/ha and therefore considered non-toxic to these microbes at rates proposed for use in Australia (35 g ai/ha).

Phytotoxicity

In a Tier 1 study on seedling germination, conducted according to USEPA requirement, there were minimal effects on germination at a rate equivalent to 53.8 g ai/ha.

In a Tier 2 study on seedling germination and emergence, conducted according to USEPA requirement (Tier 2) where a range of sown seeds are oversprayed, there were minimal effects on soybean germination and emergence. Of the other crops tested (lettuce, radish, tomato, cucumber, cabbage, oats ryegrass corn and onions), effects on seedling emergence was only significant for corn and onions at 53.8 g ai/ha, above the proposed Australian rate. Phytotoxic effects on emerged seedlings were noted, including stunting, leaf chlorosis, leaf necrosis, anthocyanin pigmentation (cabbage) and plant death. The effect on soybeans was slight, with the other seedlings judged as being severe at the highest treatment level.

In a Tier 2 study on plant vegetative vigour, conducted according to USEPA requirements using the same seedlings as previous, oversprayed after true leaves development, all seedlings showed severe phytotoxic effects, except lettuce, and all showed significantly stunted growth, except soybeans.

Prediction Of Environmental Hazard

Imazamox will be used for the post-emergent control of certain weeds in field peas, peanuts and soybeans. The products will be applied at a rate of 30 g ai/ha for field peas and 35 g ai/ha for peanuts and soybeans using boom sprayers and flat fan nozzles. Currently this application is for ground spraying and once per season only. While off-target damage is possible through spray drift, herbicide applied to the target area should be associated with the soil compartment.

Exposure of non-target organisms may occur through direct contact to spray drift or from ingestion of residues on vegetation, soil or insects. Volatilisation of either the salt or the free acid is unlikely to occur.

Terrestrial organisms

Birds could be exposed to imazamox from residues on sprayed plants or insects in fields that are oversprayed. Using EPA methodology, the residues on crops and insects oversprayed at the proposed higher application rate (ca. 36 g ai per hectare) were shown to be significantly less than the NOEC for birds. Therefore under normal conditions of use the herbicide should present a negligible hazard to herbivorous or insectivorous birds. Similar calculations performed for herbivorous mammals and bees also indicate negligible hazard.

Likewise, earthworms and soil microbes are unlikely to be effected given that at 5 times the proposed rate, tests showed that imazamox does not effect these organisms.

Aquatic organisms

Assuming a "worst-case" scenario, ie direct overspray onto shallow water, calculations showed that the resulting concentration in water is 3 orders of magnitude less than the acute and chronic NOEC for fish and *D. magna* and therefore imazamox should not present either an acute or chronic hazard to fish or aquatic invertebrates in surface waters adjacent to application areas.

Similarly, the hazard to algae is also minimal given the NOEC (or LOEC) is less than the worst case situation. But the hazard to aquatic plants from direct overspray is high and a presumption of unacceptable risk exists. However using recent methodology for estimating spray drift from the German BBF, the concentration in a waterbody 5 metres away from the boomer sprayer was calculated to be a magnitude less than the EC50 for the aquatic plant tested (duckweed) and the hazard to aquatic plants is acceptable. In addition, the label includes directions not to spray within 50 metres of wetland or waterways, which will further reduce the hazard.

Runoff and Leaching

Runoff from treated fields could represent a significant hazard to aquatic plants. However, calculations with worst case assumptions for runoff showed that there was unlikely to be any effect on aquatic organisms except to aquatic plants. With a more realistic assumption that 10% of the catchment area was treated, the hazard from runoff was acceptable.

The field dissipation studies showed that under field conditions leaching was not observed, despite rates higher than that proposed for Australia. In addition, the single application per season at relative low rates limits the possibility of leaching and runoff occurring.

Desirable vegetation

When used according to label directions, the hazard to native and non-target vegetation should be negligible. Even with the worst case of 10% spray dray, it was shown that significant phytotoxic effects on non-target plants are not expected. In addition, there is a warning to prevent spray drifting to nearby plants/crops etc.

Conclusion

It is concluded by Environment Australia that imazamox is essentially non-toxic to birds, fish, aquatic invertebrates, bees, earthworms and soil microbes. It is toxic to non-target plants but when used according to label directions, the hazard was determined to be acceptable.

22.

EFFICACY AND CROP SAFETY ASSESSMENT

This summarizes the trials conducted in Australia with *Raptor* (containing the active constituent imazamox), providing information in relation to crop safety, weed control and re-cropping studies.

Introduction

The compound imazamox has been evaluated by Cyanamid Australia (and more recently Cyanamid Agriculture) and other trial contractors since 1991. These trials focussed particularly on crops such as field peas, peanuts and soybeans where commercially acceptable weed control and crop safety in these crops was evaluated.

