

**Public Release Summary
on**

**Evaluation of the new active
chlorantraniliprole
in the products**

**DUPONT CORAGEN INSECTICIDE
DUPONT ALTACOR INSECTICIDE
DUPONT ACELEPRYN INSECTICIDE**

Australian Pesticides and Veterinary Medicines Authority

JUNE 2008

**Canberra
Australia**

©Australian Pesticides and Veterinary Medicines Authority 2003
ISSN1443-1335

This work is copyright. Apart from any use permitted under the *Copyright Act 1968*, no part may be reproduced without permission from the Australian Pesticides and Veterinary Medicines Authority. Requests and inquiries concerning reproduction and rights should be addressed to the Manager, Communication and Secretariat, Australian Pesticides and Veterinary Medicines Authority, PO Box 6182, Kingston ACT 2604 Australia.

This document is published by the Australian Pesticides and Veterinary Medicines Authority. In referencing, the APVMA should be cited as both the author and publisher of this document. For further information, please contact:

Alan Norden
Manager, Minor Use
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Ph: (02) 6210 4769
Fax: (02) 6210 4776

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 the Environment, Heritage, Water and the Arts, 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 undertaken according to accepted scientific principles. Details are outlined in the APVMA's publication of *Agricultural Manual of Requirements and Guidelines*.

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, 18 Wormald St, Symonston, ACT.

The APVMA welcomes comment on the usefulness of this publication and suggestions for further improvement. Comments should be submitted to the Pesticides Program Division Manager, Australian Pesticides and Veterinary Medicines Authority, PO Box 6182, Kingston ACT 2604.

[blank page here]

CONTENTS

Foreword	iii
List of Abbreviations and Acronyms	viii
Introduction	1
Chemistry and Manufacture	2
Active Constituent	2
Product	4
Toxicological Assessment	6
Evaluation of toxicology	6
Public Health Standards	9
Poisons Scheduling	9
NOEL/ADI	9
Acute reference dose (ArfD)	9
Residues Assessment	10
Metabolism	10
Analytical methods	12
Residue definition	13
Storage stability	13
Residue trials	13
Processing studies	18
Crop rotation	19
Animal commodity MRLs	19
Spray drift	20
Bioaccumulation potential	21
Estimated dietary intake	21
Recomendations	21
Assessment of Overseas Trade Aspects of Residues in Food	24
Commodities exported and main destinations	24
Overseas registration status	27
Potential Risk to Australian Trade	28
Occupational Health and Safety Assessment	31
Formulation, packaging, transport, storage and retailing	31
Use pattern and exposure profile	31
Risks to workers during use and recommended PPEs	31
Hazardous classification	32
Environmental Assessment	33
Environmental fate	33
Environmental effects	42
Risk assessment	47

Efficacy and Safety Assessment	49
Evaluation of efficacy and safety	49
Product labels	53
Glossary	75
APVMA Order Form	76

[blank page here]

LIST OF ABBREVIATIONS AND ACRONYMS

[This list should be modified to include all the acronyms and abbreviations that actually appear in the publication.]

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
BBA	Biologische Bundesanstalt für Land – und forstwirtschaft
bw	bodyweight
d	day
DAT	Days After Treatment
DT₅₀	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
E_bC₅₀	concentration at which the biomass of 50% of the test population is impacted
EC₅₀	concentration at which 50% of the test population are immobilised
EEC	Estimated Environmental Concentration
E_rC₅₀	concentration at which the rate of growth of 50% of the test population is impacted
EUP	End Use Product
F₀	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	Haematocrit
Hg	Haemoglobin
HPLC	High Pressure Liquid Chromatography <i>or</i> High Performance Liquid Chromatography
id	intra-dermal
im	intra-muscular
ip	intra-peritoneal
IPM	Integrated Pest Management
iv	intra-venous
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
LC₅₀	concentration that kills 50% of the test population of organisms
LD₅₀	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

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

[blank page here]

INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the three products *CORAGEN INSECTICIDE*, *ALTACOR INSECTICIDE* and *ACELEPRYN INSECTICIDE*, and approval of the new active ingredient, chlorantraniliprole. This submission has been assessed under a joint review/workshare arrangement where registrations for the same formulations and uses have been submitted concurrently in Canada, USA, Australia and Ireland.

Responses to this Public Release Summary will be considered prior to registration of the product. They will be taken into account by the 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 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, 18 Wormald St, Symonston, ACT 2609.

Written comments should be received by the APVMA by 4th July 2008. They should be addressed to:

Alan Norden
Manager, Minor Use
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4763
Fax: (02) 6210 4776
Email: alan.norden@apvma.gov.au

Applicant

DuPont (Australia) Ltd

Product Details

It is proposed to register;

CORAGEN INSECTICIDE containing 200g/L chlorantraniliprole for the control of Lepidopteran species in various vegetable crops. The product will be packaged in containers 250 mL to 10L.

ALTACOR INSECTICIDE containing 350g/kg chlorantraniliprole for the control of Lepidopteran species in various fruit crops and cotton. The product will be packaged in containers 50 g to 10 kg.

ACELEPRYN INSECTICIDE containing 200g/L chlorantraniliprole for the control of various insect pests in turf. The product will be packaged in containers 500mL to 10L

Full details of all proposed use patterns for each product are contained in the draft product labels at the conclusion of this report.

CHEMISTRY AND MANUFACTURE

Active constituent

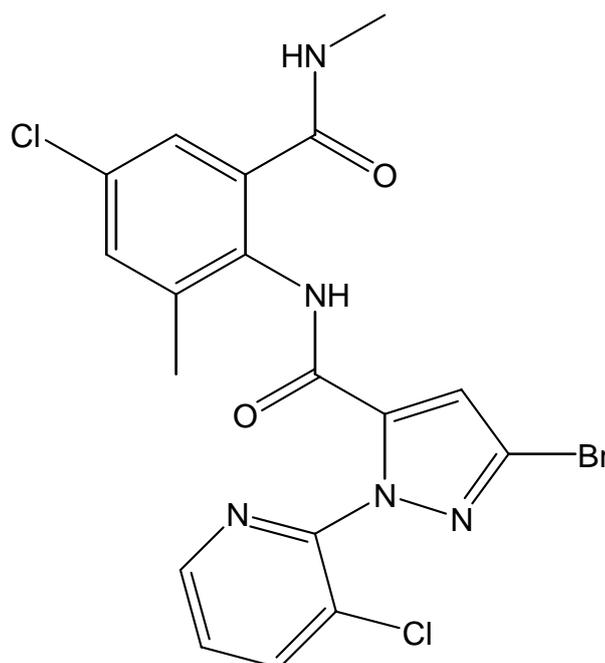
Chlorantraniliprole is a new active constituent. It is in the anthranilic diamide class of insecticidal compounds. Chlorantraniliprole binds and activates ryanodine receptors, located in the sarcoendoplasmic reticulum, to release stored intracellular calcium into the cytoplasm. Sustained exposure to chlorantraniliprole leads to impaired regulation of muscle contraction followed by complete muscle contraction, paralysis and ensuing death. This calcium-induced muscle-contraction mode of action has been shown to be highly specific to insect ryanodine receptors.

Manufacturing Sites

The active constituent chlorantraniliprole is manufactured by DuPont Iberica S.A., Valle de Tamon-Nubledo, 33469 Tamon (Asturias), Spain and DuPont Mobile Manufacturing Center, 12650 Highway 43, PO Box 565, Axis, Alabama 36505-0565, USA and has been approved by the APVMA (Approval Number: 61539).

