**Public Release Summary**
**on**

# Evaluation of the new active

# AMINOPYRALID

# in the product

# Hotshot Herbicide

**Australian Pesticides and Veterinary Medicines Authority**

**February 2006**

**Canberra**
**Australia**

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ISSN1443-1335

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# FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) 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 APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing (Office of Chemical Safety), Department of Environment and Heritage (Risk Assessment and Policy Section), and State departments of agriculture and environment.

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

The information and technical data required by the APVMA 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 APVMA's publications *Manual of Requirements and Guidelines (MORAG)*

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

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

The APVMA welcomes comment on the usefulness of this publication and suggestions for further improvement. Comments should be submitted to the Program Manager Pesticides, Australian Pesticides and Veterinary Medicines Authority, PO Box E240, Kingston ACT 2604.

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# LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **ac** | active constituent |
| **ADI** | Acceptable Daily Intake (for humans) |
| **AHMAC** | Australian Health Ministers Advisory Council |
| **ai** | active ingredient |
| **BBA** | Biologische Bundesanalstalt fur Land – und forstwirschaft |
| **bw** | bodyweight |
| **CRP** | Chemistry and Residues Program |
| **d** | day |
| **DAT** | Days After Treatment |
| **DM** | Dry matter |
| **$DT_{50}$** | Time taken for 50% of the concentration to dissipate |
| **$E_bC_{50}$** | concentration at which the biomass of 50% of the test population is impacted |
| **$EC_{50}$** | concentration at which 50% of the test population are immobilised |
| **EEC** | Estimated Environmental Concentration |
| **$E_rC_{50}$** | concentration at which the rate of growth of 50% of the test population is impacted |
| **EUP** | End Use Product |
| **Fo** | original parent generation |
| **g** | gram |
| **GAP** | Good Agricultural Practice |
| **GCP** | Good Clinical Practice |
| **GLP** | Good Laboratory Practice |
| **GVP** | Good Veterinary Practice |
| **h** | hour |
| **ha** | hectare |
| **Hct** | Heamatocrit |
| **Hg** | Haemoglobin |
| **HPLC** | High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography |
| **id** | intradermal |
| **im** | intramuscular |
| **ip** | intraperitoneal |
| **IPM** | Integrated Pest Management |
| **iv** | intravenous |
| **in vitro** | outside the living body and in an artificial environment |
| **in vivo** | inside the living body of a plant or animal |
| **kg** | kilogram |
| **$K_{oc}$** | Organic carbon partitioning coefficient |
| **L** | Litre |
| **$LC_{50}$** | concentration that kills 50% of the test population of organisms |
| **$LD_{50}$** | dosage of chemical that kills 50% of the test population of organisms |
| **LOD** | Limit of Detection – level at which residues can be detected |
| **LOQ** | Limit of Quantitation – level at which residues can be dquantified |
| **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 |
| **po** | oral |

| | |
|---|---|
| **POEM** | Predictive Operator Exposure Model (UK) |
| **ppb** | parts per billion |
| **PPE** | Personal Protective Equipment |
| **ppm** | parts per million |
| **Q-value** | Quotient-value |
| **RBC** | Red Blood Cell Count |
| **s** | second |
| **sc** | subcutaneous |
| **SC** | Suspension Concentrate |
| **SUSDP** | Standard for the Uniform Scheduling of Drugs and Poisons |
| **TGA** | Therapeutic Goods Administration |
| **TGAC** | Technical grade active constituent |
| **T-Value** | A value used to determine the First Aid Instructions for chemical products that contain two or more poisons |
| **µg** | microgram |
| **vmd** | volume median diameter |
| **WG** | Water Dispersible Granule |
| **WHP** | Withholding Period |

# INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the product *HOTSHOT HERBICIDE,* which contains the new active constituent aminopyralid. The product is proposed to be used for the control of climbing buckwheat and other broadleaf weeds in winter cereals, lantana & pasture.

Responses to this Public Release Summary will be considered prior to registration of the product. They will be taken into account by the Australian Pesticides and Veterinary Medicines Authority (APVMA) 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 aminopyralid, covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request (see order form on last page). They can also be viewed at the APVMA library located at the APVMA offices, First Floor, 22 Brisbane Avenue, Barton ACT 2604.

Written comments should be received by the APVMA by **5 March 2006**. They should be addressed to:


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**Applicant**
Dow AgroSciences Australia Ltd

**Product Details**
It is proposed to register *HOTSHOT HERBICIDE* containing 10g/L of aminopyralid as an emulsifiable concentrate. The product will be imported fully formulated and packaged in 5L,10L, 20L and 110L containers.

*HOTSHOT HERBICIDE* contains members of the pyridine group of herbicides. The product has the disrupters of plant cell growth mode of action. For weed resistance management *HOTSHOT HERBICIDE* is a Group I Herbicide.

The rate of product use is 500mL to 750mL/ha. *HOTSHOT HERBICIDE* is proposed for registration in all states.

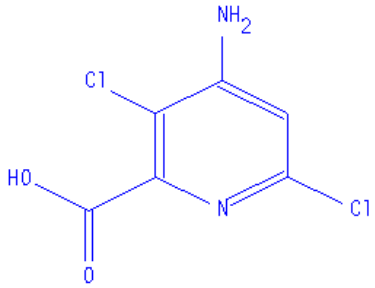
Formulations containing aminopyralid are currently registered in the USA.

## CHEMISTRY AND MANUFACTURE

Aminopyralid is a pyridine group of herbicide for the control of climbing buckwheat and other broadleaf weeds in winter cereals, lantana and certain other pasture weeds. The active constituent will not be imported into Australia as the product will be formulated in New Zealand.

**Active constituent**

| | |
|---|---|
| Common name (ISO): | Aminopyralid |
| Chemical name: | 4-amino-3,6-dichloro-2-pyridinecarboxylic acid |
| CAS Number: | 150114-71-9 |
| Molecular weight: | 207.03 |
| Molecular formula: | $C_6H_4Cl_2N_2O_2$ |
| Melting point | $163.5^0$C |
| Structural formula: | |




The Chemistry and Residues Program(CRP) of the APVMA has evaluated the chemistry aspects of the aminopyralid active constituent (manufacturing process, quality control procedure, batch analysis results and analytical methods) and found them to be acceptable.

**Formulated product**

| | |
|---|---|
| Product name | Hotshot Herbicide |
| Formulation type | Emulsifiable concentrate |
| Active constituent concentration | 10g/L aminopyralid, 140g/L fluroxypyr |

**Storage and Stability**

Stability data for 2 weeks at $54^0$C were provided for *HOTSHOT HERBICIDE* stored in fluorinated HDPE (commercial package). The changes observed are not considered to have any detrimental effect on the product. It was reported that there was no discernible change to the packaging material after the accelerated storage trial.

**Packaging**

*HOTSHOT HERBICIDE* will be packaged in 5L, 10L, 20L and 110L fluorinated HDPE containers. The packaging is not adversely affected by the product, nor is the product unstable in the packaging.

**Recommendation**

The chemistry and residues program (CRP) has evaluated the chemistry and the manufacturing aspects of *HOTSHOT HERBICIDE* in data submitted by applicant to support their application for

registration.  The CRP is satisfied that the chemistry requirements of Section 14(5) Agricultural and Veterinary Chemicals Code have been met.

# TOXICOLOGICAL ASSESSMENT

## EVALUATION OF TOXICOLOGY

The toxicological database for aminopyralid, consisting primarily of toxicological studies conducted in laboratory animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects may occur 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. Similarly, 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 adverse effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes (ADI and ARfD) at which no adverse health effects in humans are expected.

### Toxicokinetics and Metabolism Studies

Two groups of four rats received single doses by oral gavage of radiolabelled aminopyralid at 50 and 1000 mg/kg bw respectively. Another group of four rats were gavaged with daily doses of non-radiolabelled test material (Days 1 to 14) and a single dose of radiolabelled test material on Day 15 (50 mg/kg bw/d). Aminopyralid was excreted by rats quite rapidly and completely in the urine and faeces, with most of the radioactivity administered (80% or more) being excreted during the first 24 hours in all dose groups. Approximately 41-59% and 33-43% of the administered radioactivity was recovered in urine and faeces, respectively, within seven days. Only small amounts (<1%) remained in the tissues seven days after dosing. The test material was excreted, in both the urine and the faeces, without metabolic transformation.

Another study examined the absorption, distribution, metabolism, and elimination of aminopyralid and the triisopropanolamine (TIPA) salt of aminopyralid (the form of the active used in the product) following oral gavage administration to rats. Four male rats were given single oral doses ($^{14}$C-labelled) of aminopyralid (50 mg/kg bw) and four male rats were given equimolar doses of the TIPA salt of aminopyralid (96 mg/kg bw). Single oral doses of aminopyralid and aminopyralid TIPA were rapidly absorbed by the rat as the highest concentration of radioactivity in the plasma was found in the blood at 0.25 hours post-dosing for both compounds. The excretion of 38.3% (for aminopyralid) and 34.6% (for aminopyralid TIPA) of the administered radioactivity in the urine within six hours indicates that aminopyralid was rapidly absorbed and excreted regardless of whether it was administered as the acid or as the TIPA salt. The two compounds behaved similarly in terms of plasma concentration and rates and levels of excretion in the urine and faeces were also similar for the compounds. The parent compound was excreted overwhelmingly without metabolic change in both cases. Results indicate that, when administered orally to rats, aminopyralid and aminopyralid TIPA are bioequivalent in terms of absorption, distribution, metabolism and excretion.

### Acute Studies

Aminopyralid has low acute oral toxicity ($LD_{50}$ >5000 mg/kg bw), low acute dermal toxicity ($LD_{50}$ >5000 mg/kg bw) and low acute inhalation toxicity ($LC_{50}$ >5500 mg/m$^3$) in rats. It was non-

irritating to rabbit skin and non-sensitising to guinea pig skin. Aminopyralid was a severe eye irritant in rabbits.

The product, Hotshot Herbicide (containing 10 g/L aminopyralid present as the TIPA salt and 140 g/L fluroxypyr present as the methylheptyl ester), has low acute oral toxicity ($LD_{50}$=5000 mg/kg bw), low acute dermal toxicity ($LD_{50}$ >5000 mg/kg bw) and low acute inhalation toxicity ($LC_{50}$ >5260 mg/$m^3$) in rats. It was a moderate skin irritant in rabbits but not a skin sensitiser in guinea pigs. It was a severe eye irritant in rabbits.

**Short-term Studies**

Mice were given test diets containing aminopyralid at 0, 10, 100, 500 or 1000 mg/kg bw/d for four weeks. Given the observation of an increase in hepatocyte size with altered cytoplasmic staining and decrease in liver glycogen in two of the five males in the 1000 mg/kg bw/d group, the NOEL was 500 mg/kg bw/d.

Rats were fed diets formulated to contain 0, 10, 100, 500 and 1000 mg/kg bw/d aminopyralid for four weeks to evaluate the potential for systemic toxicity of the test substance. The study found an increased caecum size at 500 mg/kg bw/d, with the NOEL being 100 mg/kg bw/d.

Rats were dermally exposed to the test material at 0, 100, 500 or 1000 mg/kg bw/d for six hours per day, seven days a week, for 28 days. Possible treatment-related histopathological effects were slight epidermal hyperplasia at the test site and very slight chronic focal inflammation of the liver in males at 500 mg/kg bw/d. Given these histopathological observations, the NOEL was 100 mg/kg bw/d.

Dogs were fed diets containing 0, 0.15, 0.45 or 1.5% aminopyralid. These concentrations corresponded to dose levels of approximately 0, 62, 193 or 543 mg/kg bw/d for the males, and 0, 62, 177 and 556 mg/kg bw/d in females. Considering the slightly lower feed consumption during weeks 2-4 in male dogs given 1.5% aminopyralid, the NOEL was 193 mg/kg bw/d (0.45% aminopyralid). However, it is possible that this was actually a palatability issue rather than a toxicological effect.

**Subchronic Studies**

Mice were fed diets formulated to provide 0, 10, 100, 500 or 1000 mg/kg bw/d of aminopyralid for 90 days to evaluate the potential for systemic toxicity. Given the lack of treatment-related effects, the NOEL was 1000 mg/kg bw/d.