The rate range of 30g to 36g ac/ha imazamox, plus non-ionic surfactant (which equates approximately to 45g to 50g product per hectare of the 700g/kg water dispersible granule, or 250ml to 300ml product per hectare of the 120g/L aqueous concentrate) provides commercially acceptable, reliable control of a wide range of weeds (both monocotyledonous and dicotyledonous species) without significant crop damage or yield penalties to field peas, soybeans and peanuts.

Re-cropping investigations have also been conducted in a number of trial sites and no adverse recropping effects have been observed when the proposed plant-back intervals are observed.

Weed Control Efficacy.

Imazamox has been evaluated by Cyanamid and contractors for pre-emergence and post-emergence weed control since 1991. Early work conducted in 1991 indicated that pre-emergence applications of imazamox did not perform adequately. More active ingredient was required to provide weed control equivalent to post-emergence applications.

Since 1992, trials with imazamox have concentrated on post-emergence timings in combination with a non- ionic surfactant in all major growing regions of the proposed use crops in Australia.

Post-emergence weed control.

The weeds listed in the draft labels have been included on the basis of appropriate supporting data. The data indicate that this wide range of commercially important weeds (both monocotyledonous and dicotyledonous) are adequately controlled by imazamox at either 30g ac/ha or 36g ac/ha or both.

Effect of ammonium sulphate and surfactant

Trial data indicate that the addition of non-ionic surfactant to imazamox is necessary for adequate and consistent weed control. Furthermore, the addition of ammonium sulphate to imazamox does improve weed control when compared to the use of non- ionic surfactant alone. BS 1000 mixed with imazamox has consistently performed better than other additives.

Lower application rates

Imazamox at rates lower than 30g ac/ha (i.e., at 24g ac/ha) does not provide acceptable weed control.

Difference in the formulations for weed control.

Internal work conducted by Cyanamid Agriculture since 1994 indicated that there are no consistent trends favouring any formulation (120 AS versus 700 WDG) over the other for effective weed control. These formulations are considered to provide equivalent weed control.

Crop Safety

Field peas

Imazamox has been tested for crop safety at rates of 24g to 96g ac/ha in a number of trials on a range of field pea varieties. The growth stages of the crop at the time of application ranged from 2-8 node when weeds were at a young stage of growth development

Imazamox at 30 to 36g ac/ha plus 0.2% v/v non ionic surfactant was shown to provide good crop selectivity from more than 50 trials over a wide range of varieties. On a few occasions, when applied to the 2-4 node stage of the crop, these rates were noted to cause slight temporary phytotoxicity (mostly in the form of yellowing and stunting and reduced crop vigour) without causing significant reduction in yield. In all cases, complete recovery of crops occurred towards the end of the season. No variety showed significant reductions in yield when imazamox was applied before the 5 node stage of the crop at 30g to 36g ac/ha. Generally, the later the application timing occurred (usually beyond the 5 node stage of the crop); the more an increase in the levels of phytotoxicity was noted in the form of yellowing and stunting.

Imazamox at 36g and 48g ac/ha in combination with ammonium sulphate and non ionic surfactant caused commercially unacceptable damage to peas with no complete recovery of the crop noted. Other surfactants such as Amigo and Uptake were also trialled and not considered safe to field peas. Hence, the draft labels specifically caution against the use of other adjuvants in field peas and do not recommend mixtures with ammonium sulphate.

The proposed label rates of 250ml/ha for the 120AC formulation and 45.0g/ha for the 700WG formulation equate to 30.0 and 31.5g ac/ha imazamox respectively.

Soybeans

Imazamox has been tested for crop selectivity at rates of 24g to 96g ac/ha in a range of soybean varieties when applied from the 2 leaf stage to the early flowering stage of the crop. Imazamox at 36g and 48g ac/ha (the proposed label recommendation is to apply 36g up to 6 leaf stage of the crop) in combination with surfactant (0.2% v/v BS 1000) are considered commercially safe (with the possibility of minor transient crop vigour loss occurring) to soybeans when applied from the 2 leaf to the early flowering stage of the crop (crop height 15-30 cm). Minor temporary internodal shortening, not considered to have any commercial disadvantages; has been demonstrated at 36g ac/ha imazamox in combination with 0.2% v/v BS 1000 alone. Imazamox at 72g (2 x the recommended label rate) and 96g ac/ha may cause transient symptoms of phytotoxicity in the form of yellowing and biomass reduction without any recorded indication of yield depressions.

24.

