



**National
Registration
Authority**

For Agricultural & Veterinary Chemicals

PUBLIC RELEASE SUMMARY

**of the evaluation by the NRA of
the new active constituent:**

Imazameth

in the product:

FLAME HERBICIDE

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TABLE OF CONTENTS

| | PAGE |
|--|------|
| <i>FOREWORD</i> | iii |
| <i>ABBREVIATIONS AND ACRONYMS</i> | iv |
| 1. EXECUTIVE SUMMARY | 1 |
| 2. INTRODUCTION | 5 |
| - Applicant | |
| - Product details | |
| - Overseas registration status | |
| 3. PROPERTIES OF THE CHEMICAL ACTIVE CONSTITUENT | 6 |
| 4. AGRICULTURAL ASSESSMENT | 7 |
| - Justification for use | |
| - Proposed use pattern | |
| - Evaluation of efficacy | |
| - Phytotoxicity | |
| - Conclusion | |
| 5. ENVIRONMENTAL ASSESSMENT | 9 |
| - Environmental fate | |
| - Environmental effects | |
| - Environmental hazard | |
| - Conclusion | |
| 6. PUBLIC HEALTH AND SAFETY ASSESSMENT | 14 |
| - Evaluation of toxicology | |
| - Public health standards | |
| - Conclusion | |
| 7. RESIDUES IN FOOD AND TRADE ASSESSMENT | 17 |
| - Background | |
| - Residues in food commodities | |
| - Trade | |
| 8. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT | 20 |
| - Introduction | |
| - Manufacture, transport, storage and retailing | |
| - End use | |
| - Entry into treated areas or handling treated crops | |
| - Recommendations for safe use | |
| - Conclusion | |
| 9. ANNEX 1 : Draft label FLAME HERBICIDE | 22 |

FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent Statutory Authority with responsibility for the assessment and approval of agricultural and veterinary chemical product prior to 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 & Non-Prescription Drug Branch), the Environment Protection Agency (EPA), the National Occupational Health and Safety Commission (Worksafe Australia) and State Departments of Agriculture and Health.

The NRA has a policy of encouraging openness and transparency in its activities and seeking community involvement in decision making. The publication of Public Release Summaries for all products containing new active ingredients is a part of that process.

The information and technical data required by the NRA in order to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the document "Interim Requirements for the Registration of Agricultural and Veterinary Chemical Product" which can be obtained from the NRA.

This Public Release Summary is intended as a brief overview of the assessment that has been completed by the NRA and advisory agencies. The document 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 occupational health and safety aspects, environmental impact, and residues in food are available from the NRA on request.

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

ABBREVIATIONS AND ACRONYMS WHICH MAY APPEAR IN THIS DOCUMENT

| | |
|----------------------|---|
| Imazameth | Active constituent |
| ADI | Acceptable Daily Intake (for humans) |
| AHMAC | Australian Health Ministers Advisory Council |
| ai | Active ingredient |
| CNPDB | Chemicals & Non-Prescription Drug Branch (Department of Health and Family Services) |
| d | Day |
| EC50 | Concentration at which 50% of the test population are immobilised |
| EUP | End Use Product |
| F₀ | Original Parent Generation |
| h | Hour |
| HPLC | 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 (a legal 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 |
| po | Oral |
| ppb | parts per billion |
| PPE | Personal Protective Equipment |
| ppm | parts per million |
| s | Second |
| sc | Subcutaneous |

| | |
|----------------|--|
| SC | Suspension Concentrate |
| SUSDP | Standard for the Uniform Scheduling of Drugs and Poisons |
| T-Value | A value used to determine the First Aid Instructions for chemical product that contain two or more poisons |
| TGAC | Technical Grade Active Constituent |
| WDG | Water Dispersible Granule |
| WHP | Withholding Period |
| WSA | Worksafe Australia |

1. EXECUTIVE SUMMARY

INTRODUCTION

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has before it an application for registration of the product FLAME HERBICIDE and now invites comment from any person on whether this product should be registered. This invitation is being made as the active constituent contained in FLAME HERBICIDE (*Imazameth*) is new to agriculture in Australia.

The purpose of this document is to provide a summary of the data evaluated and of the regulatory considerations reached, during the evaluation by the NRA of FLAME HERBICIDE for the pre-emergent control of a variety of summer grasses and broadleaf weeds in fallow prior to recropping of wheat, barley or chickpeas.

Having completed its evaluation of the proposed use of *Imazameth* in FLAME HERBICIDE, the NRA provides the following description of that evaluation for public comment:

AGRICULTURAL ASPECTS

FLAME HERBICIDE contains the active constituent Imazameth in an aqueous solution formulation. It is to be used in wheat, barley and chickpea growing areas to control a variety of summer grasses and broadleaved weeds in fallow paddocks. There are no herbicides presently available for residual control of the important weeds of the summer fallow in the northern grain region. Although the registration of FLAME HERBICIDE adds another group B herbicide for use in the farming system it should present minimal risk to the development of herbicide resistance in these summer weeds if the product is used as directed. FLAME HERBICIDE, therefore, could prove to be a valuable product in the management of summer fallow weeds in conservation tillage systems.

Results of trials conducted in Australia have shown that FLAME HERBICIDE is safe to crop and non-target species, providing precautions are taken as indicated on the label, e.g, plant-back periods and warning on overlap of spray.

Registration is supported by Australian agricultural authorities.

ENVIRONMENTAL ASPECTS

Environmental exposure to FLAME™ Herbicide will primarily involve the soil and crop residues, as the product is to be applied either to bare soil or over stubble. Some potential for drift is possible, however, the use of flat fan nozzles and the limiting of application to ground based spray equipment should minimise this risk.

Under laboratory conditions, Imazameth did not bind strongly to soil, is persistent and has the potential to be mobile and leach off-site. Laboratory studies indicate that Imazameth does not breakdown in soils, but will degrade under aqueous photolysis. A number of metabolites formed when Imazameth was exposed to light in both soil and water in the laboratory.

