Public Release Summary
on

Evaluation of the new active

FLUTOLANIL

in the product

MONCUT SC FUNGICIDE

National Registration Authority for Agricultural and Veterinary Chemicals

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Australia

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FOREWORD

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

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

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

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

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

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

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

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LIST OF ABBREVIATIONS AND ACRONYMS

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
bw	bodyweight
d	day
DAT	Days After Treatment
DT_{50}	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
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
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 quantified
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
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
TRR	Total Radioactive Residues
T-Value	A value used to determine the First Aid Instructions for chemical products that contain two or more poisons
mg	microgram
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 Moncut SC Fungicide, which contains the new active constituent flutolanil. The product is proposed to be used to control seed-borne black scurf (*Rhizoctonia solani)* on potatoes.

Flutolanil is a new carboxanilide fungicide. Its mode of action is to inhibit mitochondrial respiration through interference with succinate metabolism.

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

Written comments are invited and should be submitted by **5 February 2002,** addressed to:

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Applicant:

Aventis CropScience Pty Limited

Product details:

Moncut SC Fungicide (Moncut) is a suspension concentrate formulation containing 464g/L flutolanil. The product will initially be marketed for the control of seed-borne black scurf in potatoes in all States.

The active constituent is manufactured by Central Glass Co Ltd in Japan and the product will be formulated by Nihon Nohyaku Co Ltd in Japan.

Flutolanil formulations are currently registered for use in many countries for control of fungus diseases of potatoes (including in Japan, France, Spain, Belgium, Holland, Finland, UAE, Mexico, Israel, Peru, Uruguay) and for use in rice, wheat, barley, peanuts, many vegetable crops and turf.

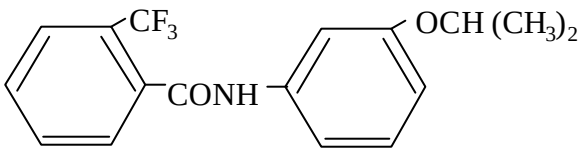
CHEMISTRY AND MANUFACTURE

Active constituent

The chemical active constituent flutolanil has the following properties:

Common name (ISO):	flutolanil
Chemical name:	α,α.α-trifluoro-3′-isopropoxy-o-toluanalide
CAS Registry Number:	66332-96-5
Empirical formula:	$C_{17}H_{16}F_3NO_2$
Molecular weight:	323.3
Physical form:	Crystalline
Colour:	Off-white
Odour:	Odourless
Melting point:	101.1 – 103.2°C
Density:	1.327g/cm^3 at 20°C
Octanol/water partition:	
coefficient (K_{ow}):	3.74
Vapour pressure at 25^{o}C:	4.87x10^{-8} mmHg

Structural formula:



Formulated product

Product name:	MONCUT SC FUNGICIDE
Formulation type:	Suspension concentrate
Active constituent content:	464g/L
Colour:	Off-white
Odour:	Citrus-like
pH:	6.68 at 25°C
Density:	1.138g/mL at 20°C

TOXICOLOGICAL ASSESSMENT

Evaluation of toxicity

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

Acute Studies

Flutolanil has low acute oral (LD_{50} >10000 mg/kg bw, no deaths), subcutaneous (LD_{50} >10000 mg/kg bw, no deaths) and intraperitoneal (LD_{50} >10000 mg/kg bw, no deaths) toxicity in mice and rats. It also has low dermal (LD_{50} >5000 mg/kg bw, no deaths) and inhalation (LC_{50} >5980 mg/m^3, no deaths) toxicity in rats. It is not a skin irritant, but is a slight eye irritant in rabbits. Flutolanil is not a skin sensitiser in guinea pigs, using the Magnusson–Kligman Maximisation Test

Flutolanil 40 SC, containing 464 g/L flutolanil, is identical to Moncut SC Fungicide. It has low acute oral (LD_{50} >5000 mg/kg bw, no deaths) and dermal (LD_{50} >4000 mg/kg bw, no deaths) toxicity in rats. It is not a skin irritant, but is a slight eye irritant in rabbits. Flutolanil 40 SC is not a skin sensitiser in guinea pigs, using the Magnusson–Kligman Maximisation Test.

Short - Term Studies

Flutolanil was administered to rats at 0, 500, 4000 and 20000 ppm (0, 37, 299 and 1512 mg/kg bw/day in males and 0, 44, 339 and 1743 mg/kg bw/day in females) in the diet for 3 months. There were no treatment−related mortalities, clinical signs or effects on body weight, food consumption or ophthalmology parameters. In females at 20000 ppm, serum phosphorous was increased and glucose was decreased. Thyroid/parathyroid gland weights were increased in males at 4000 ppm and both sexes at 20000 ppm and liver weights were increased in females at 4000 ppm and both sexes at 20000 ppm. There were no treatment−related pathological findings. The NOEL is 500 ppm (37 mg/kg bw/day in males and 44 mg/kg bw/day in females).

Flutolanil was administered to dogs at 0, 80, 400 and 2000 mg/kg bw/day in gelatin capsules for 3 months. There were no treatment−related mortalities, clinical signs or effects on body weight, food and water consumption and ophthalmology parameters. Alkaline phosphatase

levels were increased in both sexes at 2000 mg/kg bw/day, with liver weights increased at 400 mg/kg bw/day and above in females and at 2000 mg/kg bw/day in males. At 400 and 2000 mg/kg bw/day, increased pallor and swelling of hepatocytes was associated with an increased severity of glycogen deposition. The NOEL is 80 mg/kg bw/day.