The addition of BOOST (500g/L ammonium sulphate; Gullf Ag Industries) at 2% v/v to 36g ac/ha imazamox applied up to the 6 leaf stage (early post emergence) did not adversely affect crop safety, with one trial indicating minor transient internodal shortening occurring. Imazamox at 48g ac/ha in combination with ammonium sulphate plus surfactant applied early up to the four leaf stage of the crop caused some degree of phytotoxicity (chlorosis and stunting) at three weeks after treatment. The crop quickly recovered by six weeks after treatment with no significant reductions in yield of any of the five varieties.

The proposed label rates of 300ml/ha for the 120AC formulation and 50g/ha for the 700WG formulation equate to 36.0 and 35.0g ac/ha imazamox respectively.

Peanuts

A range of peanut varieties has been tested for crop selectivity to imazamox at rates of 24g to 96g ac/ha applied at the early growth stage of the crop (3-8 leaf stage). Excellent crop selectivity has been demonstrated at 36g, 48g and 72g ac/ha imazamox with no yield penalties demonstrated in any trial. The addition of 0.2% v/v non-ionic surfactant plus 2% v/v BOOST (500g/L ammonium sulphate, Gullf Ag Industries) to 36g ac/ha imazamox was also considered safe to peanuts with the possibility of minor transient internodal shortening occurring. Imazamox at 72g and 96g ac/ha may cause initial transient phytotoxicity in

the form of light yellowing without any indications of yield depressions in any of the trials.

The proposed label rates of 300ml/ha for the 120AC formulation and 50g/ha for the 700WG formulation equate to 36.0 and 35.0g ac/ha imazamox respectively.

Re-cropping

Many trial sites, both in the summer and winter cropping areas, have been assessed for follow crop effects in a wide range of crops.

Re-cropping effects have been reported from the summer rainfall areas of Queensland in barley, canola, chickpeas, faba beans, lucerne, oats, sorghum and wheat at the proposed label rate of 36g ac/ha imazamox when interim rainfall was below that proposed on the draft label. Barley sown 172 days after treatment (172 DAS) indicated stunting where the total amount of rainfall from the time of application to sowing of the crop was approximately 400mm (400mm ATS). Canola (163 DAS; 361mm ATS), chickpeas (172 DAS; 400mm ATS), faba beans (172 DAS; 400mm ATS), lucerne (172 DAS; 400mm ATS), oats (172 DAS; 400mm ATS), sorghum (71 DAS; 44mm ATS) and wheat (172 DAS; 400mm ATS) also showed signs of stunting.

Transient phytotoxicity has been observed for cotton and sunflowers at 96g ac/ha imazamox (2.7 x the proposed label rate for soybeans and peanuts).

In the winter rainfall areas, only one trial site in WA indicated very slight growth suppression (delayed growth) of wheat sown 11 months after treatment (11 MAT; 225mm ATS) at a rate lower than the proposed label rate of 30g ac/ha. Imazamox at 24g ac/ha caused milder symptoms of delayed growth development than imazamox at 48g ac/ha. The wheat recovered at both rates. Yellowing or germination failure was not observed.

All other trials conducted showed no re-cropping effects to barley, wheat, oats or canola at 30g (the proposed label rate for field peas) or 36g ac/ha imazamox.

The proposed re-cropping restrictions on the draft label take into account that residual activity of imazamox may carry over to the following growing season, particularly under conditions of limited rainfall and are designed to protect sensitive follow crops. Refer to the proposed label for these re-cropping restrictions.

Efficacy Data Assessment Summary

The major benefits offered to potential users by the registration of *Raptor* are the relatively long list of weeds controlled by post-emergence application, including important grass weeds and the relatively short follow-crop plant back periods.

Trial design was considered adequate in relation to provision of controls, treatment group size, number of replicates, plant varieties and stage of growth etc:

Appropriate records were presented for most trials detailing the experimental conditions in relation to relevant variables, such as weed pressure, weather conditions, soil type etc, under which the trials were conducted. Data were generated in a good cross section of the regions in which the product will be used.

Data generated were applicable to the use of the herbicide. Statistical analysis of results was given or results shown in terms of Least Significant Differences.

A large number of consultancies were commissioned to carry out the work, and reports were clearly presented and summarised.

Data support the use of *Raptor* to control the weeds shown on the draft label. Sufficient evidence was given that the weeds will be controlled providing they are sprayed at the correct stage, usually before the 3 leaf stage. This warning is shown appropriately on the draft labels.

Crop safety was generally satisfactory, although some transitory effects were reported. All trials indicated that final yields should not be not affected, or only slightly affected, for the crops listed on the draft label. Plant back periods have been included.

Conclusion

The data support the claims for efficacy and crop safety, and the submission is acceptable in terms of these two criteria.