Rats were fed diets formulated to contain 0, 10, 100, 500 or 1000 mg/kg bw/d of aminopyralid for 13 weeks to evaluate the potential for systemic toxicity. Recovery groups of 10 rats/sex were fed 0 or 1000 mg/kg bw/d for 13 weeks and were then given control feed for an additional four weeks to evaluate the reversibility of effects induced during the 13 weeks of treatment. Urinalysis showed some effects at the higher doses, with reductions in the pH of the urine after 13 weeks of treatment at the 500 and 1000 mg/kg bw/d dose levels and decreases in urine protein and ketones at the 1000 mg/kg bw/d levels. Because these alterations were not accompanied by histopathological changes, they were considered to be non-adverse. The recovery groups showed an apparent return to normal in these parameters after the four-week recovery period on the control diet. Rats given 500 or 1000 mg/kg bw/d for 13 weeks showed statistically significant, treatment-related increases in full caecal weights. The same was true of the weights of the empty caecum, except in the case of females on 500 mg/kg bw/d in which there was no change. The increased caecal weights were associated with histopathological observations of very slight hyperplasia of the mucosal epithelium in males at 1000

mg/kg bw/d. There was apparently a partial return to normal caecal weights in rats given 1000 mg/kg bw/d for 13 weeks followed by a 4-week recovery period on the control diet. However, weights were still significantly increased. Based on the effects on full and empty caecal weight in males at 500 mg/kg bw/d and decreased urine pH in rats at the same dose, the NOEL was 100 mg/kg bw/d.

Dogs were fed diets formulated to contain 0, 0.15, 0.75 or 3.0% aminopyralid for 13 weeks to evaluate the potential for systemic toxicity. The average test material intake for males was 0, 54.5, 282 or 1070 mg/kg bw/d, respectively, whilst that in females was 0, 52.7, 232 or 929 mg/kg bw/d, respectively. Histopathological observations on rats in the highest dose group disclosed a slight, diffuse hyperplasia and hypertrophy of the mucosal epithelium of the stomach. This was characterised by increased numbers of mucous cells and chief cells in the fundus of the stomach. Mucous cell hyperplasia was also noted in the pylorus of the stomach. Hypertrophy of mucous cells, characterised by increased cytoplasmic volume, was most prominent in mucous cells of the pylorus. There was no accompanying degeneration, necrosis or inflammation of the mucosa of the stomach. Given these histopathological observations, the NOEL was 0.75% aminopyralid (equivalent to 232 mg/kg bw/d).

GF-871 is an aqueous formulation containing 41.3% of the triisopropanolammonium (TIPA) salt of aminopyralid. Rats were given test diets formulated to supply 0, 465, 1211 or 2421 mg of GF-871/kg bw/d for 90 days. These dose levels were equivalent to 0, 192, 500 or 1000 mg/kg bw/d aminopyralid TIPA salt. The report states that caeca of all rats given 2421 mg/kg bw/d of GF-871 were enlarged by normal semi-solid ingesta. As the faeces were normally formed pellets, it was suggested that there was increased colonic water resorption with compensatory renal excretion of the additional water, which led to the observed increases in the volume of urine and its decreased specific gravity. These alterations were not accompanied by treatment-related histopathological changes. Full caecal weights were increased in rats at 2421 and 1211 mg/kg bw/d. Accordingly, the NOEL in this study with GF-871 was 465 mg/kg bw/d (equivalent to 192 mg/kg bw/d of aminopyralid TIPA).

**Chronic/Carcinogenicity Studies**

Mice were fed diets supplying 0, 50, 250 or 1000 mg/kg bw/d of aminopyralid for up to 18 months, to evaluate the potential for oncogenicity. There were no treatment-related clinical signs. The mortality rates by the end of the study were 38, 32, 34 and 42% for males and 16, 34, 30 and 42% for females in the 0, 50, 250 and 1000 mg/kg bw/d groups, respectively. The increased mortality in females in the high-dose group was interpreted as treatment-related. There were no treatment-related statistically significant histopathological (including neoplastic) abnormalities. Given the increased mortality in females in the high-dose group, the NOEL was 250 mg/kg bw/d.

Rats were fed diets supplying 0, 5, 50, 500 or 1000 mg/kg bw/d of aminopyralid for up to 24 months to evaluate its potential for systemic toxicity and/or oncogenicity. Body weights in males at 500 and 1000 mg/kg bw/d and females at 1000 mg/kg bw/d were low as the study progressed. Feed consumption was consistently increased in males at 1000 mg/kg bw/d. In males at 500 mg/kg bw/d, slightly increased feed consumption was apparent from day 372 onwards. The aspartate aminotransferase levels in females given 1000 mg/kg bw/d were slightly increased over the first year of the study, which was attributed to the test article. Urinalysis showed a consistent pattern of changes in both sexes at 500 and 1000 mg/kg bw/d that was considered to be related to the test article. The effects included increased urine volume and decreased urine specific gravity, pH, protein and ketones. The effects observed in the urinalysis were not accompanied by treatment-related renal histopathological changes. Animals given 500 or 1000 mg/kg bw/d of aminopyralid for 12 months had treatment-related, statistically significant increases in full and empty caecal weights. Similar effects were noted at 24 months. The only treatment-related gross pathological

observations at 12 and 24 months were dose-related incidences of increased size of the caecum at 500 and 1000 mg/kg bw/d. The only treatment-related histopathological observation at 12 months was a very slight, diffuse hyperplasia of the mucosal epithelium of the caecum in rats given the higher doses of aminopyralid. A similar effect was observed at 24 months in the 1000 mg/kg bw/d groups. However, it was found less frequently than at 12 months. Given the treatment-related effects at the higher doses, 50 mg/kg bw/d was the NOEL.

Dogs were fed diets formulated to provide 0, 0.03, 0.3 or 3.0% aminopyralid for one year. These concentrations corresponded to approximately 0, 9.9, 99.2 and 967 mg/kg bw/d in males and 0, 9.2, 93.2 and 1038 mg/kg bw/d in females, respectively. At termination, females given 3.0% aminopyralid had lower mean body weight (9%) and lower mean body weight gain (58%). Animals given 3.0% aminopyralid had higher relative liver weights in both sexes and higher absolute liver weight in males. The increased liver weights were associated with very slight hypertrophy of centrilobular to midzonal hepatocytes in two males and two females at this dose level. The only significant gross pathological observations were in two females at 3.0% aminopyralid that had diffuse thickening of the stomach mucosa. Histopathological changes were noted in the stomachs of all males and females given 3.0% aminopyralid. These included slight, diffuse mucosal hyperplasia and hypertrophy, very slight or slight chronic mucosal inflammation, and slight lymphoid hyperplasia of the gastric mucosa. Given the range of effects of 3.0% aminopyralid, the NOEL was 0.3% aminopyralid (equivalent to 93 mg/kg bw/d).

**Reproduction Study**

Rats were fed diets supplying 0, 50, 250 and 1000 mg/kg bw/d of aminopyralid for approximately 10 weeks prior to breeding, and continuing through breeding (2 weeks), gestation (3 weeks) and lactation (3 weeks) for two generations. Parental animals at 250 mg/kg bw/d and above tended to have higher caecal sizes and weights, particularly at the 1000 mg/kg bw/d level. Full caecal weights were increased in 1$^{st}$ generation parental males, 1$^{st}$ generation parental females and 2$^{nd}$ generation parental males at 250 mg/kg bw/d, and empty caecal weights were increased in the 2$^{nd}$ generation parental male rats at that dose level. This effect was also apparently reflected in the increased caecum size in several parental rats at this dose level. Therefore, the NOEL for parental toxicity was 50 mg/kg bw/d. There were no effects of aminopyralid in terms of reproductive or neonatal toxicity and the relevant NOELs were 1000 mg/kg bw/d, the highest dose tested.

**Developmental Studies**

In a preliminary screening study, groups of eight time-mated female rats were dosed with aminopyralid by gavage at dose levels of 0, 250, 500, 750 or 1000 mg/kg bw/d on days 6 - 20 of gestation. Treatment up to and including 1000 mg/kg bw/d produced only a transient effect on feed consumption in the maternal rats at higher doses (750 and 1000 mg/kg bw/d) and no lethal effects on embryos or foetuses at any dose.

Groups of time-mated female rats were dosed with aminopyralid by gavage at 0, 100, 300 or 1000 mg/kg bw/d on days 6-20 of gestation. Clinical observations did not reveal any treatment-related findings. Treatment did not have any effects on body weight. There were no effects on feed consumption with the exception of a slight (8%) but statistically significant decrease in feed consumption noted on gestation days 6-9 in the 1000 mg/kg bw/d group. This decrease did not correspond to any body weight effect and therefore was considered to be not toxicologically significant. There were no effects on organ weights or gross pathology. In terms of reproductive parameters, there were no significant treatment-related effects on any of the pregnancy parameters tested. There were no statistically significant effects of treatment on the incidence of any foetal alteration (external, visceral and skeletal variations and malformations). Administration of

aminopyralid up to and including 1000 mg/kg bw/d was not associated with maternal toxicity, embryonic/foetal toxicity or teratogenicity. The NOEL for maternal toxicity and for developmental toxicity was 1000 mg/kg bw/d, the highest dose tested.

Aminopyralid was administered by gavage to non-pregnant serum donor rats for three consecutive days (test days 1-3), with seven serum donor rats being given dose levels of 1000 mg/kg bw/d of aminopyralid, while seven control serum donor rats were given none. Clinical examinations were conducted daily on all serum donors throughout the study period. Approximately four hours after the last dose on test day 3, the rats (seven treated and seven control) were sacrificed by $CO_2$ inhalation and exsanguinated, with the serum being separated. Gestation day 9 rat conceptuses with intact amnion and visceral yolk sac, but with Reichert's membrane removed, were explanted from a separate group of untreated, timed-pregnant rats and were cultured in sera from the control or treated serum donor rats. After approximately 42 hours in culture, embryos were evaluated for viability, growth and morphology. All serum donors appeared normal throughout the test period and body weights were not affected by treatment with the test substance. There were no statistical differences between embryos cultured in serum from the treated rats and the controls in embryo viability, growth or morphology.

In another preliminary screening study, groups of time-mated female NZW rabbits were given aminopyralid by gavage at 0, 250, 500, 750 or 1000 mg/kg bw/d on gestation days 7 - 27. Higher dose rates (750 and 1000 mg/kg bw/d) caused maternal body weight losses that would preclude the use of these dose levels in any subsequent developmental toxicity study in this species. Given the effects of 250 mg/kg bw/d on body weight gains, no NOEL was established for maternal toxicity. The NOEL for lethality to embryos and foetuses was 500 mg/kg bw/d.

Groups of time-mated female NZW rabbits were gavaged with aminopyralid at dose levels of 0, 25, 100 or 250 mg/kg bw/d on days 7-20 of gestation (Phase I). The high dose of 250 mg/kg bw/d in this initial study did not produce sufficient evidence of maternal toxicity as defined in the Health Effects Test Guideline of the US EPA (OPPTS 870.3800). Therefore, three additional groups of 26 rabbits each were added to the study (Phase II) at dose levels of 0, 500 and 750 mg/kg bw/d. There were no effects of treatment in Phase I. In Phase II, clinical observations included incoordinated gait at 500 and 750 mg/kg bw/d. Body weight was lost in both these groups on gestation days 7-10. Feed consumption in these groups was reduced, often to a statistically significant extent at 750 mg/kg bw/d. Gross pathological observations were not made on the main group of rabbits at 750 mg/kg bw/d, which was terminated early due to excessive toxicity. However, three animals in this group that had died or were sacrificed moribund before the main group was removed were subjected to necropsy. Treatment-related gross pathological observations in these three animals included pale kidneys (cortex) and an increased incidence of alterations in the glandular mucosa of the stomach (erosion-ulcer, hyperaemia or mottled appearance). A single rabbit among those examined at the scheduled necropsy of rabbits in the 500 mg/kg bw/d group had ulcers/erosions in the glandular mucosa of the stomach which may have been treatment-related. There were no other treatment-related effects in this group. There were no effects on reproductive parameters or foetal development at 500 mg/kg bw/d. Given the maternal effects at 500 mg/kg bw/d, the NOEL for maternal toxicity was 250 mg/kg bw/d. As 750 mg/kg bw/d exceeded the maximum tolerated dose, all surviving rabbits in the dose group were removed from the study. The NOEL for developmental toxicity was 500 mg/kg bw/d, the highest dose at which observations were made.

