Public Release Summary
on

Evaluation of the new active

CYHALOFOP-BUTYL

in the product

Barnstorm Herbicide

Australian Pesticides and Veterinary Medicines Authority

July 2005

Canberra
Australia

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

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INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the product *BARNSTORM HERBICIDE,* which contains the new active constituent cyhalofop-butyl. The product is proposed to be used for the post emergence control of barnyard grasses and silver top grass in rice.

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 cyhalofop-butyl, 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 **29 July 2005**. They should be addressed to:

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Applicant
Dow AgroSciences Australia Ltd

Product Details
It is proposed to register *BARNSTORM HERBICIDE* containing 285g/L of cyhalofop-butyl as an emulsifiable concentrate. The product will be imported fully formulated and packaged in 10L and 20L containers.

BARNSTORM HERBICIDE is a member of the aryloxyphenoxy group of herbicides. The product has the acetyl CoA carboxylase inhibitor mode of action. For weed resistance management *BARNSTORM HERBICIDE* is a Group A herbicide.

The rate of product use is 0.75-1L/ha. *BARNSTORM HERBICIDE* is proposed for registration in all states where rice is grown.

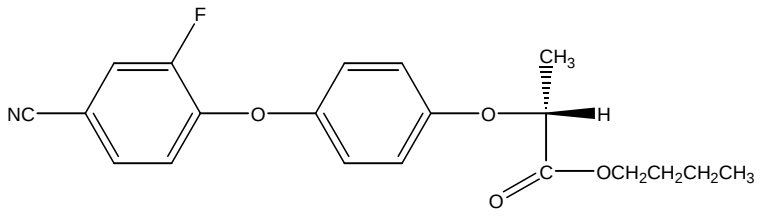
Formulations containing cyhalofop-butyl are currently registered in USA, EU (France, Italy, Greece, Spain etc), Japan and other Asian and South American countries.

CHEMISTRY AND MANUFACTURE

Cyhalofop-butyl is an aryloxyphenoxy propionate herbicide for post emergence control of barnyard grasses and silver top grass in rice. The active constituent will not be imported into Australia as the product will be formulated in New Zealand.

Active constituent

Common name (ISO):	Cyhalofop-butyl
IUPAC name:	Butyl (R)-2-[4-(4-cyano-2-fluorophenoxy) phenoxy] propionate
CAS Number:	122008-85-9
Molecular weight:	357.4
Molecular formula:	$C_{20}H_{20}FNO_4$
Physical form:	Fine granular solid
Colour:	Off-white/buff
Odour:	Faint almond like odour
Melting point	$45.5\text{-}49.5^0C$
Density:	$1.17 g/cm^3$
Vapour pressure at 25^oC:	5.3×10^{-5} pa
Structural formula:	



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

Formulated product

Product name	Barnyard Herbicide
Formulation type	Emulsifiable concentrate
Active constituent concentration	285g/L cyhalofop-butyl

Physical and Chemical Properties

Physical state	Liquid
Colour	Clear yellow liquid
PH	5.7
Bulk density	0.957-0.977 g/mL

Storage and Stability

Stability data for 2 weeks at 54^0C were provided for *BARNSTORM HERBICIDE* stored in fluorinated HDPE (commercial package). There was a slight decrease in a.c. (0.5%) but it

remained within the release specifications. The results for the appearance, density, pH, and emulsion characteristic of the product remained within specifications.

Packaging

Barnstorm Herbicide will be packaged in 5L 10L and 20L fluorinated HDPE industrial bottles. 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 *BARNSTORM 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 cyhalofop-butyl containing primarily 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

In rats, cyhalofop-butyl was rapidly and almost completely absorbed following oral dosing. Maximum plasma levels were attained within a few hours, which then declined rapidly. The highest concentrations were observed in the carcass and gastric contents, followed by the liver, whole blood, skin, muscle and kidney. Tissue levels declined rapidly with time reaching near detection limits at 24 h after treatment. The major metabolite in plasma, liver, bile, kidney, urine and faeces, was cyhalofop-butyl acid (66-78%) and a minor metabolite, 4-(4-cyano-2-fluorophenoxy) phenol. There were up to 4 further minor metabolites in plasma, liver, bile or kidney. Approximately 90-94% and 1-4% of the administered dose was eliminated in urine and faeces, respectively. Approximately 12-24% of the administered radioactivity was secreted in bile suggesting enterohepatic circulation. Of the amounts excreted in urine and faeces, approximately 99% was eliminated in 24 h. Absorption, distribution and elimination of cyhalofop-butyl was independent of the sex and dose administered, and was not affected by pre-treatment. Repeated dietary administration of cyhalofop-butyl resulted in similar kinetics.

Following a single oral dose, cyhalofop-butyl was rapidly absorbed in dogs. The maximum plasma levels were observed between 1-2 h after dosing, which then declined rapidly. The major metabolite in plasma, urine and faeces was cyhalofop-butyl acid and its decarboxylated, phenolic derivative [4-(4-cyano-2-fluorophenoxy) phenol]. There were up to 6 further minor, unidentified metabolites in plasma, urine and faeces accounting for about 7-15% of the total radioactivity in each of these medium. Both urine (43%) and faeces (50%) were major routes of elimination. Approximately 57% of the administered radioactivity was eliminated in 24 h.

Percutaneous absorption

In an *in* vitro study, absorption through human skin was under 1% for an undiluted formulation (200 g/L cyhalofop-butyl) and approximately 20% for a 1:500 dilution.

Acute Studies

Cyhalofop-butyl has low acute oral (LD_{50} >5000 mg/kg bw in mice and rats), dermal (LD_{50} >2000 mg/kg bw in rats) and inhalational toxicity (LC_{50} >5630 mg/m^3 in rats). It was a slight eye irritant, but not a skin irritant in rabbits. Cyhalofop-butyl was a not skin sensitiser in guinea pigs. No clinical signs were observed in rat oral toxicity studies with cyhalofop-butyl. In a rat acute inhalation toxicity study, bradypnoea, abnormal respiratory sounds and reddish

mucous material in the nasorostral periocular regions and wetted fur in the lower abdominal region were observed after the exposure period.

Based on the findings of acute toxicology studies with two similar products, and by extrapolation from the characteristics of the individual constituents in the product, it is expected that Barnstorm Herbicide would be of low acute oral, dermal and inhalational toxicity. It is likely to be a slight skin irritant and a severe eye irritant, but not to be a skin sensitiser.

Short-term Studies

Dogs received cyhalofop-butyl in the diet at 0, 35, 100 or 350 mg/kg bw/d for 4 weeks. There were no treatment-related mortalities. Significant decreases in food consumption accompanied by depressions in body weights were observed at 350 mg/kg bw/d. Abnormalities noted at necropsy included pale renal cortex in a male, each at the low- and mid-dose, and in males at the high-dose, dark foci in the gastric mucosa, and pale liver at the high-dose, and slight to severe thymic atrophy in all treatment groups. Histopathology showed bile duct hyperplasia in one or more dogs at all dose levels with accompanying inflammation, slight to moderate reduction of hepatic glycogen, diffuse fatty change and necrosis. Lesions in the kidney were characterised by partially or completely occluded lumen or veins with accompanying inflammation. There was a dose-related increase in the incidence of thymic atrophy involving one or more dogs in each group. Moderate to severe reduction of spermatogenesis and increase in multinucleated spermatids was seen in high-dose males. Based on bile duct hyperplasia and thymic atrophy in treated animals, no NOEL was established for this study.

In a dermal toxicity study, rats received occluded applications of cyhalofop-butyl at 0, 10, 100 or 1000 mg/kg bw/d on the clipped intact skin on the back for 6 h/d, 5 days/week for 4 weeks. Groups of 5 rats each from the control and high-dose groups were maintained for 2 more weeks to evaluate the reversibility of effects. There were no mortalities or clinical signs related to treatment. An increase in prothrombin time was observed in high-dose males. A decrease in serum cholesterol levels and increases in liver weight were observed at the high-dose. Histopathology revealed chronic inflammation in the liver at and above the mid-dose. Based on chronic inflammation in the liver at and above 100 mg/kg bw/d, the NOEL was 10 mg/kg bw/d.

Subchronic Studies

Mice received cyhalofop-butyl in the diet at doses of 0, 1 (males only), 3, 10, 30 or 100 (females only) mg/kg bw/d for 13 weeks. The study also included a satellite group of mice maintained at 0, 10 (males only), 30, 100 or 350 (females only) mg/kg bw/d for approximately 4 weeks. There were no treatment-related mortalities. A significant increase in alkaline phosphatase activity in males at 30 mg/kg bw/d, and serum cholesterol levels in females at 100 mg/kg bw/d were noted. Enlargement of the liver was seen in males at and above 30 mg/kg bw/d, and females at 350 mg/kg bw/d, with pale liver foci in one or more treated males and females at 350 mg/kg bw/d in the satellite group. Dose-related increases in liver weights were recorded at and above 10 mg/kg bw/d. Kidney weights showed slight, but statistically significant increases in females at 100 mg/kg bw/d. The liver weight changes were accompanied by hepatocellular hypertrophy in all mice at the same dietary levels. Based on liver weight increases and histopathological abnormalities at and above 10 mg/kg bw/d, the NOEL was 3 mg/kg bw/d.

Mice received cyhalofop-butyl in the diet at 0, 3, 30, 100 or 300 ppm (mean test substance intake was equal to 0, 0.37, 3.58, 12.4, 37.5 and 0.44, 4.25, 14.1, 41.4 mg/kg bw/d for males and females, respectively) for 13 weeks. There were no treatment-related mortalities. An increased incidence of perinasal region hair loss was seen in males at 300 ppm. Urinalysis

showed reduced pH and ketone levels in males at and above 30 ppm. At necropsy, increased incidence of dark coloured, enlarged livers were seen at and above 100 ppm. Significant increases in liver and/or kidney weights were noted at and above 30 ppm. Histopathology showed elevated incidence of liver and kidney abnormalities at and above 100 ppm. Renal tubular atrophy was increased in females at and above 30 ppm. Based on increased liver weights, and decreased urinary pH and ketone levels in males, and increased kidney weights, and renal tubular atrophy in females at and above 30 ppm, the NOEL was 3 ppm (0.37 mg/kg bw/d).

Cyhalofop-butyl in the diet was administered to rats at doses of 0, 3, 25, 100, 400 mg/kg bw/d or 0, 10, 100, 400 or 800 mg/kg bw/d for males and females, respectively, for 13 weeks. The study also included a satellite group of rats that were maintained at 0, 25, 400 (males only), 800 (females only) or 1600 mg/kg bw/d for approximately 4 weeks. There were no treatment-related mortalities. An increased incidence of perineal soiling was seen in males at 400 mg/kg bw/d and in females at and above 100 mg/kg bw/d. Body weight gain was depressed in females at 800 mg/kg bw/d. There were significant decreases in red blood cell counts, haemoglobin concentration and haematocrit value in males at and above 100 mg/kg bw/d. Serum albumin levels were elevated in males at the top dose and in females at and above 400 mg/kg bw/d, whilst serum globulin was decreased in both sexes at the top dose. Alkaline phosphatase activity was elevated at and above 100 mg/kg bw/d. Enlargement and pale foci in the liver were seen at 400 mg/kg bw/d. Significant and dose-related increases in liver weights were observed at and above 100 mg/kg bw/d and in males at 25 mg/kg bw/d. Kidney weights were increased significantly at the top dose. Histopathology showed diffuse or multifocal hepatocellular hypertrophy at and above 25 mg/kg bw/d. Based on increased weight and histopathological abnormalities in the livers of males at and above 25 mg/kg bw/d, the NOEL was 3 mg/kg bw/d.