Under field conditions, Imazameth appears to be moderately persistent to persistent in soils, but warm, moist conditions may assist in its breakdown. Field studies indicated that some movement through soils may occur, although the tests were conducted at rates up to four times higher than the recommended use rates for Australian conditions. It is thought that microbial degradation will be an important degradation route for Imazameth in soils. Accumulation in soils is not expected given the high solubility of the product, the relatively low treatment rate and anticipated use once a year. In addition, closely related compounds have not been found to leach to the potential extent indicated in laboratory studies.

Ecotoxicity testing has shown that Imazameth is not toxic to birds, mammals, fish, aquatic invertebrates or bees. Imazameth was not found to bioaccumulate in the fish species tested. Although the effect of Imazameth on earthworms and soil micro-organisms has not been directly assessed, by analogy to related compounds such as imazethapyr, it is not expected to impact these population adversely. In addition, the mode of action of the herbicide should minimise risk posed to the organisms.

Aquatic plants, non-target vegetation and algae are all at risk from the use of this herbicide, should it inadvertently reach waterways or non-target vegetation.

Overall, although there is a potential risk to non-target land plants, aquatic plants and algae, use of Imazameth as proposed and according to good agricultural practices, and in accordance with label warnings to avoid contamination of waterways, should not pose significant risk to the environment.

PUBLIC HEALTH AND SAFETY ASPECTS

Toxicology

Imazameth, the active ingredient of FLAME HERBICIDE, has low acute toxicity when administered orally, to the skin, or inhaled. It is a moderate eye, and a slight skin irritant, and does not cause skin sensitisation. A formulation very similar to FLAME HERBICIDE also shows a low acute oral, skin and inhalation toxicity. The formulation is a slight eye irritant, but does not cause skin irritation or sensitisation.

Long term oral dosing of up to 1,200 mg of Imazameth/kg/day in rats, and up to 1,400 mg of Imazameth/kg/day in mice, produced no significant toxicological effects. However, in dogs, long term oral dosing of approximately 1,100 mg of Imazameth/kg/day induced anaemia within 1 month. In addition, liver cell damage and increased liver weights were observed. At the lowest study dose of approximately 137 mg/kg/day, skeletal muscle damage was noted in about 25% of the dogs, and although described as minimal (affecting few muscle fibres), was considered treatment related.

The compound does not damage genetic material in *in vitro* and *in vivo* tests, and is non-carcinogenic in chronic mouse and rat studies.

Conclusion

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

RESIDUES IN FOOD AND TRADE ASPECTS

Residues in Food

Residue data were generated in Australia from trials conducted on wheat, barley and chickpeas. The data indicate that when FLAME HERBICIDE is used as a fallow treatment, there are no detectable residues in the forage or grain of the following crop, even when the product is applied at twice the recommended treatment rate. If however, Flame is applied at the end of harvest to the stubble of a previous crop, then detectable residues are likely to be found in the stubble up to 40 days after treatment. The grazing withholding period of 9 weeks will allow the residues in the treated stubble to decline to non-detectable levels, thereby reducing the exposure of animals to treated stockfeed. Animal metabolism studies indicate that Imazameth is readily excreted with negligible absorption into any tissues, and exposure of animals to levels of Imazameth at approximately 40× the potential intake from treated feed would result in non-detectable residues in animal tissues. Therefore, the residue data indicate that in accordance with the recommended use pattern and observance of a 9 week withholding period for grazing, there are unlikely to be any residues in the forage or grain of a follow crop, or in any animal commodities resulting from animals grazing treated stubble or a failed crop.

Trade

There are no detectable residues in crops planted after a fallow treatment of FLAME HERBICIDE, and unlikely to be any residues in any animal feed commodities when the 9 week withholding period is observed. Therefore, the use of FLAME HERBICIDE should not result in any residue issues which would unduly prejudice Australian trade.

OCCUPATIONAL HEALTH AND SAFETY ASPECTS

Worksafe Australia has conducted a risk assessment on FLAME HERBICIDE containing Imazameth at 240 g/L as a liquid formulation, for pre-emergence control of certain annual grass and broadleaf weeds in fallow situations.

FLAME HERBICIDE can be used safely if handled in accordance with the instructions on the product label. Additional information is available on the product Material Safety Data Sheet.

Cyanamid Australia Pty. Limited has determined that Imazameth and FLAME HERBICIDE are not hazardous substances under National Occupational Health and Safety Commission criteria.

Australian workers will not handle Imazameth as FLAME HERBICIDE is formulated overseas and shipped to Australia ready-for-use in 5 L and 20 L containers.

There are limitations on the frequency of use of FLAME HERBICIDE because of its residual effects in soils.

FLAME HERBICIDE is of low acute toxicity and demonstrates slight eye irritation but no skin irritation or skin sensitisation. End users of FLAME HERBICIDE will need to handle both the concentrate and spray. The main routes of exposure will be by skin contamination and breathing in of any spray mist.

Safety directions have been established to enable end users to minimise contamination with FLAME HERBICIDE. They include the use of elbow-length PVC gloves, to be worn by workers preparing the working strength spray.

Respiratory protection is not needed. No re-entry period is necessary for workers re-entering treated areas.

2. INTRODUCTION

The purpose of this document is to provide the public with a summary of the data evaluated, and of the regulatory considerations reached, in the evaluation by the NRA of FLAME HERBICIDE.

The use of FLAME HERBICIDE is proposed as a fallow control for summer weeds in northern NSW and Qld where wheat, barley and chickpeas are grown. The NRA now invites comment from any person on whether FLAME HERBICIDE should be registered

Comments should be sent by 31 October 1996 to:



APPLICANT

The applicant, Cyanamid Agriculture Pty Ltd, has applied for the registration of FLAME HERBICIDE, which contains a new active constituent, *Imazameth*.