Long - Term Studies

Flutolanil was administered to mice at 0, 300, 1500, 7000 and 30000 ppm (0, 32, 162, 735 and 3333 mg/kg bw/day in males and 0, 34, 168, 839 and 3676 mg/kg bw/day in females) in the diet for 78 weeks. Body weight gain and food efficiency were reduced in females at 7000 ppm and both sexes at 30000 ppm. In females at 30000 ppm, liver and spleen weights were increased, as were the incidences of centriacinar and panacinar hepatocytic fatty vacuolation. The incidence of periacinar hepatocytic fatty vacuolation was increased in males at 1500 ppm and above. There were no treatment–related neoplastic findings. The NOEL is 300 ppm (32 mg/kg bw/day in males and 34 mg/kg bw/day in females).

Flutolanil was administered to rats at 0, 40, 200, 2000 and 10000 ppm (2, 9, 87 and 461 mg/kg bw/day in males and 0, 2, 10, 103 and 536 mg/kg bw/day in females) in the diet for 24 months. Body weight gain was reduced in males at 10000 ppm until week 12. Haematocrit, haemoglobin and mean corpuscular haemoglobin were reduced in females at 2000 and 10000 ppm. At 10000 ppm, urea nitrogen and inorganic phosphorous were increased in males and cholesterol was decreased in females. Albumin:globulin ratio was increased in males at 200 ppm and in both sexes at 2000 and 10000 ppm. Bilirubin was reduced in females at 200 ppm and above. Liver (both sexes) and kidney (males) weights were increased at 10000 ppm. An increase in the severity of vacuolar degeneration of the liver was observed in females at 2000 ppm and both sexes at 10000 ppm, whereas dilatation of the sinusoid in the liver was increased in females at 200 ppm and above. At 2000 and 10000 ppm, proliferation of reticulocytes occurred in the spleen of females. There were no treatment–related neoplastic findings. The mean residual concentration of flutolanil in fatty tissues was 0.18–0.24 ppm at 2000 ppm and 0.58–0.66 ppm at 10000 ppm. The NOEL is 40 ppm (2 mg/kg bw/day).

Flutolanil was administered to Beagle dogs at 0, 50, 250 and 1250 mg/kg bw/day in gelatin capsules for 104 days. Emesis, salivation and soft stools were observed in both sexes at 250 and 1250 mg/kg bw/day. At 1250 mg/kg bw/day, mean body weight and food consumption were significantly lower than controls, and hyperaemia of the small intestine occurred. The NOEL is 50 mg/kg bw/day.

Reproduction and Developmental Studies

Flutolanil was administered to rats at 0, 1000 and 10000 ppm in the diet over 3 generations. At 1000 and 10000 ppm, body weight gain and food and water consumption were reduced. Body weight gain of F_1 and F_2 pups was reduced at 1000 and 10000 ppm. Liver weights were increased in F_0 and F_1 animals at 10000 ppm. At 1000 and/or 10000 ppm, an increase in the incidence of poorly ossified sternebra of the sternum and a reduction in the proportion of foetuses with 5 ossified metatarsals occurred. Enlargement of the renal pelvis was also observed at 10000 ppm. There is no NOEL for adult rats, reproduction toxicity or developmental effects.

Flutolanil was administered to rats at 0, 200, 2000 and 20000 ppm in the diet over 2 generations. There were no treatment–related effects on mating and fertility indices, gestation length or parturition during either generation. At 20000 ppm, liver weights were increased in

both sexes of adult F_0 rats and in female adult F_1 rats. There were no treatment−related pathological findings in adults or pups. The NOEL for adult rats is 2000 ppm (157 mg/kg bw/day) and for reproduction toxicity is 20000 ppm (1614 mg/kg bw/day).

Flutolanil was administered to rats at 0, 40, 200 and 1000 mg/kg bw/day by gavage on days 6−15 of gestation. There were no treatment−related effects on reproductive performance and no maternal toxicity. The NOEL for maternal and developmental effects is 1000 mg/kg bw/day.

Flutolanil was administered to rabbits at 0, 40, 200 and 1000 mg/kg bw/day by gavage on days 6−18 of gestation. There were no treatment−related effects on reproductive performance or on foetal toxicity. Adrenal gland weight was reduced 11% in maternal animals at 1000 mg/kg bw/day. The NOEL for maternal effects is 200 mg/kg bw/day and for developmental effects is 1000 mg/kg bw/day.

Genotoxicity

In the presence and absence of metabolic activation, flutolanil (100−250000 µg/mL) was not mutagenic in the Ames Test in *Salmonella typhimurium* and *Escherichia coli* strains and was negative in a forward mutation assay at the thymidine kinase locus in mouse lymphoma cells at concentrations of 6−100 µg/mL. Flutolanil (1000−500000 µg/mL) did not induce DNA damage in *Bacillus subtilis* strains and did not increase chromosomal aberrations in human lymphocytes, in the presence and absence of metabolic activation, at concentrations up to 1000 µg/mL. However, at 48.5 µg/mL, flutolanil induced chromosomal aberrations in cultured Chinese hamster lung cells in the presence of metabolic activation, although this effect was relatively weak. No effect was observed in the absence of metabolic activation. Using cultured rat hepatocytes *in vitro*, unscheduled DNA synthesis was not induced by flutolanil at concentrations up to 80 µg/mL. In an *in vivo* study, flutolanil was not genotoxic in the micronucleus assay in mouse bone marrow cells after single oral doses of 6400, 8000 and 10000 mg/kg bw or after repeat doses at 10000 mg/kg bw/day.