A study was undertaken to characterise further the observations in the previous study that included transient incoordination of the gait after dosing in rabbits given 500 and 750 mg/kg bw/d of aminopyralid. Three non-pregnant rabbits were used in this study, which was conducted in two phases: Phase I included behavioural acclimation and 22 days of dosing with 500 mg/kg bw/d of aminopyralid; Phase II consisted of 20 days of dosing with 1000 mg/kg bw/d. There were no

effects in Phase I. During the first 18 days of dosing in Phase II, only one rabbit showed signs of incoordination, namely stumbling (dysergia) when trying to walk or turn in the open field. There was also evidence of forelimb hypometria (reduced amplitude of otherwise normally formed movements). The incoordination was usually observed after approximately two hours following dosing, occurring on test days 2, 3, 4, 7, 9, 10, 14, 17 and 19. On test day 19, another rabbit showed signs of incoordination 30 minutes after dosing. Clinical chemistry parameters were measured before and after the sixteenth dose of aminopyralid. There were no indications of an effect of dosing on serum chemistry, including osmolality and osmolar gap (with the possible exception of phosphate, which was consistently somewhat higher post-dose).

*Studies with aminopyralid TIPA*
A study was performed to evaluate any developmental effects of GF-871 (an aqueous formulation consisting of 41.3% aminopyralid TIPA salt) when administered once daily by oral gavage to pregnant rats during the period of organogenesis; from gestation day 6 to gestation day 19 at dose levels of 200, 500 and 1000 mg/kg bw/d (expressed in terms of the active ingredient, aminopyralid TIPA; equivalent to 484, 1211 and 2421 mg/kg bw/d of GF-871, respectively). There was no maternal or reproductive toxicity. There were no toxicologically meaningful effects on the occurrence of foetal malformations or developmental variations. A dose level of 1000 mg/kg bw/d of the active constituent, aminopyralid TIPA salt (equivalent to 2421 mg/kg bw/d of GF-871 formulation), was the NOEL for maternal effects and foetal development. A NOEL of 1000 mg/kg bw/d of aminopyralid TIPA is equivalent to 520 mg/kg bw/d of aminopyralid.

A further study was undertaken to determine a NOEL for maternal clinical effects (incoordination) in rabbits administered GF-871 (aminopyralid TIPA). Groups of time-mated female NZW rabbits were administered GF-871 by gavage on gestation days 7 – 27 at targeted dose levels of 0, 50 and 150 mg/kg bw/d (expressed in terms of the active ingredient, aminopyralid TIPA). These dose levels were equivalent to 0, 121 and 363 mg/kg bw/d of GF-871, respectively. Transient incoordination was observed in 3 of 26 animals at 150 mg/kg bw/d. In two of these cases, this was associated with a repetitive chewing behaviour. No treatment-related effects were observed in rabbits given 50 mg/kg bw/d. Accordingly, the NOEL for maternal effects was 50 mg/kg bw/d of aminopyralid TIPA, equivalent to 26 mg/kg bw/d of aminopyralid.

**Genotoxicity Studies**
Aminopyralid tested negative for genotoxicity in a bacterial reverse mutation assay and in a Chinese hamster ovary cell/hypoxanthine-guanine-phosphoribosyl transferase (CHO/HGPRT) forward mutation assay. Aminopyralid induced a clastogenic response in rat lymphocyte cultures treated continuously for 24 hours without activation by S9. The magnitude of the response was considered to be relatively weak because the frequencies of aberrant cells in treated cultures were only slightly greater than the upper boundary of the laboratory historical negative control data. On the other hand, there was evidence of a dose-response relationship. Aminopyralid did not increase the incidence of micronuclei in a mouse bone marrow micronucleus test.

GF-871 (an aqueous formulation containing 41.3% of the active ingredient aminopyralid TIPA) was negative for genotoxicity in all tests undertaken, including a bacterial reverse mutation assay, an *in vitro* chromosomal aberration assay utilising rat lymphocytes, an *in vitro* Chinese hamster ovary cell/hypoxanthine-guanine-phosphoribosyl transferase (CHO/HGPRT) forward gene mutation assay, and a mouse bone marrow micronucleus test.

**Neurotoxicity Studies**
Rats were dosed by oral gavage with 0, 500, 1000 or 2000 mg/kg bw of aminopyralid to evaluate its potential to produce acute neurotoxicity. Treatment with aminopyralid had no effects in this study

apart from a transient soiling effect seen in high-dose animals. No identifiable neurotoxic effects were observed at any dose level.

A one-year chronic neurotoxicity study was conducted as part of a two-year chronic toxicity/oncogenicity study to assess the effects of dietary exposure to aminopyralid at levels of 0, 5, 50, 500 and 1000 mg/kg bw/d in male and female rats. Increased defaecation in treated males, particularly at the high dose, was considered to be related to the increased caecal size observed in all rats in the 500 and 1000 mg/kg bw/d groups at necropsy. Given that the increase in defaecation was not an expression of neurotoxicity, and the lack of evidence of any neuropathology, the NOEL for neurotoxicity in this study was 1000 mg/kg bw/d.

## PUBLIC HEALTH STANDARDS

### Poisons Scheduling

In June 2005, the National Drugs and Poisons Schedule Committee (NDPSC) agreed that, based on the assessment of toxicity and having regard to severe eye irritancy, aminopyralid be included in Schedule 6 of the SUSDP.

## NOEL/ADI

The Acceptable Daily Intake (ADI) is that quantity of an agricultural compound, which can safely be consumed on a daily basis for a lifetime and is based on the lowest NOEL obtained in the most sensitive species. This NOEL is then divided by a safety factor, which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

A LOEL of 150 mg/kg bw/d, with the endpoint being maternal toxicity in pregnant rabbits consisting of transient incoordination, was associated with a NOEL of 50 mg/kg bw/d of aminopyralid TIPA. This was equivalent to 26 mg/kg bw/d of aminopyralid itself, making this the lowest NOEL observed. A safety factor of 100 is considered appropriate in view of the extensive database for aminopyralid. Therefore, an ADI of 0.26 mg/kg bw/d is established, which can be rounded up to 0.3 mg/kg bw/d.

### Acute Reference Dose (ARfD)

The acute reference dose (ARfD) is the maximum quantity of an agricultural or veterinary chemical that can safely be consumed as a single, isolated, event. The ARfD is derived from the lowest single or short term dose which causes no effect in the most sensitive species of experimental animal tested, together with a safety factor which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

In studies with pregnant rabbits using aminopyralid TIPA, transient incoordination was observed shortly after dosing at the level of 150 mg/kg bw. Dose levels of 50 mg/kg bw had no effect. Accordingly, after applying a 100-fold safety factor, an ARfD of 0.50 mg/kg bw aminopyralid TIPA is obtained, which is equivalent to 0.26 mg/kg bw of aminopyralid or 0.3 mg/kg bw.

Based on the assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of Hotshot Herbicide when it is used in accordance with the label directions. There are provisions for appropriate First Aid Instructions and Safety Directions on the product label.

# RESIDUES ASSESSMENT

## Introduction

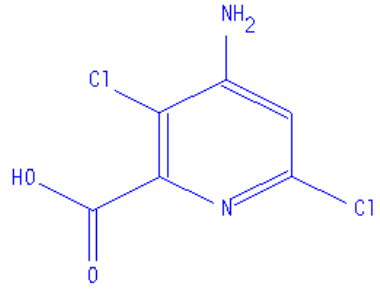
The product is intended for broadleaf weed control in winter cereals, for control of lantana and other weeds in pasture and other non-crop situations. As part of the residue assessment for aminopyralid, plant and animal metabolism studies, supervised residue trials, trade aspects, environmental fate and chemistry were considered. In addition, residue data and trade aspects were also assessed for fluroxypyr, which is co-formulated in the product.

## Metabolism

Aminopyralid

Plant metabolism studies were conducted on **pasture grasses and wheat**. Following the application of 360 g ai/ha of $^{14}$C-radiolabelled aminopyralid on pasture, total radioactive residues (TRR) on forage declined very rapidly. At 7 days after treatment, 36 mg/kg of aminopyralid equivalents were found on forage, and the parent accounted for ~50% of the total radioactive residues. Analysis of the metabolite fraction showed that it consisted of a mixture of three multi-component water-soluble complexes that upon hydrolysis gave additional aminopyralid. The complexes were determined to be sugar conjugates, such as glucose ester conjugates of aminopyralid. Apart from the formation of sugar conjugates, the only other metabolite found was the hydroxyl-aminopyralid conjugate at <1% of the TRR.

Similar observations were found in studies conducted on wheat, following application of $^{14}$C-aminopyralid at 40 or 80 g ai/ha on wheat at the tillering growth stage. Most of the extractable radioactivity consisted of free aminopyralid or was converted to free aminopyralid following hydrolysis, indicating the presence of sugar conjugate metabolites.

| | |
|---|---|
| **Structural formula** |  <br>Aminopyralid |
| • ***Empirical formula*** | $C_6H_4Cl_2N_2O_2$ |
| • ***Molecular weight*** | 207.03 |

**Laying hens** were dosed with $^{14}$C-radiolabelled aminopyralid for 7 consecutive days at 1.024 mg/kg bw /day, equivalent to 11.56 ppm in the diet. Of the administered dose, over 80% was eliminated in the excreta and was largely comprised of free aminopyralid (>92% of the TRR). There were only traces of residues found in any of the edible tissues, with liver, skin and eggs each accounting for <0.1% TRR. There were no discernable residues found in fat or muscle tissue of laying hens.

**Lactating goats** were dosed with $^{14}$C-radiolabelled aminopyralid for 6 consecutive days at a dose level of 0.27 mg/kg bw/day, equivalent to 14 ppm in the diet. Approximately 93% of the administered dose was eliminated in the excreta, equally apportioned between the urine and faeces. The TRR found in milk was low (0.003-0.008 mg/kg), accounting for less than 0.1% TRR. Residues in tissues were also low; the highest radioactive residue was in kidney at a level of 0.071

mg/kg aminopyralid equivalents. The metabolic profile showed it predominantly consisted of aminopyralid parent compound. Residues in other tissues were less than 0.01mg/kg equivalents, with liver and fat having a TRR of 0.008 mg/kg and 0.001 mg/kg, respectively. Residues in muscle were non-detectable (<0.0008 mg/kg).

In summary, there is very limited metabolism of aminopyralid observed in plants; aminopyralid conjugates were the only major metabolites present apart from free aminopyralid. Hydrolysis converted all of the conjugates to parent aminopyralid. In animals, there was limited absorption of aminopyralid residues into tissues, milk and eggs. Only traces of free aminopyralid were observed in liver tissue.

Fluroxypyr

No additional assessment of fluroxypyr metabolism was required. The metabolism of fluroxypyr has been adequately assessed in previous submissions (see Starane 200 Herbicide).

**Analytical methods**

Determination of aminopyralid residues in plants

Validated analytical methods were used to determine aminopyralid and conjugated aminopyralid residues in cereal grains, fodder and forage, and pasture crops. The method involved sequentially hydrolysing the samples under acidic and basic conditions to release aminopyralid from the sugar conjugates. The hydrolysed samples are cleaned-up using disposable sep-pak cartridges. The final eluant containing the aminopyralid residue is chemically derivatized to form the 1-butyl ester derivative before analysis. Samples are analysed by liquid chromatography with positive-ion electrospray tandem mass spectrometry (LC/MS/MS). The LOQ of the method is 0.01 mg/kg for grain, forage and hay; and 0.05 mg/kg for fodder.

Determination of aminopyralid residues in animal tissues

To homogenize tissues, meat and offal samples are ground with a hammer mill. Whole milk, cream and skim milk samples were thoroughly mixed before sampling. Residues of aminopyralid are partitioned with a basic methanol solution. An aliquot of the extract is cleaned-up on disposable sep-pak cartridges. The extract containing aminopyralid residues is eluted from the column and chemically derivatized to form the 1-butyl ester derivative before analysis. Samples are then analysed by liquid chromatography with positive-ion electro-spray tandem mass spectrometry (LC/MS/MS). The LOQ of the method is 0.01 mg/kg for meat, offal, and milk. The method was not validated on eggs or other poultry tissues.