Chemical Characteristics of the Active Constituent

Common Name:	Chlorantraniliprole
IUPAC Name:	3-Bromo- 4'-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide
CA Name:	3-Bromo- <i>N</i> -[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1 <i>H</i> -pyrazole-5-carboxamide
CAS Number:	500008-45-7
Manufacturer's Codes:	DPX-E2Y45 IN-E2Y45
Minimum Purity:	950 g/kg
Molecular Formula:	C ₁₈ H ₁₄ BrCl ₂ N ₅ O ₂
Molecular Weight:	483.15 g/mole
Structure:	



Chemical Family:	Anthranilic diamide
Mode of Action:	Binds and activates ryanodine receptors

Physical and Chemical Properties of Pure Active Constituent and Technical Material

Colour	Off-white (pure) Brown (tech)																				
Physical state	Fine crystalline powder (pure) Fine powder (tech)																				
Melting point	208-210°C (pure) 200-202°C (tech)																				
Dissociation constant (pKa)	10.88																				
Vapour pressure at 20°C	6.3×10^{-12} Pa																				
Density at 20°C	1.5070 g/mL (pure) 1.5189 g/mL (tech)																				
UV/Vis absorption maxima	<table border="0"> <thead> <tr> <th><u>pH</u></th> <th><u>λ max (nm)</u></th> </tr> </thead> <tbody> <tr> <td>neutral</td> <td>290</td> </tr> <tr> <td>acidic</td> <td>290</td> </tr> <tr> <td>basic</td> <td>320</td> </tr> </tbody> </table>	<u>pH</u>	<u>λ max (nm)</u>	neutral	290	acidic	290	basic	320												
<u>pH</u>	<u>λ max (nm)</u>																				
neutral	290																				
acidic	290																				
basic	320																				
Octanol/water partition co-efficient (K_{ow})	<table border="0"> <thead> <tr> <th><u>pH</u></th> <th><u>log K_{ow}</u></th> </tr> </thead> <tbody> <tr> <td>Milli-RO Water</td> <td>2.76</td> </tr> <tr> <td>4</td> <td>2.77</td> </tr> <tr> <td>7</td> <td>2.86</td> </tr> <tr> <td>9</td> <td>2.80</td> </tr> </tbody> </table>	<u>pH</u>	<u>log K_{ow}</u>	Milli-RO Water	2.76	4	2.77	7	2.86	9	2.80										
<u>pH</u>	<u>log K_{ow}</u>																				
Milli-RO Water	2.76																				
4	2.77																				
7	2.86																				
9	2.80																				
Solubility at 20°C:	<table border="0"> <thead> <tr> <th><u>Solvent</u></th> <th><u>Solubility (mg/mL)</u></th> </tr> </thead> <tbody> <tr> <td>Acetone</td> <td>3.4</td> </tr> <tr> <td>Acetonitrile</td> <td>0.71</td> </tr> <tr> <td>Ethyl acetate</td> <td>1.1</td> </tr> <tr> <td>Dichloromethane</td> <td>2.5</td> </tr> <tr> <td>Dimethylformamide</td> <td>124</td> </tr> <tr> <td>n-Octanol</td> <td>0.39</td> </tr> <tr> <td>Methanol</td> <td>1.7</td> </tr> <tr> <td>o-Xylene</td> <td>0.16</td> </tr> <tr> <td>n-Hexane</td> <td>< 0.1 μg/mL</td> </tr> </tbody> </table>	<u>Solvent</u>	<u>Solubility (mg/mL)</u>	Acetone	3.4	Acetonitrile	0.71	Ethyl acetate	1.1	Dichloromethane	2.5	Dimethylformamide	124	n-Octanol	0.39	Methanol	1.7	o-Xylene	0.16	n-Hexane	< 0.1 μ g/mL
<u>Solvent</u>	<u>Solubility (mg/mL)</u>																				
Acetone	3.4																				
Acetonitrile	0.71																				
Ethyl acetate	1.1																				
Dichloromethane	2.5																				
Dimethylformamide	124																				
n-Octanol	0.39																				
Methanol	1.7																				
o-Xylene	0.16																				
n-Hexane	< 0.1 μ g/mL																				

Water solubility at 20°C:	<u>pH</u>	<u>Solubility (mg/L)</u>
	Deionized Water	1.023
	4	0.972
	7	0.880
	9	0.971
Stability in presence of metals after 2 weeks	Product is stable when in contact with the metals iron and aluminium, and stable when in contact with the metal ions from iron (II) acetate and aluminium acetate solutions.	
Stability: 2 weeks at 54°C and 12 months at ambient temperature	Stable Stable	

FORMULATED PRODUCTS

Distinguishing name: **Dupont Altacor Insecticide**
 Formulation type: Water dispersible granule
 Active constituent concentration: Chlorantraniliprole 350 g/kg

Physical and Chemical Properties of the Product

Appearance (colour, odour, physical state)	Light brown granules with faint semi-sweet smell
pH	9.4 (1% w/v dilution)
Bulk/tap density	0.695 g/mL (loose) 0.782 g/mL (tapped)
Flammability	Not a flammable solid
Explosive properties	Not explosive
Oxidising action	Does not exhibit oxidising properties
Corrosion characteristics	The product will be packed in HDPE containers
Storage stability	Stability data provided by applicant indicates that the product is expected to remain within specification for at least 2 years when stored under normal conditions in HDPE containers

Distinguishing name: **Dupont Coragen Insecticide & DuPont Acelepryn Insecticide**
 Formulation type: Suspension concentrate
 Active constituent concentration: Chlorantraniliprole 200 g/L

Physical and Chemical Properties of the Product

Appearance (colour, odour, physical state)	White, slightly viscous liquid with a slight alcohol odour
pH	7.8 (1% w/v dilution)
Relative density	1.094 g/mL (20°C)
Viscosity	583 cps (30 rpm) 1895 cps (6 rpm)
Flammability	Not highly flammable
Explosive properties	Not explosive
Oxidising action	Does not exhibit oxidising properties
Corrosion characteristics	The product will be packed in HDPE and PET containers
Storage stability	Stability data provided by applicant indicates that the product is expected to remain within specification for at least 2 years when stored under normal conditions in HDPE and PET containers
Low temperature stability	No separation or sediment was recorded for the product stored for 7 days at 0°C

Recommendation

Based on a review of the chemistry and manufacturing details provided by the applicant, registration of DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Acelepryn Insecticide is supported.

TOXICOLOGICAL ASSESSMENT

Evaluation of toxicology

The toxicological database for chlorantraniliprole, 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 (ADI and ARfD) at which no adverse health effects in humans would be expected.

Toxicokinetics and Metabolism

The absorption of ¹⁴C-chlorantraniliprole was rapid with peak concentrations occurring at 5-12 hours after low or high (10 or 200 mg/kg bw) dose administration. Absorption at the low dose (10 mg/kg bw) was determined to be 72.9-85.2% compared with 11.8-13.3% at the high dose (200 mg/kg bw) using bile duct cannulated rats. The plasma elimination half-lives ranged from 38-82 hours. Tissue distribution of the absorbed dose was extensive and indicated low potential for accumulation. The tissue residues were higher in female than male rats consistent with female rats having a longer elimination half-life and higher AUC in plasma. Excretion was substantially complete by 48-72 hours after dosing. Faecal excretion was the primary route of elimination followed by the urine with no significant excretion occurring by exhalation. Metabolism of the absorbed dose was extensive and involved sex differences primarily in initial tolyl methyl and N-methyl carbon hydroxylation. Further metabolism of the hydroxylated metabolites included N-demethylation, nitrogen-to-carbon cyclisation with loss of a water molecule resulting in the formation of the pyrimidone ring, oxidation of alcohols to carboxylic acids, amide bridge cleavage, amine hydrolysis, and O-glucuronidation. Most of the administered dose (88-97%) was eliminated in the excreta. Tissue:plasma concentration ratios (<1) indicated low potential for accumulation.

Following 14 days of dose administration, steady-state kinetic behaviour was apparent in male rats. The slight increase in plasma and tissue concentrations through the 14 days of oral dosing indicated that female rats were near steady state. After cessation of dosing, the ¹⁴C residues were readily eliminated from the plasma and tissues. The overall tissue distribution in male and female rats at 1 and 7 days after dosing was similar to that found after single dose administration and confirmed minimal potential for accumulation. Cumulative excretion in faeces was the predominant route of elimination. The profile of metabolites in urine and faeces indicated extensive metabolism consistent with that observed for the single dose study.

Acute Studies

Chlorantraniliprole has no significant acute toxicity *via* the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant and does not cause skin sensitisation.

Short term studies

The NOEL in a 14-Day oral gavage study in rats was the highest dose tested, 1000 mg/kg

bw/day. No test-substance related adverse effects were noted in the study. A mild increase in hepatic cytochrome P450 enzyme content was observed in females at all dose levels which was consistent with the subsequent increase in liver weight observed in female rats exposed to chlorantraniliprole in the diet for 28 days.