PUBLIC HEALTH STANDARDS

Poisons Scheduling

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

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

NOEL/ADI

The Acceptable Daily Intake is that quantity of an agricultural or veterinary 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 flutolanil was established at 0.02 mg/kg bw/day based on a NOEL of 2 mg/kg bw/day in a 24 month rat dietary study and using a 100−fold safety factor in recognition of the extensive toxicological database available for flutolanil.

Acute Reference Dose (ARfD)

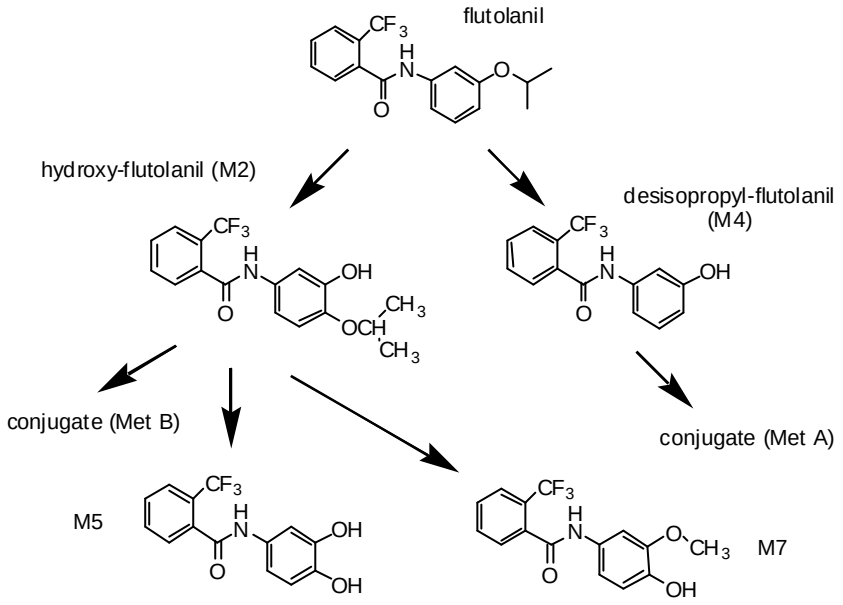
The acute reference dose is the maximum quantity of an agricultural or veterinary chemical that can safely be consumed as a single, isolated, event. The ARfD is derived from the lowest single or short term dose which causes no effect in the most sensitive species of experimental animal tested, together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

Since acute or short−term dosing with flutolanil failed to produce significant general toxicity or adverse effects on foetal development, an ARfD was not considered necessary.

METABOLISM AND TOXICOKINETICS ASSESSMENT

Metabolism and toxicokinetics

The metabolism of flutolanil is similar in plants and animals. The parent compound initially undergoes deisopropylation or hydroxylation at the aniline ring to form M4 and M2 respectively. The resulting products are subsequently conjugated or may undergo further transformations. The hydroxylated metabolite can also be deisopropylated to form M5 and then methylated to form M7.



In rats given an oral dose of 20 and 100 mg/kg bw of ^{14}C–labelled flutolanil, levels in blood peaked after 2 hours, and declined to low levels after 7 days. Only a small amount of radioactivity was recovered in tissues, mainly in the liver, but also in the kidney. A 20 mg/kg bw ^{14}C–dose was eliminated in urine (41–69%) and faeces (27–42%), but flutolanil was mainly excreted in the faeces (67–78%) after a 1000 mg/kg bw dose. The majority of faecal and urinary excretion occurred within 24 hours after dosing.

In rats pre–treated with unradiolabelled flutolanil for 2 weeks, the amount of test material in blood and tissues was also low, but elimination of the dose was primarily in urine (70–71%). Up to 12 metabolites were identified in the excreta, of which the deisopropylated flutolanil accounted for 57% (51% in urine and 6% in faeces) of the administered radioactivity. In one study, unchanged parent compound accounted for only 4% of the administered dose in excreta. However, in a subsequent study, approximately 35–40% of the administered dose occurred as unchanged parent compound in the faeces.

In **rats** the combined excretion in urine and faeces accounted for 76-100% of the administered dose. The TRR in tissues at sacrifice accounted for <0.1% of the dose. No particular organ or tissue accumulated exceptional concentrations.

In **goats** concentrations of flutolanil in the milk fluctuated with dose. In tissues levels of radioactivity were highest in liver and kidney. Desisopropyl-flutolanil was identified in liver

and kidney at >10% of the applied radioactivity. Accumulated radioactivity was higher in fat than in muscle.

In **potato** tubers, the largest proportion of radioactivity was due to a conjugate of the metabolite desisopropyl flutolanil (23% of the TRR). The parent compound comprised approximately 16% of the TRR and a second conjugate identified as hydroxy-flutolanil contributed 14% of the TRR. Up to 39% of the TRR was not extractable with organic solvents. Small amounts of the residual radioactivity were released by acid and base hydrolysis.