Determination of fluroxypyr residues in plant and animal matrices

Analysis of fluroxypyr residues in plant matrices was performed by a gas chromatographic method with a mass spectroscopic detector. The LOQ for fluroxypyr in cereal forage and grain was 0.01 mg/kg. The LOQ for fluroxypyr residues in straw was 1 mg/kg. The analytical methodology for fluroxypyr residues in animal tissues was evaluated in an earlier submission, which was assessed as being acceptable. The reported LOQ is 0.01 mg/kg in eggs and milk, and 0.05 mg/kg in muscle and fat.

**Storage stability**

Storage stability studies conducted on wheat forage, hay, straw and grain indicate residues of aminopyralid remain stable for at least 17 months when samples are stored frozen at –20 °C. With respect to animal commodities, there was minimal degradation of the radioactive profile after 24 months of frozen storage (-18 °C). The data demonstrate that residues of aminopyralid remain stable under freezer conditions in both plant and animal matrices.

**Residue definition**
Aminopyralid metabolism data indicate that the compound is quickly eliminated following ingestion by animals with little biotransformation. In plants, sugar conjugates were the only significant metabolites found in association with the parent compound. The extent of conjugation in plant tissues was variable, being up to 50% of the TRR in forage samples. The analytical methodology used for plants is capable of measuring free and conjugated aminopyralid.

On the basis of the metabolism data and analytical methodology, a residue definition of free and conjugated aminopyralid residues is recommended for plant commodities and parent only for animal commodities.

The following residue definition is recommended for aminopyralid:

| | |
|---|---|
| **Aminopyralid** | Commodities of plant origin: Sum of aminopyralid and conjugates, expressed as aminopyralid.<br>Commodities of animal origin: Aminopyralid. |

The residue definition proposed is similar to that established in the USA and is appropriate for monitoring compliance with good agricultural practice.

**Residue trials**
*Aminopyralid*

*Cereals*
21 residue trials were conducted in Australia in 2002-2003 involving broadcast application of aminopyralid on wheat (9), barley (6) and oats (6). Aminopyralid was applied at rates equivalent to 7.5, 10, 15 and 20 g ai/ha (1, 1.25, 2, 2.7 ×). The treatments were applied in accordance with the proposed label instructions for Hotshot Herbicide, up to the first node growth stage of the crop.

In addition, data from 37 trials conducted in USA/Canada and 6 trials in the EU (Italy, Spain, Hungary, Poland) following the broadcast application of aminopyralid on wheat and other cereal crops were considered. The use patterns in these overseas trials were consistent with the proposed Australian use pattern, and the data were considered relevant for MRL setting.

When applied to cereals at 7.5 –10 g ai/ha (1×-1.3×) in Australia, residues of aminopyralid in grain collected at harvest, 80-117 days after treatment, were: ND (4), <LOQ (3), 0.01 (5), 0.02 (3), 0.03 (6), 0.04, 0.06, and 0.07 (3) mg/kg.

When considering cereal grain data from supervised trials conducted in Australia, USA/Canada and Europe (n =64), the highest residue found in cereal grain was 0.07 mg/kg. This occurred in three separate Australian trials on wheat and barley. These data support a cereal grains MRL of 0.1 mg/kg. The Supervised Trial Median Residue (STMR) of 0.01 mg/kg will be used in the chronic dietary estimate of aminopyralid. The highest residue of 0.07 mg/kg will be used in the corresponding acute dietary estimate.

When applied to cereals at 7.5-10 g ai/ha (1-1.3 ×) in Australia, aminopyralid residues in forage at 6-7 days after treatment were in ranked order: 0.16, 0.34, 0.40, 0.45, 0.48, 0.54, 0.71, 0.77, 0.79 and 1.02 mg/kg (dry weight). Similarly, samples treated at 15 g ai/ha (2×), forage residues at 7 days after treatment in ranked order were: 0.45, 0.5, 0.59, 0.66, 0.99, 1.04, 1.09, 1.27, 1.33, and 1.43 mg/kg (dry weight). When corrected to the proposed 1× rate, the equivalent residue levels were: 0.23, 0.25, 0.30, 0.33, 0.50, 0.52, 0.55, 0.64, 0.67 and 0.72 mg/kg.

When forage data from Australian and USA/Canada trials are considered as one dataset (n=20), the highest residue (HR) found was 1.08 mg/kg from a USA trial; the Australian highest residue was 1.02 mg/kg. These data support an MRL of 3 mg/kg for forage of cereal grains. In conjunction with the MRL, a 7 day grazing/cutting withholding period is recommended.

When applied to cereals at 7.5-10 g ai/ha (1-1.3×) in Australia, residues of aminopyralid in straw collected at harvest, 80-117 days after treatment, were: 0.02, 0.02, 0.02, 0.03, 0.03, 0.03, 0.04, 0.04, 0.04, 0.04, 0.04, 0.04, 0.05, 0.05, 0.06, 0.06, 0.07, 0.07, 0.07, 0.08, 0.08, 0.09, 0.1, 0.11, 0.12, and 0.13 mg/kg (dry weight).

When considering the straw data from supervised trials conducted in Australia, Europe and USA (n=20), the HR was 0.17 mg/kg from a USA trial on wheat. The equivalent highest residue in Australian trials was 0.13 mg/kg. These data support an MRL of 0.2 mg/kg for cereal straw when Hotshot Herbicide is used as directed.

*Pasture*

In pasture situations, Hotshot Herbicide is applied by targeted spot spraying to the point of run-off using a high volume of application of 3000L/ha. The equivalent broad-acre rate of aminopyralid is 210 g ai/ha.

In Australia, 12 supervised trials were conducted in 2003-2004 following the application of aminopyralid on pasture. Single treatments were applied at rates of 210, 270, 420, 540 g ai/ha of aminopyralid (1-2.6×). Forage samples were collected at 0 (<4 hours), 1, 3, 7, 14, 28, 56 days after treatment. Residue levels were determined on an 'as received' basis, and expressed on a dry weight basis. Data show that residues on forage decline with an estimated $t_{1/2}$ = 13-18 days.

When aminopyralid was applied at 210 g ai/ha (1×) on pasture, aminopyralid residues on forage at 0 days after treatment were: 19.7, 25.7, 31.8, 40.3, 41.1, 43.3, 44.6, 48, and 50 mg/kg (dry weight). Similarly, when applied at 420 g ai/ha (2×), residues on forage collected at 0 days after treatment were: 47.7, 74.7, 91.4, 92.7, 115, and 138 mg/kg (dry weight). When applied at 270 g ai/ha (1.3×), residues of aminopyralid in forage collected at 0 days after treatment were: 19.6, 37.1, 37.2, 52.5, 66.1, and 103 mg/kg (dry weight). Similarly, when applied at 540 g ai/ha (2.6×), residues of aminopyralid in forage collected at 0 days after treatment were: 51.6, 76.7, 86.5, 97.7, 134, 212 mg/kg (dry weight). When the Australian data are corrected to 1-1.3× the assumed broad-acre rate of 210 g ai/ha, the equivalent residues are: 19.6, 19.7, 20.1, 23.9, 25.7, 29.8, 31.8, 33.6, 37.1, 37.2, 37.4, 38.0, 40.3, 41.1, 43.3, 44.6, 45.7, 46.4, 48.0, 50.0, 52.1, 52.5, 57.5, 66.1, 69.0, 82.4 and 103.0 mg/kg (dry weight).

Six trials were conducted in New Zealand in 2002 and 2003. In 2002, aminopyralid was applied at 60, 120, 240 and 480 g ai/ha (0.3, 0.6, 1.1, 2.3×). In 2003, aminopyralid was applied to pasture at rates of 60, 120, 300 and 600 g ai/ha (0.3, 0.6, 1.4, 2.9×). Data from trials conducted at 240-600 g ai/ha are considered for MRL setting. When applied at 240 g ai/ha, residues at 0 days after treatment were: 100 and 150 mg/kg (dry weight). When applied at 300 g ai/ha, residues at 0 days after treatment were: 141, 221, 238 and 245 mg/kg (dry weight). When applied at 600 g ai/ha, residues at 0 days after treatment were: 324, 402, 430, and 482 mg/kg (dry weight). When the NZ residue data are corrected to 1-1.1× the proposed rate of 210 g ai/ha, the equivalent residues are: 66.5, 98.7, 100, 113.4, 130.4, 140.7, 150, 150.5, 154.7, 166.6, 168.7 and 171.5 mg/kg (dry weight).

Additionally, 20 trials were conducted in USA/Canada and 22 trials were conducted in EU. However, as the application rates used in these trials are lower (0.3-0.6 ×) than the propose Australian rate, these data have not been included for MRL setting purposes.

The forage data from the Australian and New Zealand trials show that following aminopyralid treatment at 1-1.3× the proposed rate of 210 g ai/ha, residues in forage at 0 days after treatment were: 19.6, 19.7, 20.1, 23.9, 25.7, 29.8, 31.8, 33.6, 37.1, 37.2, 37.4, 38.0, 40.3, 41.1, 43.3, 44.6, 45.7, 46.4, 48.0, 50.0, 52.1, 52.5, 57.5, 66.1, 66.5, 69.0, 82.4, 98.7, 100.0, 103.0, 113.4, 130.4, 140.7, 150.0, 150.5, 154.7, 166.6, 168.7 and 171.5 mg/kg (dry weight).

These data support a pasture MRL of 200 mg/kg for aminopyralid when Hotshot Herbicide is used as directed.

In conjunction with the MRL, the following grazing/cutting withholding period is supported:

Not required when used as directed.

It is assumed that a spot spray treatment in pasture will be equivalent to less than 30% of the broad-acre application rate for the purposes of the residues assessment, and this factor is considered when determining the likely livestock exposure to residues. Therefore, the estimated highest residue for livestock exposure is 51.5 mg/kg (ie 30% × 171.5 mg/kg). This value will be considered further in relation to the cattle feeding study and proposed animal commodity MRLs for meat, milk and edible offal.

Fluroxypyr

*Cereals*

In Australia, 10 supervised trials were conducted in 2002-2003 to determine fluroxypyr residues from application of Hotshot Herbicide on wheat (5), oats (3) and barley (2). Broadcast treatments at rates of 105 and 210 g ai/ha of fluroxypyr (1× and 2×) were made using a spray volume of 250 L/ha. Sprays were applied to cereal crops at the tillering growth stage.

When fluroxypyr was applied at 210 g ai/ha (1×), residues of fluroxypyr on cereal grains at 80-117 days after treatment were: ND (5), <0.01, 0.01 and 0.07 mg/kg. The highest residue HR =0.07 mg/kg was from a trial conducted in barley. The data confirm that the existing cereal grains MRL of 0.2 mg/kg is appropriate and is adequate to account for fluroxypyr residues following use of Hotshot Herbicide on cereals. For chronic dietary exposure estimates, the STMR of <0.01 mg/kg will be used.

When fluroxypyr was applied to cereals at 210 g ai/ha (1×), residues in cereal forage at 6 days after treatment were 23 and 25 mg/kg (dry weight). The decline data show that residues in forage dissipate quickly with an estimated $t_{1/2}$ =3-11 days. These data show that when Hotshot Herbicide is used as directed on cereals, fluroxypyr residues on cereal forage at the proposed withholding period of 7 days after treatment are unlikely to exceed the existing fluroxypyr MRL of 100 mg/kg for forage of cereal grains and other grass-like plants. Therefore, the existing MRL is appropriate and will adequately account for fluroxypyr residues following use of Hotshot Herbicide on cereals.

When fluroxypyr was applied to cereals at 210 g ai/ha (1×), residues of fluroxypyr in harvested straw/hay at 80-117 days after treatment were: ND (7) and 2.2 mg/kg (dry weight). The only detectable residue was found in a barley trial. The data confirm that the existing fluroxypyr MRL of 100 mg/kg for Straw and fodder (dry) and hay of cereal grains and other grass-like plants MRL is appropriate to account for fluroxypyr residues in straw following the use of Hotshot Herbicide.