No toxicological effects were observed in subchronic (90-Day) feeding studies conducted with chlorantraniliprole in rats, mice, and dogs and in a one-year (52-week) study in dogs. The NOELs were the highest dietary concentrations administered (20000 ppm in rats, 7000 ppm in mice, and 40000 ppm in dogs). Early in product development, a 28-Day feeding study in rats was conducted where the highest dose tested was 8000 ppm. This dietary concentration was selected due to the limited quantity of test material available at the time the study was conducted. In a 28-Day oral dosing study in dogs, where chlorantraniliprole was administered via capsule, the NOEL was 1000 mg/kg bw/day. Reduced body weight gain was observed in male mice at a dietary concentration of 7000 ppm in an early 28-Day feeding study but was considered to have been a spurious finding. No reductions in overall mouse body weight gain occurred at the same dietary concentration in subsequent studies of similar or longer duration including a 90-Day feeding study, an 18-month oncogenicity study and a 28-Day immunotoxicity study. Mild increases in liver weight (which were induced in the absence of clinical or histopathological findings indicative of liver toxicity) were reported in the 90-Day rat, mice and dog studies and 52-week long term dog study at the high dose tested. The slight liver weight increases were not considered adverse. Increases in cytochrome P450 liver enzyme content were noted in a 14-Day oral dosing study in rats, the 28-Day feeding study in mice and the 28-Day oral (capsule) study in dogs, suggesting that the increased liver weights in all three species were due to non-adverse pharmacological responses to metabolism. A slight increase in the degree of microvesiculation in the adrenal cortex due to lipid was present in some male rats in the 90-Day feeding study. Based on subsequent investigations, this finding was determined to have no toxicological impact on adrenal cortical cell function and was therefore considered as non-adverse.

Reductions in body weight gain occurred in high dose (1000 mg/kg bw/day) male and female rats in the 28-Day dermal toxicity study. Since no treatment-related effects on overall body weight was observed, the reduction in body weight gain, in isolation, was not considered an adverse effect; therefore, the NOEL in the study was established at the highest dose tested. Also in the dermal study, a slight increase in the degree of adrenal cortical cell microvesiculation due to lipid was observed in males. As noted above, results of further studies have demonstrated that this microscopic finding had no adverse effect on adrenal gland function.

Chronic toxicity

Chlorantraniliprole was not carcinogenic in rats or mice. The NOEL for chronic toxicity in rats was 20000 ppm and was based on the absence of any treatment-related toxicity at any dietary concentration evaluated in the study. Mild increases in liver weight occurred in the 4000 and 20000 ppm female rats at 1 year. These changes were not associated with other changes indicative of liver toxicity and were consistent with the non-adverse pharmacological response to metabolism that was observed in short-term feeding studies with chlorantraniliprole. A minimal to mild increase in the degree of microvesiculation in the adrenal cortex due to lipid was present in some male rats at 1 and 2 years. Based on further investigative work, this finding was determined to have no toxicological impact on adrenal cortical cell function and was not considered toxicologically relevant.

In mice, there were treatment-related effects in males at the highest dose tested, but not in females administered chlorantraniliprole up to and including a maximum dietary concentration of 7000 ppm. Increased liver weights in males and females and small increases

in the incidence of hepatocellular hypertrophy in males were observed at the two highest concentrations tested. The liver changes at the mid dose were consistent with the non-adverse induction of liver enzymes observed in short-term feeding studies with chlorantraniliprole. However, the slight increase in the incidence of eosinophilic foci (5/70) of cellular alteration in the livers of high dose male mice was considered treatment related and adverse.

The NOEL in male mice is 158 mg/kg/day based on the slightly increased, minimal eosinophilic foci of cellular alteration accompanied by hepatocellular hypertrophy and increased liver weight in male mice. The NOEL for female mice was 1155 mg/kg bw/day due to the lack of adverse treatment-related effects on any parameter at any dietary level of chlorantraniliprole evaluated.

Based on the results of chronic feeding studies in rats and mice, chlorantraniliprole is not carcinogenic at the durations and doses tested in these animal toxicity studies.

Genetic toxicity

Chlorantraniliprole was negative for gene mutations in bacteria and mammalian cells *in vitro* and clastogenicity in an *in vitro* cytogenetics assay using human peripheral blood lymphocytes. Chlorantraniliprole was not clastogenic (by evaluation of micronuclei) in mouse bone marrow cells following single-dose oral gavage of 2000 mg/kg bw. Collectively these results provide sufficient evidence to conclude that chlorantraniliprole is neither inherently genotoxic nor does it have genotoxic potential in the whole animal.

Reproductive and Developmental toxicity

In the two-generation reproduction toxicity study with chlorantraniliprole, the NOEL for parental toxicity was 20000 ppm, the highest dietary concentration tested. This NOEL was based on the lack of effects on body weight and nutritional parameters, clinical signs of toxicity, and gross or microscopic pathology in P₁ and F₁ males and females. The NOEL for reproductive and fertility effects was 20000 ppm, based on the absence of any effects on reproduction and fertility. The NOEL for effects on pup growth and development was 20000 ppm, based on the absence of any adverse effects. At 20000 ppm a slight decrease in F₁ male and female pup weights occurred during the latter half of lactation. After weaning, F₁ body weight gains were similar to those of the control group, and by Day 35 post-weaning, body weight was similar to control as the F₁ offspring continued to receive 20000 ppm diet during a period of rapid growth. Based on the transient nature of the decreased body weight and the lack of an effect on F₂ pup weight, the slight reduction in F₁ pup weight was considered non-adverse and possibly spurious. A slight increase in the degree of microvesiculation in the adrenal cortex due to lipid was present in some P₁ and F₁ males and a few F₁ females. Based on subsequent investigative studies, this finding was determined to have no toxicological impact.

Chlorantraniliprole was not teratogenic and was not uniquely toxic to the rat or rabbit conceptus. In the developmental toxicity study in rats, the NOEL for both maternal and fetal effects was 1000 mg/kg bw/day, the highest dose evaluated, based on the lack of effects on any maternal or fetal parameter. In the developmental study conducted in rabbits, the maternal and fetal NOELs were 1000 mg/kg bw/day based on the absence of any treatment-related effects in the does or foetuses.

Assessment of adrenal cortical cell structure and function

In several studies conducted with chlorantraniliprole in rats there was a slight increase in the degree of microvesiculation caused by lipid in the adrenal cortex of some animals. The toxicological significance of this finding in chlorantraniliprole treated rats was investigated in studies to assess the structural and functional basis of the slight increases in lipid in adrenal

cortical cells. Ultrastructural observation of tissues by electron microscopy indicated that all cellular structures evaluated in the adrenal cortex were unaffected by treatment, no abnormal structures were observed in controls or treated rats, and the presence of lipid droplets was consistent with the normal morphology of the adrenal cortex. In studies designed to assess the functional impact of the increased degree of microvesiculation showed that chlorantraniliprole did not affect corticosterone levels under both non-stressed (i.e. basal) conditions and under conditions of simulated physiological stress (i.e., ACTH-induced).

Thus, the slight increase in microvesiculation caused by lipid, which was observed microscopically in some male rats following exposure to chlorantraniliprole, is a morphologic variation of what is observed in control animals. The histological change observed with chlorantraniliprole administration was not associated with functional changes in the adrenal cortex or its capacity to respond to stress. Therefore, this change is considered to have no toxicological impact and was not considered as the basis for establishing NOELs in studies conducted with chlorantraniliprole.

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. At its 52nd meeting, in February 2008, the NDPSC noted that due to chlorantraniliprole's low overall toxicity it did not require scheduling and should therefore be placed in Appendix B of the SUSDP.

NOEL/ADI

The Acceptable Daily Intake 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 chlorantraniliprole was established at 1.58 mg/kg bw/day based on a NOEL of 158 mg/kg bw/day in an 18 – month mouse feeding study and using a 100-fold safety factor.

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. Establishment of an acute reference dose is not justified for chlorantraniliprole based on the lack of identified hazard in the acute oral toxicity study which reported LD₅₀ value of >5,000 mg/kg in female Crl:CD (SD) IGS BR rats.