In **rice**, after application of [^{14}C]-flutolanil to the paddy water, most radioactivity had accumulated in the leaf (31% TRR 81 days after application). Relatively little accumulated in the grain (0.16%). In rice, cucumber and peanuts desisopropyl-flutolanil was the primary metabolite identified. In peanuts desisopropyl-flutolanil formed a significant component of both the free and conjugated %TRR in vines, hulls and nuts, compared to the parent compound. The parent compound accounted for 1-17% of the TRR.

RESIDUES ASSESSMENT

Data concerning residues in potato, metabolism in plants and animals, and chemistry were considered as part of the residue evaluation of the application.

Analytical methods

A validated analytical method for determination of flutolanil residues in potatoes was provided. The practical Limit of Quantitation (LOQ) was 0.01 mg/kg. Flutolanil was determined by GC-MS as a single chromatographic peak following sequential extraction with acetone, chloroform and subsequent methylation. Animal tissues (muscle, fat, kidney, liver, milk and eggs) were subjected to base hyrolysis, followed by derivitisation to form 2-trifluoromethyl benzoic acid methyl ester. The residue is then expressed in flutolanil equivalents (LOQ = 0.05 mg/kg).

Storage stability

Flutolanil residues in potato tubers were shown to be stable for at least 67 months when stored at -20°C. The maximum frozen storage interval for residue trial samples was 14 months, a period that was covered by the storage stability trials. Storage stability data for tissues, milk and eggs were cited and indicated that residues were stable up to 120 days. The maximum period between tissue collection and analysis was 119 days.

Residue definition

For the purposes of monitoring GAP in potatoes a residue definition of the parent compound is adequate. The analytical method for determining residues in animal commodities involves hydrolysis of flutolanil and related metabolites followed by derivitisation to form 2-trifluoromethyl benzoic acid methyl ester. The residue is then expressed in flutolanil equivalents. The residue definition will therefore be as follows:

Flutolanil	*commodities of plant origin:* flutolanil *commodities of animal origin:* flutolanil and metabolites hydrolysed to 2-trifluromethyl-benzoic acid and expressed as flutolanil.

Residue trials

The proposed maximum application rate is 150 mL product/ tonne of tubers. This is equivalent to 69.6g flutolanil/ tonne. The applicant provided residue data from 7 Australian trials and 2 European trials that were considered to comply with proposed Australian GAP.

In the Australian trials, the highest residue detected in potatoes was 0.02 mg/kg 4-5 months after application. Residues detected in overseas trials were generally higher than those detected in Australia, the highest residue detected was 0.035 mg/kg, although the PHIs were significantly shorter. The trial data listed in rank order (median underlined) is <0.002, <0.01, <0.01, <0.01, <u>0.01</u>, 0.01, 0.014, 0.02, 0.035 mg/kg. Taken as a whole the residue data (including European trials) adequately reflect the residues that are likely to occur in potato when flutolanil is applied as a seed treatment.

In trials conducted according to proposed Australian GAP (48.72-90.18 g flutolanil/tonne, PHI ~2-5 months) residues in potato were below 0.02 mg/kg. Taken as a whole the residue data support the establishment of an MRL of 0.05 mg/kg for potato.

Processing studies

No processing data were presented. Finite residues are unlikely to occur in processed potato products.

Animal commodity MRLs

In the animal transfer study in cows the lowest feed level was equivalent to 44 ppm in the diet (approximately 1.56 mg/kg bw/day based on a 500 kg animal consuming 20 kg DM/day). At this feed level the maximum residues of flutolanil and metabolites in fat, milk and offal (kidney and liver) were up to 0.05, <0.05 and 2.03 mg/kg respectively. Residues in all tissues declined after a 7 day depuration period. Residues in meat [in the fat], milk and offal would be undetectable as a result of feeding 5% potato culls containing flutolanil at the MRL. It is recommended that animal commodity MRLs be set at the Limit of Quantitation. The appropriate MRLs are meat (mammalian, in the fat) *0.05 mg/kg, edible offal *0.05 mg/kg and milk *0.05 mg/kg. The maximum feeding level for mammals is approximately 1 ppm in the diet.

In a poultry animal transfer study, laying hens fed flutolanil at 4.3 ppm in the diet for 28 days showed no residues present at sacrifice in eggs, muscle, fat or skin. Residues were present in liver at 0.2 mg/kg. Based on the predicted residue level in potatoes the dietary burden for poultry is considered to be very low. Quantifiable residues are unlikely to occur in poultry products. The appropriate MRLs are poultry meat (in the fat) *0.05 mg/kg and eggs *0.05 mg/kg. The maximum feeding level for poultry is approximately 1 ppm in the diet.

Estimated dietary intakes

The chronic dietary risk is estimated by the National Estimated Daily Intake calculation encompassing all registered/temporary uses of the chemical and dietary intake data from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with the *Guidelines for Predicting Dietary Intake of Pesticide Residues (revised)* (WHO, 1997).

The refined NEDI for flutolanil is equivalent to less than 3% of the ADI. It is concluded that the chronic dietary exposure is small and the risk is acceptable.

Consideration of acute dietary exposure is not required as an acute reference dose was not considered necessary due to the low acute toxicity of flutolanil.