PRODUCT DETAILS

FLAME HERBICIDE is an aqueous solution formulation containing 240g/L *Imazameth*. The product will be formulated and packaged outside Australia.

CURRENT OVERSEAS REGISTRATIONS OF *Imazameth*

FLAME HERBICIDE is not currently fully registered in any other country, although conditional registration has been granted (as CADRE) for use in peanut fields and non-crop areas in the USA.

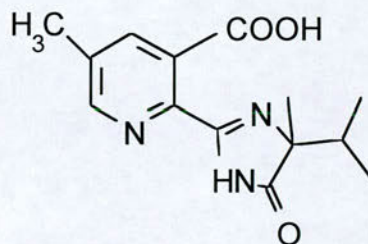
3. PROPERTIES OF THE CHEMICAL ACTIVE CONSTITUENT

The chemical active constituent *Imazameth* is manufactured in USA or Brazil and has the following properties:

Name: (\pm) 2-[4, 5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridine carboxylic acid (CA)
 (\pm) 2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methylnicotinic acid (IUPAC)

Common name: Imazameth
 Other names: CADRE
 FLAME
 AC 263, 222
 CAS number: 81334-60-3
 Molecular formula: $C_{14}H_{17}N_3O_3$
 Molecular weight: 275.3
 Purity of TGAC: 950 g.kg⁻¹

Structural formula:



Appearance: white powder
 Melting Point: 207-208°C
 Boiling Point: expected to be very high
 Relative Density: not supplied
 Vapour Pressure: $< 1 \times 10^{-7}$ mmHg at 25°C
 Water Solubility: 2.15 g.L⁻¹
 n-Octanol/Water
 Partition Coefficient
 (average apparent K_{ow}):

| | |
|-----|--------|
| pH4 | 0.462 |
| pH5 | 0.158 |
| pH6 | 0.0318 |
| pH7 | 0.0101 |
| pH8 | 0.0053 |
| pH9 | 0.0024 |

This reflects an increase in solubility with increasing pH as the proportion of carboxylate form increases.

4. AGRICULTURAL ASSESSMENT

JUSTIFICATION FOR USE

Control of weeds to conserve soil water in the fallow period between successive crops is an essential feature of dryland cropping in north-eastern Australia to ensure reliable crop production.

Conservation tillage practices, and in particular zero tillage, have facilitated more efficient conservation of soil water during this period, with retention of crop residues increasing the infiltration rate of rainfall. Where winter crops are grown in continuous rotation, control of successive germinations of summer grass weeds with knockdown herbicides has been difficult.

The prospect of unreliable weed control over the summer has been an impediment to the adoption of zero-tillage practices in many districts. Cost has also been a factor as up to 3 applications of a knockdown herbicide may be required.

A need exists to complement the current range of herbicides available for fallow weed control to provide for consistent control of successive germinations of summer grass weeds. The short to medium term residual control demonstrated by FLAME HERBICIDE would appear to be capable of meeting this need and thereby improve the management and viability of conservation tillage systems.

Registration is supported by Australian agricultural authorities.

PROPOSED USE PATTERN

For use in fallow prior to planting wheat, barley or chickpeas. Treatments may be applied by ground application only, in Qld or northern NSW, from the end of the previous crop harvest but not less than 4 months prior to the planting of a winter crop. Rate of use is 150 to 200ml of product per ha and, as Imazameth has pre-emergent action, best results are obtained where treatments are applied to dry, weed free soil prior to weed germination. Sufficient rainfall is required after application and prior to weed emergence to wet soil to a depth of 5cm.

EVALUATION OF EFFICACY

The applicant, Cyanamid Agriculture Pty Ltd, provided efficacy data to support the claims of FLAME HERBICIDE. The reviewer of this data was satisfied that the claims for FLAME HERBICIDE were supported by the data presented. Details of the efficacy data are:

Imazameth has been evaluated by Monsanto Australia Ltd since 1988, and by Cyanamid Agriculture Pty Ltd since early 1994, for pre-emergence control of weeds emerging in fallow during summer months. Imazameth, at rates equivalent to 150 to 200 g/ha of FLAME HERBICIDE, either as a pre-emergence treatment alone, or a post emergence treatment with a knockdown herbicide, provided 2 to 4 months control of major grass weeds and commercially acceptable control of a number of broadleaf weeds in the northern grain region.

Best results were obtained when treatments were applied prior to the onset of major weed germinations rather than in combination with a knockdown treatment after the occurrence of major germinations of summer grasses.

Efficacy data were adequate and were collected from a sufficient number of field trials that would adequately reflect the variation in environmental conditions for the proposed use patterns.

PHYTOTOXICITY

Grain yield of wheat, barley and chickpea established between 4 and 8 months following application of 200g/ha FLAME HERBICIDE was unaffected relative to fallows maintained exclusively with knockdown herbicides. No risk of injury to follow crops and safety to non-target species has been demonstrated provided precautions are taken as indicated on the label e.g. plant-back periods and warning on overlap of spray.

CONCLUSION

FLAME HERBICIDE has been shown in trials to be effective for pre-emergence control of summer germinating annual grasses and certain broadleaf weeds, while providing for the successful establishment of wheat, barley and chickpea 4 to 7 months after application. .

5. ENVIRONMENTAL ASSESSMENT

Environmental Fate

Imazameth will be applied at relatively low rates to bare soil, or possibly to crop residues on soils, with one application per season recommended. It will be applied with boom spray, with no aerial application. Following application, residues are expected to pass into the soil. Aquatic contamination is possible via run-off, in which case Imazameth is expected to dissolve in the water column. It is not expected to sorb to sediments. Some spray drift may occur, depending on the size of droplet used in application.

The following tests have been used to determine the environmental fate of Imazameth.

- **Hydrolysis**

Imazameth is unlikely to hydrolyse in the environment. In laboratory tests, no hydrolysis was observed at pH levels of 5, 7 and 9.