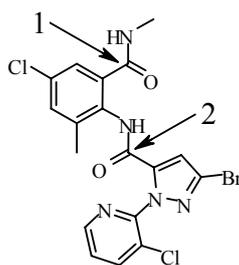
RESIDUES ASSESSMENT

Introduction

As part of the residues assessment for chlorantraniliprole, plant and animal metabolism studies, supervised residue trials, crop rotation studies, processing studies, and trade aspects were considered and details are provided below.

Metabolism

Metabolism data for ^{14}C -labelled chlorantraniliprole in cotton, rice, apples, tomatoes and lettuce were provided. This covers four of the five crop groups for which metabolism studies are normally conducted (fruit, leafy vegetables, cereals, and pulses/oilseeds).



1. [Benzamide carbonyl- ^{14}C]-DPX-E2Y45
2. [Pyrazole carbonyl- ^{14}C]-DPX-E2Y45:

In the apple, tomato, cotton, and lettuce studies, in which ^{14}C labelled chlorantraniliprole was applied as foliar sprays, parent compound was the major component of the extracted radioactivity in all food and feed items. More complex metabolic profiles were found for rice following soil application, with a number of metabolites being found in addition to the parent compound, particularly in straw, at levels of less than 7% of the total radioactive residue. Parent compound was still the major component of the radioactivity, at >50% of the TRR at maturity. A residue definition of 'chlorantraniliprole' is therefore proposed for plant commodities.

Metabolism data were provided for ^{14}C -labelled chlorantraniliprole in lactating goats and laying hens.

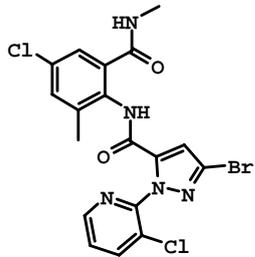
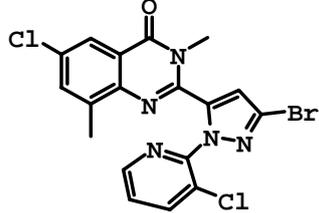
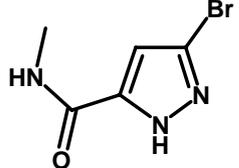
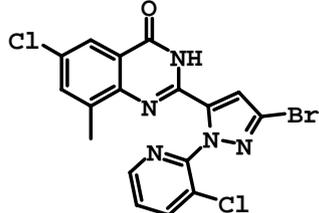
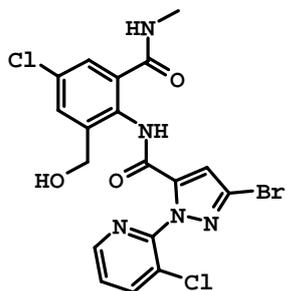
In the laying hen metabolism study, a mixture of 1:1 ^{14}C benzamide carbonyl and ^{14}C pyrazole carbonyl chlorantraniliprole was orally given to hens for 14 consecutive days. At the end of the 14-day period, eggs and edible tissues contained approximately 3% of the administered dose, with the remainder being recovered from excreta. The major components of the radioactivity in eggs were parent chlorantraniliprole and the metabolite 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-methyl-4(3*H*)-quinazolinone (IN-GAZ70); in tissues, it was parent chlorantraniliprole.

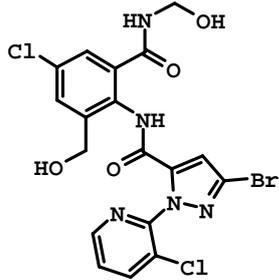
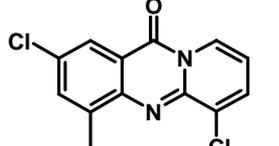
Goats were also dosed with a mixture of 1:1 ^{14}C benzamide carbonyl and ^{14}C pyrazole carbonyl chlorantraniliprole at the equivalent of 10 ppm in feed for 7 days. 93.57% of the administered dose was eliminated in the excreta. Parent chlorantraniliprole was the major component of the extracted radioactivity identified in kidney, muscle, and fat samples and was also identified in liver. In milk, parent compound accounted for 23.58% of the milk TRR. Three metabolites were identified in addition to parent compound: 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide (IN-K9T00), 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-

carboxamide (IN-HXH44) and *N*-[2-aminocarbonyl]-4-chloro-6-(hydroxymethyl)phenyl]-3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide (IN-HXH40) at 26.1%, 26.92% and 5.87% of the TRR, respectively. Metabolites IN-K9T00 and IN-HXH44 were detected in similar proportions to parent compound in milk in the lactating cattle feeding study; at some dose levels, IN-K9T00 and IN-HXH44 were detected in the absence of parent compound, Therefore, these two additional metabolites were included in the residue definition for milk and milk products. The following animal commodity residue definitions are therefore proposed:

- Commodities of animal origin other than milk: chlorantraniliprole
- Milk and milk products: sum of chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, and 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[[((hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, expressed as chlorantraniliprole.

Structures of chlorantraniliprole and possible metabolites

Chlorantraniliprole DPX-E2Y45	
IN-EQW78 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1 <i>H</i> -pyrazol-5-yl]-6-chloro-3,8-dimethyl-4(3 <i>H</i>)-quinazolinone	
IN-F6L99 5-Bromo- <i>N</i> -methyl-1 <i>H</i> -pyrazole-3-carboxamide	
IN-GAZ70 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1 <i>H</i> -pyrazol-5-yl]-6-chloro-8-methyl-4(3 <i>H</i>)-quinazolinone	
IN-HXH44 3-Bromo- <i>N</i> -[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1 <i>H</i> -pyrazole-5-carboxamide	

<p>IN-K9T00 3-Bromo-<i>N</i>-[4-chloro-2-(hydroxymethyl)-6- [[hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1<i>H</i>- pyrazole-5-carboxamide</p>	
<p>IN-ECD73 2,6-dichloro-4-methyl-11<i>H</i>-pyrido[2,1-<i>b</i>]quinazolin-11-one</p>	

Analytical methods

Determination of chlorantraniliprole residues in raw plant commodities

The main method used for analysis of chlorantraniliprole residues in raw crop samples involved extraction of samples with acetonitrile. Clean up was achieved using solid phase extraction (a SAX column in series with an HLB column), followed by LC/MS/MS analysis.

The method was validated with limits of quantitation (LOQs) of 0.01 mg/kg for representative plant commodities. Recoveries were conducted with fortification at concentrations of 0.01 or 0.1 mg/kg and were 81-88% in corn fodder, 87-96% in grapes, 90-95% in raisins, 84-95% in soybean, 90-99% in cottonseed, 86-99% in cotton gin trash, 86-93% in white rice, 85-99% in brown rice, 91-106% in tomato, 87-97% in capsicum, 97-106% in lettuce and 84-88% in tea.

An alternative method involved the same extraction and clean-up procedure, but followed the clean-up with heating of the sample with aqueous base to convert chlorantraniliprole to a more thermally stable derivative. Analysis was conducted by GC-ECD. The same LOQ and similar recoveries were achieved.

Determination of chlorantraniliprole and degradation products in processed plant commodities

Oil samples were diluted with hexane and cleaned up by partition with methanol, or by solid phase extraction (SPE). Solid samples were extracted with water and acetonitrile, then purified by SPE. Juice samples were combined with acetonitrile, then cleaned up by SPE. Analysis was conducted using LC/MS/MS. Limits of quantitation of 0.01 mg/kg were achieved for the parent compound and each of the processing/degradation products (IN-EQW78, IN-ECD73, IN-F6L99). Recoveries were determined by fortification at concentrations of 0.01 or 0.1 mg/kg, and for parent compound only were 103-125% for tomato ketchup, 91-108% for raisins, 89-113% for orange peel, 98-109% for grape pomace, 92-106% for cooked spinach, 85-109% for grape juice, 83-108% for apple juice, 105-121% for cottonseed oil, and 96-116% for vegetable oil.