Rats received cyhalofop-butyl in the diet at 0, 30, 300, 1000 or 3000 ppm (mean intake was equal to 1.72, 17.4, 60.5, 189.5 and 1.96, 19.6, 65.3, 199.6 mg/kg bw/d for males and females, respectively) for 13 weeks. There were no treatment-related mortalities. Males showed a decrease in haemoglobin concentration, and an increase in mean corpuscular volume at 3000 ppm, and a decrease in red blood cell counts and an increase in mean corpuscular haemoglobin level at and above 1000 ppm. In males, an increase in serum blood urea nitrogen and albumin/globulin ratio, and decreases in globulin and cholesterol values were noted at and above 300 ppm. Serum phosphorus and total protein levels were elevated at and above 1000 ppm and 3000 ppm, respectively. The alkaline phosphatase activity was increased, whilst the alanine aminotransferase and aspartate aminotransferase activities were decreased at and above 1000 ppm. Increases in serum albumin levels and albumin/globulin ratio at and above 1000 ppm, and a decrease in globulin at 3000 ppm were seen in females. Enlarged and/or dark in colour livers were seen at and above 1000 ppm, with dark in colour kidneys at 3000 ppm. The liver weights were elevated in males at and above 300 ppm, and in females at and above 1000 ppm. Absolute kidney weight was elevated in males at and above 300 ppm with the relative kidney weight being greater at and above 1000 ppm. In females, absolute kidney weights were increased at and above 1000 ppm, whilst the relative kidney was increased at 3000 ppm. Treatment-related histopathological lesions included hepatocellular swelling in males at and above 300 ppm and in females at 3000 ppm. Males at 3000 ppm showed pigmentation and decreased acidophilic bodies in the renal proximal tubules, but only the former was seen in females at this dose level. Based on significant alterations in clinical chemistry parameters, increased liver and kidney weights, and liver histopathological abnormalities in males at and above 300 ppm, the NOEL was 30 ppm (1.72 mg/kg bw/d).

Dogs received cyhalofop-butyl in the diet at 0, 100, 500 or 2500 ppm (mean test substance intake was equal to 0, 2.9, 14.7, 75.2 and 0, 3.2, 15.6, 79.4 mg/kg bw/d for males and females, respectively) for 13 weeks. There were no treatment-related mortalities. Increased incidences

of loose stools were seen in high-dose males and in females at and above the mid-dose during the latter part of the study. High-dose males showed a lower body weight gain. High-dose females had significantly reduced red blood cell counts, haemoglobin levels, increased platelet counts and a decrease in haematocrit value. Whilst serum bilirubin level was increased, triglycerides tended to be depressed at the high-dose. At necropsy, distended gall bladders were observed in females at the mid-dose, and in the majority of animals at the high-dose together with brown coloured atrophic thymuses. Liver weight tended to be increased at the high-dose, while thymus weights were markedly depressed at the high-dose. Mid-dose females showed increased incidence of cytoplasmic eosinophilia of hepatocytes. In addition, decreased glycogen content in the liver, thymic atrophy associated with depletion of the cortical lymphocytes, hyaline droplet degeneration of renal proximal tubular cells and epithelial hypertrophy and increased mucous secretion in the gall bladder were seen at the high-dose. Based on clinical signs, necropsy findings and histopathological abnormalities in the livers of females at and above the mid-dose, the NOEL was 100 ppm (2.9 mg/kg bw/d).

Chronic/Carcinogenicity Studies

Mice received cyhalofop-butyl in the diet at 0, 3, 10 or 100 ppm for 18 months (mean daily intake of cyhalofop-butyl was equal to 0, 0.3, 0.9, 10 and 0.3, 0.98, 10.3 mg/kg bw/d for males and females, respectively). There were no treatment-related mortalities. Increased incidences of enlarged dark in colour livers were seen in males at and above 10 ppm. In females, an increased incidence of dark in colour livers was seen at 100 ppm. Thickening of the wall of glandular stomach in males and an increased incidence of kidneys with coarse surfaces were observed in 100-ppm females. At 100 ppm, there were significant increases in liver weights in males throughout the study, and in females at 26 weeks. Tumour incidence was unaffected by treatment. Hepatocellular swelling with minute eosinophilic granules in males at and above 10 ppm and in females at 100 ppm, hyperplasia in the mucosal epithelium of the glandular stomach in 100 ppm males, chronic nephritis in females at 100 ppm, increased brown pigment deposition in the cortico-medullary junction of the adrenals in females at and above 10 ppm, and extra-medullary haematopoiesis in the spleen in 100 ppm males were observed. Based on hepatocellular swelling and histopathological abnormalities in the adrenals in females at and above 10 ppm, the NOEL was 3 ppm (equal to 0.3 mg/kg bw/d).

Rats received cyhalofop-butyl in the diet at 0, 3, 6, 24 or 100 ppm for males, and 0, 6, 60 or 600 ppm for females for 2 years (mean daily intake of cyhalofop-butyl was equal to 0, 0.1, 0.2, 0.8, 3.44 and 0, 0.2, 2.4, 25.0 mg/kg bw/d for males and females, respectively). There were no treatment-related mortalities or clinical signs. An increase in albumin/globulin ratio and a decrease in triglyceride levels in males at 100 ppm, and decreases in triglyceride and bilirubin levels in females at 600 ppm were noted. Incidence of macroscopic abnormalities in the liver and kidney were elevated in males at 100 ppm and females at 600 ppm. Females at 60 ppm showed a significant increase in the incidence of spots in the liver. Increases in the liver, kidney or spleen weights were recorded at 100 or 600 ppm at some observation times, but not at study termination. Tumour incidence was unaffected by treatment. An increase in brown pigment in renal proximal tubular cells was seen in 100 ppm males and 600 ppm females. Females at 600 ppm showed hepatocellular swelling and mineralisation in the kidney. Based on the increased incidence of spots in the livers of females at and above 60 ppm, the NOEL was 6 ppm (equal to 0.2 mg/kg bw/d).

Dogs received cyhalofop-butyl in the diet at 0, 50, 300 or 1800 ppm for 12 months (equal to approximately 0, 1.22, 7.6, 46.7 and 0, 1.3, 7.63, 45.9 mg/kg bw/d for males and females, respectively). There were no treatment-related mortalities. Body weight gain was depressed in males at and above 300 ppm. Significant differences were seen in some clinical chemistry variables at 1800 ppm at 26 weeks. These included a decrease in triglyceride levels in males, increases in bilirubin, phosphorus and a decrease in gamma-glutamyl transferase activity in

females. At necropsy, elevated incidences of gall bladders with black sandy contents were observed in females, as well as a distended gall bladder in a male at 300 ppm, and distended gall bladders with black sandy contents in both sexes at 1800 ppm. Discolouration of the liver and kidney were seen at 1800 ppm. Histopathology showed cytoplasmic eosinophilia in hepatocytes of dogs at 1800 ppm. Based on decreased body weight gain in males, and increased incidence of gall bladders with black sandy contents in females at and above 300 ppm, the NOEL was 50 ppm (equal to 1.2 mg/kg bw/d).

Reproduction Study

Rats received cyhalofop-butyl in the diet at 0, 10, 100 or 1000 ppm for 2 generations (mean intake was equal to approximately 0, 0.8, 7.8, 80 and 0, 0.9, 9.0, 92.2 mg/kg bw/d for males and females, respectively). There were no mortalities or clinical signs related to treatment. Increased incidences of enlarged and cloudy livers were seen in F1 adults at 1000 ppm. Significant increases in liver weights were seen in F0 and F1 adults at 1000 ppm. Kidney weights were increased in F0 males at 1000 ppm, and in F1 males at and above 100 ppm. Histopathology showed diffuse hepatocellular swelling in F0 and F1 adults, and swelling of renal tubular cells in F0 and F1 males at 1000 ppm. Because there were no treatment-related effects in any of the reproductive or foetal parameters tested, the NOEL for reproductive/foetotoxicity was >1000 ppm (92.2 mg/kg bw/d). Based on increased kidney weights in F1 males at and above 100 ppm, the overall NOEL for the study was 10 ppm (0.8 mg/kg bw/d).

Developmental Studies

Cyhalofop-butyl was administered to mated, female rats at 0, 25, 250 or 1000 mg/kg bw/d on days 6 through 15 post-coitum. There were no mortalities or clinical signs attributable to treatment. Food consumption was depressed at the high-dose during gestation days 6 through 12. Depressions in body weight were also seen at the high-dose. There were no external, soft tissue or skeletal alterations related to treatment. The NOEL for maternal toxicity was 250 mg/kg bw/d, based on decreased food consumption and weight gain at 1000 mg/kg bw/d. Because there were no treatment-related effects on any of the developmental toxicity parameters tested, the NOEL for developmental toxicity was >1000 mg/kg bw/d.

Cyhalofop-butyl was administered to artificially inseminated, female rabbits at 0, 40, 200 or 1000 mg/kg bw/d on days 6 through day 18 post insemination. Nine does at 1000 mg/kg bw/d died during or after the dosing period. One doe at 200 mg/kg bw/d died after the dosing period, and another aborted on day 25 of gestation. Haematuria was seen at and above 200 mg/kg bw/d. Decreases in food consumption were seen during gestation days 14 through 18 together with a slight decrease in body weight gain at 1000 mg/kg bw/d during gestation days 11 through 18. Necropsy showed cloudy or dark coloured kidneys at and above 200 mg/kg bw/d. The number of implantations, and therefore, of live foetuses were decreased, whilst the foetal body weight was increased at 1000 mg/kg bw/d. The incidence of skeletal abnormalities and variations was greater at 200 mg/kg bw/d. Based on increased number of litters with foetuses at 200 mg/kg bw/d having skeletal abnormalities and variations, the NOEL for developmental toxicity was 40 mg/kg bw/d. The NOEL for maternotoxicity was also 40 mg/kg bw/d, based on mortality, abortion, haematuria, and cloudy or dark coloured kidney at and above 200 mg/kg bw/d.

Genotoxicity Studies

The genotoxicity of cyhalofop-butyl has been examined in four *in vitro* genotoxicity studies including the Ames test, gene mutation test and DNA repair and chromosome aberration assay in Chinese hamster lung cells, and an *in vivo* micronucleus assay. Of these, an *in vitro* chromosome aberration assay conducted with Chinese hamster lung cells yielded increased frequencies of polyploid metaphases in the absence of metabolic activation. However, no chromosomal aberrations were observed in the study, and hence, cyhalofop-butyl is not genotoxic.

Neurotoxicity Studies

n an acute neurotoxicity study, groups of rats received a single dose of cyhalofop-butyl by oral gavage at 0, 200, 600 or 2000 mg/kg bw. The animals were tested using functional observational battery (FOB) and motor activity test protocols for neurotoxicity, including neuropathology. There were no mortalities or clinical signs or effects on any of the parameters tested related to treatment. Histopathology did not reveal any treatment-related effects. Based on the lack of any effects at the highest dose tested, the NOEL for acute neurotoxicity was >2000 mg/kg bw.

Groups of rats received cyhalofop-butyl in the diet at doses of 0, 2 (male only), 20, 75 or 250 (female only) mg/kg bw/d for 13 weeks. The animals were tested for neurotoxicity using functional observational battery (FOB) and motor activity test protocols, including neuropathology. There were no mortalities or clinical signs. Enlarged livers were seen in all male rats at 75 mg/kg bw/d, and 4/5 females at 250 mg/kg bw/d. No treatment-related effects were observed in any of the other parameters tested. Histopathology did not reveal any treatment-related effects. The NOEL for subchronic neurotoxicity was >75 mg/kg bw/d.