- **Photolysis**

Photolysis was observed in the laboratory in aqueous solutions, where half-lives were less than a day in samples held under light. In soil photolysis studies, a half-life of 106 days was calculated, indicating that although Imazameth will gradually degrade in soils under sunlight, this process will not be rapid, and Imazameth may persist in soils.

- **Metabolism in Soils**

Aerobic soil metabolism studies in the laboratory indicated that Imazameth will be very persistent in soils, with a half-life of 2010 days calculated (using one soil only). Anaerobic soil tests also indicated persistence in soils with a half-life of 2400 days calculated. Although these half-life values should be treated with caution, as they are the results of extrapolation of a 12 month study period, they do indicate that it is likely to be very persistent in soils.

A number of metabolites were found to form as a result of degradation during aqueous and soil photolysis laboratory tests. No information was provided on metabolite formation during field degradation.

- **Mobility in Soils**

No laboratory leaching studies were presented. Adsorption/desorption tests on six soils conducted showed that Imazameth is weakly adsorbed to soils, and may be classed as a mobile compound. Although related compounds such as imazethapyr were found to sorb more strongly to low pH soils, with degree of adsorption influenced by the amount of clay and organic matter in the soils, no such relationships were demonstrated for Imazameth.

Imazameth may be expected to be highly mobile in soils, as it is very soluble, does not strongly adsorb to soils and does not readily degrade (except during aqueous photolysis). However, field studies conducted did not detect large amounts of Imazameth moving through soil profiles beyond 45 cm.

- **Field Dissipation**

Six field dissipation studies were presented, with all using three to four times the Australian recommended treatment rate. All studies indicated that Imazameth will be moderately persistent to persistent in soils, with half-lives varying from 31 to 223 days. Downward movement of Imazameth was noted in three of the studies at the highest rate, with residues in the parts per billion range detected up to 45 cm in the soil strata tested.

- **Accumulation and Bioaccumulation**

Laboratory and field data presented indicate that Imazameth should not accumulate in soil, sediments or water due to the high water solubility and single application to soils.

Bioaccumulation testing demonstrated that Imazameth will not bioaccumulate in aquatic organisms, as would be expected from the high solubility and low K_{ow} of the substance.

Environmental Effects

Birds

Acute oral, dietary and 21 day acute oral toxicity tests indicated that Imazameth is practically non-toxic to bobwhite quail and mallard ducks, using US EPA criteria ($LD_{50s} > 2\ 150\text{ mg.kg}^{-1}$ for acute oral, $LC_{50} > 5\ 000\text{ ppm}$ dietary tests). No clinical abnormalities or mortalities were observed during the studies, although some feeding inhibition was noted during dietary tests with both species.

Aquatic Toxicity

Acute toxicity testing on bluegill sunfish, channel catfish, rainbow trout and *Daphnia magna* indicate that Imazameth is practically non-toxic to these organisms (96 hr $LC_{50} > 100\text{ mg.kg}^{-1}$ for fish, 48 hr $LC_{50} > 100\text{ mg.kg}^{-1}$ for *Daphnia*), under US EPA guidelines.

Aquatic plant toxicity testing showed that Imazameth is very toxic to aquatic plants (with an EC_{50} of 6.10 ppb for *Lemna gibba*) and toxic to algae. This result is not unexpected given the proposed mode of action of this herbicide.

Non-target invertebrates

Imazameth was found to be practically non-toxic to honey bees in contact toxicity tests. No toxicological data was presented to allow assessment of the effect of this compound on earthworms or soil invertebrates.

Earthworm toxicity testing conducted using imazethapyr (a closely related compound) indicated that Imazameth should not be toxic to non-target invertebrates.

Soil micro-organisms

No specific soil microbial toxicity testing was conducted using Imazameth, although some of the soil degradation studies indicated that soil microbial populations remained viable throughout the tests. The imidazolinone group of herbicides are generally believed to be subject to microbial attack, with microbial degradation thought to be a major route of breakdown in the field.

Phytotoxicity

Trials on non-target vegetation also showed the Imazameth is phytotoxic, with plant height and dry weight both significantly reduced in treated plants. However, germination and percent survival 21 days after germination did not appear to be significantly affected. In addition, during efficacy trials, Imazameth did not provide comprehensive knockdown of existing weeds.

Environmental Hazard

As Imazameth is to be imported fully formulated and packed into Australia, there will be no hazard posed by these operations. The notifier has provided instruction for dealing with spills, and has also suggested a means for dealing with spray tank washings, to allow the residues from rinsing time to degrade (via aqueous photolysis) prior to disposal.

Imazameth will be applied in such a way as to produce minimal drift (although if applied under inappropriate conditions, drift is always possible). The main environmental compartments to be affected will be the soil and possibly vegetation.

• Terrestrial Hazard

Application at the highest proposed rate of 200 mL.Ha⁻¹ (equivalent to 48 g a.i.Ha⁻¹) would leave residues of approximately 10 ppm on grass, 1 ppm on small insects and 6 ppm on large insects (under fresh weight conditions; 33, 23 and 4 ppm under dry weight).

Imazameth will pose a negligible hazard to birds and mammals, as residues expected on vegetation and food items will be well below bird or mammalian toxicity values. There is limited potential for exposure to these groups.

Application of Imazameth made to soil will present minimal hazard to bees, as they are not expected to come into contact with the spray droplets to any large extent. Residues expected on plants are also below those that were used for toxicity testing in bees.

The mode of action of Imazameth should mean that there is little risk for earthworms. In addition, based on toxicity data from a related compound, imazethapyr, it is expected that Imazameth will not be toxic to these organisms.

Soil microbial degradation is recognised as an important route of breakdown for imidazolinone herbicides as a group, and thus little adverse effect of these compounds would be expected.