*Pasture*

In pasture situations, Hotshot Herbicide is applied by targeted spot spraying to the point of run-off using a high volume of application of 3000L/ha. The equivalent broad-acre rate of fluroxypyr is 2940 g ai/ha.

In Australia, twelve supervised trials were conducted in 2002 and 2003. Fluroxypyr, formulated as Hotshot Herbicide or Starane Herbicide was applied to pastures at rates of 600 and 2940-3000 g ai/ha (0.2, 1×). Forage samples were collected at 0 (<4 hours), 1, 3, 7, 14, 28 and 56 days after treatment. The data show that fluroxypyr residues in pasture dissipated with an estimated $t_{1/2}$ = 18-42 days.

When fluroxypyr was applied to pasture at ~3000 g ai/ha (1×), residues of fluroxypyr on forage at 0 days after treatment were: 245, 345, 361, 379, 429, 434, 463, 487, 506, 537, 599, and 655 mg/kg (dry weight). These data support a fluroxypyr MRL of 700 mg/kg for Mixed pasture (leguminous/grasses) when Hotshot Herbicide is used on pasture.

In conjunction with the above MRL, the following grazing withholding period is recommended for pasture:

Not required when used as directed.

It is assumed that a spot spray treatment in pasture will be equivalent to less than 30% of the broad-acre application rate for the purposes of the residues assessment, and this factor is considered when determining the likely livestock exposure to residues. Therefore as the treatment is estimated at 30% of the pasture rate and the likely residue, the estimated highest residue for livestock exposure is 196.5 mg/kg (ie 0.3 × 655 mg/kg). This value will be considered further in relation to existing fluroxypyr animal commodity MRLs for meat, milk and edible offal.

**Processing studies**

Following application of 50 g ai/ha of aminopyralid to a wheat crop, the residue levels found in grain and grain fractions were: 0.055 mg/kg in the bulk grain, 0.338 mg/kg in aspirated grain fractions, 0.133 mg/kg in bran, 0.032 mg/kg in middlings, 0.067 mg/kg in shorts, 0.008 mg/kg in flour, and 0.020 mg/kg in wheat germ. Based upon the cereal grains MRL of 0.1 mg/kg, the maximum residue level anticipated in cereal bran is ~0.24 mg/kg. The data support an MRL of 0.3 mg/kg for wheat bran, unprocessed. Other processed commodity MRLs are not required for aminopyralid as they are covered by the cereal grain MRL.

**Animal commodity MRLs**

*Aminopyralid*

*Grazing animals*

The estimated maximum feed level (MFL) for livestock exposure to aminopyralid residues is 51.5 ppm.

Animal transfer studies have been conducted on lactating cows dosed at 33, 65, 182 and 645 ppm of aminopyralid in the diet. The maximum anticipated exposure of aminopyralid residues in the diet of grazing livestock is 51.5 ppm, based upon intake of treated pasture. At this exposure level, residue levels above the LOQ of 0.01 mg/kg are predicted to occur in kidney at ~0.20 mg/kg and liver at ~0.01 mg/kg. Due to the 10-fold difference in residues expected in kidney compared to liver, a separate kidney MRL of 0.3 mg/kg is recommended. For offal other than kidney, an MRL of 0.02 mg/kg is recommended. No detectable residues are expected to occur in meat or fat and the data support a mammalian meat MRL of *0.01 mg/kg. No detectable residues are expected to occur in milk and milk products. For monitoring purposes, the data support a milk MRL of *0.01 mg/kg.

*Poultry*

No poultry feeding studies were conducted using aminopyralid. However, laying hen metabolism data are adequate to determine whether there is significant transfer of residues into poultry tissues and eggs from exposure to grain. When laying hens were fed 12 ppm of radio-labelled aminopyralid in the diet for 7 days, the maximum total radioactive residues (TRR) found in liver and skin were

0.0024 and 0.0029 mg/kg equivalents respectively. There were no detectable radioactive residues found in fat or muscle tissue above the reported LODs of 0.0017-0.0019 mg/kg. The maximum TRR found in eggs was 0.004 mg/kg. At the anticipated maximum exposure of 0.07 mg/kg for poultry (ie 100% grain from treated crops), no detectable residues are expected in poultry meat, offal and eggs. Based upon these results, the data support MRLs of *0.01 mg/kg for poultry meat, offal and eggs.

Fluroxypyr

*Grazing animals*

Animal commodity MRLs have been established for fluroxypyr as part of the evaluation of Starane 200 Herbicide. Following use of Hotshot Herbicide, the expected maximum livestock dietary exposure to fluroxypyr residues is ~200 ppm in the diet. At this exposure, residues are expected to occur in liver at ~0.08 mg/kg, kidney ~0.6 mg/kg, muscle <0.05 mg/kg, fat ~0.07 mg/kg and milk 0.06 mg/kg. The data show that low levels of residues may occur in fat, but not in meat. It is recommended that the current mammalian meat MRL of 0.1 mg/kg be amended to mammalian meat (in the fat) MRL of 0.1 mg/kg. The expected residue level in kidney is 10-fold higher than in kidney, which supports a separate kidney MRL. It is recommended that the Edible offal MRL of 2 mg/kg be amended to a Mammalian kidney MRL of 1 mg/kg and Offal other than kidney MRL of 0.1 mg/kg. The current milk MRL of 0.1 mg/kg remains appropriate.

*Poultry*

The estimated exposure of poultry to fluroxypyr residues is expected to remain low, and not result in any detectable residues in poultry tissues and eggs. The current egg MRL of *0.01 mg/kg and poultry offal and meat MRLs of *0.05 mg/kg remain appropriate.

**Estimated human dietary intake**

Aminopyralid

The chronic and acute dietary intake estimates of aminopyralid have been assessed. The National Estimated Daily Intake (NEDI) of aminopyralid is equivalent to <1% of the ADI of 0.3 mg/kg bw/day. With respect to acute dietary intake, the highest acute dietary intake was estimated at <1% of the ARfD of 0.3 mg/kg bw/day. It is concluded that the chronic and acute dietary exposure to aminopyralid is low, and residues in food will not pose an undue hazard to the safety of people.

Fluroxypyr

The NEDI for fluroxypyr is equivalent to <1% of the ADI of 0.2 mg/kg bw/day. There is no ARfD established for fluroxypyr. It is concluded that fluroxypyr residues in food do not pose an undue hazard to the safety of people.

**Bioaccumulation potential**

Aminopyralid

The log $P_{OW}$ for aminopyralid is 0.201 and residues of aminopyralid are not expected to accumulate in fatty tissues. In depuration studies conducted on lactating cows, aminopyralid residues declined quickly in all tissues, including fat.

Environmental fate data indicate that aminopyralid residues dissipate effectively in soil ($t_{1/2}$ < 1 year). Soil residue levels were between 3-15% of the initial level following harvest of a cereal crop. It is concluded that aminopyralid is not a bioaccumulatory or bio-retentive compound.

Fluroxypyr

The log $P_{0W}$ for fluroxypyr is –1.24 (unstated pH) and the log $P_{0W}$ for fluroxypyr methylheptyl ester is 4.53. There is a slight tendency of residues to concentrate in the fat as indicated by results from the dairy cow feeding study.

**Recommended amendments to the MRL Standard:**

**Table 1**

| Compound | Food | | MRL (mg/kg) |
|---|---|---|---|
| ADD: | | | |
| **Aminopyralid** | GC 0080 | Cereal grains | 0.1 |
| | MO 0105 | Edible offal (mammalian) [except kidney] | 0.02 |
| | PE 0112 | Eggs | *0.01 |
| | | Kidney (mammalian) | 0.3 |
| | MM 0095 | Meat (mammalian) | *0.01 |
| | ML 0106 | Milks | *0.01 |
| | PM 0110 | Poultry meat | *0.01 |
| | PO 0111 | Poultry, edible offal of | *0.01 |
| | CM 0654 | Wheat bran, unprocessed | 0.3 |
| **Fluroxypyr** | | | |
| DELETE: | MO 0105 | Edible offal (mammalian) | 2 |
| | MM 0095 | Meat (mammalian) | 0.1 |
| ADD: | MO 0105 | Edible offal (mammalian) [except kidney] | 0.1 |
| | | Kidney (mammalian) | 1 |
| | MM 0095 | Meat (mammalian) [in the fat] | 0.1 |

**Table 3**

| Compound | Residue |
|---|---|
| ADD: | |
| **Aminopyralid** | Commodities of plant origin: Sum of aminopyralid and conjugates, expressed as aminopyralid.<br>Commodities of animal origin: Aminopyralid. |

**Table 4**

| Compound | Animal feed commodity | | MRL (mg/kg) |
|---|---|---|---|
| ADD: | | | |
| **Aminopyralid** | AF 0081 | Forage of cereal grains | 3 |
| | AS 0081 | Straw and fodder of cereal grains (dry) | 0.2 |
| | | Mixed pastures (leguminous/grasses) | 200 |
| **Fluroxypyr** | | | |
| DELETE: | | Mixed pastures (leguminous/grasses) | 150 |

| | | |
|---|---|---|
| ADD: | Mixed pastures (leguminous/grasses) | 700 |

The above MRLs in Table 1 and residue definition in Table 3 will be conveyed to Food Standards Australia New Zealand for inclusion in the Food Standards Code.

The following withholding periods are required in conjunction with the above MRLs:

Withholding periods:
*Cereals (barley, oats, triticale and wheat):*
Harvest: NOT REQUIRED when used as directed.
Grazing and Cutting for Stock Food: DO NOT graze or cut crops for stock food for 7 days after application.

*Pasture:*
Cutting or Grazing Pastures for Stock Food: NOT REQUIRED when used as directed.

## ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

### Commodities exported and main destinations

The major export commodities that may be affected by the proposed use of Hotshot Herbicide are cereal grains of wheat, barley, triticale, and oats. Additionally, beef and dairy exports may be affected as a result of livestock feeding on treated produce, such as pasture, cereal forage or grain.

Cereal grains

Australian wheat production in 2003-04 was 24,920 ktonne, of which 15,188 ktonne was exported at a value of $3.75 billion. The 5 largest export markets for Australian wheat by volume is shown below (Australian Commodity Statistics 2004).

| Destination | Volume, kt |
|---|---|
| Indonesia | 2647 |
| Egypt | 2534 |
| Japan | 1250 |
| Iraq | 1111 |
| Korea | 1065 |
| Total | 15188 ($3,475M) |

Production volume of other cereal grains is shown below. However, details of the export quantity were not available (Australian Commodity Statistics 2004).

| Cereal grain | Volume, kt |
|---|---|
| Barley | 8625 |
| Oats | 1520 |
| Triticale | 674 |

Beef

Australia exported 860 kilo tonnes of beef in 2003, with an estimated value of $3792 M. The major export markets for beef and veal include USA, Japan, Republic of Korea, Canada, Chinese Taipei, Philippines, and Indonesia (Australian Commodity Statistics, 2004).

Dairy

Australia exported 2179 kt of dairy produce in 2003, with an estimated value of $2179 M. Major export markets for dairy products include Japan, Saudi Arabia, United Kingdom, USA, Egypt, Philippines, Malaysia, Chinese Taipei, and Singapore (Australian Commodity Statistics, 2004).

### Overseas registration status

Aminopyralid

Aminopyralid has been approved in USA (August 2005) for control of weeds in cereals and pastures. The USA has established the following tolerances/ MRLs for aminopyralid. The applicant states that aminopyralid is pending approval in Canada and in the EU.

USEPA tolerances / MRLs for aminopyralid

| Commodity | USA MRL/Tolerance (mg/kg) |
|---|---|
| Mammalian fat (cattle, goat, horse, sheep) | 0.02 |
| Mammalian kidney (cattle, goat, horse, sheep) | 0.3 |
| Mammalian meat (cattle, goat, horse, sheep) | 0.02 |
| Mammalian meat by-products, excluding kidney (cattle, goat, horse, sheep) | 0.02 |
| Milk | 0.03 |

| | |
|---|---|
| Wheat grain | 0.04 |

Fluroxypyr

Fluroxypyr is approved in Australia and in overseas countries for use on cereal grains and pasture (ie Starane 200 Herbicide by Dow Agrosciences Limited). In the current proposal for Hotshot Herbicide, residues of fluroxypyr in export commodities are not expected to vary significantly from the current situation. Accordingly, there are unlikely to be any additional residues in trade issues with respect to fluroxypyr.