DRAFT PACK LABEL FILENAME: RAPTORAS2.DOC

RAPTOR* HERBICIDE

Active Constituent:

120g/L IMAZAMOX present as the ammonium salt.

For the post-emergence control of certain annual grass and broadleaved weeds in field peas, peanuts and soybeans as specified in the DIRECTIONS FOR USE table. IMPORTANT: READ THE ATTACHED LEAFLET BEFORE USE



CYANAMID AGRICULTURE PTY. LIMITED 5 Gibbon Road, Baulkham Hills, N.S.W. 2153

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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. 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.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre (Telephone - 131126 - Australia-wide).

MSDS

Additional information is listed in the Material Safety Data Sheet.

WARRANTY

This product is designed only to be used in accordance with the label directions which reflect the opinion of experts based on field use and tests. If it is so used, Cyanamid Agriculture Pty. Limited warrants its effectiveness, but takes no responsibility whatsoever for the consequences of the user failing to follow these directions exactly.

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THIS PRODUCT IS NOT CONSIDERED TO BE A DANGEROUS GOOD UNDER THE AUSTRALIAN CODE FOR THE TRANSPORT OF DANGEROUS GOODS BY ROAD AND RAIL.

FOR SPECIALIST ADVICE IN AN EMERGENCY ONLY PHONE **1 800 033 111** TOLL FREE - ALL HOURS -AUSTRALIA WIDE

PRODUCT NO: BATCH NO: DATE OF MANUFACTURE: NRA APPROVAL NO.: DRAFT LABEL LEAFLET FILENAME: RAPTORAS2.DOC

RAPTOR* HERBICIDE

Active Constituent:

120g/L IMAZAMOX present as the ammonium salt.

For the post-emergence control of certain annual grass and broadleaved weeds in field peas, peanuts and soybeans as specified in the DIRECTIONS FOR USE table. THIS LEAFLET IS PART OF THE LABEL.



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DIRECTIONS FOR USE: RESTRAINTS:

Do NOT apply to crops or weeds stressed by factors such as root or foliar diseases, water logging, nutrient deficiencies or extremes of temperature and moisture.

CROP	WEEDS CONTROLLED	RATE	CRITICAL COMMENTS
		PER HA.	
Post-	Barley grass (Hordeum	250mL	Do NOT apply to field peas
emergence	leporinum), brome grass (Bromus	plus	beyond the 4 node stage.
Field peas	spp.), deadnettle (Lamium	BS 1000, or	
(Following	amplexicaule), Indian hedge	equivalent,	Do NOT use adjuvants other
varieties	mustard (Sisymbrium orientale),	at 200mL per	than BS 1000 or equivalent.
only:	turnip weed (Rapistrum rugosum),	100L water	
Alma,	volunteer barley (Hordeum		Apply to actively growing
Bonzer,	vulgare), volunteer oats (Avena		broadleaved weeds in the
Dun,	sativa), volunteer lupins (Lupinus		cotyledon to 3 leaf stage.
Dundale,	spp.), volunteer triticale		Apply to grass weeds up to
Glenroy,	(Triticosecale spp.), volunteer		the 2 tiller stage.
Laura,	wheat (Triticum aestivum), wild		
Wirrega)	oats (Avena fatua), wild turnip		Good crop growth will aid
	(Brassica tournefortii),		weed control. Weeds may not
	*doublegee (Emex australis),		be totally controlled but
	* shepherds purse		populations will be significantly
	(Capsella bursa- pastoris),		reduced and surviving plants
	*threehorn bedstraw		will generally be severely
	(Galium tricornutum),		retarded.
	* wild radish (Raphanus		
	raphanistrum),		* Surviving plants will generally
	*wireweed (Polygonum aviculare)		be retarded and will not
			compete with good crop
			growth.
			Defense anon seferic section of
			label.
			Refer to FOLLOW CROPS
			section of this label regarding
			follow crops.

CROP	WEEDS CONTROLLED	RATE	CRITICAL
		PER HA.	COMMENTS
Post-	Amaranth (Amaranthus spp.),	300mL	Do NOT apply to crops
emergence	bell vine (Ipomoea plebeia),	plus	beyond the 6 leaf stage.
Soybeans,	barnyard grass (Echinochloa crus-galli),	BS 1000, or	
peanuts	fathen (Chenopodium album), fierce	equivalent,	Apply to actively growing
	thornapple (Datura ferox), liverseed	at 200mL	weeds in the cotyledon to
	grass	per 100L	2 leaf stage. Apply to grass
	(Urochloa panicoides), wild gooseberry	water plus	weeds up to the 2 tiller
	(Physalis minima),	BOOST at	stage.
	* anoda weed (Anoda cristata),	2L per	
	* barnyard grass (Echinochloa colona),	100L water.	* Surviving plants will
	* blackberry nightshade (Solanum		generally be retarded and
	nigrum),		will not compete with good
	* caltrop (Tribulus terrestris),		crop growth.
	* chickweed (Stellaria media),		
	* crabgrass (Digitaria ciliaris),		Refer to FOLLOW
	* Noogoora burr (Xanthium pungens),		CROPS section of this
	* shepherd's purse		label regarding follow
	(Capsella bursa-pastoris),		crops.
	* wild radish (Raphanus raphanistrum)		