- **Aquatic Hazard**

The ecotoxicological profile of Imazameth to aquatic organisms raises no concerns for fish and aquatic invertebrates. In the case of a direct overspray at the highest proposed rate to a shallow (15 cm) water, residues expected (approximately 32 ppb) are at least two orders of magnitude below levels used in toxicity tests, with no mortality noted.

Aquatic plants and algae will be at risk in the event of a direct overspray to water. Expected residues levels of 32 ppb are greater than the EC_{50} of 6.1 ppb for the most sensitive aquatic plant, *Lemna gibba*. In the event of either drift or run-off (assuming 10% of the applied treatment will reach the waterway), the expected residue level of 3.2 ppb is only marginally lower than the EC_{50} for *Lemna* noted above, and does not afford a notable margin of safety. Therefore, under the above assumed worst-case scenario, a hazard may exist for aquatic plants.

The notifier has included warning statements regarding buffer zones for spraying near waterways and on the treatment of spills, and these combined with the low potential for spray drift and the apparent low field mobility (despite laboratory indication to the contrary), should mean that hazard to this compartment of the environment is minimised. However, the notifier has agreed to provide groundwater studies arising from a US EPA request for information, to the EPA as soon as these are available. In addition, changes to the label and MSDS as requested will also minimise the hazard to this compartment.

- **Desirable vegetation**

Non-target plant toxicity testing and efficacy trials both showed that non-target vegetation may exhibit growth inhibition and other symptoms of phytotoxicity as a result of exposure to rates of application similar to those in the field. As Imazameth will be used in cropping areas, it is anticipated that the amount of native vegetation remaining in areas of use will be low. Therefore, hazard to native plants would be considered to be low. Instructions on the label, and use according to good agricultural practices should ensure minimal hazard to non-target vegetation.

Conclusions

The application contains generally adequate environmental fate and toxicity data to demonstrate that the use of Imazameth according to label and good agricultural practices is unlikely to result in acute poisoning of most wildlife.

Laboratory studies provided indicates that Imazameth will be persistent in soils, with a high potential to leach. The very long soil half lives observed in the laboratory, indicating that Imazameth may be relatively more persistent than many of the other imidazolinone herbicides, did not occur in field studies, where half-lives for Imazameth were observed to be similar to the range noted for imazethapyr in earlier studies. The notifier has provided data suggesting that although the herbicide has a high potential to leach when assessed under laboratory conditions, downward and lateral movement through the soil profile should be minimal under field conditions, with microbial breakdown of the compound expected to reduce half-lives in the field. However, the potential for Imazameth to leach remains a matter for concern. These concerns are offset in the proposed registration by the low application rate and single application per year. The notifier has agreed to notify the EPA of reported groundwater/ surface water contamination, and of any reported non-target effects in plants and animals. The company has indicated that results of the US groundwater study will be available on completion and has agreed to provide this study to the EPA as soon as possible.

6. PUBLIC HEALTH AND SAFETY ASSESSMENT

EVALUATION OF TOXICOLOGY

The toxicological database for Imazameth which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses which are high compared to likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

Toxicokinetics and Metabolism

In rats, greater than 95% of orally administered Imazameth is absorbed from the gastrointestinal tract, and subsequently excreted in the urine. Unchanged compound accounts for 93-100% of the material in urine. Metabolites of Imazameth and several minor unknown components are also detected at low levels. Relatively small amounts (less than 4% of that administered) is excreted in the faeces. The majority (66%) of the compound contained in the faeces is unchanged, with small quantities of metabolites also detected. A negligible proportion of the administered dose is detected in the serum and tissue 7 days after administration.

Acute Studies

Technical Imazameth exhibits low oral, skin and inhalation toxicity. Imazameth is a moderate eye irritant and a slight skin irritant, but does not cause skin sensitisation.

A liquid formulation, very similar to FLAME HERBICIDE and containing 22.7% Imazameth, has low oral, skin and inhalation toxicity. The formulation is a slight eye irritant, and did not cause skin irritation or sensitisation.

Short-Term Studies

Doses of 0, 250, 500 or 1000 mg of Imazameth/kg were applied daily to the exposed skin of New Zealand White rabbits for 5 days a week for a total of 3 weeks. At the conclusion of the study, a slight increase in the number of circulating red blood cells was seen in rabbits receiving 1000 mg/kg/day. No other treatment related changes were noted.

Groups of Beagle dogs were fed dietary levels of approximately 130, 280, 525, 950 mg of Imazameth/kg/day, for 14 days. A slight increase in the a blood enzyme, which may indicate liver damage, was noted in males fed the highest dose, and a decrease in blood calcium was seen in females fed the highest three doses. No other treatment related abnormalities were noted during the study.

Groups of rats were fed dietary levels of approximately 400, 800, or 1600 mg of Imazameth/kg/day, for 13 weeks. No treatment related effects were noted over the duration of the study.

Long-Term Studies

Groups of mice were provided dietary levels of approximately 320, 650 or 1300 mg of Imazameth/kg/day for 18 months. No treatment related effects were reported during the study.

Groups of rats were provided dietary levels of approximately 280, 550 or 1100 mg of Imazameth/kg/day for 24 months. No treatment related effects were noted over the duration of the study.

Groups of Beagle dogs were given dietary levels of approximately 137, 515 or 1100 mg of Imazameth/kg/day, for 1 year. Excess salivation was reported in males and females fed 515 or 1100 mg/kg/day, and an increased frequency of vomiting was seen amongst dogs fed the highest dose. Weight gain was reduced in males and females given dietary levels of 1100 mg/kg/day. Evidence of anaemia was seen at the highest dose. An abnormally large number of cells in the bone marrow, and increased red blood cell production were noted in males and females fed the highest two doses. Evidence of liver damage was seen at the highest study dose. Skeletal muscle damage in dogs fed 137 (minimal), 515 (minimal) or 1100 (minimal to moderate) mg of Imazameth/kg/day was noted. Similar effects were described in the muscular tissue of the oesophagus and diaphragm.