**Codex Alimentarius Commission CXLs (ie Codex MRLs)**

The Codex Alimentarius Commission (Codex) through the Codex Committee on Pesticide Residues (CCPR) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries and some countries may accept Codex CXLs when importing foods.

No Codex MRLs are established for aminopyralid or fluroxypyr. Aminopyralid is scheduled for review by JMPR in October 2006 and interim MRLs will be in the step process for ratification by the Codex Alimentarius Commission in 2007.

**Potential risk to Australian export trade**

Export of treated produce containing finite (measurable) residues of aminopyralid or fluroxypyr may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Aminopyralid

*Australian grain export*

Residue data show that grain (wheat, barley, triticale, and oats) from crops treated with aminopyralid may have low levels of residues when harvested. The proposed Australian cereal grain MRL of 0.1 mg/kg may potentially impact upon the export of Australian cereal grain in countries which do not have a standard or the equivalent standard is lower. The USA has established a wheat grain MRL/tolerance of 0.04 mg/kg, which is lower than the Australian standard. There are no other known standards established for aminopyralid. It is anticipated that interim Codex MRLs will be established in 2007. The APVMA welcomes comment in relation to whether aminopyralid residues will unduly prejudice Australian trade in wheat and other cereal grains.

*Australian meat exports*

The APVMA has considered the trade statement for livestock that have been exposed to Hotshot Herbicide through grazing or feeding of treated cereal crops or pastures.

When Hotshot Herbicide is used in accordance with label directions and treated crops are grazed or fed to livestock, detectable residues may be found in kidney and/ or liver commodities. Residues below the LOQ are expected in meat, milk and fat. Depuration data in the cattle feeding study show that after 3 days on clean feed, the equivalent maximum residue expected in liver is ND and kidney of <<0.01 mg/kg. These data support an ESI of 3 days for livestock exposed to aminopyralid residues in the feed when destined for overseas meat markets.

Residue decline data in pasture were available to determine an appropriate period of time after treatment when an ESI was not required. Based upon an estimated half-life of 14 days, maximum

residues in pasture declined from ~9 mg/kg at 28 days (2 half-lives) to ~2mg/kg at 56 days (4 half-lives). At a feed intake of ~4 ppm, no detectable residues are expected to occur in animal tissues and this occurs at 42 days after treatment (ie ~ 3 half-lives). As clearance of aminopyralid from animal tissues is rapid, 42 days (6 weeks) of continuous grazing will be conservative enough to ensure that no detectable residues will be found in any edible tissues. These data support a 42 day export grazing interval (EGI) and a 42 day export animal feed interval (EAFI). The export intervals will be applicable to both pasture and cereal forage crops following use of Hotshot Herbicide. The export intervals are not applicable to grain or straw animal feeds.

The following trade statements are supported with respect to feeding treated produce to livestock destined for export markets:

LIVESTOCK DESTINED FOR EXPORT MARKETS
The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, that the export slaughter interval, export grazing interval or export animal feed interval are observed before stock are sold or slaughtered.

EXPORT SLAUGHTER INTERVAL (ESI) – 3 days.
After observing the grazing withholding period, livestock that have been grazing on treated crops should be placed on clean feed for 3 days prior to slaughter.

EXPORT GRAZING INTERVAL (EGI) – 42 days
Livestock that has been grazing on treated crops or pasture should not be sold for export slaughter for 42 days (6 weeks) after application of the chemical product, unless the export slaughter interval has been observed.

EXPORT ANIMAL FEED INTERVAL (EAFI) – 42 days
Do not cut treated crops for 42 days (6 weeks) after application of the chemical product for stock feed for animals intended to be slaughtered for export.

When Hotshot Herbicide is used in accordance with the withholding periods and ESI/ EGI/ EAFI instructions, no detectable residues of aminopyralid are likely to be found in meat and meat by-products (ie offal). The trade risk posed by aminopyralid residues to the meat industry is expected to be low. The APVMA welcomes comment on the potential trade implications to the meat industry when livestock are exposed to aminopyralid residues.

*Australian dairy exports*
No detectable residues of aminopyralid are likely to occur in milk and milk products when Hotshot Herbicide is used in accordance with the withholding periods. The USA has established an aminopyralid tolerance/MRL of 0.03 mg/kg in milk. As no detectable residues will occur in milk, the risks to the dairy export industry are expected to be low. The APVMA welcomes comment on trade implications for the dairy industry when livestock are exposed to aminopyralid residues.

<u>Fluroxypyr</u>
The existing fluroxypyr MRL of 0.2 mg/kg for cereal grains is adequate to account for the proposed use Hotshot Herbicide. The current fluroxypyr feed MRL of 150 mg/kg is being amended to 700 mg/kg. However, livestock exposure to fluroxypyr animal exposure is expected to be ~200 ppm following the use of Hotshot Herbicide.

Based upon fluroxypyr animal transfer data, the current Edible offal MRL of 2 mg/kg is amended to MRLs for Kidney (mammalian) of 1 mg/kg and Edible offal (mammalian) [except kidney] of 0.1

mg/kg. The mammalian meat MRL of 0.1 mg/kg is amended to Meat (mammalian) [in the fat] of 0.1 mg/kg. The existing animal commodity MRLs for milk (0.1 mg/kg), eggs (*0.01 mg/kg), poultry offal and meat (*0.05 mg/kg) remain appropriate. The amended animal commodity MRLs are not expected to unduly impact upon the trade situation with respect to fluroxypyr residues in cereal grains or animal commodities.

## OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

**Formulation, packaging, transport, storage and retailing**

The product will be formulated by the DuPont Australia Ltd formulation plant at Girraween, NSW and the Dow AgroSciences NZ Ltd formulation plant at New Plymouth, New Zealand. It will be available in 5, 10, 20 and 110 L containers.

**Use and exposure profile**

Hotshot Herbicide is intended to be used for the control of weeds in barley, oats, triticale and wheat and to control woody weeds in agricultural non-crop areas, commercial and industrial areas, forests, pastures and rights-of-way.

When controlling weeds in crops, the product is to be used at 500 - 750 mL/ha with a minimum spray volume of 80 L/ha. When controlling weeds in other situations, it is to be used at 500 - 700 mL/100 L water with 3000 L/ha maximum spray volume.

In broadacre cropping situations and pastures, Hotshot Herbicide will be applied with a boom sprayer. In non-crop areas, commercial and industrial areas and right-of-way, the product will be applied using knapsack or hand application equipment. In woody weed situations, the recommended mix is to be applied as a coarse to very coarse quality spray with a spray volume of 3000 L water/ha.

Workers may be exposed to the product during mixing/loading, application, cleaning up spills and maintaining equipment. The main routes of exposure to the product are expected to be dermal and inhalational, although ocular exposure may also occur.

There are no worker exposure studies on aminopyralid or fluroxypyr available for assessment. Therefore standard models (POEM, PHED) were used to estimate worker exposure to the active constituents during mixing/loading and application for both ground boom and hand-held (knapsack) application.

**Risks to workers during use**

*Acute risks*

The acute hazards associated with the product are severe eye irritation and moderate skin irritation. During application, the product will be diluted to concentrations less than 1%. At these lower concentrations, the spray is unlikely to cause eye or skin irritation. However there are no data to confirm this and it seems prudent to assume that both the undiluted product and the spray have irritant properties.

*Repeat dose risks*

The NOEL used for aminopyralid was based on a toxicology report (May 2005) for aminopyralid, which identifies a NOEL of 26 mg/kg bw/d, based on maternal toxicity (incoordination) in a rabbit developmental study. This NOEL was the lowest observed, which makes it suitable for all OH&S considerations. Route-to-route extrapolations usually involve a consideration of the internal dose, and in the case of oral-to-dermal extrapolation this involves taking into account the extent of absorption across the gastrointestinal (GI) tract following oral administration. About 50% of an

oral dose of aminopyralid is absorbed. Therefore the GI-absorption adjusted NOEL is 0.5 x 26 = 13 mg/kg bw/d. The NOEL used for fluroxypyr was the same as that used in a previous occupational health and safety assessment for another product containing fluroxypyr, namely, 20 mg/kg bw/d. This was based on a 90 day dietary study with effects on the thyroid and kidney.

No dermal absorption studies for aminopyralid are available. Consequently, a default value for dermal absorption should be used in assessments of exposure when using the product. A 28 day dermal study in rats found a NOEL of 100 mg/kg bw/d based on a LOEL of 500 mg/kg bw/d associated with very slight chronic focal inflammation of the liver in males. The NOELs from oral studies of the same duration were comparable. Therefore data from toxicological studies is consistent with dermal absorption being at least comparable to oral absorption. A default figure of 100% absorption was therefore used.

No dermal absorption studies have been provided for fluroxypyr. The occupational health and safety assessment for another product containing fluroxypyr used a default dermal absorption factor of 10% based on its low acute dermal toxicity. Also, a 21 day dermal toxicity study in rabbits with doses of fluroxypyr up to 1000 mg/kg bw/d did not indicate any toxicity.

OCS utilised the margin of exposure (MOE) approach in the calculation of risks to workers exposed to the two actives in the product. The MOE is the ratio of the NOEL to the expected daily dose, calculated from the exposure models (POEM, PHED). MOEs of 100 or more are considered acceptable, to allow for interspecies and intraspecies variability.

*Personal protective equipment*

The acute risks identified were moderate skin irritation and severe eye irritation from both the undiluted product and the spray. Accordingly, personal protective equipment (PPE) recommended included cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and goggles to be used when opening the container, preparing the spray and using the prepared spray. Repeat dose risks from both aminopyralid and fluroxypyr were considered. In the case of both actives, MOEs were adequate (>100) even without the use of gloves, according to PHED modelling. However POEM modelling indicated that gloves would be required to achieve acceptable MOEs for both actives and both application methods. Therefore, gloves were recommended when preparing and using the spray. (Gloves were part of the PPE already required because of the acute risks.)

**Entry into treated areas**

No re-entry statement is required because the use situation is either to spray cereal crops at an early stage of development or to spray lantana in pastures, rights-of-way, commercial and industrial areas; and there is no reason for people to enter treated areas immediately after spraying.

## CONCLUSIONS

Hotshot Herbicide can be used safely if handled in accordance with the instructions and safety directions on the product label and in accordance with relevant OHS and public health standards and regulations. There are no objections on toxicological and occupational health grounds to the registration of Hotshot Herbicide

# ENVIRONMENTAL ASSESSMENT

## Environmental exposure

Environmental exposure to aminopyralid will primarily involve the soil in treated areas. Aminopyralid will largely remain in soil pore water because of its hydrophilicity, with some potential for aquatic exposure but very limited atmospheric exposure. Residues entering aquatic environments will partition only slowly to sediment and will not bioaccumulate in fish.

Aminopyralid is hydrolytically stable but photolyses rapidly in solution and at a more moderate rate on the surface of soils. The main mode of degradation in the environment is expected to be microbial metabolism in soils, where aminopyralid is likely to be slightly to moderately persistent (typical half-lives of a week to 3 months under laboratory conditions). Microbial metabolism can be slow in some soils and appears generally to be very slow (half-lives well above a year) in aquatic systems, although as noted above rapid photolysis can be expected in sunlit waters. There are no significant breakdown products as the slow initial degradation leads rapidly to complete mineralisation via dechlorination and ring cleavage, or to inactive soil-bound residues.

Aminopyralid is classified as very highly mobile based on its sorptive behaviour in the laboratory. In the field, mobility is limited by the relatively rapid degradation (typical field half-lives in the order of a month) such that quantifiable residues are largely confined to the upper 30 cm of the soil profile.

## Environmental effects

Testing indicates that aminopyralid is a typical water-soluble herbicide in being practically nontoxic to birds, aquatic organisms, insects and soil-dwelling organisms, but highly toxic to some terrestrial plants.

Survival, growth and reproduction in bobwhite quail and mallard ducks were not affected by acute oral or by subacute or chronic dietary exposures to aminopyralid.