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

WITHHOLDING PERIODS:

GRAZING

Field peas:	DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 6 WEEKS
	AFTER APPLICATION.
Peanuts, soybeans:	DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS
	AFTER APPLICATION.
TLADVECT	

HARVEST

Field peas, peanuts, soybeans: NOT REQUIRED WHEN USED AS DIRECTED.

GENERAL INSTRUCTIONS

This product is for early post-emergence weed control in field peas, soybeans and peanuts. Weeds will either die or remain stunted and will not compete with the crop. For weeds marked with an asterisk in the above table, the level of control will vary significantly depending on factors such as climatic conditions following application, crop vigor, weed seed depth, etc.

The non-ionic surfactant, BS1000 or equivalent, must be added when used in all three crops, while Boost liquid ammonium sulphate should also be added when used in peanuts and soybeans.

Good crop competition is essential for effective weed control.

MIXING

RAPTOR Herbicide is an aqueous concentrate and mixes readily with water. Part fill the spray tank with water, then with the agitator running, add the required amount of product, then fill the tank with water. When tank mixing this product with other recommended compatible products, first add the other product to the tank and mix thoroughly before adding this product.

APPLICATION

For ground application only: Apply with boom equipment in not less than 50 L/ha water using flat fan nozzles. Avoid overlap and do not overspray headlands.

Do NOT apply by aircraft.

RAPTOR Herbicide should be applied a minimum of two hours before rainfall or overhead irrigation. Do NOT apply RAPTOR more than once per growing season.

EQUIPMENT CLEAN-UP

Thoroughly flush all spray equipment with water following the use of RAPTOR and before use with other products.

COMPATIBILITY

The product is compatible with dimethoate, metribuzin, diflufenican, FASTAC* 100, phosmet, omethoate and endosulfan.

Do NOT tank mix with selective post-emergence grass herbicides. Do NOT apply these herbicides following use of RAPTOR until grasses have resumed active growth.

GROUP

B

HERBICIDE

RESISTANT WEEDS WARNING

RAPTOR Herbicide is a member of the Imidazolinone group of herbicides. The product has the ALS mode of action. For weed resistance management, the product is a Group B herbicide.

Some naturally-occurring weed biotypes resistant to the product and other ALS herbicides may exist through normal genetic variability in any weed population. The resistant individuals can eventually dominate the population if these herbicides are used repeatedly. These resistant weeds will not be controlled by this product or other ALS herbicides.

Since the occurrence of resistant weeds is difficult to detect prior to use, Cyanamid Agriculture Pty Limited accepts no liability for any losses that may result from failure of this product to control resistant weeds.

FOLLOW CROPS

Under conditions, such as very dry seasons, which do not favor breakdown of this product, carry-over soil residues can affect susceptible follow crops. As environmental and agronomic factors make it impossible to eliminate all risks associated with this product, rotational crop injury is always possible. The following minimum re-cropping intervals (months after application) should be observed.

MONTHS AFTER APPLICATION			
0	10	21	
field peas	chick peas	All other crops including	
	faba beans	canola	
	lucerne	oats	
	lupins	safflower	
	pasture legumes		
	vetch		
	*barley		
	*wheat		
	*triticale		

Following use in field peas:-

- * The following additional requirements apply if it is intended to sow WHEAT, BARLEY or TRITICALE during the next winter season.
- *Do NOT apply RAPTOR later than the end of August.* Do NOT use RAPTOR in areas where rainfall from the time of spraying to sowing of cereals is expected to be below 200mm.

Furthermore:

Do NOT use on soils of pH 5.5 (CaCl₂) or less in areas where rainfall from spraying to sowing of cereals is expected to be below 300mm.

Following use in summer crops:-Irrigated only:

MONTHS AFTER APPLICATION			
0	5	10	18
mungbeans	*chick peas	**maize	All other crops
peanuts	*lucerne	**sorghum	(providing rainfall and
soybeans	*lupins	**cotton	irrigation exceeds
	*pasture legumes	**oats	2000mm)
	*barley	**sunflower	
	*wheat		

* Do NOT plant these crops unless interim rainfall (rainfall plus irrigation) from application to sowing is at least 500mm.