Determination of residues of chlorantraniliprole and animal metabolites in animal tissues

Three methods were presented for determination of chlorantraniliprole and animal metabolites in meat, offal, milk and eggs. Samples were extracted using acetonitrile and water, followed by partitioning with solvents such as hexane, ethyl acetate or cyclohexane. A clean-up step by solid phase extraction or gel permeation chromatography was included. Analyses were conducted using LC/MS/MS. An alternative method for determination of the parent compound only involved heating the cleaned-up samples with an aqueous base to convert chlorantraniliprole to a thermally stable derivative, followed by analysis using GC-ECD.

LOQs of 0.01 mg/kg were achieved for chlorantraniliprole and the metabolites IN-K9T00 and IN-HXH44. Recoveries were determined by fortification of samples at 0.01 or 0.1 mg/kg, and for chlorantraniliprole were 94-114% in milk, 93-116% in egg, 91-115% in muscle, 84-118% in liver, and 95-107% in fat. For the metabolite IN-K9T00, recoveries were 93-114% in milk, while the recovery for IN-HXH44 in milk was 93-114%.

Overall, the methods appear to be suitable for the proposed purposes and are acceptable.

Residue definition

The following residue definition is recommended for chlorantraniliprole for the purposes of dietary exposure assessment and for compliance and monitoring of MRLs:

Compound	Residue definition
Chlorantraniliprole	<i>Commodities of plant origin and commodities of animal origin other than milk: chlorantraniliprole</i>
	<i>Milk and milk products: sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole</i>

The residues of chlorantraniliprole are classified as ‘fat-soluble’; see discussion below on fat-solubility.

Storage stability

Storage stability studies were conducted for chlorantraniliprole in representative raw agricultural commodities, and for chlorantraniliprole and metabolites formed on processing in representative processed agricultural commodities, and for chlorantraniliprole and animal metabolites in bovine milk, liver, kidney, muscle and fat. All samples were stored at -20 °C.

The data provided demonstrates that:

- Residues of chlorantraniliprole in representative raw agricultural commodities (water-rich acidic fruits and vegetables such as apples, grapes and tomatoes, root crops such as potatoes, cereal grains e.g. wheat, oilseeds, e.g. cottonseed, forage and fodder such as wheat straw and alfalfa hay, leafy vegetables, such as lettuce, and brassicas such as cauliflower) are sufficiently stable on storage at -20 ±10 °C for at least 24 months.
- Residues of chlorantraniliprole and processing metabolites (IN-EQW78, IN-ECD73, IN-F6L99) in representative processed agricultural commodities (tomato products such as ketchup, fruit juices e.g. apple juice, dried fruit e.g. raisins, animal feeds such as cottonseed meal, and vegetable oils e.g. cottonseed oil) are sufficiently stable on storage at -20 ±10 °C for at least 12 months.
- Residues of chlorantraniliprole and animal metabolites (IN-K9T00, IN-HXG44) in representative animal commodities (milk, muscle, offal and fat) are sufficiently stable on storage at -20 ±10 °C for at least 6 months (milk), or for at least 3 months (muscle, offal and fat).

Residue trials

The proposed use of *DuPont Coragen Insecticide* in Australia is foliar application to lettuce, other leafy vegetables, tomatoes, eggplant, capsicum (including chilli peppers), potatoes, celery, rhubarb, at rates of 20 or 30 g ai/ha. Up to three applications per crop are permitted.

A harvest withholding period is not required for potatoes when used as directed, while withholding periods of 3 days are recommended for all leafy vegetables, cucurbits, and non-cucurbit fruiting vegetables, and 7 days for brassica vegetables.

The proposed use of *DuPont Altacor Insecticide* in Australia is foliar application to cotton with up to three applications per season at rates of 31.5-52.5 g ai/ha to grapevines or pome fruit, by dilute foliar application up to three times per season (pome fruit) and twice per season (grapevines) at spray concentration of 3.15 g ai/100 L, and to apricots, cherries, nectarines, peaches, and plums twice per season at spray concentrations of 3.15 or 4.2 g ai/100 L, depending on the pest. Harvest withholding periods of 28 days for cotton, 8 weeks for grapes, and 14 days for pome fruit and stone fruit are recommended.

A large number of crop residues trials in relevant vegetables were conducted in Australia, New Zealand, the USA, Canada and various countries in northern and southern Europe and were provided with the application for registration of *DuPont Coragen Insecticide*. The numbers and locations of trials for each commodity are summarised in the table below.

Crop	Number of trials conducted					
	Australia	New Zealand	USA	Canada	N. Europe	S. Europe
Potato	-	-	19	10	4	2
Broccoli	4	4	7	2	-	-
Head cabbage	6	4	7	3	-	-
Cauliflower	2	-	-	-	-	-
Brussels sprouts	4	-	-	-	-	-
Head lettuce	4	-	7	-	11 field, 9 greenhouse	
Leafy lettuce	-	-	7	-	5 greenhouse	
Spinach	-	-	7	-	-	-
Mustard greens	-	-	6	2	-	-
Celery	-	-	7	-	-	-
Tomato	2 (field)	-	13	7	3 greenhouse	7 field, 6 greenhouse
Capsicum	-	-	7	4	2 greenhouse	5 field, 3 greenhouse
Chilli pepper	-	-	4	5	1 greenhouse	2 field, 1 greenhouse
Cucumber	-	-	7	-	-	-
Rockmelon	-	-	6	-	-	-
Honeydew melon	-	-	1	-	-	-
Zucchini	-	-	6	-	-	-

A large number of residues trials in grapes (both wine and table), pome fruit (both apples and pears), stone fruit (apricots, peaches, plums and sweet and sour cherry varieties) and cotton were conducted in Australia, New Zealand, the USA, Canada, Argentina, and northern and southern Europe. These trials were supplied with the application for *DuPont Altacor Insecticide*. The numbers and locations of trials for the fruit crops and cotton are summarised in the table below.

Crop	Number of trials conducted						
	Australia	NZ	USA	Canada	N. Europe	S. Europe	Argentina
Apple	12	12	13	4	5	5	6
Pear	8	-	7	4	2	2	-
Apricot	-	-	-	-	-	2	-
Peach	3	-	12	11	-	5	4
Cherry	-	-	12	-	-	-	-

Plum	-	-	12	5	-	-	-
Table grape	-	-	6	3	-	5	-
Wine grape	8	-	6	8	4	4	-
Cotton	4	-	14	-	-	-	-

Results of the residues trials are summarised in tables below.

Potatoes

Dataset	Application details	WHP (days)	Residues (mg/kg)
US/Canadian trials	3 x 75 g ai/ha	14	<0.01 (27)
	3 x 50 g ai/ha	14	<0.01 (2)
	3 x 375 g ai/ha	14	<0.01
European trials	2 x 10-13 g ai/ha	14	<0.01 (6)

Brassica vegetables

Dataset	Application details	WHP (days)	Residues (mg/kg)
Australian broccoli trials	3 x 20 g ai/ha	7	0.12, 0.16
	3 x 40 g ai/ha	7	0.22, 0.27
Australian cabbage trials	3 x 20 g ai/ha	7	0.05, 0.081, 0.086
	3 x 40 g ai/ha	7	0.13, 0.17, 0.20
Australian Brussels sprouts trials	3 x 20 g ai/ha	7	0.08, 0.19
	3 x 40 g ai/ha	7	0.20, 0.28
Australian cauliflower trials	3 x 20 g ai/ha	7	0.11
	3 x 40 g ai/ha	7	0.23
New Zealand broccoli trials	3 x 20 g ai/ha	7	0.03, 0.07
	3 x 40 g ai/ha	7	0.07, 0.12
New Zealand cabbage trials	3 x 20 g ai/ha	7	<0.01, 0.03
	3 x 40 g ai/ha	7	<0.01, 0.08
US/Canadian cabbage trials	2 x 112.5 g ai/ha	3	0.043, 0.082, 0.11, 0.31, 0.32, 0.52, 0.64, 0.72, 0.78, 1.2
US/Canadian broccoli trials	2 x 112.5 g ai/ha	3	0.13, 0.34, 0.36 (2), 0.38, 0.40, 0.41, 0.44, 0.71