Bioaccumulation potential

Pure flutolanil has a log P_{OW} value of 3.74 (initial concentration in n-octanol = 10^{-2M}) and 3.79 (initial concentration in n-octanol = 10^{-3M}). Flutolanil should be considered somewhat fat-soluble. In cows residues in fat were higher than in muscle. In hens and goats the highest radioactive residues (ppm parent compound equivalents) were observed in offal. In the lactating goat metabolism study residues in whole milk did not accumulate, but fluctuated with dose.

Recommended amendments to the MRL Standard:

Table 1

Compound	Food		MRL (mg/kg)
ADD:			
Flutolanil	VR 0589	Potato	0.05
	MM 0095	Meat (mammalian, in the fat)	*0.05
	ML 0106	Milks	*0.05
	MO 0105	Edible offal (mammalian)	*0.05
	PM 0110	Poultry meat (in the fat)	*0.05
	PO 0111	Poultry, edible offal	*0.05
	PE 0112	Eggs	*0.05

* at or about the limit of quantitation

Table 3

Compound	Residue Definition
ADD:	
Flutolanil	*commodities of plant origin:* flutolanil *commodities of animal origin:* flutolanil and metabolites hydrolysed to 2-(trifluromethyl)-benzoic acid and expressed as flutolanil.

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

Withholding periods

The following withholding period is recommended in relation to the above MRL:

Harvest and Grazing:

POTATO: NOT REQUIRED WHEN USED AS DIRECTED.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Commodities exported and main destinations

Australia produced 1327 kt of potatoes in 1999. Exports accounted for 21293 tonne (1.6% of production), with Singapore, Mauritius and Korea as major destinations and a total value of $8.9 million. (Figures from ABARE, Australian Commodity Statistics 2000/2001). Australian exports of beef/veal and live cattle in 1998/99 were 855.3 kt and 511.2 kt respectively. Major export markets for beef/veal were US (285.2 kt) and Japan (320.9 kt). The value of beef/veal exports to these two markets alone was worth over $2 billion in 1998.

Overseas registration status

Aventis advised that flutolanil is currently registered in a large number of countries for use on potatoes, rice and a wide range of vegetable crops.

Aventis advised that the following MRLs are established in relation to registration of flutolanil in Japan, France and Spain:

Country	Commodity	MRL (mg/kg)*
Japan	potatoes	0.02
France	potatoes	0.01
Spain	potatoes	0.05

* at or about the Limit of Quantitation

CODEX Alimentarius Commission MRLs

Flutolanil has not been considered by CODEX.

Potential risk to Australian trade

In seven Australian residue trials flutolanil residues in potatoes treated at the proposed rate were <0.01 mg/kg in 5 trials. Residues up to 0.02 mg/kg were observed in the other two trials. In crops grown from tubers treated at 2× the proposed application rate, residues in potatoes were 0.01 mg/kg in 5 out of 7 trials. Although an MRL has been recommended at 0.05 mg/kg, under actual conditions of use the frequency of finite residues occurring in potatoes would be low. Finite residues are not expected to occur in livestock consuming potatoes or foliage grown from treated seed. It is considered that the proposed use of flutolanil is unlikely to unduly prejudice trade.

As an additional precaution, the applicant has proposed that the following statement be incorporated on the product label:

"Export of Treated Produce
Growers should note that suitable MRLs or import tolerances may not be established in all markets for produce treated with Moncut SC Fungicide. If you are growing produce for export please check with Aventis CropScience Pty Ltd for the latest information on MRLs and import tolerances BEFORE using Moncut."

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Flutolanil is not on the NOHSC *List of Designated Hazardous Substances*. Based on the available information, NOHSC cannot classify flutolanil as hazardous. It has low acute oral, dermal and inhalation toxicity in rats. It is not a skin irritant, but is a slight eye irritant in rabbits. Flutolanil is not a skin sensitiser in guinea pigs.

Moncut SC Fungicide is a suspension concentrate. It has low acute oral and dermal toxicity in rats, is not a skin irritant, but is a slight eye irritant in rabbits. Moncut SC Fungicide is not a skin sensitiser in guinea pigs. Aventis CropScience Pty Ltd has determined Moncut SC Fungicide to be a non hazardous substance, according to NOHSC *Approved Criteria for Classifying Hazardous Substances*.

Formulation, repackaging, transport, storage and retailing

Moncut SC Fungicide will be formulated overseas and imported into Australia in Intermediate Bulk Containers. From Intermediate Bulk Containers, the product will be transferred to a bulk filling station and then to the final packs (1L, 2.5L and 5 L high density polyethylene containers) via a closed system. Transport workers, store persons, and retailers will handle the packaged product and could only become contaminated if the packaging were breached.

Advice on safe handling of the active or the product during routine use will be provided in the Material Safety Data Sheet (MSDS) for Moncut SC Fungicide.

Use and exposure

Moncut SC Fungicide is indicated for the control of seed-borne black surf in potatoes (seed-borne infections only). The product will be applied at or prior to planting, at the maximum application rate of 150 mL/tonne of seed potatoes, diluted with water, to ensure thorough, even coverage of seed potatoes. It will be applied using an open system where seeds are sprayed on a roller conveyor belt. The draft label indicates that treated seed should be dried prior to planting.