** Do NOT plant these crops unless interim moisture (rainfall plus irrigation) from application to sowing is at least 800mm.

	MO	NTHS AFTER APPL	JICATION	
0	8	10	15	22
mungbeans peanuts soybeans	*lucerne *barley *wheat	**chick peas **maize **sorghum **cotton **oats **sunflower	pasture legumes lupins	All other crops (providing rainfall exceeds 2000mm)

Dryland only:

* Do NOT plant these crops unless interim rainfall from application to sowing is at least 500mm.

** Do NOT plant these crops unless interim rainfall from application to sowing is at least 800mm.

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.

Do NOT spray within 50 m of wetlands or waterways.

Crop safety: This product may cause shortening of plant internodes and may in some circumstances lead to transient crop yellowing but plants will soon recover. This effect is more pronounced under poor growth conditions.

Do not use this product on field pea varieties other than Alma, Bonzer, Dun, Dundale, Glenroy, Laura and Wirrega.

Replanting: If replanting is necessary in a field previously treated with RAPTOR, the field may be replanted to field peas (above listed varieties only), soybeans or peanuts. Do NOT apply a second treatment of RAPTOR.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Toxic to aquatic flora. Do NOT contaminate streams, rivers or waterways with the chemical or used containers.

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. 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.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre (Telephone - 131126 - Australia-wide).

MSDS

Additional information is listed in the Material Safety Data Sheet.

WARRANTY

This product is designed only to be used in accordance with the label directions which reflect the opinion of experts based on field use and tests. If it is so used, Cyanamid Agriculture Pty. Limited warrants its effectiveness, but takes no responsibility whatsoever for the consequences of the user failing to follow these directions exactly.

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ITEM NO: NRA APPROVAL NO.:

DRAFT PACK LABEL FILENAME: RAPTORWG2.DOC

CAUTION KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING

RAPTOR* WG HERBICIDE

Active Constituent: 700g/kg IMAZAMOX.

For the post-emergence control of certain annual grass and broadleaved weeds in field peas, peanuts and soybeans as specified in the DIRECTIONS FOR USE table. IMPORTANT: READ THE ATTACHED LEAFLET BEFORE USE



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NET CONTENTS: 2.5, 5 KG * Registered trademark of American Cyanamid Company

STORAGE AND DISPOSAL

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

Will irritate the eyes. When opening the container and preparing spray, wear face shield or goggles. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use, wash face shield or goggles.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre (Telephone - 131126 - Australia-wide).

MSDS

Additional information is listed in the Material Safety Data Sheet.

WARRANTY

This product is designed only to be used in accordance with the label directions which reflect the opinion of experts based on field use and tests. If it is so used, Cyanamid Agriculture Pty. Limited warrants its effectiveness, but takes no responsibility whatsoever for the consequences of the user failing to follow these directions exactly.

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FOR SPECIALIST ADVICE IN AN EMERGENCY ONLY PHONE 1 800 033 111 TOLL FREE - ALL HOURS -AUSTRALIA WIDE

PRODUCT NO: BATCH NO: DATE OF MANUFACTURE: NRA APPROVAL NO.:

DRAFT LABEL LEAFLET FILENAME: RAPTORWG2.DOC

CAUTION KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING

RAPTOR* WG HERBICIDE

Active Constituent: 700g/kg IMAZAMOX.

For the post-emergence control of certain annual grass and broadleaved weeds in field peas, peanuts and soybeans as specified in the DIRECTIONS FOR USE table. THIS LEAFLET IS PART OF THE LABEL.



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DIRECTIONS FOR USE: RESTRAINTS:

Do NOT apply to crops or weeds stressed by factors such as root or foliar diseases, water logging, nutrient deficiencies or extremes of temperature and moisture.