Leafy vegetables

Dataset	Application details	WHP (days)	Residues (mg/kg)
Australian head lettuce trials	3 x 30 g ai/ha	3	0.07, 0.24
	3 x 60 g ai/ha	3	0.19, 0.33
European head lettuce trials (field)	2 x 40 g ai/ha	1	<0.01 (2), 0.31, 0.37, 0.45, 0.46, 0.83, 0.86, 0.88, 1.0, 1.7
European head lettuce trials (glasshouse)	2 x 40 g ai/ha	1	0.093, 0.15, 0.38, 1.3, 1.4, 1.6, 1.8, 2.0, 2.3
European corn salad trials (glasshouse)	2 x 40 g ai/ha	1	3.2, 4.1 (2), 7.8, 8.0
US head lettuce trials (field)	2 x 112.5 g ai/ha	1	0.004, 0.016, 0.59, 0.64, 1.5, 2.3, 2.5
US leafy lettuce trials (field)	2 x 112.5 g ai/ha	1	3.4, 4.1, 4.2, 4.5, 4.8, 5.4, 6.3
US spinach trials (field)	2 x 112.5 g ai/ha	1	3.5, 5.8, 7.3 (2), 7.9, 8.7, 9.7
US mustard greens trials (field)	2 x 112.5 g ai/ha	3	1.3, 1.8, 2.3, 3.7, 3.8, 4.7, 5, 6.1

Fruiting vegetables, cucurbits

Dataset	Application details	WHP (days)	Residues (mg/kg)
US zucchini trials (field)	2 x 112.5 g ai/ha	1	0.022, 0.037, 0.044, 0.058, 0.078, 0.093
US cucumber trials (field)	2 x 112.5 g ai/ha	1	0.006, 0.013, 0.014, 0.017, 0.022, 0.081, and 0.083
US rockmelon trials (field)	2 x 112.5 g ai/ha	1	0.028, 0.082, 0.084, 0.087, 0.1, 0.12
US honeydew melon trials (field)	2 x 112.5 g ai/ha	1	0.011

EU glasshouse cucumber and zucchini trials	2 x 50.4 g ai/ha	1	0.008, 0.016, 0.021, 0.039, 0.058, 0.064, 0.083, 0.1, 0.13
EU glasshouse melon trials	2 x 50.4 g ai/ha	1	0.01, 0.019 (2), 0.023, 0.03, 0.032 (2), 0.038, 0.068

Fruiting vegetables other than cucurbits

Dataset	Application details	WHP (days)	Residues (mg/kg)
Australian tomato trials	4 x 20 g ai/ha	0	0.02
	4 x 40 g ai/ha	0	0.03
US/Canadian tomato trials (field)	2 x 112.5 g ai/ha	1	0.018, 0.034 (2), 0.045, 0.049, 0.050, 0.052, 0.065, 0.071, 0.074, 0.076, 0.088, 0.099, 0.12 (2), 0.13, 0.14, 0.15, 0.18, 0.19
US/Canadian capsicum trials (field)	2 x 112.5 g ai/ha	1	0.014, 0.022, 0.024, 0.025, 0.095, 0.11, 0.12, 0.14 (2), 0.16, 0.19
US/Canadian chilli pepper trials (field)	2 x 112.5 g ai/ha	1	0.021, 0.037, 0.070 (2), 0.071, 0.083, 0.14, 0.22, 0.43
European field tomato trials	2 x 30-35 g ai/ha	1	0.013, 0.018 (2), 0.023, 0.025, 0.029, 0.03, 0.033, 0.036 (2), 0.041, 0.055, 0.062
European greenhouse tomato trials	2 x 45-52.5 g ai/ha	1	<0.004, 0.009, 0.012, 0.015 (2), 0.018, 0.028*, 0.034, 0.037, 0.061, 0.079, 0.079*, 0.09*, 0.095, 0.11*, 0.15*
European field capsicum trials	2 x 35 g ai/ha	1	0.018, 0.019, 0.02, 0.022, 0.025, 0.037, 0.049, 0.066, 0.15
European greenhouse capsicum trials	2 x 35 g ai/ha	1	0.029, 0.036, 0.048, 0.049, 0.052, 0.058, 0.062, 0.072, 0.11
European field chilli pepper trials	2 x 35 g ai/ha	1	0.089, 0.11, 0.13, 0.18, 0.20
European greenhouse chilli pepper trials	2 x 35 g ai/ha	1	0.064, 0.16, 0.17, 0.39, 0.57

*Indicates result for cherry tomatoes

Stalk and stem vegetables

Dataset	Application details	WHP (days)	Residues (mg/kg)
US celery trials	2 x 112.5 g ai/ha	1	1.1, 1.4, 2.1, 2.6, 2.8, 3.7, 3.8

Pome fruit

Dataset	Application details	WHP (days)	Residues (mg/kg)
Australian/New Zealand pome fruit trials	1x GAP	14	0.02, 0.06, 0.09, 0.10, 0.11 (3), 0.12, 0.14 (2), 0.16, 0.17, 0.18 (2), 0.19
	2x GAP	14	0.06, 0.13, 0.14, 0.17, 0.20, 0.25, 0.26, 0.32 (2), 0.38, 0.48
Canadian pome fruit trials	Two applications at 1.46x the Australian rate, giving 0.93-1x the Australian seasonal rate	14	0.013, 0.031, 0.061, 0.075, 0.076, 0.081, 0.091, 0.11
US pome fruit trials	Two applications at 1.46x the Australian rate, giving 0.93-1x the Australian seasonal rate	14	0.010, 0.022, 0.027, 0.034, 0.038, 0.041, 0.045, 0.061, 0.065, 0.066, 0.070, 0.078, 0.081, 0.091, 0.098, 0.10, 0.12 (2), 0.14, 0.30
European trials	2 applications at 0.51-0.76x the Australian rate, giving 0.34-0.51x the Australian seasonal rate	14	<0.004, 0.009, 0.022, 0.024, 0.034, 0.039, 0.046, 0.048, 0.053, 0.054, 0.055, 0.066, 0.068, 0.069, 0.076, 0.077, 0.082, 0.096, 0.11, 0.13
Argentine trials	2 applications at 1.52x the Australian rate, giving 1.04x the Australian seasonal rate	14	<0.06, 0.14, 0.20

Stone fruit

Dataset	Application details	WHP (days)	Residues (mg/kg)
---------	---------------------	------------	------------------

US/Canadian peach data	Two applications at 1.34x the Australian rate, giving 1.34x the Australian seasonal rate	10	0.0665, 0.0779, 0.0908, 0.0926, 0.0950, 0.0985, 0.104, 0.107, 0.110, 0.111, 0.119, 0.127, 0.130, 0.132, 0.137, 0.151, 0.155, 0.164, 0.171, 0.204, 0.268, 0.311, 0.352
US/Canadian sweet cherry data	Two applications at 1.34x the Australian rate, giving 1.34x the Australian seasonal rate	10	0.072, 0.12, 0.13, 0.15, 0.21, 0.27
US/Canadian sour cherry data	Two applications at 1.34x the Australian rate, giving 1.34x the Australian seasonal rate	10	0.19, 0.23, 0.37, 0.48, 0.49 0.61
US/Canadian plum data	Two applications at 1.34x the Australian rate, giving 1.34x the Australian seasonal rate	10	0.005, 0.006, 0.007, 0.008 (2), 0.010, 0.011, 0.013, 0.016, 0.018, 0.023, 0.031, 0.036, 0.055, 0.074, 0.076, 0.085
European peach data	Two applications at 0.48-0.71x the Australian rate, giving 0.48-0.71x the Australian seasonal rate	14	0.023, 0.029, 0.031, 0.044, 0.045
European apricot data	Two applications at 0.48-0.71x the Australian rate, giving 0.48-0.71x the Australian seasonal rate	14	0.052, 0.12
Argentine peach data	Two applications at 1.07x the Australian rate, giving 1.07x the Australian seasonal rate	14	<0.05, <0.05
Argentine peach data	Two applications at 2.14x the Australian rate, giving 2.14x the Australian seasonal rate	14	0.14, 0.20
Australian peach data	Four applications at rates of 0.33-0.49x GAP, giving 0.85x the seasonal rate	14	0.18, 0.25
Australian peach data	Four applications at 0.66-0.98x GAP, giving 1.7x the seasonal rate	14	0.67