Other Studies

Groups of rats received cyhalofop-butyl in the diet at 0, 3, 25, 100 or 400 mg/kg bw/d for 13 weeks. Following week 1, 2, 4 and 13 on study, groups of 5 rats per dose were sacrificed and necropsied. One week prior to sacrifice, an osmotic pump was implanted subcutaneously on each animal, through which 5-bromo-2'-deoxyuridine (BrdU) was infused. There were no mortalities or clinical signs attributable to treatment. Enlargement of the liver was seen at 400 mg/kg bw/d after one week of treatment, but by the end of the study, this was also noted at 100 mg/kg bw/d. Pale liver foci were observed at 400 mg/kg bw/d after 4 weeks of treatment, which was also detected at 25 mg/kg bw/d after 13 weeks of dosing. Liver weights were increased in a dose-related manner at and above 25 mg/kg bw/d, with histopathological evidence of diffuse hypertrophy. In most cases, this was accompanied by focal or multifocal necrosis or necrosis in hepatocytes. There were significant increases in the number of labelled nuclei at and above 25 mg/kg bw/d after one week of treatment. Thereafter, it was seen only at 400 mg/kg bw/d, treated for either 2 or 4 weeks.

Mice received a single dose of cyhalofop-butyl intra-peritoneally (ip) at 0, 4.8, 19.5, 78.1, 313, 1250 or 5000 mg/kg bw. Male rabbits were given a single dose of cyhalofop-butyl orally at 0, 313, 1250, 2500 or 5000 mg/kg bw. Mortality, clinical signs and behaviour of the animals were monitored at 0.5, 1, 3, and 6 h post dose together with some physiological parameters being recorded for rabbits. All mice at 1250 mg/kg bw died within a day after dosing, suggesting that the acute toxicity of cyhalofop-butyl in mice was increased by ip administration, for which species the oral LD_{50} was >5000 mg/kg bw. Clinical signs and behavioural abnormalities with respect to awareness, motor activity, posture, motor incoordination, muscle tone, reflexes and autonomic signs were observed at and above 1250 mg/kg bw, generally about 0.5 h after dosing. No abnormalities were detected in any of the parameters tested in rabbits.

Conclusion

Cyhalofop-butyl has low oral, dermal and inhalational toxicity. It is a slight eye irritant, but not a skin irritant in rabbits or skin sensitiser in guinea pigs. It did not induce acute or delayed neurotoxicity in rats. Long term toxicity and carcinogenicity studies conducted in mice and rats provided no evidence that cyhalofop-butyl is carcinogenic. The overall acute toxicity of cyhalofop-butyl was low. The compound was not mutagenic, carcinogenic or teratogenic. However, it induced liver and kidney abnormalities in experimental animals. Barnstorm Herbicide is expected to be of low oral, dermal and inhalational toxicity. It is expected to be a severe eye, and slight skin irritant, but not a skin sensitiser.

PUBLIC HEALTH STANDARDS

Poisons Scheduling

The National Drugs and Poisons Schedule Committee (NDPSC) considered the toxicity of the product and its active ingredients.

On the basis of its toxicity, the NDPSC has included cyhalofop-butyl in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate First-Aid Instructions and Safety Directions on the product label.

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.

The ADI for cyhalofop-butyl was established at 0.002 mg/kg bw/d based on a NOEL of 0.2 mg/kg bw/d in a 2-year rat study. A 100-fold safety factor was used to derive this ADI in recognition of the extensive toxicological database available for cyhalofop-butyl.

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.

The ARfD is 0.03 mg/kg bw based on a NOEL of 3.0 mg/kg bw in a 13-week rat study, using a 100-fold safety factor.

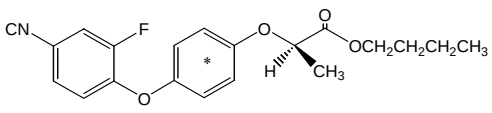
RESIDUES ASSESSMENT

Introduction

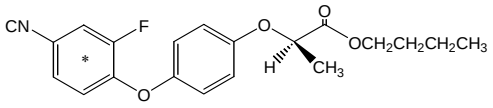
The product is intended for the post-emergence control of barnyard grasses and silver top grass by application to the foliage. As part of the residue assessment of cyhalofop-butyl, metabolism studies for rice and animals, supervised trials in rice and trade aspects were considered.

Metabolism

Plant metabolism studies were conducted on **rice**. Rice was subject to treatment with either α-phenyl ^{14}C cyhalofop-butyl or β-phenyl ^{14}C cyhalofop-butyl by various methods and the uptake and distribution of radioactivity was monitored.



α-phenyl ^{14}C cyhalofop-butyl



β -phenyl ^{14}C cyhalofop-butyl

The results indicate that following applications to water and/or foliage the uptake of radioactivity in immature rice plants was generally higher within the first two weeks and declined towards maturity (14-16 weeks). This was irrespective of the radiolabel used. In grain, a high proportion of the radioactivity (80% of TRR) was unextractable and incorporated into natural plant constituents, such as starch, cellulose, lignin and plant proteins. In straw, the unextractable portion accounts for 16% of TRR. Extractability in grain and straw were <5% and <40% of the TRR, respectively (TRR in grain was 0.29 mg equiv./kg and in straw was 0.89 mg equiv./kg). The key metabolic transformation of cyhalofop-butyl in rice plants involves hydrolysis of the butyl ester side-chain to give cyhalofop acid, and subsequent oxidation of cyano group to a carboxylic acid (diacid).

In **laying hens** orally fed for 5 consecutive days with [^{14}C] cyhalofop-butyl at 12 ppm in the feed, the majority of the total dose was eliminated in the excreta within 24 hours accounting for 90% of total administered α-phenyl or β-phenyl [^{14}C] cyhalofop-butyl. The level of total radioactivity (TRR) in composite muscle, abdominal fat and eggs (day 5) was low (<0.04% of the total administered dose). In liver, no parent ester was detected. The major metabolite identified in liver is the acid (4.4%TRR, 0.003 mg equiv/kg) metabolite. These data suggest that low levels of radioactivity (0.8%TRR) were absorbed in the collected hen tissues, and only 0.2% was transferred into eggs. The major metabolic pathway for cyhalofop butyl in laying hens appears to be hydrolysis to the acid metabolite.

In **lactating goats** orally dosed for three consecutive days with cyhalofop butyl equivalent to 10 ppm in the diet, urinary excretion was a major pathway accounting for 97 and 88% of the total α–phenyl and β–phenyl doses, respectively. Only 1.1% of the applied dose was distributed in tissues and 0.37% in milk. Total radioactive residues in milk in all samples accounted for less than 0.4% of the total dose. The levels of radioactivity in tissues, except for kidney and fat, were comparable for both radiolabels. Distribution of the α-label in kidney was slightly higher accounting for 0.8% of the total dose, compared to 0.5% of the dose recovered in the kidney of the β-label dosed goat. Distribution of the radioactivity in fat accounted for 0.1% and 0.3% of the total administered dose for α- and β- labels, respectively. The magnitude of total radioactive residues in tissues were in the order Kidney > liver > fat > muscle.

In whole milk and milk fat, the unknown metabolite 1A was the predominant metabolite. Of the total hexane extractable residues in fat (90.8% TRR), 78.4% of the TRR is due to unknown metabolite 1A, and less than 10% of the TRR is acid. Analysis of the residues in fat

(including milk fat) showed that virtually all the radioactivity was present as glyceride conjugates. In liver and kidney, metabolites were present at comparable levels, with acid and unknown 1A metabolites (~50%TRR and ~10%TRR, respectively) being the major component of the radioactivity. The major metabolic routes for cyhalofop-butyl in lactating ruminants appear to be hydrolysis of the ester bond and acid formation, followed by conjugation to give triglyceride conjugate.

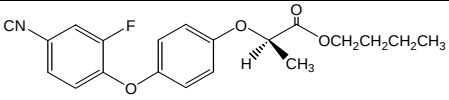
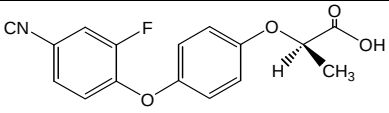
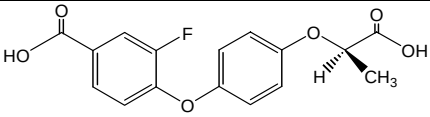
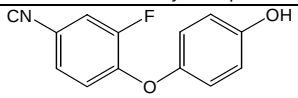
Key metabolic transformations of cyhalofop-butyl included:

(i) hydrolysis of the butyl ester side-chain to give cyhalofop acid (detected in rice, laying hens, lactating goats).

(ii) oxidation of cyano group to a carboxylic acid to form diacid (detected in rice, laying hens (mainly in excreta) and lactating goats).

(iii) hydrolysis of the propanoic acid group to form cyhalofop DP (rice and lactating goats).

(iv) a fourth process produces unidentified metabolites (Unknown 1 that is present in the milk and all edible tissues, and UK8 that was present in rice grain). With respect to UK8, this process most likely involves cleavage of the ether bond and the subsequent transformation to fatty acids and triglycerides through synthetic pathways of fatty acids.

CODE	Chemical name	Molecular structure
Cyhalofop-butyl (BE 537)	[R-(+)-2-(4-(2-fluoro-4-cyano-phenoxy)phenoxy)propanoic acid]	 Cyhalofop-butyl
Cyhalofop-Acid	[R-(+)-2-(4-(2-fluoro-4-cyano-phenoxy)phenoxy)propanoic acid]	 Cyhalofop acid
Cyhalofop-Diacid	[R-(+)-2-(4-(4-carboxyl-2-fluoro-4-hydroxy-phenoxy)phenoxy)propanoic acid]	 Cyhalofop-diacid
Cyhalofop DP	4-(2-fluoro-4-cyanophenoxy)phenol	 Cyhalofop DP

Residue definition

The parent compound was a significant residue found in immature rice foliage and straw (following foliar application only). It was not a predominant residue in commodities of animal origin. The acid metabolite is a predominant residue in both animal and plant commodities. Adequate analytical methodologies are available for the determination of cyhalofop-butyl and its acid metabolite in both rice plant and animal matrices. The diacid metabolite was a minor residue found in all matrices except for rice straw and immature plants. Analytical methodologies are available to measure diacid in rice matrices. On the basis of the metabolism studies the **residue definition for cyhalofo-butyl is sum of parent compound and the acid metabolite expressed, as the parent,** for the purposes of monitoring GAP and the estimation of dietary intake.

Analytical methods

Determination of residues in plant tissues

Analytical methods were provided for the determination of cyhalofop-butyl and selected metabolites in immature rice plants, rice straw and grain. All methods were adequately

validated and gave acceptable recoveries. The methods involve acetone extraction, purification by solvent partitioning and chromatography using either silica gel or by amino-propyl SPE. Cyhalofop conjugates are released by acid hydrolysis. Residues of cyhalofop-butyl and its metabolites in rice matrices are quantified by GC/MS or GC/NPD, and in animal matrices by GC/NPD techniques.