Workers could be exposed to the product when opening the container, preparing the spray mix, applying the spray, maintaining and cleaning the equipment and handling treated potatoes. The main routes of exposure will be dermal and ocular, though inhalation exposure to product and spray mist can also occur.

Moncut SC Fungicide has low oral and dermal toxicity and is not a skin irritant or sensitiser. Therefore, skin protection is not needed for the users of this product. It is a slight eye irritant, but the spray is not expected to cause eye irritation at the diluted concentration of the product. Therefore, eye protection is not needed for the workers using the product, but warning statements are warranted.

Worker exposure studies on flutolanil and Moncut SC Fungicide are not available. NOHSC cannot use the UK Predictive Operator Exposure Model (POEM) to estimate worker exposure, as it is not suitable for the proposed use pattern.

The risk assessment, which took into consideration repeat dose toxicity, indicated that personal protective equipment is not needed, as it is unlikely for a worker to be contaminated

with large quantities of product or spray during routine use. Therefore, NOHSC does not recommend personal protective equipment for the workers using Moncut according to label directions.

Recommendations for safe use

Users should follow the instructions and Safety Directions on the product label.

Information provision

Material Safety Data Sheet (MSDS)

Aventis CropScience Pty Ltd has produced a MSDS for Moncut SC Fungicide. This should contain information relevant to Australian workers, as outlined in the NOHSC National Code of Practice for the Preparation of MSDS. Employers should obtain the MSDS from the supplier and ensure that their employees have ready access to it.

Conclusion

Moncut SC Fungicide can be used safely if handled in accordance with the instructions on the product label. Additional information is available on the MSDS for Moncut SC Fungicide.

ENVIRONMENTAL ASSESSMENT

Moncut SC Fungicide will be applied to potato seed pieces at 150 mL Moncut (70 g flutolanil) per tonne of seed pieces prior to or at the time of planting. This equates to a maximum application rate of 210 g/ha flutolanil.

Flutolanil has low water solubility, low vapour pressure, and high octanol/water partition coefficient. These properties indicate that flutolanil is likely to associate mainly with the soil, with little partitioning to air or water.

Environmental Chemistry and Fate

Standard laboratory environmental fate studies indicated that flutolanil was resistant to abiotic hydrolysis, photolysis in aqueous solution and on the soil surface, and biodegradation in soils (extrapolated half-lives in the order of 6 months to a year). Metabolite concentrations remained low because of the slow degradation, with the only main metabolite being the dealkylated product, desisopropyl flutolanil, formed at low levels by soil metabolism. Laboratory mobility tests (adsorption/desorption in five soils and column leaching in three) indicated that flutolanil has low mobility in soils and is unlikely to leach to groundwater. These results confirm that flutolanil will mainly remain associated with the soil following potato planting.

Limited field data further confirm that flutolanil will remain associated with the soil and undergo little or no leaching. A biphasic degradation was evident in the one soil studied, with a half-life of around 8 months after an initial period of more rapid degradation. Desisopropyl flutolanil was the only metabolite observed in the field. While this phenolic metabolite may be expected to be more mobile than flutolanil, it was only detected near the soil surface.

The above properties indicate that no significant accumulation of flutolanil is expected to occur in soils where potatoes are grown. Laboratory studies indicate that flutolanil is unlikely to bioaccumulate significantly in fish, particularly as aquatic exposure will be limited due to the strong retention of flutolanil by soils.

Environmental Effects

In acute and short-term studies, flutolanil has been shown to have low toxicity to both Bobwhite quail and Mallard duck. Reproduction parameters were affected only at daily administration rates of 4800 ppm and the no-observed effect concentration with each species was 1920 ppm. Mammalian toxicity is also low, based on toxicology summaries.

Acute toxicity studies on bluegill sunfish, rainbow trout and *Daphnia magna* indicate that flutolanil has moderate aquatic toxicity under conditions of acute exposure.

Longer term aquatic studies indicate slight aquatic toxicity under conditions of chronic exposure. Growth of fathead minnow fry was reduced at 0.49 mg/L, and daphnid reproduction was impaired at 1.1 mg/L. The proposed use of this product will present little opportunity for direct contamination of waterways.

It was concluded from two tests that flutolanil has little effect on the honey bee when applied as a spray to rapeseed or directly to bees at rates of 367 g ai/ha. In Australia flutolanil will not be applied as a spray to crops, but as a treatment to potato seed pieces prior to planting.

Soil concentrations of 1000 mg ai/kg soil were non-toxic to earthworms.

Flutolanil is not readily biodegraded and has no significant effect on organisms involved in sewage breakdown. The effect of flutolanil on nitrification in soil was investigated and it appeared that the disappearance of ammonium was not influenced by the presence of flutolanil, although nitrate formation was briefly retarded.

Prediction of Environmental Hazard

The properties of flutolanil (low water solubility, low vapour pressure and high partition coefficient) indicate that it is likely to remain associated with the soil, with little partitioning to air or water. These expectations are confirmed by results from laboratory and field studies, which also indicate that flutolanil is persistent in soil but not expected to accumulate to any significant extent. Leaching to groundwater is not expected to occur because of good retention by soil.