No harmful effects were seen from acute exposures in rainbow trout, bluegill sunfish, sheepshead minnow, leopard frog tadpoles, *Daphnia magna,* mysid shrimp and eastern oysters. Similarly, there were generally no harmful effects from chronic exposures of *Daphnia magna* and midge larvae. Emergence of the latter was reduced at very high exposures (500 and 1000 mg/L) but this effect appears to be related to low pH associated with the acidity of aminopyralid. The most sensitive endpoint was a NOEC of 1.36 mg/L from early life stage testing in fathead minnows. As with the midge test, acidity appears to be largely responsible for the slight acute toxicity that was seen in testing with aminopyralid in green algae, blue-green algae and freshwater diatoms. No such toxicity was seen in green algae exposed to the TIPA salt, or to marine diatoms exposed to aminopyralid in seawater with its greater buffering capacity. The growth of duckweed was not harmed by exposure to aminopyralid.

Testing with honeybees, earthworms, parasitic wasps and predatory mites found no harmful effects from exposure to aminopyralid. Soil microbial function remained unaffected by aminopyralid, even at highly exaggerated exposures.

Testing with a range of plants found that some dicotyledonous plants are highly sensitive to

aminopyralid, particularly with foliar exposure as seedlings. Vegetative vigour in soybean seedlings was impaired at rates in the order of 1 g/ha.

**Environmental risk assessment**

The predicted residues of aminopyralid on vegetation and in soil are well below levels that might cause harmful effects in birds and soil dwelling organisms. Similarly, the predicted exposure of bees to spray will be well below levels that could be harmful.

The main risk arising from the proposed use of aminopyralid is its potential to cause phytotoxicity in nontarget plants. For example, legumes are likely to be sensitive to application rates in the order of 1 g/ha. The draft label warns that legumes present in the crop will be killed at the time of spraying and that their regeneration or establishment may be adversely affected by soil residues in the following season.

Spray drift may harm sensitive nontarget plants where it exceeds about 1 g/ha. This is unlikely to be an issue with the low rates (5-7.5 g/ha) applied in cereals. Although higher rates are required for woody weeds, the draft label recommends use of a coarse to very coarse spray that will minimise any spray drift. Strict instructions to minimise spray drift are included on the draft label. Similar instructions are included to minimise off target movement of aminopyralid in runoff or through movement of soils, vegetation or manure.

The predicted residues of aminopyralid in shallow water contaminated by direct overspray are well below concentrations that could be harmful to fish, tadpoles, aquatic invertebrates, algae or aquatic plants. The risk of aminopyralid to aquatic life is assessed as minimal.

# EFFICACY AND SAFETY ASSESSMENT

**Justification for use**

Hotshot Herbicide is to be used for the post emergence control of climbing buckwheat and other broadleaf weeds in winter cereals, and lantana and other woody weeds in pastures and non pasture situations. This use is justified if the issue of resistance is considered to be a major factor in determining the reasons for releasing the product. Broadleaf weeds can be a major problem in cereal production and it could be argued that there should be as many chemical groups available to rotate into the production to reduce the development of resistance.

**Adequacy of efficacy data:**

The trials were very comprehensive and were more than adequate. The inclusion of various crop establishment and management options gave valuable information as to the residual problems that my be encountered as well as the limitations the product has in the Southern and Western Australian cropping rotational systems.

A small problem was encountered with cereal growth stage identification used for some of the experiments. In some experiments the growth stage was recorded under Zadok scoring while in others an in house system using an identical growth stage but different coding has been used. This did cause some initial confusion to the reviewer.

Experimental conditions were satisfactory although a couple of experiments had very low weed burdens, such as those for bindweed and prickly lettuce.

Analysis of trial data was satisfactory and conclusions as a result should give a workable interpretation for applying the instructions contained on the label.
Trial validation was satisfactory.

**Conclusions drawn from the assessment of the data**

Sufficient data has been provided to show Hotshot Herbicide will be effective for the post emergence control of climbing buckwheat, and other broadleaf weeds in winter cereals and lantana and other woody weeds in pastures and non pasture situations.
Data was well set out apart from the minor problem mentioned regarding interpretation of cereal growth stages, was easily read and understood.

It is recommended that on the basis of efficacy and crop safety Hotshot Herbicide be considered for registration.

# CAUTION

**KEEP OUT OF REACH OF CHILDREN**

**READ SAFETY DIRECTIONS BEFORE OPENING OR USING**

# Hotshot*

## Herbicide

**ACTIVE CONSTITUENTS:** **10 g/L AMINOPYRALID present as triisopropanolamine salt**
**140 g/L FLUROXYPYR present as methylheptyl ester**

**SOLVENT:** **418 g/L LIQUID HYDROCARBON**

**GROUP I HERBICIDE**

**For the control of climbing buckwheat and other broadleaf weeds in winter cereals, lantana and certain other pasture weeds.**

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

**Contents:** 5, 10, 20 L 110L

**Dow AgroSciences Australia Limited**
A.B.N. 24 003 771 659
Level 5, 20 Rodborough Road
Frenchs Forest NSW 2086
www.dowagrosciences.com.au

**CUSTOMER SERVICE TOLL FREE** **1-800 700 096**

* Trademark of Dow AgroSciences

*Back Label for 5 L, 10 L, 20 L*

**STORAGE AND DISPOSAL**

- Store in the closed, original container in a cool, well ventilated area.
- **DO NOT** store for prolonged periods in direct sunlight.
- **DO NOT** store near food, feedstuffs, fertilisers or seed.

- **Recycled containers (5, 10 and 20L):**
  This container can be recycled if it is clean, dry, free of visible residues and has the drumMUSTER logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate by adding to the spray tank. Do not dispose of undiluted chemicals on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management site. The cap should not be replaced but may be taken separately.

- **Non-recycled containers (5, 10 and 20L):**
  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 500mm 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.

## SMALL SPILL MANAGEMENT

Wear protective equipment (See SAFETY DIRECTIONS). Apply absorbent material such as earth, sand, clay granules or cat litter to the spill. Sweep up material for disposal when absorption is completed and contain in a refuse vessel for disposal (see STORAGE AND DISPOSAL section). If necessary wash the spill area with an alkali detergent and water and absorb as above the wash liquid for disposal as described above.

## SAFETY DIRECTIONS

- Will damage the eyes.
- Will irritate the skin.
- Avoid contact with eyes and skin.
- If product in eyes, wash it out immediately with water.
- If product on skin immediately wash area with soap and water.
- Wash hands after use.
- When opening the container, preparing the spray and using the prepared spray wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and goggles.
- After each day's use, wash gloves, goggles and contaminated clothing

## FIRST AID

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

(Ph: Australia 13 11 26)

- If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

## MATERIAL SAFETY DATA SHEET

*Back label for 5, 10, 20L*

Additional information is listed in the Material Safety Data Sheet for Hotshot Herbicide which is available from Dow AgroSciences on request. Call Customer Service Toll Free on 1-800 700 096 or visit www.dowagrosciences.com.au

**NOTICE**

Seller warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. No warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of the product contrary to label instructions or under off-label permits not endorsed by Dow AgroSciences, or under abnormal conditions.

**EMERGENCY RESPONSE**
(All Hours)
RING FROM ANYWHERE IN AUSTRALIA
1-800 033 882
(LOCAL CALL FEE ONLY)


IN A TRANSPORT EMERGENCY ONLY
DIAL 000
FOR POLICE OR FIRE BRIGADE

Barcode for stock identification

D.O.M/Batch No.:

APVMA Approval No.: xxxx/5L, 10 & 20L/xxxx
GMID:

## STORAGE AND DISPOSAL

- Store in the closed, original container in a cool, well ventilated area.
- DO NOT store for prolonged periods in direct sunlight.
- **DO NOT** store near food, feedstuffs, fertilisers or seed.

- **Returnable containers (110L):**

  Do not tamper with the dry valves or security seal. Do not contaminate the drum with water or any other foreign matter. After each use of the product ensure that the dry valve coupler, delivery system and hoses are disconnected, triple rinsed with clean water and drained. Add the rinsings to the spray tank. When the drum is empty close all valves and return to the point of purchase. The drum remains the property of Dow AgroSciences and must be returned.

## SAFETY DIRECTIONS

- Will damage the eyes.
- Will irritate the skin.
- Avoid contact with eyes and skin.
- If product in eyes, wash it out immediately with water.
- If product on skin immediately wash area with soap and water.
- Wash hands after use.
- When opening the container, preparing the spray and using the prepared spray wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and goggles.
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RING FROM ANYWHERE IN AUSTRALIA
1-800 033 882
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IN A TRANSPORT EMERGENCY ONLY
DIAL 000
FOR POLICE OR FIRE BRIGADE

Barcode for stock identification

D.O.M/Batch No.:

APVMA Approval No.: xxxx/110L/xxxx GMID

# CAUTION

**KEEP OUT OF REACH OF CHILDREN**

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# Hotshot*

## Herbicide

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* Trademark of Dow AgroSciences

**DIRECTIONS FOR USE**

**RESTRAINTS:**

**DO NOT** apply to crops or weeds which are not actively growing or to plants which may be stressed (not actively growing) due to prolonged periods of extreme cold, moisture stress (water-logged or drought affected) or previous herbicide treatment, as crop damage or reduced levels of control may result.

**DO NOT** spray if rain is likely to occur within one hour.

**AVOID** double overlaps to reduce risk of injury to rotational crops the following season.

**DO NOT** apply by aerial application.

**Table 1: Northern New South Wales and Queensland**

| CROP | CROP GROWTH STAGE | WEEDS CONTROLLED | WEED GROWTH STAGE | RATE /ha | CRITICAL COMMENTS |
|---|---|---|---|---|---|
| Barley, Oats, Triticale, Wheat | Apply from 3 leaf to first node (Z13 to Z31). | Climbing buckwheat (black bindweed) | Seedling up to 2 leaf. | 500 mL | |
| | | Climbing buckwheat (black bindweed)<br>Prickly lettuce<br>Volunteer chickpea<br>Volunteer faba bean<br>Volunteer field pea | Seedling up to 6 leaf. | 750 mL | |
| | | Deadnettle<br>Wireweed | Seedling up to 4 leaf. | 750 mL + 5 g of 600 g/kg metsulfuron | DO NOT USE in oats.<br>Add a 100% concentrate non-ionic surfactant (e.g. BS-1000®) at the rate of 100 mL/100 L water. |
| | Apply from 4 leaf to first node (Z14 to Z31). | Common sowthistle<br>Mustards<br>Turnip Weed<br>Volunteer canola | | 750 mL + 500 or 700 mL MCPA LVE | Use the higher rate of MCPA LVE only from 5 leaf cereal growth stage onwards. |

**Table 2: Southern New South Wales, Victoria, South Australia and Western Australia.**

| CROP | CROP GROWTH STAGE | WEEDS CONTROLLED | WEED GROWTH STAGE | RATE /ha | CRITICAL COMMENTS |
|---|---|---|---|---|---|
| Barley, Oats, Triticale, Wheat | Apply from 3 leaf to first node (Z13 to Z31). | Volunteer faba bean<br>Volunteer field pea<br>Vounteer lupin<br>Volunteer vetch | Seedling up to 4 leaf. | 500 mL | **DO NOT** plant susceptible crops for 2 seasons after application, as specified in GENERAL INSTRUCTIONS - MINIMUM RECROPPING PERIODS. |

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**Table 3: Woody Weed Situations – High Volume Spraying.**

| AGRICULTURAL NON-CROP AREAS, COMMERCIAL AND INDUSTRIAL AREAS, FORESTS, PASTURES AND RIGHTS-OF-WAY. | | | | |
|---|---|---|---|---|
| **WEEDS CONTROLLED** | **WEED GROWTH STAGE** | **STATE** | **RATE 100 L Water** | **CRITICAL COMMENTS** |
| Lantana (*Lantana camara*) | Seedlings and regrowth from 0.5 to 1.2 m high | All States | 500 mL | Apply to actively growing plants from October to April. Spray to thoroughly wet all foliage, but not to cause run-off. |
| | Mature plants and regrowth from 1.2 to 2 m high | | 700 mL | |
| Cockspur thorn (*Maclura cochinchinensis*) | Up to 3 m high | All States | 700 mL | |
| Creeping lantana (*Lantana montevidensis*) | At flowering | | | |
| Crofton weed (*Ageratina adenophora*) Mistflower (*Ageratina riparia*) | Seedlings and young plants up to flowering. | | | |
| Docks (*Rumex* spp.) | Seedlings and rosettes up to 30 cm high. | | | |
| Small flowered mallow (Marshmallow) (*Malva parviflora*) | Seedlings and young plants up to flowering | | | |
| Wattles (including *Acacia aulacocarpa* *A. decora* *A. harpophylla* *A. leiocalyx* *A. salicina*) | Seedling plants or regrowth 0.5 to 1.2m high | | | Apply to actively growing plants when soil moisture is plentiful. Some regrowth may occur particularly when treating old woody plants with sparse canopies and under dry conditions. |

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

## WITHHOLDING PERIOD

Cereals (Barley , Oats Triticale and Wheat,):
Harvest: NOT REQUIRED when used as directed.
Grazing: DO NOT graze or cut crops for stock food for 7 days after application.