	Analyte	Technique	LOQ, mg/kg
Immature rice plants, forage	Cyhalofop-butyl	GC/MS, GC/NPD	0.05
	Cyhalofop acid		
	Cyhalofop-butyl and acid expressed as Cyhalofop-butyl	GC/MS, GC/NPD	0.1
Straw	Cyhalofop-butyl	GC/MS	0.01
	Cyhalofop acid	GC/MS	0.01
	Cyhalofop diacid derivatives expressed as diacid	GC/MS	0.019
	Cyhalofop-butyl and acid expressed as Cyhalofop-butyl	GC/MS, GC/NPD	0.1
	Cyhalofop-butyl and acid expressed as Cyhalofop acid	GC/MS	0.019
Grain	Cyhalofop-butyl	GC/MS	0.005
	Cyhalofop acid	GC/MS	0.01
	Cyhalofop diacid derivatives expressed as diacid	GC/MS	0.01
	Cyhalofop-butyl and acid expressed as Cyhalofop-butyl	GC/MS	0.01
	Cyhalofop-butyl, the acid and DP expressed as Cyhalofop acid	GC/MS	0.01
Animal tissues	Cyhalofop-butyl	GC/NPD	0.05
	Cyhalofop acid	GC/NPD	0.05

Determination of residues in animal tissues

Although animal transfer studies were not provided, a validated analytical method for the determination of cyhalofop-butyl in meat, eggs, milk and fat was submitted. This method has been provided for determination of cyhalofop residues and its metabolites in ground meat. The method involves extraction of fat with petroleum ether. Residues are separated from extracted fat using multiple step ether- extraction, and cleaned up using Florisil column (4 g) and acetonitrile-petroleum. Ether eluants at this stage are suitable for residue determination by gas chromatography. Acceptable recoveries were shown at the fortification levels of 0.05-0.5 mg/kg.

Storage stability

Storage stability of residues has been determined on rice commodities. Residues of cyhalofop remained stable in rice straw and grain for 17 months when stored under frozen conditions. The maximum frozen storage intervals in all trials conducted in Australia and overseas range from 1 to 17 months. The data from the trials adequately reflect levels present at the time of harvest.

Residue trials

Rice-grain

There were a total of 44 trials conducted on rice grown in Australia (10), Brazil (6), Greece (2), Italy (5), Spain (3) and the USA (18). Cyhalofop was applied at 0.74-2.5 × the proposed Australian rate (285 g ai/ha). The data show that cyhalofop residue levels in harvested grain are below the limit of quantification of 0.01 mg/kg when cyhalofop was applied according to GAP. The calculated STMR is <0.005 mg/kg. The results support establishment of an MRL of *0.01 mg/kg for rice grain. In association with this MRL, a harvest-withholding period is not required when Barnstorm Herbicide is used as directed.

Rice-forage

Data for rice forage were reported in 10 trials conducted in Australia (5), Greece (1), Italy (2) and Spain (2). The results from trials indicate that following use of Barnstorm Herbicide on rice, residue levels in forage sampled at the proposed withholding period of 8 weeks were <0.1 mg/kg. Rice forage may be used as an animal feed, particularly in failed crop situations. The data support an animal feed commodity MRL of *0.1 mg/kg for rice forage (fresh weight). In conjunction with the above MRL, an 8-week withholding period for grazing or cutting for stockfeed should be observed when Barnstorm Herbicide is used as directed.

Rice-straw

Data for rice straw were reported in 38 trials conducted in Australia (10), Greece (2), Italy (5), Spain (3) and the USA (18). The residue levels in straw were in the range of <0.01-0.2 mg/kg (STMR=0.02 mg/kg, n=38, HR=0.2 mg/kg). The data in the trials support an animal feed commodity MRL of 0.2 mg/kg for rice straw and fodder (dry).

Processing studies

Processed products of bran, polished rice and hulls, prepared in the commercial manner using the bulk field grain samples had residues no greater than the residue levels in grain samples. On the basis of these results, the rice MRL of *0.01 mg/kg adequately covers residues in processed rice commodities.

Animal commodity MRLs

Potential animal feed commodities derived from crops treated with cyhalofop-butyl include rice grain, straw and forage. Rice grain can comprise up to 100% of the diet for laying hens. Rice straw and forage can comprise up to 100% of the diet for ruminant livestock.

No animal transfer studies were provided in the submission. Metabolism studies conducted on laying hens and lactating goats, show that cyhalofop-butyl is rapidly absorbed and eliminated from animals. Following an oral dose of ~10 ppm of radiolabelled cyhalofop-butyl in hens and goats, the majority of the radioactivity (>93% in both species) was eliminated via urine and faeces. Residues in milk were <0.04 mg equiv/kg in all samples from two radiolabelled dosed groups. The highest residues in milk were observed after the 2nd day of dosing, indicating that residues plateau quickly. Analytical methodology has been provided for determining cyhalofop-butyl residues in animal commodities, with an LOQ of 0.05 mg/kg.

The poultry metabolism study indicated a low potential for transfer of cyhalofop-butyl to poultry tissues and eggs.

On the basis of non-detectable residues resulting in animal commodities, the following animal commodity MRLs are recommended:

Animal commodity		Recommended MRLs (mg/kg)
MO 0105	Edible offal (mammalian)	*0.05
PE 0112	Eggs	*0.05
MM 0095	Meat [mammalian], in the fat	*0.05
ML 0106	Milks	*0.05
PO 0111	Poultry, edible offal of	*0.05
PM 0110	Poultry meat	*0.05

Estimated dietary intake

The theoretical chronic and acute dietary intakes for cyhalofop have been assessed. The ADI for cyhalofop is 0.002 mg/kg bw/day, based upon a NOEL of 0.2 mg/kg bw/day and a 100-fold safety factor. The NEDI of cyhalofop is equivalent to <1% of the ADI. With respect to the acute dietary intake, the acute reference dose (ARfD) for cyhalofop is 0.03 mg/kg bw/day. The highest acute dietary intake was estimated at <1%. It is concluded that chronic and acute dietary exposure to cyhalofop is low and the risk from residues in food is acceptable.

Bioaccumulation potential

The goat metabolism study confirms that cyhalofop-butyl residue deposition in fat of tissues and partitioning into the cream of milk is less than 1% of the administered dose (TRR_{meat} = 0.001 mg/kg, TRR_{fat} = 0.006 mg/kg). The TRR in milk (0.037 mg/kg) and milk fat (0.032 mg/kg) was the same.

Recommendations

The following amendments be made to the MRL Standard:

Table 1

Compound	Food		MRL (mg/kg)
ADD:			
Cyhalofop-butyl			
	MO 0105	Edible offal (mammalian)	*0.05
	PE 0112	Eggs	*0.05
	MM 0095	Meat [mammalian], in the fat	*0.05
	ML 0106	Milks	*0.05
	PM 0110	Poultry meat	*0.05
	PO 0111	Poultry, edible offal of	*0.05
	GC 0649	Rice	*0.01

Table 3

Compound	Residue
ADD:	
Cyhalofop-butyl	Sum of cyhalofop-butyl and cyhalofop acid, expressed as parent

Table 4

Compound	Animal Feed Commodity		MRL (mg/kg)
ADD:			
Cyhalofop-butyl			
	AS 0649	Rice straw and fodder (dry)	0.2
		Rice forage (fresh weight)	*0.1

The following withholding period is required in conjunction with the above MRLs:

Grazing: Do not graze, or cut for stock food for eight weeks after application.
Harvest: Not required when used as directed.

Conclusion

Consideration of the residues of cyhalofop-butyl in food leads to the conclusion that the use of cyhalofop-butyl is unlikely to be an undue risk to human health from a dietary perspective. The proposed use of cyhalofop-butyl for the post-emergent control of barnyard grasses and silver top grass in rice crops is unlikely to unduly prejudice Australian trade.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Overseas registration status

There are no Codex MRLs established for cyhalofop-butyl. Of Australia's major export markets for rice, only a few countries (Japan, Turkey and Spain) have MRLs established for rice. The proposed Australian MRL is lower than the MRLs of these international markets.

The following overseas MRLs are established for cyhalofop butyl.

Country	Commodity	MRL Value (mg/kg)
Argentina	Rice	0.01
France	Rice	0.02
Italy	Rice	0.01
Japan	Rice	0.1
Spain	Rice	0.05
Spain	Rice straw and fodder, dry	0.05
Turkey	Rice	0.01
USA	Rice	0.03
USA	Rice straw and fodder, dry	8.0

Potential risk to Australian export trade

Export of treated produce containing detectable residues of cyhalofop-butyl 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.

Rice is Australia's third largest cereal grain export, and the ninth largest agricultural export. Although Australian rice only represents around 0.2% of world rice production, our exports represent over 4% of world trade. Australia's rice is exported to over 70 major international destinations. Papua New Guinea is the main Australian rice export market and accounts for 25% of the exports. Other major markets include Japan, Hong Kong, Turkey, Iraq, Spain, South Korea, New Zealand, Fiji and the Solomon Islands.

The proposed use of cyhalofop-butyl on rice is unlikely to prejudice Australian trade, as there are no detectable residues expected on rice grain, or its processed commodities, including rice bran. Similarly, there are no residues expected in/on animal commodities as a result of animal exposure to rice (forage, straw and grain) from treated crops. Therefore, the proposed use is not expected to unduly prejudice Australian trade in animal commodities.

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Formulation, packaging, transport, storage and retailing

Cyhalofop-butyl is manufactured in Japan. Barnstorm Herbicide will be formulated in New Zealand and transported to Australia fully packed. The product will be packaged in 5 L, 10 L and 20 L fluorinated high-density polyethylene (FHDPE) drums.

The 5 L containers will have a neck size of 45 mm and the 20 L containers will have neck sizes of either 33 mm or 64 mm.

Use and exposure profile

Barnstorm Herbicide is proposed for the post-emergence control of barnyard grasses and silver top in rice crops. The product may be applied by air or ground equipment. The maximum recommended application rate is 1 L product per hectare in 40 L (aerial spray) or 100 L (ground spray) water. Only one application per season will be required. Individual rice growers will use the product for 1-2 days per year.

Transport workers, store persons and retailers will handle packaged product and could be exposed to the product only if packaging were breached. Farmers and contract sprayers will be the main users of the product. Contract workers will be exposed to the product repeatedly. Workers may become contaminated with the product during mixing/loading, spraying, cleaning up spills, maintaining equipment and when entering treated areas. The main routes of exposure to the product will be dermal and inhalation, though ocular exposure may also occur. Workers may also be exposed to spray mist.

There are no worker exposure studies on cyhalofop-butyl or Barnstorm Herbicide available for assessment. Therefore, in the absence of worker exposure data, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide (1998) was used to estimate worker exposure to Barnstorm Herbicide during mixing/loading and ground application. Exposure estimates determined from PHED were standardised to the amount of active ingredient handled per day under Australian use patterns for the product.

Exposures during re-entry were estimated using the standard methodology for Dislodgeable Foliar Residues (DFR). Default transfer coefficients of 1500 and 2500 were considered appropriate for the re-entry activities required.

Risks to workers during use

The main acute risks arising from exposure to Barnstorm Herbicide are slight skin irritation and severe eye irritation. Mixer/loaders may be exposed to the product by inhalation or by skin and ocular contact. The main risk during this activity is skin and eye and respiratory tract irritancy.

The main effects associated with repeat dose toxicity of cyhalofop-butyl in animals were hepatocellular proliferation, inflammation and gross enlargement of liver and bile duct hyperplasia. Macroscopic and microscopic abnormalities in liver and kidneys were also consistently observed.

The product will be used only once per season. However, contract sprayers may use it more often during the season. Therefore, seasonal exposure (up to 3 months a year) of workers is anticipated. The most appropriate NOEL for use in the occupational risk assessment was determined as 3 mg/kg bw/d from a 13-week oral rat study. As an oral NOEL was selected for the risk characterisation, dermal absorption factors of 1% for concentrated product

(mixing/loading) and 20% for diluted product (spray application) were utilised in the calculation of internal doses.

OCS utilised the Margin of Exposure (MOE) approach in the calculation of risks to workers exposed to cyhalofop-butyl, where estimated exposures (doses) from PHED were compared to the NOEL. MOE at or around 100 are considered acceptable as the NOEL is based on animal data to account for intraspecies and interspecies variability.