CROP	WEEDS CONTROLLED	RATE	CRITICAL COMMENTS
		PER HA.	
Post-	Barley grass (Hordeum	45g plus	Do NOT apply to field peas
emergence	leporinum), brome grass	BS 1000, or	beyond the 4 node stage.
Field peas	(Bromus spp.), deadnettle	equivalent,	
(Following	(Lamium amplexicaule),	at 200mL per	Do NOT use adjuvants other than
varieties	Indian hedge mustard	100L water	BS 1000 or equivalent.
only:	(Sisymbrium orientale), turnip		
Alma,	weed (Rapistrum rugosum),		Apply to actively growing
Bonzer,	volunteer barley (Hordeum		broadleaved weeds in the
Dun,	vulgare), volunteer oats (Avena		cotyledon to 3 leaf stage. Apply to
Dundale,	sativa), volunteer lupins		grass weeds up to the 2 tiller stage.
Glenroy,	(Lupinus spp.), volunteer		
Laura,	triticale (Triticosecale spp.),		Good crop growth will aid weed
Wirrega)	volunteer wheat (Triticum		control. Weeds may not be totally
	aestivum), wild oats (Avena		controlled but populations will be
	fatua), wild turnip (Brassica		significantly reduced and surviving
	tournefortii),		plants will generally be severely
	*doublegee (Emex australis),		retarded.
	* shepherds purse		
	(Capsella bursa-pastoris),		*Surviving plants will generally be
	*threehorn bedstraw		retarded and will not compete with
	(Galium tricornutum),		good crop growth.
	* wild radish (Raphanus		
	raphanistrum),		Refer to crop safety section of
	*wireweed (Polygonum		label.
	aviculare)		
			Refer to FOLLOW CROPS
			section of this label regarding
			follow crops.

CROP	WEEDS CONTROLLED	RATE	CRITICAL COMMENTS
		PER HA.	
Post-	Amaranth (Amaranthus spp.),	50g plus	Do NOT apply to crops
emergence	bell vine (Ipomoea plebeia),	BS 1000,	beyond the 6 leaf stage.
Peanuts,	barnyard grass (Echinochloa	or	
soybeans	crus-galli), fathen (Chenopodium	equivalent,	Apply to actively growing
	album), fierce thornapple (Datura	at 200mL	weeds in the cotyledon to
	ferox), liverseed grass (Urochloa	per 100L	2 leaf stage. Apply to grass
	panicoides), wild gooseberry (Physalis	water plus	weeds up to the
	minima),	BOOST at	2 tiller stage.
	* anoda weed (Anoda cristata),	2L per	
	* barnyard grass (Echinochloa colona),	100L	* Surviving plants will
	* blackberry nightshade	water.	generally be retarded and will
	(Solanum nigrum),		not compete with good crop
	* caltrop (Tribulus terrestris),		growth.
	* chickweed (Stellaria media),		
	* crabgrass (Digitaria ciliaris),		Refer to FOLLOW CROPS
	* Noogoora burr (Xanthium pungens),		section of this label regarding
	* shepherd's purse		follow crops.
	(Capsella bursa-pastoris),		
	* wild radish (Raphanus raphanistrum)		

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

WITHHOLDING PERIODS:

GRAZING	
Field peas:	DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 6 WEEKS
	AFTER APPLICATION.
Peanuts, soybeans:	DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS
	AFTER APPLICATION.

HARVEST

Field peas, peanuts, soybeans: NOT REQUIRED WHEN USED AS DIRECTED.

GENERAL INSTRUCTIONS

This product is for early post-emergence weed control in field peas, soybeans and peanuts. Weeds will either die or remain stunted and will not compete with the crop. For weeds marked with an asterisk in the above table, the level of control will vary significantly depending on factors such as climatic conditions following application, crop vigor, weed seed depth, etc.

The non-ionic surfactant, BS1000 or equivalent, must be added when used in all three crops, while Boost liquid ammonium sulphate should also be added when used in peanuts and soybeans. Good crop competition is essential for effective weed control.

MIXING

RAPTOR WG Herbicide is a water dispersible granule formulation. Part fill the spray tank with water, then with the agitator running, add the required amount of product, then fill the tank with water. When tank mixing this product with other recommended compatible products, first add the other product to the tank and mix thoroughly before adding this product.

APPLICATION

For ground application only: Apply with boom equipment in not less than 50 L/ha water using flat fan nozzles. Avoid overlap and do not overspray headlands.

Do NOT apply by aircraft.

RAPTOR WG Herbicide should be applied a minimum of two hours before rainfall or overhead irrigation.

Do NOT apply RAPTOR more than once per growing season.

EQUIPMENT CLEAN-UP

Thoroughly flush all spray equipment with water following the use of RAPTOR and before use with other products.

COMPATIBILITY

The product is compatible with dimethoate, metribuzin, diflufenican, FASTAC* 100, phosmet, omethoate and endosulfan.

Do NOT tank mix with selective post-emergence grass herbicides. Do NOT apply these herbicides following use of RAPTOR until grasses have resumed active growth.

RESISTANT WEEDS WARNING

GROUP B HERBICIDE

RAPTOR WG Herbicide is a member of the Imidazolinone group of herbicides. The product has the ALS mode of action. For weed resistance management, the product is a Group B herbicide.

Some naturally-occurring weed biotypes resistant to the product and other ALS herbicides may exist through normal genetic variability in any weed population. The resistant individuals can eventually dominate the population if these herbicides are used repeatedly. These resistant weeds will not be controlled by this product or other ALS herbicides.