Grapes

Dataset	Application details	WHP (days)	Residues (mg/kg)
EU wine grape data	One application at 1.1-1.75x the Australian rate, with seasonal rates at 0.56-0.87x the Australian seasonal rate	56	0.004, 0.006, 0.01, 0.016, 0.021, 0.031, 0.046, 0.055 (STMR = 0.016)
		30	0.021, 0.022, 0.03, 0.031, 0.033, 0.036, 0.044, 0.058, 0.061, 0.068, 0.074, 0.08, 0.12, 0.13, 0.15
EU table grape data	Two applications at 1.1-1.35x the Australian rate, with seasonal rates at 1.1-1.35x the Australian seasonal rate	56	0.038, 0.082, 0.12
		3	0.02, 0.035, 0.069, 0.087, 0.1, 0.12 (2), 0.13, 0.23
US/Canadian wine and table grape data	Two applications at around 3.5x the Australian rate, with a seasonal rate of ~3.5x the Australian seasonal rate,	14	0.014, 0.040, 0.050, 0.053, 0.056, 0.058, 0.062, 0.075, 0.086, 0.10, 0.11 (2), 0.13, 0.22, 0.23, 0.27, 0.29, 0.31, 0.37, 0.38, 0.53, 0.59 (2)
Australian wine grape data	Two applications, giving individual and seasonal application rates of 1.15-1.63x the maximum for Australia	56-67	0.02 (2), 0.03

Cotton

Dataset	Application details	WHP (days)	Residues (mg/kg)
---------	---------------------	------------	------------------

Australian trials	Three applications, giving 1x the proposed maximum individual and seasonal rates for Australia	28	<0.01 (2)
	Three applications, giving 2x the proposed maximum individual and seasonal rates for Australia	28	<0.01 (2)
US trials	Two applications giving 2.1x the proposed individual rate and 1.33x the seasonal rate for Australia	20-23	0.006, 0.019 (2), 0.022, 0.029, 0.032, 0.051, 0.054, 0.063, 0.081, 0.084, 0.085, 0.15, 0.23

Chlorantraniliprole MRLs are recommended for brassica vegetables (0.3 mg/kg); head lettuce (3 mg/kg); leafy vegetables (except head lettuce) (15 mg/kg); potatoes (*0.01 mg/kg); celery (5 mg/kg); rhubarb (5 mg/kg); fruiting vegetables (cucurbits) (0.2 mg/kg); fruiting vegetables other than cucurbits (except chilli) (0.3 mg/kg); peppers (chilli) (1 mg/kg); pome fruit (0.3 mg/kg); stone fruit (1 mg/kg); grapes (0.3 mg/kg); cottonseed (0.3 mg/kg). [Note: *denotes that the MRL has been set at the limit of analytical quantitation.]

Processing studies

Processing studies were supplied for apples, grapes (both table and wine varieties), plums, cotton and tomatoes. The following processing factors were determined:

Commodity	Processing factor (from the raw commodity)
Dried plums	1.9
Dried grapes	4.2
Grape pomace (dry)	6.1 (white wine), 12 (red wine)
Wine	<0.29 (white wine), 1.2 (red wine)
Grape juice (finished)	1.3
Dried apples	6.9
Apple pomace (dry)	11
Apple sauce	0.27
Apple juice	<0.19
Apple puree	<0.19
Canned apples	<0.19
Apple preserve	<0.19
Cottonseed oil	0.25
Cottonseed hulls	2.1
Cottonseed meal	0.75
Peeled tomatoes	<0.28
Crushed tomatoes	1.4
Tomato puree	1.5
Tomato paste	1.5
Tomato juice	0.84
Canned tomatoes	0.47
Tomato ketchup	1.1
Tomato pomace (dry)	18

Slight concentrations of chlorantraniliprole were noted in grape juice, red wine, crushed tomatoes, and tomato paste, puree and ketchup, although additional MRLs for these processed commodities are not necessary as they are accommodated by the MRL for the Raw Agricultural Commodity (RAC). Residues concentrated in dried fruit (particularly dried grapes and apples); as a result an MRL of 2 mg/kg is proposed for dried fruit. Residues of chlorantraniliprole also concentrate in pomaces of apples, grapes and tomatoes, and in cottonseed by-products. These products are significant stockfeeds, therefore stockfeed MRLs are recommended (see the discussion on animal feeds below).

Animal feeds

Evaluation of the processing studies for cotton, tomatoes, apples, plums and grapes showed

that chlorantraniliprole residues could concentrate in tomato, apple and grape pomace, and in cottonseed meal and hulls (see the above discussion on processing). The following stockfeed MRLs were recommended: tomato pomace (dry): 2 mg/kg, grape pomace (dry): 2 mg/kg, apple pomace (dry): 3 mg/kg, and cottonseed meal and hulls: 0.7 mg/kg.

Crop rotation

A number of crops included in the applications are considered as being rotational crops: cotton, brassica vegetables, leafy vegetables, potatoes, tomatoes, eggplant, capsicum, cucumber, squash, zucchini, melons, pumpkins, celery and rhubarb.

Confined crop rotation trials were conducted for soybeans, wheat, beetroot, radishes, and lettuce planted at various intervals (0, 30, 120 or 365 days) after a single application of ¹⁴C-labelled chlorantraniliprole to bare soil at 150, 300 or 900 g ai/ha. Field rotational crop studies were conducted at five sites in various climatic zones in the USA and Canada for leafy vegetables (spinach, lettuce and chard), legumes (soybeans), cereals (wheat and oats), and root vegetables (beetroot, radish and turnip) planted at intervals from 13 to 279 days after application of a total of 200, 225, or 600 g ai/ha chlorantraniliprole to bare soil or to a preceding crop.

Evaluation of the confined and field crop rotation studies showed the possibility of residues occurring in succeeding crops planted in rotation with crops to which chlorantraniliprole is to be applied. In field-grown wheat and oats, residues of chlorantraniliprole in grain were below the LOQ for all plant-back intervals from 15 to 238 days, and for application rates up to 600 g ai/ha (4X the maximum proposed seasonal rate for chlorantraniliprole). Quantifiable residues were observed in forage, straw and hay of wheat and oats.

Low, but quantifiable residues were observed in lettuce, spinach and chard planted at intervals from 13 to 151 days after application of chlorantraniliprole to bare soil or a preceding crop. However, the levels observed were well below the proposed MRLs for head lettuce and other leafy vegetables. Roots of radish, beetroot and turnip did not show any quantifiable residues of chlorantraniliprole, at plant-back intervals varying from 13-279 days after seasonal applications of up to 600 g ai/ha. Detectable residues (0.155 mg/kg in leaves and 0.049 mg/kg in roots) were observed for radish planted 30 days after a 150 g ai/ha application. Residues in soybean pods and seeds were below the LOQ, but residues in soybean forage and fodder were 0.08 and 0.075 mg/kg dry weight after application at 225 g ai/ha.

To account for the possibility of residues in following crops, an MRL of *0.01 mg/kg is recommended for 'all other foods' in Table 1 of the APVMA Standard, as the rotational crop trials have shown that residues of chlorantraniliprole are unlikely to be found above the LOQ in edible portions of following crops not already covered by MRLs for direct application. An MRL of 0.5 mg/kg is recommended for 'primary feed commodities [other than apple pomace, dry; cottonseed meal and hulls; grape pomace, dry; and tomato pomace, dry]'. Given that residues of chlorantraniliprole in food and feed commodities were well below these proposed MRLs at all planting intervals tested (13-279 days), plant-back intervals are not required from a residues perspective.

Animal commodity MRLs

Feeding studies have been conducted for chlorantraniliprole in lactating dairy cattle. Four groups of three cattle were dosed at levels ranging 0.11 to 0.55 mg/kg bw/day chlorantraniliprole daily for 28 days; these doses correspond to feed concentrations of 1, 3, 10 and 50 ppm dry weight. An additional two cattle were treated daily for 28 days with 50 ppm in feed for generation of depuration data. In the study, no residues were found in the muscle,

liver, kidney or fat of any animals in the low dose group, while in the high dose group, low levels of chlorantraniliprole at the LOQ were found in the liver of one animal. The maximum feed level for dairy cattle is 0.3 mg/kg bw/day, while the maximum expected feed level for a meat-producing animal is 0.38 mg/kg bw/day (for sheep). Therefore, detectable residues of chlorantraniliprole are not expected in the milk, offal or meat of mammalian livestock.