Conclusions from the acute and repeated exposure risk assessments indicate the following:

- Eye protection is indicated for handling undiluted product due to the potential for severe acute eye irritation.
- Gloves are not indicated from dermal MOE (repeated exposure), but are required when handling undiluted product due to the potential for skin irritation.
- Respiratory protection is indicated for handling undiluted product due to the potential for respiratory tract irritation.
- One layer of clothing is indicated when handling undiluted product due to irritation potential and from PHED risk estimates.
- Cotton overalls (or equivalent clothing) are not indicated from acute hazard (to spray solution) or PHED risk estimates for applicators.

Entry into treated areas

Based on re-entry risk assessment, the risk to re-entry workers was determined to be low from day 0 for low exposure activities (eg: irrigation). For activities resulting in high exposure to treated foliage (eg. hand harvesting), a re-entry period of 5 days is indicated.

CONCLUSIONS

Barnstorm 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 Barnstorm Herbicide containing 285g/L cyhalofop-butyl.

ENVIRONMENTAL ASSESSMENT

Introduction

Dow AgroSciences Australia Ltd has applied for the registration of a new product, Barnstorm Herbicide containing the new active constituent cyhalofop butyl at 285 g ac/L. It is to be used for the control of barnyard grass (*Echinochloa spp*) and silver top (*Lepthochloa fusca*) in rice. Barnstorm Herbicide will be applied at 0.5-1.0 L/ha (142-285 g ac/ha) as a foliar spray together with spraying oil at 1 L/ha. The label recommends both ground and aerial applications with a minimum of 40 L/ha spray volume. Almost all applications (~95%) are expected to be aerially applied with just ~5 % applied by groundrigs. Droplet sizes will be medium (ASAE) and the volume medium diameter (vmd) is approximately 220-350 μm. There is a label restraint not to apply by chemigation or SCWIIRT (Soluble Chemical in Water Injection Into Rice Technique). There is no limitation on repeat applications, but the company has indicated that in most instances only one application per rice crop would occur and only occasionally two. The first application would be early in the rice crop with the latter a 'salvage' treatment only if required.

Environmental Fate

Hydrolysis

A preliminary test on the hydrolysis of cyhalofop butyl was conducted in buffered distilled water at pH 4, 7 and 9. The results indicated that cyhalofop butyl hydrolysed very rapidly in alkaline conditions, slowly in acid conditions and at pH 7 the half-life was approximately 7 days.

In a study conducted to OECD Guidelines, the hydrolysis of cyhalofop butyl was pH-dependent and followed first order kinetics. At pH 4 there was only slight degradation over the testing period and the half-lives at 25 and 37°C were estimated as >1 year (highly persistent). The half-lives at pH 7 and 9 (25°C) were 96 days (moderately persistent) and 43 hours (non-persistent) respectively. Cyhalofop butyl was hydrolysed to give cyhalofop acid as the only hydrolysis product.

Photolysis

Aqueous photolysis

In a test conducted to meet US EPA Guidelines an aqueous solution of cyhalofop butyl was photolysed with natural sunlight in sterile buffered water (pH 5) or humic water (sterile buffered water (pH 5) containing synthetic humic acid). Half-lives under irradiated conditions were calculated as 28 days for both buffered and synthetic humic water, whereas for the dark control the half-life was 159 days (buffered water only). The analysis of the degradates showed several minor photolysis products together with water soluble material that was not analysed further. Recovery of applied material ranged from 79 to 86% of applied and was only just acceptable. None of the photo-degradates were identified in the guideline study, although a supplemental study, conducted to examine the poor recoveries, tentatively identified two additional photodegradates.

Soil photolysis

Cyhalofop butyl was applied to a silt loam soil from USA and photolysed with natural sunlight according to US EPA requirements. There was little difference between light exposed samples and the dark controls with the only difference being the non-extractable fraction in the soil. The DT50s were the same (0.5 days) using a two compartment model.

Cyhalofop butyl was applied to an Italian sandy loam soil then irradiated with artificial light to meet EC requirements. After 30 days natural sunlight equivalence, 82% of cyhalofop butyl remained together with 4% of cyhalofop acid and several unidentified minor products. It was

concluded that there was no significant soil photolysis of cyhalofop butyl. In contrast, the dark control had just 3% of cyhalofop butyl remaining together with the primary degradates cyhalofop acid, the amide and the diacid. The rapid degradation in the dark controls was interpreted as showing that the irradiated sample became very dry due to the continuous irradiation from the lamp but the dark controls remained damp and therefore biotic degradation continued (DT50 was 5.4 days in the dark controls).

Due to the rapid metabolism of cyhalofop butyl in soil, soil photolysis is unlikely to make a significant contribution to environmental degradation.

Atmospheric photolysis

The atmospheric degradation of cyhalofop butyl was determined using an atmospheric oxidation program based on structure activity relationships. For cyhalofop butyl, the atmospheric half-life was determined as 5.9 hours. The low volatility will limit this route of degradation and it is unlikely to be a significant pathway of degradation in the environment.

Biotic Degradation

Aerobic soil– European soils

The metabolism of cyhalofop butyl was studied in 4 European soils from Italy, Germany and the UK to meet EU requirements. The soils were dosed with the radiolabelled cyhalofop butyl and then incubated for 120 days in the dark at 20°C. At the end of the aerobic incubation period, there were significant levels of mineralisation, between 36 to 46% of applied radioactivity in the $^{14}CO_2$ traps, with soil bound residues making up most of the remaining radioactivity, between 35-46% of applied radioactivity.

The degradation curves were biphasic with an initial degradation which lasted for 8-24 hours and accounted for >85% degradation of parent. The half-lives ranged from 3.2 to 9.8 hours. The DT90 was determined empirically from the graphed data and gave values of 16-62 hours.

In addition, the DT50s of the 3 major metabolites were also determined using a first order degradation model and this showed that cyhalofop acid and amide had DT50s of <1 day while the diacid, the most stable degradate, had DT50s of approximately 1-4 days in the various soils used.

Aerobic soil– Japanese soils

The metabolism of cyhalofop butyl was studied in 2 Japanese soils according to Japanese Guidelines. The soils were used under two conditions, moist (50% of the moisture holding capacity) or flooded (1 cm of water above the soil layer) before being treated with radiolabelled cyhalofop butyl and then incubated for 28 days in the dark at 25°C. The results shows that the parent was degrading rapidly and after 12 hours accounted for <5% for all soils and conditions. The major metabolites were cyhalofop acid, amide and diacid and there was no really significant difference between the moist and flooded soils. One additional metabolite that reached 19% of applied which was identified as 3-fluoro-4-(4-hydroxyphenoxy)benzoic acid and there were another 6 unidentified metabolites, all <10% of applied. The ultimate fate of the applied radioactivity was incorporation into the soil matrix and/or mineralisation to carbon dioxide. For the sterile soils, there was limited degradation of parent. The half-life of cyhalofop butyl was not determined, which is acceptable given the very rapid degradation.

Aerobic soil metabolism – US soils

The metabolism of cyhalofop butyl was studied in 2 soils from Arkansas and California according to US EPA Guidelines. The soils were treated with radiolabelled cyhalofop butyl and then incubated for 30 days in the dark at 25°C. The HPLC analysis showed that the parent was degrading rapidly and after the first day was <8% for both soils. The major

metabolites were cyhalofop acid, amide and diacid as before. The ultimate fate of the applied radioactivity was incorporation into the soil matrix and/or mineralisation to carbon dioxide. The half-life of the cyhalofop butyl was determined using a two-compartment model and the DT50s were 2.2 and 2.9 hours for the Arkansas and Californian soil respectively. In addition, the DT50s for cyhalofop acid, amide and diacid were 0.04, 0.21 and 0.8 days respectively for the Arkansas soil and 0.04, 0.12 and 0.4 days for the California soil. It is concluded that the results show that degradation of cyhalofop butyl is quick and the initial degradation product is cyhalofop acid, which is rapidly degraded to the diacid via the amide. Further degradation gives soil bound material and carbon dioxide.

Aerobic aquatic metabolism

European sediment

The aerobic aquatic metabolism of cyhalofop butyl was conducted according to BBA registration requirements using two sediment-water systems collected from two locations in the Europe. Each system consisted of water (6 cm deep above sediment) and sediment (2.5 cm deep) and the radiolabelled cyhalofop butyl was applied to the water surface. The systems were incubated aerobically at 20°C in the dark. The waters remained aerobic while the Spanish sediment was anaerobic and French sediment was slightly anaerobic/reducing.

As in the soil studies, there was rapid degradation of parent to give cyhalofop acid initially, then the amide and diacid. The radioactivity after 98 days was mainly recovered as CO_2 (maximum of 62% of applied) and soil bound material (maximum of 26.3% of applied). The half-lives were 3.2 hours for cyhalofop butyl and for the main degradates cyhalofop acid, amide and diacid the half-lives were 6.5, 12.9 and 27 hours respectively. It is concluded that cyhalofop butyl degrades rapidly in aerobic aquatic conditions via hydrolysis of the ester to give cyhalofop acid and this further degrades to the amide and then the diacid. The diacid is finally incorporated into the soil and is rapidly mineralised.

USA sediment

The aerobic aquatic metabolism of cyhalofop butyl was conducted according to US EPA Guidelines. The USA water/sediment was dosed in the water phase with the radiolabelled cyhalofop butyl then aerobically incubated at 25°C in the dark.

During the incubation, the overlying water in each system remained essentially aerobic and the sediments were initially aerobic but then rapidly became anaerobic after dosing (7 hours) and remained anaerobic. As in the soil studies, there was rapid degradation of parent to give cyhalofop acid initially then the amide and diacid. Thereafter the applied radioactivity in the aqueous phase declined with corresponding increases in the formation of CO_2 (32% of applied) and non-extractable soil bound material (35.3% of applied).

The half-lives for cyhalofop butyl was determined as 3.2 hours and the main degradates cyhalofop acid, amide and diacid were calculated as 7.8, 2.2 and 14 days respectively. It is concluded that this study supports the previous studies for degradation, although it shows longer half-lives for the main degradates (cyhalofop acid, amide and diacid) than the previous study using sediment from two sites in Europe.

Anaerobic Aquatic Metabolism

USA sediment and soil

The anaerobic aquatic metabolism of cyhalofop butyl was conducted according to US EPA Guidelines using natural sediment and a soil, both from Arkansas. The soil or sediment was flooded with the pond water then dosed with radiolabelled cyhalofop butyl. The dosed systems was then incubated in the dark at 25±1°C under nitrogen for 1 year.

As in the other soil studies, there was rapid degradation of cyhalofop butyl to give cyhalofop

acid initially then the diacid. However, there was minimal formation of CO_2 and of non-extractable soil residues. The half-lives for cyhalofop butyl were determined as 0.2 days using first order kinetics. The average DT50 for cyhalofop acid was 39 days and the amide 2.7 days. The DT50 for the diacid could not be determined as it was stable under these conditions.

Anaerobic Aquatic Metabolism - European soil

The anaerobic aquatic metabolism of cyhalofop butyl was conducted according to EU Directive using a sandy loam soil. The soil was flooded with water before being dosed with cyhalofop butyl and incubated for 120 d. As in the other studies, there was rapid degradation of cyhalofop butyl to initially give cyhalofop acid, which then degraded further to the amide and diacid. There was significant mineralisation with formation of CO_2 (49.4% of applied) together with soil bound residues (19.4% of applied). This is significantly different to the US anaerobic study and could indicate that conditions were not as anaerobic in this study as they were in the US study (anaerobic conditions were not measured).

The half-life for cyhalofop butyl could not be determined. The average first order degradation rates for the main degradates cyhalofop acid, amide and diacid were given as 2.6, 2.5 and 15.9 (22 and 9.8 days) days respectively.