Since the occurrence of resistant weeds is difficult to detect prior to use, Cyanamid Agriculture Pty Limited accepts no liability for any losses that may result from failure of this product to control resistant weeds.

FOLLOW CROPS

Under conditions, such as very dry seasons, which do not favor breakdown of this product, carry-over soil residues can affect susceptible follow crops. As environmental and agronomic factors make it impossible to eliminate all risks associated with this product, rotational crop injury is always possible. The following minimum re-cropping intervals (months after application) should be observed.

MONTHS AFTER APPLICATION		
0	10	21
field peas	chick peas	All other crops including
	faba beans	canola
	lucerne	oats
	lupins	safflower
	pasture legumes	
	vetch	
	*barley	
	*wheat	
	*triticale	

Following use in field peas:-

- * The following additional requirements apply if it is intended to sow WHEAT, BARLEY or TRITICALE during the next winter season.
- *Do NOT apply RAPTOR later than the end of August.* Do NOT use RAPTOR in areas where rainfall from the time of spraying to sowing of cereals is expected to be below 200mm.

Furthermore:

Do NOT use on soils of pH 5.5 (CaCl₂) or less in areas where rainfall from spraying to sowing of cereals is expected to be below 300mm.

Following use in summer crops:-Irrigated only:

MONTHS AFTER APPLICATION			
0	5	10	18
mungbeans	*chick peas	**maize	All other crops
peanuts	*lucerne	**sorghum	(providing rainfall and
soybeans	*lupins	**cotton	irrigation exceeds
	*pasture legumes	**oats	2000mm)
	*barley	**sunflower	
	*wheat		

* Do NOT plant these crops unless interim rainfall (rainfall plus irrigation) from application to sowing is at least 500mm.

** Do NOT plant these crops unless interim moisture (rainfall plus irrigation) from application to sowing is at least 800mm.

	MO	NTHS AFTER APPL	JICATION	
0	8	10	15	22
mungbeans peanuts soybeans	*lucerne *barley *wheat	**chick peas **maize **sorghum **cotton **oats	pasture le gumes lupins	All other crops (providing rainfall exceeds 2000mm)
		**sunflower		

Dryland only:

* Do NOT plant these crops unless interim rainfall from application to sowing is at least 500mm.

** Do NOT plant these crops unless interim rainfall from application to sowing is at least 800mm.

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.

Do NOT spray within 50 m of wetlands or waterways.

Crop safety: This product may cause shortening of plant internodes and may in some circumstances lead to transient crop yellowing but plants will soon recover. This effect is more pronounced under poor growth conditions.

Do not use this product on field pea varieties other than Alma, Bonzer, Dun, Dundale, Glenroy, Laura and Wirrega.

Replanting: If replanting is necessary in a field previously treated with RAPTOR, the field may be replanted to field peas (above listed varieties only), soybeans or peanuts. Do NOT apply a second treatment of RAPTOR.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Toxic to aquatic flora. Do NOT contaminate streams, rivers or waterways with the chemical or used containers.

STORAGE AND DISPOSAL

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

Will irritate the eyes. When opening the container and preparing spray, wear face shield or goggles. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use, wash face shield or goggles.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre (Telephone - 131126 - Australia-wide).

MSDS

Additional information is listed in the Material Safety Data Sheet.

WARRANTY

This product is designed only to be used in accordance with the label directions which reflect the opinion of experts based on field use and tests. If it is so used, Cyanamid Agriculture Pty. Limited warrants its effectiveness, but takes no responsibility whatsoever for the consequences of the user failing to follow these directions exactly.

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ITEM NO: NRA APPROVAL NO.:

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 octonol water partioning 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

- Goring, C.A.I. et al. 1975, 'Principles of pesticide degradation in soil', in *Environmental Dynamics* of *Pesticides*, edited by R. Haque and V.H. Freed, Plenum Press, New York, pp 135-72.
- Matthews, G.A. 1992, *Pesticide Application Methods*, 2nd ed., Longman, London.
- National Registration Authority for Agricultural and Veterinary Chemicals 1996, *Ag Manual: The Requirements Manual for Agricultural Chemicals*, NRA, Canberra.
- National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Requirements Series: Guidelines for Registering Agricultural Chemicals*, NRA, Canberra.
- National Registration Authority for Agricultural and Veterinary Chemicals 1996, *MRL Standard: Maximum Residue Limits in Food and Animal Feedstuffs*, NRA, Canberra.
- National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Labelling Code—Code of Practice for Labelling Agricultural Chemical Products*, NRA, Canberra.

NRA PUBLICATIONS ORDER FORM

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National Registration Authority for Agricultural and Veterinary Chemicals
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