The estimated soil concentration of 0.12 mg/kg is well below no effect levels determined in testing with earthworms and soil microorganisms, indicating negligible hazard to these species. Higher concentrations will arise in the immediate vicinity of planted seed potatoes but are expected to remain localised until they degrade. Therefore, no significant effects on populations of soil dwelling organisms are expected.

Exposure of organisms that live above the soil, such as mammals, birds and bees, is expected to be negligible as flutolanil will be applied to seed potatoes which are then planted and buried. Even in the worst case situation of direct consumption of treated seed potatoes by birds and mammals, the exposure concentration is only 70 mg/kg, well below no effect levels in acute and chronic testing with birds and mammals.

The predicted hazard to aquatic organisms is low because the use pattern will deliver flutolanil beneath the soil surface where it is well retained with little or no partitioning to water. Even if the proposed application rate of 210 g/ha flutolanil were added directly to 15 cm water, the resultant concentration would be 0.14 mg/L, below no effect levels in acute and chronic laboratory testing with aquatic organisms.

Conclusion

The submission seeking registration of Moncut SC Fungicide contains sufficient data to demonstrate that use of the product on seed potatoes according to label and Good Agricultural Practice is not likely to give rise to significant environmental contamination or adverse effects to non-target organisms.

EFFICACY AND SAFETY ASSESSMENT

Justification and proposed use pattern

Black scurf, caused by the fungus *Rhizoctonia solani,* is a major disease of potatoes worldwide. The use of a tuber treatment to control the disease is standard practice in the industry and the introduction of new chemistry with Moncut should improve control of this problem.

Although there are no data on resistant strains of *Rhizoctonia* in Australia there have been some reports of poor control with existing chemicals. The use of new chemistry will provide a further mode of action which will reduce the likelihood of resistant fungicide strains developing.

The proposed directions for use are to spray the product at the rate of 150mL/ tonne on to seed potatoes at or prior to planting. Further details are shown on the proposed draft label in the next section of this document.

Evaluation of efficacy and safety

Fifteen trials were conducted in Australia over three consecutive seasons using naturally infected tuber seed, which would be similar to that occurring in a commercial situation. The trials were conducted in 4 States and on 6 cultivars, in small plots, replicated, and included untreated controls, other registered products as standards, and several rates of Moncut. Assessments were made on emergence, phytotoxicity, disease incidence and severity and yield. The data have been statistically analysed and demonstrate a statistically significant difference between treatments at the proposed rate and the untreated controls.

The trials were in most cases undertaken on commercial properties and the results are considered to be applicable to commercial conditions.

The data supports use of the product at a rate of 150mL product per tonne of tubers for the control of *Rhizoctonia* on seed tubers. Control was sometimes achieved at lower rates but it is considered that this rate is needed to cover the variation in efficacy that is likely to arise due to different levels of soil attached to tubers at the time of treatment.

A minimum total application volume of 3 litres per tonne seed potatoes is recommended based on trial work where total application volumes of 150 mL, 1.5 L, 3.0 L and 6.0 L per tonne of seed were compared in three trials. In one trial application at 1.5 L total volume did not perform as well as 3.0 or 6.0 L. It is considered necessary therefore, at this stage, to suggest a minimum total application volume of 3.0 litres per tonne of seed.

The use of cement dust is not recommended on tubers to be treated with Moncut based on trial work where various dusts (firbark, lime, mancozeb or cement dust) were applied to cut seed potatoes prior to Moncut treatment in two trials. In one trial pre-treatment with cement dust reduced *Rhizoctonia* control compared with pre-treatment with other dusts. It is considered necessary therefore, at this stage, to suggest that cement dust not be used as a pre-treatment where Moncut is to be used.

A slight delay in plant emergence in the first few weeks after planting was found in some trials but plants recovered and no difference between treatments was obvious by harvest time. It is therefore considered that there are not likely to be any significant adverse crop effects when Moncut is applied in accordance with the proposed label instructions.

LABELLING REQUIREMENTS

The draft label proposed for the product is as follows:

MAIN PANEL

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Moncut®

SC FUNGICIDE

Active Constituent: 464 g/L FLUTOLANIL

GROUP G FUNGICIDE

*** L**

For the control of seed-borne black scurf (*Rhizoctonia solani*) in potatoes as per the DIRECTIONS FOR USE Table.
IMPORTANT: READ THE ATTACHED BOOKLET BEFORE USE.

Aventis

(label code)

* 1, 2.5, 5 L

REAR PANEL

MONCUT SC FUNGICIDE
Active Constituent: 464 g/L FLUTOLANIL

STORAGE AND DISPOSAL
Product and product container
Keep out of reach of children.
Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight.
Triple or preferably pressure rinse containers before disposal. Add rinsings to spray tank when diluting product. Do not dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush or puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

Application equipment
Thoroughly rinse all application equipment with clean water immediately after use and dispose of rinsings in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots.

SAFETY DIRECTIONS
Will irritate the eyes. Avoid contact with eyes. Wash hands after use.

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

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

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

NRA Approval No.: 53217/

Moncut® is a Registered Trademark of Nihon Nohyaku Co., Ltd.