Mobility

Adsorption/desorption – European soils

The adsorption/desorption of cyhalofop butyl to 4 soils was studied using the batch equilibrium method according to OECD Guidelines. A screening study showed that there was considerable degradation of parent, <50% remained after 1 hour and formation of cyhalofop acid, amide and diacid. The Kd and Koc for cyhalofop butyl were determined using sterile soils, while for the metabolites the screening results were used. The Koc for cyhalofop butyl ranged from 2066 to 9637, for the acid from 176 to 195, for the amide the Koc was 50 (one value only) and for the diacid from 79 to 614. The study demonstrates that cyhalofop butyl is strongly adsorbed and classified as immobile while the metabolites are rated as having medium to very high mobility.

Adsorption/desorption – US soils

The adsorption/desorption of cyhalofop butyl and cyhalofop acid to 5 US soils was studied using the batch equilibrium method according to US EPA Guidelines using radiolabelled material. The soils were sterilised by gamma radiation prior to use. The Koc for cyhalofop butyl ranged from 2889 to 7960 and for cyhalofop acid from 57 to 152. The study demonstrates that cyhalofop butyl is strongly adsorbed and classified as of low to slight mobility or immobile and cyhalofop acid is rated as having high to very high mobility.

Leaching potential

A leaching column study was conducted in accordance with Japanese Guidelines using 2 soils from Japan. The soils were dosed with radiolabelled cyhalofop butyl and then applied to the top of the soil column filled with untreated soil and then eluted over 8 days. There was significant loss of applied radioactivity (46%) which was probably lost as CO_2 (the column leaching was not done in a closed system). The remaining radioactivity was retained in the upper soil segments as the metabolites (acid and diacid) or soil bound. The experiments showed that there is limited leaching potential of cyhalofop butyl or its metabolites due to the rapid degradation.

Field Dissipation

Italy.

The dissipation of cyhalofop butyl was studied under field conditions in an Italian rice paddy according to EU and German Guidelines. One application of cyhalofop butyl (European

formulation) was made at 300 g ac/ha to the rice plots without standing water and the rice plots were flooded 3 days after application. There were no detectable residues of cyhalofop butyl in any soil or water sample at anytime. The only quantifiable residue in the soil was the diacid on day 7 at 0.01 mg/kg and there were trace levels (<0.01 mg/kg) of the cyhalofop acid and diacid in the day 3 to 7 samples. This field study confirms the laboratory results in that the cyhalofop butyl degrades quickly to give cyhalofop acid, which further degrades to the more stable diacid.

Field study US.

The dissipation of cyhalofop butyl was studied at Arkansas and California in the US following US EPA Guidelines. Two applications of cyhalofop butyl (USA formulation) were made, the first at 310 g ac/ha and the second at 210 g ac/ha. The first application to Arkansas was to dry soil while all other application was to plots with standing water (2.5 and 7.5 cm deep for Arkansas and California respectively).

The results showed that the parent cyhalofop butyl was rapidly degraded at both sites. There was no carryover of parent at the California site from the first to the second application (14 days apart) or of any of the main metabolites. In contrast, because the first application was made to dry soil, soil residues were found to carryover from the first to second application (15 days apart) at Arkansas but only for the metabolites. It was concluded that the field studies in the US confirm the laboratory results showing that cyhalofop butyl is very rapidly degraded (half life <2 hour), initially to cyhalofop acid and then to the diacid.

Bioaccumulation

Japanese Guidelines

A bioaccumulation study was conducted to meet Japanese requirements using non-labelled cyhalofop butyl under flow-through conditions using Koi carp. After 28 days no residues were detected in the fish (<0.065 μg/g) and therefore the BCF was given as <8. The report shows that the bioaccumulation potential of cyhalofop butyl is low.

US EPA Guidelines

The bioaccumulation and elimination of radiolabelled cyhalofop butyl was investigated in accordance with US EPA and OECD Guidelines using rainbow trout. After 28 days analysis of the fish tissues showed that no cyhalofop butyl was present or at low levels, and there were 3 metabolites detected together with some very minor peaks. The most significant ones were identified as cyhalofop acid, the taurine conjugate of cyhalofop acid and an unknown. Because there was no parent detected, only metabolites, the bioconcentration factors were calculated for total radioactivity as 470, 27 and 624 for whole fish, muscle and viscera respectively. There was rapid depuration of accumulated radioactivity from the fish tissues.

Environmental Toxicity

Avian

Cyhalofop butyl is practically non-toxic to bobwhite quail and mallard ducks by the single oral dose route with NOEC values of2,250 mg ac/kg bw. Similarly for the 5-day dietary exposures, the LC50s were greater than 5260 mg/kg, the maximum dose tested, although there was a slight effect on mallard duckling chicks with a NOEC of 1780 mg ac/kg bw compared to that for bobwhite quail of 5620 mg ac/kg bw. One-generation tests also showed that it was not toxic to bobwhite quail and mallard ducks and did not affect reproduction at 800 mg/kg feed (nominal), the maximum exposure tested.

Aquatic

Under flow-through conditions in a test conducted to meet OECD requirements, cyhalofop butyl is rated as moderately toxic to rainbow trout with a 96 h LC50 of 1.54 mg ac/L but a high concentration of an additive was used in order to exceed the water solubility of

cyhalofop butyl. In a flow-through study with rainbow trout, conducted to meet US EPA requirements, the LC50 was >0.32 mg ac/L, the maximum soluble concentration of cyhalofop butyl reached in the test. It may be more toxic to the bluegill sunfish with a LC50 of between 0.12-0.99 mg ac/L. For the Atlantic silverside the LC50 was 0.569 to 0.905 mg ac/L. An EC formulation (EF-1218, 19.8% active; a similar formulation to that proposed but less concentrated) was toxic to rainbow trout when tested under static conditions with LC50 of 3.45 to 6.6 mg formulation/L, corresponding to 0.71 to 1.36 mg ac/L – the formulation increased the water solubility of cyhalofop butyl.

The chronic toxicity was tested in an early life stage study conducted using fathead minnow according to US EPA guidelines under flow-though conditions. The sublethal effects of decreased number of normal larvae, reduced larval survival and decreased larval survival from hatch to thinning were noted at 0.163 mg ac/L. The NOEC was 0.065 mg ac/L and LOEC 0.163 mg ac/L and the MATC 0.101 mg ac/L.

The main aquatic metabolites (cyhalofop acid, diacid and amide [bluegill only]) were practically non-toxic in acute limit tests to both rainbow trout and bluegill sunfish with NOEC of ~100 mg/L. The diacid was also tested in an early life stage test conducted as a limit test and the NOEC was 9.4 mg diacid/L.

For *Daphnia magna*, the acute 48 h toxicity test under static conditions gave an EC50 of >2.7 mg ac/L and NOEC of 2.7 mg ac/L. In a test conducted under flow-through conditions to US EPA and OECD Guidelines, the acute 48 h daphnia toxicity test gave an EC50 of >0.56 mg ac/L and a NOEC of 0.56 mg/L. The acute toxicity of an EC formulation (EF-1218) determined according to OECD and EC Guidelines under static conditions gave the EC50 as 19.1 mg formulation/L, corresponding to 3.62 mg ac/L, and the NOEC was 10 mg formulation/L, corresponding to 1.81 mg ac/L. In the chronic 21 days study, conducted according to US EPA Guidelines under flow-through conditions, the NOEC and LOEC for daphnia were 12.8 and 23 μg ac/L respectively, with effects on growth of surviving adults being the most sensitive effect observed in the study.

Tests showed that both cyhalofop acid and the diacid were practically non-toxic to daphnia in acute 48 h tests and the diacid was practically non-toxic to daphnia in a chronic test.

For grass shrimp tested according to US EPA guidelines, a 96 h limit test showed there were no observable effects at a measured concentration of 1.21 mg ac/L (= NOEC). Using a freshwater gammarid, tested according to draft US EPA guidelines, the EC50 was 0.81 mg total cyhalofop (measured as ester + acid) and was rated as highly toxic. In a test using a freshwater snail, total cyhalofop (ester + acid) was rated as moderately toxic with LC50 of > 1.4 mg/l and NOEC of 1.4 mg/L. For oysters tested according to US EPA Guidelines, shell growth over 96 h was reduced and the EC50 = 0.52 mg/L for total cyhalofop (ester + acid).

Cyhalofop butyl was rated as moderately toxic to green alga *(Selenastrum capricornutum*) with a 96-h E_bC50 of >0.96 mg/L and NOEC of 0.96 mg/L using initial measured concentrations in a limit test conducted according to US EPA and OECD Guidelines. An EC formulation (EF-1218) when test according to US EPA and OECD Guidelines had E_bC50 of 9.7 mg ac/L (initial measured) and this formulation is rated as moderately toxic to green algae. Cyhalofop butyl did not affect blue-green algae (NOEC = 9.72 mg ac/L initial measured) or saltwater diatoms (NOEC = 2.01 mg ac/L, initial; measured) and is highly toxic to freshwater diatoms (E_bC50 = 0.742 mg ac/L initial measured) in tests conducted to US EPA Guidelines. Cyhalofop acid and diacid metabolites showed no effect on the green algae *S. capricornutum* at 78.2 and 96.4 mg/L respectively in limit tests conducted according to OECD Guidelines.

In a limit test using cyhalofop butyl under semi-renewal conditions according to US EPA Guidelines there was no effect at 5.03 mg ac/L, above the water solubility, and is rated as moderately toxic to the aquatic macrophyte duckweed *(Lemma gibba*).

Non-Target Terrestrial Invertebrates

The NOEC for cyhalofop butyl (technical) to bees was 100 µg/bee for the oral and contact exposure routes, tested according to US EPA and EPPO Guidelines. The formulated product EF-1218 was also rated as harmless to bees with an oral LD50 of >200 µg/L corresponding to >40 µg ac/L) and the contact NOEC is 500 µg/bee (80 µg ac/bee). There were harmful effects on parasitic wasps and predatory mites when tested according to standard laboratory procedures to dry residues of EF-1218 on glass at ~1.50 L/ha and 3 L/ha (300 and 600 g ac/ha: proposed rate for Australia is ~300 g ac/ha) but no effect on 2 species of spiders (*Lepthyphantes tenuis* and *pardosa spp*), a predatory bug (*Orius laevigatus*) and a ground dwelling beetle (*Poecilus cupreus*). When the parasitic wasps were further tested under semi-field conditions according to European Guidelines there was no effect on the wasps and EF-1218 was rated as harmless. It was concluded that cyhalofop butyl is harmless to bees, parasitic wasps, spiders, predatory bugs and ground beetles and presumably to a range of other terrestrial insects under field conditions. It was rated as slightly harmful to predatory mites at the maximum Australian rate proposed based on a laboratory study.

Earthworms

In tests on the effect of cyhalofop butyl on earthworms conducted according to OECD and EU Guidelines using artificial soil there was no mortality and the LC50 was determined as > 1120 mg ac/kg and NOEC was 1120 mg ac/kg soil based on measured concentrations. In a test using the formulation EF-1218 also conducted according to OECD and EU Guidelines using artificial soil, the LD50 was 200 mg formulation/kg corresponding to 41 mg ac/kg soil and the NOEC was 104 mg formulation/kg corresponding to 22 mg ac/kg soil.

Microorganisms

Investigations into the effects of cyhalofop butyl on soil microbial activity were conducted according to EU Guidelines at 300 g/ha, the European field rate, and 5 times that rate. There was no significant effect on respiration or on nitrogen turnover after 28 days. In a standard OECD test on sewage microbes, there was no inhibitory effect on these microbes as 100 mg/L (nominal).