Reproduction and Developmental Studies

In a two-generation reproduction study, groups of rats were given dietary levels of approximately 270, 600 or 1300 mg of Imazameth/kg/day. No adverse treatment related effects were noted during the study.

Similarly, groups of pregnant rats were administered 0, 250, 500 or 1,000 mg of Imazameth in corn oil/kg orally on gestation days 6- 15. No significant treatment related maternal or embryo/foetal effects were noted.

Groups of pregnant rabbits were administered 0, 175, 350, 500 or 700 mg of Imazameth/kg by daily oral administration on gestation days 7- 19. An increased number of adults fed 700 mg/kg/day showed dark red lungs and ulcerated, reddened stomachs. The number of foetal rudimentary ribs were increased in rabbits fed 700 mg/kg/day.

Genotoxicity

Imazameth did not exhibit mutagenicity in the bacteria, *S typhimurium* and *E coli*. Furthermore, it did not induce genetic damage as indicated by negative results in the *in vitro* Chinese hamster ovary cell and rat liver cell assays, and in the *in vivo* rat bone marrow cell study.

PUBLIC HEALTH STANDARDS

Poisons Scheduling

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

The NDPSC recommended that Imazameth be listed in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate warning statements and first-aid directions on the label.

NOEL/ADI

The most sensitive species was the dog, with a Lowest Effect Level (LEL) of 137 mg/kg/day. In order to calculate the acceptable daily intake (ADI) for humans, a safety factor is applied to the NOEL, or in this case the LEL, in the most sensitive species. The magnitude of the safety factor is selected to account for uncertainties in extrapolation of 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 500, an ADI of 0.3 mg/kg/day for Imazameth was established.

7. RESIDUES IN FOOD AND TRADE ASSESSMENT

Background

Imazameth, the active constituent in FLAME HERBICIDE and Flame 700 WDG Herbicide is used in fallow situations for the pre-emergence control of broad leaf weeds and annual grasses. The product may be applied at the end of the previous crop harvest, a few months prior to planting winter cereals such as wheat, barley and chickpeas. The products have been issued with a provisional registration in the U.S. for use in peanut crops.

Appropriate residue and metabolism studies were provided in accordance with the *Interim Requirements For The Registration Of Agricultural And Veterinary Products*, to support the fallow use of Imazameth in Australia.

Residues In Food Commodities

Residue data were presented for wheat stubble, wheat, barley and chickpea forage and grains. All of the residue trials were conducted in Australia.

Wheat Stubble, Forage and Grain

Five wheat trials were conducted in Queensland, where wheat was sown between 5½ – 7½ months after a single application of FLAME HERBICIDE at a rate of either 50 g ai/ha (1×) or 100 g ai/ha (2×). In 3 trials, forage and grain were analysed for residues; data for treated stubble and weeds were provided in 4 trials. Imazameth was only detected in the stubble, with levels ranging 4.8 – 7.7 mg/kg and 8.6 – 18.1 mg/kg for the 1× and 2× treatments, respectively. On day 0. At 61 days after treatment, the residues had declined to below the limit of detection, 0.1 mg/kg, for both the 1× and the 2× treatments. Levels of the metabolite* ranged < 0.1 – 0.2 mg/kg for the 1× treatment and < 0.1 – 0.3 mg/kg for the 2× treatment. As with the parent compound, the metabolite had declined to non-detectable levels within 61 days after treatment. The applicant has requested a 9 week withholding period before grazing. This withholding period would allow any residues to decline to below the limits of analytical determination, therefore animals grazing in treated areas would not be exposed to any residues and there would not be any corresponding residues in any animal commodities.

In wheat forage and grain, there were no detectable residues found in any of the samples from the 5 trials. As there are no residues in the forage of the follow crop, the issue of a “failed crop” situation is adequately addressed.

Barley Forage and Grain

Barley was planted at 5½ months after a fallow treatment of FLAME HERBICIDE at a rate of either 50 g ai/ha or 100 g ai/ha. Samples of forage and grain were collected at 280 and 328 days after treatment. No detectable residues were found in any of the samples.

* The hydroxymethyl derivative of Imazameth.

Chickpea Forage and Grain

A chickpea trial was conducted where chickpeas were sown 5½ months after a fallow treatment of FLAME HERBICIDE at either the 1× or the 2× treatment rate. Samples of forage and peas were collected at 280 and 328 days after treatment. As in the barley trial above, no detectable residues were found in any of the forage or grain samples.

Overall, the residue trials indicate that when Flame is used as a fallow treatment only, there are no detectable residues in the forage or grain of the following crop, even at twice the maximum recommended treatment rate. If however, Flame is applied at the end of harvest to the stubble of a previous crop, then detectable residues are likely to be found in the stubble up to 40 days after treatment. The grazing withholding period of 9 weeks will allow the residues in the treated material to decline to non-detectable levels, thereby substantially reducing the exposure of animals to treated stockfeed. In the case of a failed crop situation, there are unlikely to be detectable residues in any animal commodities from animals which have been grazing a failed crop, as there are no detectable residues in the forage or grain of the follow crop.

In conclusion, the residue data indicate, that in accordance with the recommended use pattern, and in observance of a 9 week withholding period for grazing after treatment, there are unlikely to be any residues in the forage or grain of a follow crop or in any commodities from animals grazing the treated stubble or the follow crop.