Pasture:
Cutting or Grazing Pastures for Stock Food: NOT REQUIRED when used as directed.

## LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, that the Export Slaughter Interval, Export Grazing Interval or Export Animal Feed Interval is observed before stock are sold or slaughtered.

## EXPORT SLAUGHTER INTERVAL (ESI) – 3 days:

After observing the grazing withholding period, livestock that has been grazed on or fed treated pasture should be placed on clean feed for 3 days prior to slaughter.

## EXPORT GRAZING INTERVAL (EGI) – 42 days.

Livestock that has been grazing on treated pasture should not be sold for export slaughter for 42 days (6 weeks) after application of the chemical product, unless the export slaughter interval has been observed.

**EXPORT ANIMAL FEED INTERVAL (EAFI) – 42 days**

Do not cut treated pasture for 42 days (6 weeks) after application of the chemical product for stock feed or animals intended to be slaughtered for export.

When Hotshot Herbicide is used as directed and the above withholding periods and/or export intervals are observed, treated grain and livestock commodities are considered acceptable for export. However, export requirements are subject to change. Consult your exporter for updated information about specific market requirements.

# GENERAL INSTRUCTIONS

**MINIMUM RECROPPING PERIODS**

Aminopyralid remains active in the soil for extended periods depending on rate of application, soil type (clay content), rainfall, temperature, humidity, soil moisture and soil organic matter. The following tables show plantback periods to particular crops following application of Hotshot Herbicide in different areas in Australia.

**Southern New South Wales, Victoria, South Australia & Western Australia**

Plantback peiords for rotational crops following application of Hotshot Herbicide for rates up to 500 mL/ha

| Crop | Plantback Period (months) |
|---|---|
| Wheat | 4 |
| Barley | 4 |
| Canola | 4 |
| Faba bean | 20 |
| Chickpea | 20 |
| Lupin | 20 |
| Field pea | 20 |
| Lucerne | 20 |
| Medic | 20 |
| Sub clover | 20 |

**Northern New South Wales & Queensland**
Plantback peiords for rotational crops following application of Hotshot Herbicide for rates up to 750 mL/ha

| Crop | Plantback Period (months) |
|---|---|
| Wheat | 4 |
| Barley | 4 |
| Canola | 4 |
| Chickpea | 6 |
| Lucerne | 6 |
| Faba bean | 9 |

**Note**: Before using Hotshot Herbicide in tank mixes with other herbicides, check the plant-back information on all product labels. The most residual product, i.e. the product with the longest plant-back period, will determine the time between spraying and planting the next crop.

**MIXING**

- Hotshot Herbicide can be mixed with water only.
- Mix only sufficient chemical for each day use and avoid storing mix.
- Half fill the spray tank with water and add the required quantity of Hotshot Herbicide and complete filling. Agitate continuously to ensure thorough mixing before and during application.
- **Tank mixtures:** Wettable powder or dry flowable formulations (*e.g.* water dispersible granules) should be added to the spray tank first, followed by suspension concentrates (flowables), water soluble salts and then emulsifiable concentrate formulations (e.g. Starane* 200 Herbicide). Add spraying oils and surfactants (wetters) last, if required.

**COMPATIBILITY**
Hotshot Herbicide is compatible with the following:
(Read and follow all label directions, restraints, plant-back periods, withholding periods and safety directions on the partner label as well as those on the Hotshot Herbicide label).

**Broadleaf Herbicides**

MCPA LVE metsulfuron-methyl Starane* 200 Herbicide

**Grass Herbicides**

Topik® 240EC (wild oats only)

**Adjuvants**

BS-1000 (when mixed with metsulfuron-methyl)

Uptake* Spraying Oil (when mixed with Topik® 240 EC)

## APPLICATION METHODS

**Broadcast application in cropping situations.**

### A. Ground Application (Boom)

- Apply Hotshot Herbicide with an accurately calibrated boom sprayer, in at least 80 L/ha water.
- Use a medium quality spray as defined by ASAE (S572).
- Set the boom at a height to ensure a double overlap of the nozzle pattern.

Woody weed situations

### A. High Volume Application

- Apply the recommended mix to obtain full coverage of leaves and stems using a coarse to very coarse quality spray as defined by ASAE (S572) eg a number 6 – 8 spray tip at 700 to 1500 kPa. To obtain good coverage, a spray volume of 3000 L water/ha is required per treated hectare.
- Ensure thorough coverage to the point of runoff.

## CLEANING SPRAY EQUIPMENT

**Rinse water should be discharged onto a designated disposal area or, if this is unavailable, onto wasteland away from desirable plants and water courses.**

- **Rinsing:** After using Hotshot Herbicide, empty the tank completely and drain the whole system. Thoroughly wash inside the spray unit using a pressure hose. Drain, and clean any filters in the tank, pump, lines, hoses and nozzles

- After cleaning the tank as above, quarter fill with clean water and circulate through the pump, lines, hoses and nozzles. Drain and repeat the rinsing procedure twice.

- **Decontamination (before spraying cotton and other sensitive crops; see PROTECTION OF CROPS):** Wash the tank and rinse the system as above. Then quarter fill the tank and add a standard alkali based laundry detergent at 500 g (or mL)/100 L water and circulate throughout the system for at least 15 minutes. If using a concentrated laundry detergent use 250 g (or mL)/100 L water.and circulate throughout the system for at least 15 minutes. Do not use chlorine based cleaners.

- Drain the whole system. Remove filters and nozzles and clean them separately. Finally flush the system with clean water and allow draining.

## RESISTANT WEEDS WARNING

**GROUP I HERBICIDE**

Hotshot Herbicide contains members of the pyridine group of herbicides. The product has the disrupters of plant cell growth mode of action. For weed resistance management, the product is a Group I Herbicide.

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

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

Strategies to minimise the risk of herbicide resistance are available. Contact your farm chemical supplier, consultant, local Department of Agriculture, or local Dow AgroSciences representative.

## PROTECTION OF CROPS, NATIVES AND OTHER NON-TARGET PLANTS

- **DO NOT** use on land to be cultivated for growing susceptible crops for up to 24 months of applying Hotshot Herbicide. See MINIMUM RECROPPING Section under GENERAL INSTRUCTIONS. Legumes, vines, vegetables, cotton, tomatoes, ornamentals and many other plants are highly susceptible to this herbicide during both growing and dormant periods. Cereal crops, canola and grasses can be sown safely after using Hotshot Herbicide.
- This product will kill legumes (clovers, medics) present in the crop at the time of spraying. In the season, following application of this product the regeneration or establishment of sensitive legumes (clover, medics, peas, and lupins) may be adversely affected by soil residues.
- **DO NOT** allow spray drift onto sensitive native vegetation or susceptible crops, such as cotton, tomatoes, vines, fruit, potatoes, vegetables, ornamentals, tobacco, lupins and other legumes, safflower, sugar beet, hops, flowers or shade trees. **DO NOT** use under meteorological conditions or with spraying equipment likely to produce drift. Minimise spray drift by using low pressures and nozzles, which **DO NOT** give a fine droplet size.
- **DO NOT** apply close to or on areas containing roots of desirable vegetation, where treated soil may be washed to areas growing, or to be planted to desirable plants, or on sites where surface water from heavy rain can be expected to run off to areas containing or to be planted to susceptible crops or plants.
- **DO NOT** move soil, which may have been sprayed, to areas where desirable plants are to be grown.
- **DO NOT** apply Hotshot Herbicide to crops or pastures, which are intended to be cut for the production of compost or mulches to be used for with susceptible crops or plants. The use of straw, hay or other plant material treated with Hotshot Herbicide for composting or mulching susceptible crops may damage these crops. Do not use Hotshot Herbicide on plants that will be used to make mushroom substrate because if the substrate is not properly cured aminopyralid residues may remain in the spent substrate or the mushrooms.
- **DO NOT** use manure from animals grazing treated areas or feeding on treated hay on land used for growing broadleaf crops, ornamentals, orchards or other susceptible, desirable plants as injury to susceptible plants may occur.

## PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

- **DO NOT** contaminate streams, rivers or waterways with the chemical or used containers.

## STORAGE AND DISPOSAL

- Store in the closed, original container in a cool, well ventilated area
- DO NOT store for prolonged periods in direct sunlight.
- **DO NOT** store near food, feedstuffs, fertilisers or seed.

The method of disposal of the container depends on the container type. Read the STORAGE AND DISPOSAL instructions on the label that is attached to the container.

## SMALL SPILL MANAGEMENT

Wear protective equipment (See SAFETY DIRECTIONS). Apply absorbent material such as earth, sand, clay granules or cat litter to the spill. Sweep up material for disposal when absorption is completed and contain in a refuse vessel for disposal (see STORAGE AND DISPOSAL section). If necessary wash the spill area with an alkali detergent and water and absorb as above the wash liquid for disposal as described above.

## SAFETY DIRECTIONS

- Will damage the eyes.
- Will irritate the skin.
- Avoid contact with eyes and skin.
- If product in eyes, wash it out immediately with water.
- If product on skin immediately wash area with soap and water.
- Wash hands after use.
- When opening the container, preparing the spray and using the prepared spray wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and goggles.
- After each day's use, wash gloves, goggles and contaminated clothing

## FIRST AID

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

(Ph: Australia 13 11 26)

- If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

## MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet for Hotshot Herbicide which is available from Dow AgroSciences on request. Call Customer Service Toll Free on 1-800 700 096 or visit www.dowagrosciences.com.au

**NOTICE**

Seller warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. No warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of the product contrary to label instructions or under off-label permits not endorsed by Dow AgroSciences, or under abnormal conditions.

**EMERGENCY RESPONSE**
(All Hours)
RING FROM ANYWHERE IN AUSTRALIA
1-800 033 882
(LOCAL CALL FEE ONLY)

IN A TRANSPORT EMERGENCY ONLY
DIAL 000
FOR POLICE OR FIRE BRIGADE

Barcode
for stock
identification

APVMA Approval No. xxx//xxxx
GMID:

# 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

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Matthews, G.A. 1992, *Pesticide Application Methods*, 2nd ed., Longman, London.

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Australian Pesticides and Veterinary Medicines Authority 1997, *Ag Requirements Series: Guidelines for Registering Agricultural Chemicals*, APVMA, Canberra. (See footnote below)

Australian Pesticides and Veterinary Medicines Authority 1996, *MRL Standard: Maximum Residue Limits in Food and Animal Feedstuffs*, APVMA, Canberra. (See footnote below)

Australian Pesticides and Veterinary Medicines Authority 2001, *Ag Labelling Code—Code of Practice for Labelling Agricultural Chemical Products*, APVMA, Canberra. (See footnote below)

Footnote:
Updated versions of these documents are available on the APVMA website http://www.apvma.gov.au.

# APVMA PUBLICATIONS ORDER FORM

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

David Hutchison
Pesticides Division
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
Kingston ACT 2604

Alternatively, fax this form, along with your credit card details, to:
David Hutchison at 02 6272 3218.

Name (Mr, Mrs, Ms, Dr)_____

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I enclose payment by cheque, money order or credit card for $_____

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Signature_____ Date _____