Non-target vegetation

The effect of an EC formulation of cyhalofop butyl (29.6% active, similar to that proposed for Australia) on non-target plants was evaluated in a seedling emergence and vegetative vigour study at rates from 8 to 520 g ac/ha (maximum US total field rate) according to US EPA Guidelines. The results showed that cyhalofop is more herbicidal to grass and has higher toxicity post-emergent than pre-emergent. The most sensitive species were barnyard grass, a target species, and corn. The NOEC, EC25 and EC50 for Barnyard grass of <8, 19 and 27 g ac/ha and for corn the values were 16, 39 and 51 g ac/ha respectively. Seedling emergence and vegetative vigour tests were also conducted with five soil metabolites of cyhalofop; cyhalofop acid, the amide, diacid, FHPBA and HPPA according to US EPA Guidelines. The tests were conducted with cyhalofop acid, diacid and amide at 580 g ac/ha while for FHPBA and HPPA, tests were conducted at 350 g ac/ha. There was no effect on seedling emergence or vegetation from any of the metabolites.

Following reports of damage to peach and nectarine trees due to spraydrift from application of cyhalofop butyl (Clincher CA; 29.6% ac), a study was conducted in California where Clincher was applied to peaches at 5% of the minimum rate (0.5 oz formulated produced/acre) corresponding to 10.8 g ac/ha as a simulated spraydrift event (very worst case). There was injury to peaches in the form of spots on the leaves and shotholes and the injury was more

severe when spraying oil added to the application. It was concluded that the damage to peaches is unexpected and the damage was not due to herbicidal activity *per se* but another mode of action such as a hypersensitive response of the leaf.

Risk Assessment

- ***Hazard to Terrestrial Organisms***

Birds

Based on the typical diet of northern bobwhite quail the concentration of cyhalofop butyl in the diet was calculated as 30 mg ac/kg food. With the dietary LD50 for quail and mallards of >5620 mg ac/kg food and NOECs of 5620 and 1780 mg ac/kg food respectively, all significantly above the dietary EEC, clearly there is no hazard to birds from feeding on food items directly oversprayed.

Earthworms

The most sensitive 14-d LC50 for the earthworm was 41 mg ac/kg soil from the European EC formulation EF 1218 and is 100 times higher than the calculated concentration in soil of 0.41 mg ac/kg soil in the top 5 cm of soil. Therefore, the proposed use is not expected to pose an acute hazard to earthworms. There were no studies on chronic toxicity to earthworms but given the large safety margin for acute effects, rapid degradation in both aerobic and anaerobic soils and that earthworms are not expected to populate rice paddies in large numbers, chronic effects are very unlikely.

Beneficial arthropods

The hazard to honey bees is expected to be low as the single application rate of 285 g ac/ha (equivalent to 2.85 μg ai/cm^2) is 100 times lower than the most sensitive contact NOEC of 100 μg ac/bee, assuming that a honeybee is approximately 1 cm^2 in surface area.

Effects on species such as parasitic wasps, spiders, predatory bugs and ground beetles are not expected as applications at rates similar to that proposed there were no or limited effects in laboratory or semi-field testing. There were effects on predatory mites in laboratory tests but at the proposed rate, these effects were only rated as slightly harmful. Further, IPM is not practiced in rice growing.

Soil micro-organisms

The information presented on the effect of cyhalofop butyl on soil micro-organisms showed these organisms were not affected at 1200 g ac/ha in laboratory test. Therefore, a hazard to soil micro-organisms and soil processes is unlikely at the proposed rate of 285 g ac/ha.

- ***Hazard to Aquatic Organisms***

Direct overspray

The worst-case scenario of a direct overspray of a 15 cm deep body of water with an application rate of Barnstorm Herbicide (285 g ac/ha) would result in concentration of 0.19 mg ac/L. Using the most sensitive acute adverse effect on fish of 0.121 and 0.99 mg ac/L for bluegill sunfish, calculations indicate that there is a low to high risk to fish from direct overspray. Acute effects on waterfleas are calculated to be unlikely, with a 48 hour LC50 of >0.56 mg ac/L. While the 97-day NOEC for early life stages of the rainbow trout (0.065 mg ac/L) indicates a possible hazard for chronic exposure, the very rapid degradation in natural water/sediment systems shows that there is unlikely to be a chronic hazard to any aquatic organism.

For other aquatic invertebrates, the most sensitive tested were a gammarid with an EC50 of 0.81 mg ac/L and Eastern oysters with an EC50 of 0.52 mg ac/L, and calculations showed that

there is a possible risk to these organisms from direct overspray of Barnstorm Herbicide. There is unlikely to be any effects on green alga with the lowest EC50 (cell density) of 9.7 mg ac/L using the formulated product EF-1218 (an European formulation), significantly higher than the concentration in water from direct overspray. For other photosynthetic aquatic micro-organisms, the most sensitive species test was a freshwater diatom with 120 h E_bC50 of 0.74 mg ac/L and calculations indicated that on the risk to diatoms is mitigable. The hazard to aquatic plants is also low as the NOEC was 5.03 mg ac/L under static conditions, significantly above the concentration in water.

Spraydrift
Assuming a worst-case scenario of 10% of a single application reaching the aquatic environment via spraydrift the concentration in water would be 0.019 mg ac/L. There were several test species where direct overspray demonstrated mitigable risk. However, with 10% spraydrift, the risk for all these test organisms is reduced by tenth and all calculations showed that effects on these organisms from spraydrift are unlikely.

Further, cyhalofop butyl is rapidly degraded in aerobic aquatic system and the metabolites are practically non-toxic to most organisms tested (fish, daphnia and green algae). Therefore any effects on non-target organisms will be limited to immediate area.

Run-off – release of tailwater
Run-off from rice paddies soils is considered not to occur due to levies around the paddies but tailwater could be released. The label for Barnstorm Herbicide has a restraint not to release drain water into local drains, waterways or water systems for at least 7 days or as defined by the local authority (21-28 days), which ever is longer. With the very rapid degradation in natural water with sediment from the laboratory studies (~3 hours), cyhalofop butyl will be degraded well before the water is released.

During the growing season, release of water from the bays only occurs after prolonged heavy rainfall and in such events, overflow is directed either into a recirculation system that allows water reuse or onto adjacent fields where the water is absorbed into the soil. Overflow is unlikely to enter river systems. Further, the rapid degradation will reduce cyhalofop butyl to levels below where environmental effects were observed in the laboratory tests, and the metabolites are essentially non-toxic.

Leaching
Cyhalofop butyl is only slightly water soluble, with strong binding to soil and a short half-life in soil of <10 hours. Leaching of parent is very unlikely. In addition, water leakage though the underlying clay layer in rice paddies is low and therefore leaching is unlikely, including the more mobile metabolites.

Multiple Applications
The label does not give any direction as to the maximum number of applications but 2 applications are the maximum likely. Given that cyhalofop butyl degrades in water/sediment (t1/2 <2 hours from USA field studies), and assuming 7 days between applications, there is unlikely to be any increase in the maximum concentration and therefore the additional aquatic hazard from 2 possible applications per year is considered very low and acceptable.

- ***Desirable vegetation***

At the proposed maximum spray rate of 285 g ac/ha, adverse effects on non-target plants are considered likely and direct overspray is a high hazard. When used according to label directions, the exposure to non-target vegetation should be limited to spraydrift. In tests using both dicotyledon and monocotyledons seedlings, only grasses were effected, with corn being the most sensitive non-target plant tested and barnyard grass the most sensitive plant (also the

main weed target). DEH used the conservative EC05 (= NOEC) endpoint for corn, the most sensitive non-target plant tested, as the endpoint for non-target native grasses due to the unexpected effect on peaches and nectarines leaves from spraydrift of cyhalofop butyl.

For applications by ground rig, the German tables for spraydrift from field crops shows that a 1 metre buffer is needed to protect the non-target grasses and the USA AgDrift model showed that a 2 metre buffer is required. For aerial application, calculations using the AgDrift model showed that a spraydrift buffer of 52 metres is needed to protect non-target grasses. The proposed spraydrift buffer on the label of 50 metres is sufficient for aerial applications, known to be the preferred method of application. Therefore, the proposed downwind spraydrift buffer of 50 metres for protection of crops should be extended for the protection of non-target desirable native grasses.

Aerial application in the USA has caused damage to peaches and nectarine leaves with the result that a 6.4 (4 mile) downwind spraydrift buffer was imposed and on the proposed Barnstorm Herbicide label there is a 5 km downwind buffer for aerial applications and 200 metres for ground applications. The field test in California showed that at 10.8 g ac/ha, there was considerable visual damage to peaches and nectarine leaves but only one rate was used. Assuming that a tenth of the test rate would minimise damage on these trees, then the 'safe level' is 1 g ac/ha (0.35% of the application rate) and calculations using AgDrift showed that a 1 km buffer would be required for aerial application and for ground rigs a 92 metre would be required (10 metres according to the Ganzelmeier tables). Therefore, the proposed spraydrift buffers are acceptable for peaches and nectarines.

In California, where the peaches and nectarines leaves were showing damage, other stone fruits (plums etc) that were nearby were not damaged. DEH comments that effects on other non-target trees are possible but there are no data to show if Australian native trees would be at risk. Peaches and nectarines are varieties of the species *Prunus persica*; there are no endemic species in this genus in Australia, and on this basis, the DEH does not recommend any further labels statements in order to protect other native non-target trees.

Mammals
There is unlikely to be any significant effect on non-target mammals. As there was no acute toxicity to rats even at 2000 mg/kg bw, the hazard to mammals is expected to be low. Also, chronic toxicity is unlikely given the rapid degradation.

- **Conclusion**

Provided the label statements are amended to include non-target native grasses/vegetation and toxicity to all aquatic organisms, DEH concludes that use of Barnstorm Herbicide in accordance with the label instructions is unlikely to have any unintended effects that are harmful to plants, animals or things or to the environment.

EFFICACY AND SAFETY ASSESSMENT

Justification for use

The availability of Barnstorm Herbicide will provide assistance in the management of herbicide resistance. The efficacy of Barnstorm on barnyard grasses and silver top grass will provide an alternative mode of action to the three herbicide groups currently used for grass weed control in rice. Barnstorm can be either used sequentially with another grass herbicide in the same season to provide a second mode of action, and/or by rotating or alternating herbicides with different modes of action from one season to the next. This will enhance the recommended programs for the control of barnyard grasses and the management of the potential development of herbicide resistance in grass weeds in rice fields.

The most widely used herbicides currently registered for the control of Barnyard grasses in rice are generally restricted to application in the presow up to 3 or 4 leaf weed stage. The availability of Barnstorm will provide a wider window of application for the effective control of grass weeds from the 3-5 leaf stage up to the 4 tiller stage of grass weeds.

The availability of this herbicide will give improved control options for silver top grass. Most of the currently available grass herbicides are less efficacious and have a narrower application window on silver top grass than the barnyard grasses. Barnstorm provides good efficacy on silver top grass and a wider application window from seedling to tillering stages.

The herbicide also shows good crop selectivity and safety. Previous candidate herbicides for extended and later control of grass weeds have often had phytotoxicity problems. Barnstorm provides high selectivity and safety for use on rice.

There is more than adequate justification for the registration and use of this proposed product label. The availability of this product will provide potential benefits to the NSW rice industry.

Adequacy of efficacy data as it relates to:

- ***Trial design in relation to provision of controls, treatment group size, number of replicates, age and type of animal, plant varieties and stage of growth etc*:** The design of the trials, number of replicates, provision of controls, treatment group size and treatment stages of growth were satisfactory. The trial data listed covered a range of rice varieties.
- ***Experimental conditions in relation to relevant variables, such as pest/disease* pressure, *weather conditions, soil type etc*:**
  The trials covered a satisfactory range of weather, soil, and weed environments.
- ***Analysis of trial data and its interpretation, including efficacy relative to dose/application rate and application/administration:*** The analysis of the trial data and it interpretation were generally satisfactory.
- ***Trial validation with respect to the person responsible for the trial, location of the* trial, *date of trial*:** The personnel/companies responsible for the experimental work and the trial locations are experienced in this work and are well accepted.
- ***General applicability of the trial data to the use of the candidate preparation under commercial conditions*:** In general the trial data can be applied to commercial conditions.