Metabolism Studies

Plant Metabolism

Metabolism studies were conducted in the USA on peanut plants using ¹⁴C labelled Imazameth. Peanut plants were treated with the labelled formulation at 30 days post-emergence at a rate of 72 g ai/ha, approximately 1.5× the maximum recommended treatment. Green plants were collected for analysis at 0, 21 and 61 days after treatment, and hay and peanuts were collected at harvest at 131 days after treatment. Residues in all of the samples were a mixture of the parent Imazameth and two metabolites[†], with varying amounts of the three components being found in the different samples. Highest levels of Imazameth were detected at day 0 in the green plant material, at 3.61 mg/kg. This value had decreased to 0.003 mg/kg by day 61. The highest levels of the two metabolites were found in the peanut hay at 0.055 and 0.032 mg/kg of the hydroxymethyl form and its conjugate, respectively. Equivalent or lower levels were present in the hulls at 0.025 and 0.032 mg/kg, and there were very low levels in the nutmeat 0.001 and 0.006 mg/kg, respectively. Imazameth was present at or below the limit of determination in the hulls and nutmeat.

The results of the study show that Imazameth is readily metabolised in peanut plants to form two major compounds, which are present at detectable levels in the peanut hay and the peanut hulls; the residues in the peanut meat are at or below the limit of analytical determination.

Animal Metabolism

Animal metabolism studies were conducted in rats, hens and lactating goats. Common metabolic trends were observed in all three animal types. Both the parent and the primary plant metabolite were investigated at varying dose levels, up to 1000× and 240× the maximum potential intake in feed for hens and goats respectively. Most of the dose was excreted at up to 98, 90 and 94% in the rats, hens and goats, respectively. Similarly for the metabolite, up to 89 and 96% was

[†] The two metabolites are the hydroxymethyl derivative of Imazameth, and its glucose conjugate.

excreted in hens and goats. Of the remaining residue, levels of 0.04 and 0.05 mg/kg were found in the omental fat and kidney of the goats treated with the 240× dose. Residues were not found in any other tissues or milk. Similarly, no detectable residues were found in the eggs or tissues of hens, even at the highest dose rate. The results of the metabolism studies indicate that Imazameth is readily excreted with negligible absorption into any tissues.

A detailed description of the analytical method used for determining residues in plant material was provided. The parent Imazameth and the hydroxymethyl metabolite were determined directly by HPLC, after a series of extractions and solid-phase clean-up steps. The limit of determination of the method is 0.1 mg/kg and has been validated in the method used for determining residues in the Australian trials.

MRL Standard

As there are no detectable residues in the forage or grain of the follow crop, and unlikely to be any residues in animal feed commodities after a 9 week withholding period, the requirement of a *situation where residues do not or should not occur in foods or animal feeds* has been satisfied and therefore a Table 5 entry to the *MRL Standard* is recommended:

Table 5

| <i>Compound</i> | <i>Use</i> |
|------------------|--------------------------------------|
| Add: | |
| Imazameth | Fallow use prior to planting cereals |

Trade Implications

With regard to trade implications and export commodities, there are no detectable residues in the crops planted after the fallow treatment, and unlikely to be any residues in any animal feed commodities when a 9 week grazing restraint is observed. In addition, the metabolism studies in lactating goats and hens indicate that there are unlikely to be any detectable residues in milk, eggs, meat or offal when animals are exposed to exaggerated amounts of Imazameth and its metabolite. Therefore, there do not appear to be any residue issues of concern, relating to trade.

8. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Imazameth is not on the National Occupational Health and Safety Commission (NOHSC) List of Hazardous Substances. Cyanamid Australia Pty. Limited has reviewed the health effects of Imazameth and determined that it is not a hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances.

Cyanamid Australia Pty. Limited has also determined that FLAME HERBICIDE, containing 240 g/L Imazameth, is not a hazardous substance according to NOHSC criteria. The product has very low acute oral and dermal toxicity, low inhalation toxicity, demonstrates slight eye irritation but no skin irritation or skin sensitisation.

FLAME HERBICIDE is formulated overseas and shipped to Australia ready-for-use in 5 L and 20 L containers. Cyanamid Australia Pty. Limited may formulate the product in Australia at a later date.

Imazameth and FLAME HERBICIDE are not classified as Dangerous Goods under the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code).

Formulation, transport, storage and retailing

Advice on safe handling of FLAME HERBICIDE during routine transport and storage is provided in the Material Safety Data Sheet (MSDS).

End use

FLAME HERBICIDE is to be applied at 150 to 200 mL/ha by ground boom sprays for pre-emergence control of summer grasses and weeds in fallows prior to cropping. Working strength spray will contain 0.3 to 0.4% product, corresponding to 0.07 to 0.1% Imazameth.

Owner-operators or contractors may apply FLAME HERBICIDE. It may be used over large cropping areas, but use is seasonal and application rates, number of repeat applications and re-cropping times are limited by the residual soil effects. FLAME HERBICIDE may be used over consecutive days during the spraying season and in repeated episodes if multiple paddocks are sprayed.

End users of FLAME HERBICIDE will need to handle both the concentrate and spray. The main routes of exposure will be by skin contamination and breathing in of any spray mist. The product is a slight eye irritant but has no topical dermal effects. Worker exposure under Australian use conditions has been estimated using the Predictive Operator Exposure Model. Consideration of worker exposure and risk indicates that short-term and long-term use of the product is safe. Sufficient skin protection will be given by elbow-length PVC gloves and these should be worn by workers preparing the working strength spray. Respiratory protection is not needed.

Entry into treated areas

Considering the use pattern of FLAME HERBICIDE and the low toxicity of its residues, there are no occupational health and safety concerns for workers entering treated areas.

Recommendations for safe use - all workers

Any future Australian workers involved in formulation or re-packing of FLAME HERBICIDE should be protected by engineering controls, such as enclosed processes and ventilation, safe work practices and training. In addition to these controls or where other control measures are not practicable, workers involved in manufacture, formulation or packing may require protective clothing, gloves, goggles and a respirator.

End users should follow the instructions and Safety Directions on the FLAME HERBICIDE label. Safety Directions require that end users wear elbow-length PVC gloves when opening the container and preparing the spray.