IMPORTANT: READ THE ATTACHED BOOKLET BEFORE USE

REAR PANEL (cont)

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

*

BAR
CODE

Aventis CropScience Pty Ltd
A.B.N. 87 000 226 022
391-393 Tooronga Rd
East Hawthorn Vic. 3123

Phone: (03) 9248 6888
Fax: (03) 9248 6800
Website: www.aventis.com.au

Batch Number:
Date of Manufacture:

(label code)

* drummuster logo required for 2.5 and 5 L containers only

Front page of BOOKLET

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

MONCUT SC FUNGICIDE

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STORAGE AND DISPOSAL

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

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NRA Approval No.: 53217/

Moncut® is a Registered Trademark of Nihon Nohyaku Co., Ltd.

IMPORTANT: READ THIS BOOKLET BEFORE USE

DIRECTIONS FOR USE

CROP	DISEASE	RATE	CRITICAL COMMENTS
Potatoes	Black scurf (*Rhizoctonia solani)* (seed-borne infections only)	150 mL/ tonne of seed potatoes	Spray Moncut onto seed potatoes at or prior to planting. Prior to application Moncut should be diluted with sufficient water to ensure thorough, even coverage of seed potatoes. A minimum total application volume of 3 litres per tonne of seed is recommended. Where conditions are likely to favour seed piece decay (eg. high temperatures and wet soil soon after planting); • Ensure cut tubers are properly cured before application • Ensure treated seed is dry prior to planting • Avoid treatment on the planter, or immediately prior to planting

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

WITHHOLDING PERIOD NOT REQUIRED WHEN USED AS DIRECTED.

GENERAL INSTRUCTIONS

Moncut SC Fungicide is for the protection of potatoes against seed-borne black scurf (*Rhizoctonia solani*). Moncut is sprayed onto seed potatoes prior to planting, or at the time of planting. When applied as directed, this product will protect progeny tubers from infection via seed-borne *Rhizoctonia solani*. No claim is made for protection of tubers against soil-borne *Rhizoctonia solani*. Best results will be achieved where other management practices (such as crop rotation) are employed to reduce the occurrence of soil-borne *Rhizoctonia solani*.

Fungicide Resistance Warning **GROUP G FUNGICIDE**

Moncut is an anilide fungicide. For fungicide resistance management, Moncut is a Group G fungicide. Some naturally-occurring fungal biotypes resistant to Moncut, and other Group G fungicides may exist through normal genetic variability in any fungal population. The resistant individuals can eventually dominate the fungal population if these fungicides are used repeatedly. These resistant fungi will not be controlled by Moncut and other Group G fungicides, thus resulting in a reduction in efficacy and possible yield loss.

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

Export of Treated Produce
Growers should note that suitable MRLs or import tolerances may not be established in all markets for produce treated with Moncut SC Fungicide. If you are growing produce for export, please check with Aventis CropScience Pty Ltd for the latest information on MRLs and import tolerances BEFORE using Moncut.

Equipment
Moncut is applied to seed potatoes prior to, or at planting. Application must be conducted with an applicator suitable for liquid treatments. The equipment must be accurately calibrated to ensure even coverage and correct application rates.

Application
Prior to application Moncut should be diluted with sufficient water to ensure thorough, even coverage of seed potatoes. A minimum total application volume of 3 litres per tonne seed potatoes is recommended. Apply the diluted product onto dry tubers with a fine spray, ensuring even coverage of all surfaces. Tubers should be free from soil deposits at application.

Diluted product should be constantly agitated in the spray tank during application. Prepare sufficient product for the quantity of seed to be treated. Do not store diluted product.

Compatibility
If using dust treatments (firbark, lime or mancozeb), these should be applied to tubers before applying Moncut. The use of cement dust is not recommended on tubers to be treated with Moncut.

PRECAUTIONS
Do not use treated seed potatoes for human or animal consumption.
Do not allow potatoes intended for human or animal consumption to become contaminated with this product.
Store treated seed potatoes away from other potatoes, animal feed or foodstuffs, in a cool, dry storage area. Clearly label bins, bags or other containers of treated seed potatoes, to indicate that they have been treated with Moncut. Do not use bins, bags or containers that have held Moncut treated potatoes for any other purpose, including storage of potatoes intended for human or animal consumption.

PROTECTION OF LIVESTOCK
DO NOT use treated potato seed for animal consumption.
DO NOT allow feed intended for animal consumption to become contaminated with this product.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT
DO NOT contaminate streams, rivers or waterways with the product or used containers.

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.

SUGGESTED FURTHER READING

Felton, J.C., Oomen, P.A. & Stevenson, J.H. 1986, 'Toxicity and hazard of pesticides to honeybees: harmonisation of test methods', *Bee World*, vol. 67, no. 3, pp. 114-24.

Goring, C.A.I. et al. 1975, 'Principles of pesticide degradation in soil', in *Environmental Dynamics of Pesticides*, edited by R. Haque and V.H. Freed, Plenum Press, New York, pp 135-72.

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

National Registration Authority for Agricultural and Veterinary Chemicals 1996, *Ag Manual: The Requirements Manual for Agricultural Chemicals*, NRA, Canberra.

National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Requirements Series: Guidelines for Registering Agricultural Chemicals*, NRA, Canberra.

National Registration Authority for Agricultural and Veterinary Chemicals 1996, *MRL Standard: Maximum Residue Limits in Food and Animal Feedstuffs*, NRA, Canberra.

National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Labelling Code—Code of Practice for Labelling Agricultural Chemical Products*, NRA, Canberra.

NRA PUBLICATIONS ORDER FORM

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

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

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

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