Claims

Efficacy data supporting the label claims

In general the efficacy data supports the label claims proposed for use of Barnstorm Herbicide

Safety to target and non target species including adequacy of precautionary advice.

- ***Target Crop Safety*.** The data presented illustrates the high level of selectivity and crop safety with Barnstorm Herbicide
- ***Non Target Species Safety*** Barnstorm Herbicide does present a hazard to some other crops.

  The buffer zone proposed for grass crops and pastures is 50 metres, which similar to the US Clincher label of 45 metres for aerial application in the southern states, but much less than the 135 metres for aerial application in California.

  The buffer zone proposed for peaches and nectarines is 200 metres downwind for ground application (similar to the US Clincher labels), and 5 km downwind for aerial application, compared to 6.4 km for the US labels.

  These buffer zones proposed are accepted. However, the experience in California, USA suggests that this issue of Safety to Non Target Plants (domestic situations, as well as commercial situations) with cyhalofop-butyl is very important, and will require a strong stewardship approach from the company.

Conclusions drawn from assessment of the data

- The proposed Barnstorm Herbicide label claims have generally been shown to provide acceptable control of the weed species of rice listed in the Direction for Use and acceptable crop safety within the conditions and limitations outlined. It is recommended that on the basis of efficacy and crop safety Barnstorm Herbicide be considered for registration.

CAUTION

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Dow AgroSciences™

Barnstorm*

Herbicide

ACTIVE CONSTITUENT: **285 g/L CYHALOFOP BUTYL**
SOLVENT: **607 g/L LIQUID HYDROCARBON**

GROUP A HERBICIDE

For post-emergent control of barnyard grasses and silver top in rice as specified in the Directions for Use

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

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

Contents: 10 Litres

GMID:

* Trademark of Dow AgroSciences

DIRECTIONS FOR USE

RESTRAINTS

DO NOT apply if crop or weeds are stressed due to prolonged periods of extreme cold, dry conditions, poor nutrition or previous herbicide treatment as reduced levels of control may result.

DO NOT apply directly into floodwater either by SCWIIRT (Soluble Chemical Water Injection into Rice Technique) or the aerial Bickley Boom. Apply only as a foliar spray.

CROP/SITUATION: Barnstorm Herbicide may be applied to any direct seeded rice crop (combine sown, sodseeded, dry broadcast sown followed by flooding and aerial sown into flooded bays) from the 1-2 leaf stage up to late tillering of the rice. Within these rice stages, choose the rate and timing as required by the growth stage of the target weeds (*see below*).

WEEDS CONTROLLED	WEED GROWTH STAGE	RATE (L/ha)	CRITICAL COMMENTS
For resistance management the application of an alternate mode of action grass herbicide as a pre or at sowing treatment is recommended			
Barnyard grasses (*Echinochloa* spp.) Silver top (*Lepthochloa fusca*)	3 to 5 leaf	0.75 – 1 L/ha + 1 L/ha Uptake* Spraying Oil	Barnstorm Herbicide must be applied directly to the foliage of actively growing weeds by aircraft or ground boom equipment. Apply post-flooding. Water must be at least 1-2 cm deep in fields at spraying to ensure active growth of weeds and sufficient exposure of weeds to allow coverage by the foliar spray. See under General Instructions – Water Management. Commence reflooding after 2 hours and fill as soon as possible to limit germination of new weeds. Only use 0.75L/ha for 3-5 leaf weeds when light weed infestations, excellent soil moisture and good crop competition is present. Use the 1L/ha rate if any of these conditions are not present at treatment time.
	1 to 4 tillers	1 L/ha + 1 L/ha Uptake* Spraying Oil	
Weed suppression (reduced seedset) only will be obtained if Barnstorm is applied to advanced grass weeds (larger than 4 tiller), or to high weed densities or to moisture stressed weeds.			

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

HARVEST WITHHOLDING PERIOD:

NOT REQUIRED WHEN USED AS DIRECTED

STOCK FOOD WITHHOLDING PERIODS:

Rice straw at harvest: NOT REQUIRED WHEN USED AS DIRECTED

Failed crop (green fodder): DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 8 WEEKS AFTER APPLICATION

DRAINAGE WITHHOLDING PERIOD:
DO NOT drain water into regional drains within 7 days after Barnstorm Herbicide application or as defined by the local irrigation authority, whichever is the greater time period.

RESISTANT WEEDS WARNING

GROUP A HERBICIDE

Barnstorm Herbicide is a member of the aryloxyphenoxy propionate group of herbicides. The product has the acetyl CoA carboxylase inhibitor mode of action. For weed resistance management Barnstorm Herbicide is a Group A herbicide.

Some naturally occurring weed biotypes resistant to the product and other inhibitors of acetyl CoA carboxylase 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 the product or other inhibitors of acetyl CoA carboxylase.

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

GENERAL INSTRUCTIONS

Barnstorm Herbicide is a post-emergence foliar herbicide for selective control of specific grass weeds in drilled and water seeded rice. Barnstorm Herbicide does not provide pre-emergence or soil residual weed control. Only actively growing grass weeds already emerged at the time of treatment are controlled. Barnstorm Herbicide will not control broadleaf weeds or sedges.

WATER MANAGEMENT: There must be at least 1 to 2 cm of water in fields at spraying to ensure active growth of weeds while allowing adequate exposure of weeds to the foliar spray. For 3-5 leaf weeds, ensure that 75% of foliage is exposed above floodwater. For 1-4 tiller weeds, all tillers and 75% of foliage must be exposed above floodwater. **DO NOT** treat weeds if mud, cracks or firm soil have appeared throughout fields prior to treatment, as poor control will result.

MIXING

Add water to the spray tank to 10 cm above the level of agitation and ensure the agitation device is working vigorously. If tank mixing, firstly add any soluble liquid formulations and allow agitation for approximately one minute. Then add Barnstorm at the point where agitation is strongest. Allow further agitation for one minute. Half fill the spray tank. If using wettable powder or water dispersible granules, or other emulsifiable concentration formulations (e.g. Lorsban* 500EC Insecticide) these should be added after the Barnstorm to the half-full spray tank, ensuring vigorous agitation. Finally add UPTAKE* Spraying Oil and continue filling the tank to the required volume, maintaining agitation at all times. Only mix sufficient solution for immediate use. Barnstorm and any other tank mixes should be applied immediately for best results.

APPLICATION

Aerial

Apply this product by an accurately calibrated aircraft using a minimum water volume of 40 L/ha. Sprayers should aim to apply medium quality spray based on BCPC specifications and in accordance with ASAE (American Society of Agricultural Engineers) standard S-572.

Precautionary Statement: DO NOT use human flaggers/markers unless they are protected by engineering controls such as enclosed cabs.

Ground

Apply using a vehicle mounted boom, using a minimum water volume of 100L/ha. Sprayers should aim to apply medium quality spray based on BCPC specifications and in accordance with ASAE (American Society of Agricultural Engineers) standard S-572.

COMPATIBILITY

Barnstorm Herbicide can be tank mixed with Lorsban* 500 EC Insecticide or with the herbicide pendimethalin.

DO NOT apply Barnstorm as a tank mix with MCPA, Basagran® M60, bensulfuron methyl or carfentrazone as reduced grass weed control will occur. If these products are to be used in the same spray program as Barnstorm, separate applications by at least 7 days.

CLEANING SPRAY EQUIPMENT

If broadleaf herbicides, particularly sulfonylureas, have been used in the spray equipment at any time prior to use of Barnstorm, particular care should be taken to follow the directions on the relevant broadleaf herbicide label for equipment cleaning, or damage to the rice may occur.

After using Barnstorm, empty the tank completely and drain the whole system. Thoroughly wash inside the tank using a pressure hose, drain the tank and clean any filters in the tank, pump, line and nozzles.

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

To decontaminate: Before spraying other cereals, maize, sorghum or other sensitive crops, wash the tank and rinse the system as above. Then quarter fill the tank and add an alkali detergent (e.g. SURF®, Cold Water SURF Concentrate®, DynamoMatic Concentrate®, OMO® or DRIVE®) at 500 mL/100 L of water or the powder equivalent at 500 g/100 L of water, and circulate throughout the system for at least fifteen minutes. Drain the whole system. Remove filters and nozzles and clean them separately. Finally flush the system with clean water and allow to drain. Chlorine-based cleaners are not recommended.

Rinse water should be discharged onto a designated disposal area, or if this is unavailable, onto unused land away from desirable plants and water sources.

RE-ENTRY PERIOD

DO NOT allow entry into treated areas for irrigation and scouting until the spray has dried unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves.

PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS

- Other cereals (eg. maize and sorghum) and grasses (eg. seed crops, turf) are highly sensitive to damage from Barnstorm Herbicide, as may be non-target native grasses/vegetation. Maintain a buffer zone of at least 50 m downwind from these for aerial applications.
- **Peaches and nectarines are very sensitive** to spotting from spray drift. Ensure that these crops are more than 5 kms downwind before spraying Barnstorm Herbicide by air and 200m downwind when applying by ground.
- DO NOT rotate treated land to crops other than rice for 3 months after application.
- DO NOT apply under weather conditions, or from spraying equipment, that may cause spray to drift onto nearby susceptible plants/crops, cropping lands or pastures.

PROTECTION OF LIVESTOCK

- DO NOT graze or cut treated crop for stock food except as specified under withholding periods.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

- Barnstorm Herbicide is toxic to aquatic organisms.
- DO NOT contaminate streams, rivers or waterways with the chemical or used container.
- DO NOT drain water into regional drains within 7 days after Barnstorm Herbicide application or as defined by the local irrigation authority, whichever is the greater time period.

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 feedstuffs, fertilisers or seeds.

This container can be recycled if it is clean, dry, free of visible residues and has the ***drum****MUSTER* 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 ***drum****MUSTER* collection or similar container management site. The cap should not be replaced but may be taken separately.

If not recycling, break, crush or puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

SMALL SPILL MANAGEMENT

Wear protective equipment (see SAFETY DIRECTIONS section). Apply absorbent material such as earth, sand, cat litter or clay granules to the spill. When absorption is complete, sweep up material 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 this wash liquid for disposal as described above.

SAFETY DIRECTIONS

- Will damage the eyes
- Will irritate the nose and throat and skin
- Avoid contact with eyes and skin.
- Do not inhale vapour.
- If product in eyes, wash it out immediately with water.
- Wash hands after use.
- When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, goggles, elbow-length rubber gloves and a disposable fume mask.
- After each day's use, wash gloves, goggles and contaminated clothing.

FIRST AID

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

MATERIAL SAFETY DATA SHEET

Additional information is listed on the Material Safety Data Sheet for Barnstorm Herbicide which is available from Dow AgroSciences on request. Call Customer Service Toll Free on 1-800 700 096

NOTICE

Seller warrants that the product conforms to its chemical description and 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. 58613/10L/0805
D.O.M. Batch No.

* Trademark of Dow AgroSciences

Made in New Zealand

[The proposed approved label for products containing the active constituent should be inserted.]

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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Australian Pesticides and Veterinary Medicines Authority 1996, *Ag Manual: The Requirements Manual for Agricultural Chemicals*, APVMA, Canberra.

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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 cyhalofop-butyl in the product Barnstorm 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)_____

Position _____

Company/organisation _____

Address _____

Contact phone number (___) _____

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

Make cheques payable to 'Australian Pesticides and Veterinary Medicines Authority'.

___ Bankcard ___ Visa ___ Mastercard

Card number _____/_____/_____/_____ Expiry date ...../...../.....

Signature_____ Date _____