Any personal protective equipment worn by formulation workers or end users should conform with Standards Australia AS 1337-1992 Eye Protection for Industrial Applications, AS/NZS 1715-1994 Selection, Use and Maintenance of Respiratory Protective Devices, AS/NZS 1716-1994 Respiratory Protective Devices, AS 2161-1978 Industrial Safety Gloves and Mittens (Excluding Electrical and Medical Gloves), AS/NZS 2210-1994 Occupational Protective Footwear and AS 3765-1990 Clothing for Protection against Hazardous Chemicals.

Manufacturers and importers should produce MSDS for any hazardous products containing Imazameth. 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.

End users are advised to obtain the FLAME HERBICIDE MSDS for additional information.

Conclusions

FLAME HERBICIDE can be used safely if handled in accordance with the instructions on the product label. Additional information is available on the product MSDS.

1
DRAFT LABEL
FLAME.doc (11/9/96)

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

FLAME™ HERBICIDE

Active constituent: 240 g/L IMAZAMETH present as the ammonium salt.

| | | |
|-------|---|-----------|
| GROUP | B | HERBICIDE |
|-------|---|-----------|

For the pre-emergence control of certain annual grass and broadleaf weeds in fallow situations as specified in the DIRECTIONS FOR USE section of this label.



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

DIRECTIONS FOR USE:**RESTRAINTS:**

Do NOT apply more than 200 mL/ha per season on cropland.
 Do NOT apply in more than two successive seasons on cropland.
 Do NOT overspray headlands.
 Do NOT apply to soils saturated with water.
 Do NOT apply by aircraft.

| SITUATION | WEEDS CONTROLLED | STATE | RATE mL/ha | CRITICAL COMMENTS |
|--|--|----------------------|---------------|---|
| Fallow prior to planting wheat, barley or chickpea | barnyard grass (<i>Echinochloa colona</i>), liverseed grass (<i>Urochloa panicoides</i>), stink grass (<i>Eragrostis cilianensis</i>), blowaway grass (<i>Panicum decompositum</i>), button grass (<i>Dactyloctenium radulans</i>), pigweed (<i>Portulaca oleraceae</i>), yellow vine (<i>Tribulus terrestris</i>), mintweed (<i>Salvia reflexa</i>), Boggabri weed (<i>Amaranthus mitchelli</i>), dwarf amaranth (<i>Amaranthus macrocarpus</i>), peachvine/cowvine (<i>Ipomea lonchophylla</i>) | Qld, Nthn NSW. | 150 to 200 | <p>Treatments may be applied from the end of the previous crop harvest but not less than 4 months prior to planting of winter crop.</p> <p>Best results are obtained where treatments are applied to dry, weed-free soil prior to weed germination. Treatments can be applied to standing crop residues.</p> <p>Sufficient rainfall is required after application and prior to weed emergence to wet soil to a depth of 5 cm.</p> <p>Use the higher rates for increased residual control of weeds or anticipated high weed pressure.</p> <p>Emerged weeds must be controlled by prior cultivation, or by application of a knockdown herbicide. Where infestation of emerged weeds is light, tank mix treatment with Roundup®CT or Pacer®Soltech™ Herbicide.</p> <p>Cultivation following application of treatments may reduce pre-emergence weed control provided by FLAME.</p> <p>Prolonged wet soil conditions following treatment will reduce the effective life of pre-emergence treatments.</p> <p>Weed escapes may require follow up application of knockdown herbicides.</p> |

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

WITHHOLDING PERIOD: DO NOT GRAZE TREATED STUBBLE OR WEEDS WITHIN 9 WEEKS AFTER TREATMENT.

GENERAL INSTRUCTIONS

This product is for use in fallow prior to the planting of wheat, barley or chickpea. FLAME is a pre-emergence herbicide which is recommended to provide short term (6 - 12 weeks) pre-emergence control of summer germinating grasses and broadleaf weeds in cultivated or uncultivated fallow.

MIXING

FLAME is an aqueous suspension. Part fill the spray tank with water, then with 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.

EQUIPMENT CLEAN-UP

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

COMPATIBILITY

FLAME is compatible with Roundup®, Roundup®CT, Pacer® Sol-Tech™.

RESISTANT WEEDS WARNING

| GROUP | B | HERBICIDE |
|-------|---|-----------|
|-------|---|-----------|

FLAME herbicide is a member of the Imidazolinone group of herbicides and has the ALS (Group B) mode of action. Some naturally-occurring weed biotypes resistant to FLAME 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 FLAME or other ALS herbicides. Since the occurrence of resistant weeds is difficult to detect prior to use, Cyanamid accepts no liability for any losses that may result from failure of FLAME to control resistant weeds.

FOLLOW CROPS

Under conditions which do not favour 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.

Following use in summer fallow:-

| MONTHS AFTER APPLICATION | | | |
|---------------------------------|-------------------|-------------------------------|-----------------|
| 4 | 12 | 24 | 36 |
| wheat*, barley*, chickpea | mungbean, lucerne | sorghum, cotton, sunflower | any other crops |

* The following additional requirements apply if it is intended to plant wheat or barley during the next winter season.

Do NOT apply FLAME later than the end of December.

Do NOT apply FLAME in areas where rainfall from spraying to sowing of cereals is expected to be below 200 mm.

PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS

Do NOT allow spray drift to contact desirable vegetation or crops or cropping land not to be treated with FLAME Herbicide.

Do NOT spray within 50 m of wetlands or waterways.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Do NOT contaminate dams, waterways, streams or drains with this product or used containers.

STORAGE AND DISPOSAL

Store in the closed, original container, in a well ventilated area as cool as possible.

Do NOT store for prolonged periods in direct sunlight.

Triple or (preferably) pressure rinse containers before disposal. Add rinsings to spray tank. Do NOT dispose of undiluted chemicals on-site.

Break, crush or puncture and bury empty containers in a local authority landfill. If not available, bury the containers below 500mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Empty containers and product should NOT be burnt.

SAFETY DIRECTIONS

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

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre.

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.:

QN 9/96