Following a 9-day depuration period for a cow dosed at 50 ppm, no residues of any analyte were detected in liver, kidney, muscle, or fat with the exception of a residue of 0.004 mg/kg chlorantraniliprole in liver. Following a 23-day depuration period for a cow dosed at 50 mg/kg, no residues of any analyte were detected in liver, kidney, muscle, or fat. Residues in milk collected from the depuration animals were ND (<0.003 mg/kg) at 3 days after cessation of dosing.

A feeding study for poultry was not provided. Forage is not commonly eaten by poultry, while legume and oilseed grains are not expected to contain residues above the limit of quantitation. The maximum feed level in poultry is 0.0018 mg/kg bw/day for broiler chickens. The only relevant feeds commonly given to poultry are not expected to contain quantifiable residues of chlorantraniliprole. Therefore, quantifiable residues of chlorantraniliprole are not expected to be found in poultry meat, offal or eggs.

Based upon the cattle feeding studies and the hen metabolism study, the associated livestock dietary burden calculation, and the residues data, the following animal commodity MRLs are recommended: edible offal [mammalian] (*0.01 mg/kg); eggs (0.03 mg/kg); meat [mammalian] (in the fat) (*0.01 mg/kg); milks (*0.01 mg/kg); poultry, edible offal of (*0.01 mg/kg); and poultry meat (in the fat) (*0.01 mg/kg).

Spray drift

The proposed use in cotton is of most concern from a spray drift perspective, as aerial application is proposed, and the highest application rate for any use is for cotton. The maximum application rate in cotton is 150 g/ha (52.5 g ai/ha). A maximum feeding level of 3 ppm was determined from the dairy cattle feeding study evaluated with the primary product (category 1) application. At this level, residues of chlorantraniliprole in liver were at the limit of quantitation (LOQ) of 0.01 mg/kg. In all other tissues (kidney, fat and muscle), and in milk, at a feed level of 3 ppm, residues of each component of the residue definition were either undetectable or below the LOQ. The maximum feeding level of 3 ppm corresponds to an allowable drift level of 4.5 g ai/ha.

Computer modelling of spray drift was conducted using typical parameters for aerial application to cotton. The modelling determined that a no-spray zone is not required provided the droplet size is medium or larger according to the American Society of Agricultural Engineers definition. The following statement is therefore proposed for inclusion on the label:

Use medium spray quality or larger according to the ASAE S572 definition for nozzles.

The only other crop for which aerial application is likely is potatoes. As the application rate for potatoes is 100 mL/ha (20 g ai/ha), any spray drift will be significantly lower than that for cotton, and a no-spray zone is not required for aerial application to potatoes.

Modelling of airblast application to orchards and ground rig application to cotton also showed that no-spray zones are not required.

Bioaccumulation potential

The reported log P_{ow} for chlorantraniliprole at pH 7 is 2.86. The ratios of chlorantraniliprole in goat muscle vs omental fat, or renal fat or subcutaneous fat were 1:3.4, 1:6.3 and 1:7.3, respectively. Similarly, residues concentrated in cream vs whole milk in a ration of 5.4: 1. . Residues of chlorantraniliprole in composite fat vs muscle in the cattle study were approximately in a ratio of 5:1, following dosing at the highest feed level of 50 ppm. All of the above provide evidence that chlorantraniliprole and its residues may be designated as being ‘fat-soluble’. MRLs for chlorantraniliprole in mammalian and poultry meat have therefore been proposed as [in the fat] to indicate the fat-soluble nature of the residues.

RISK ASSESSMENT CONCLUSIONS

Estimated dietary intake

The chronic dietary exposure for chlorantraniliprole has been assessed. The ADI for chlorantraniliprole is 1.58 mg/kg bw/day, based upon a NOEL of 158 mg/kg bw/day and a 100 fold safety factor. The NEDI calculation is made in accordance with WHO Guidelines¹ and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for chlorantraniliprole is equivalent to 0.09% of the ADI. DIAMOND Modelling² of chronic dietary exposure is also performed on new chemicals, and chemicals with estimated dietary exposure greater than 90% of the ADI. The DIAMOND model estimated the chronic dietary exposure of chlorantraniliprole as 0.13% using Supervised Trial Median Residue (STMR) values, where available.

There is no acute reference dose (ARfD) for chlorantraniliprole, as it was determined to be unnecessary given the absence of an identified short term hazard. Hence NESTIs cannot be calculated. It is concluded that short term intake of chlorantraniliprole at the levels expected in practice is unlikely to be a hazard to consumers of treated produce.

It is concluded that the dietary exposure to chlorantraniliprole is low and the risk from residues in food is acceptable when *DuPont Coragen Insecticide* and *DuPont Altacor Insecticide* are used according to label directions.

Recommendations

The following amendments to the MRL Standard are recommended in relation to the proposed use of *DuPont Coragen Insecticide* and *DuPont Altacor Insecticide*:

Table 1

Compound	Food	MRL (mg/kg)
ADD:		
Chlorantraniliprole	All other foods	*0.01
	VB 0040 Brassica vegetables	0.3
	VS 0624 Celery	5
	SO 0691 Cottonseed	0.3
	DF 0167 Dried fruit	2
	MO 0105 Edible offal (mammalian)	*0.01
	PE 0112 Eggs	0.03
	VC 0045 Fruiting vegetables, cucurbits	0.2

1 Guidelines for predicting dietary intake of pesticide residues, WHO, 1997.

2. DIAMOND: The Diamond Modelling Of Nutritional Data is a computer dietary modelling program based upon statistical software that is used by FSANZ.

VO 0050	Fruiting vegetables, other than cucurbits (except peppers, chilli)	0.3
FB 0269	Grapes	0.3
VL 0053	Leafy vegetables (except lettuce, head)	15
VL 0482	Lettuce, head	3
MM 0095	Meat (mammalian) [in the fat]	*0.01
ML 0106	Milks	*0.01
VO 0444	Peppers, chilli	1
FP 0009	Pome fruits	0.3
VR 0589	Potato	*0.01
PO 0111	Poultry, edible offal of	*0.01
PM 0110	Poultry meat (in the fat)	*0.01
VS 0627	Rhubarb	5
FS 0012	Stone fruits	1

*MRL set at the limit of quantitation.

Table 3

Compound	Residue definition
ADD: Chlorantraniliprole	<i>Commodities of plant origin and commodities of animal origin other than milk: chlorantraniliprole</i> <i>Milk and milk products: sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole</i>

Table 4

Compound	Animal feed commodity	MRL (mg/kg)	
ADD: Chlorantraniliprole	AB 0226	Apple pomace, dry Cottonseed meal and hulls	3 0.7
	AB 0269	Grape pomace, dry Primary feed commodities [other than apple pomace, dry; cottonseed meal and hulls; grape pomace, dry; and tomato pomace, dry] Tomato pomace, dry	2 0.5 2

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

HARVEST WITHHOLDING PERIOD

Potatoes: Withholding period not required when used as directed.

Bok choy, capsicum, celery, Chinese broccoli, Chinese cabbage, choy sum, cress, cucumbers, eggplant, endive, fennel, gai choy/am soi, Indian mustard, kai choy, kale, lettuce, leafy mustard, melons, mibuna, mustard spinach, pak choy, peppers, pumpkin, rhubarb, silverbeet, spinach, squash, tat soi, tomato, zucchini: DO NOT harvest for 3 days after application.

Broccoli, Brussels sprout, cabbage, cauliflower: DO NOT harvest for 7 days after application.

Apples, apricots, cherries, nashi pears, nectarines, peaches, pears, plums: DO NOT harvest for 14 days after application.

Grapes: DO NOT harvest for 8 weeks after application.

Cotton: DO NOT harvest for 28 days after application.

GRAZING WITHHOLDING PERIOD

Cotton: Do not graze or cut for stock food.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Commodities exported and main destinations

Some of the commodities of interest in connection with the proposed products, namely pome fruit, stone fruit, grapes (including dried grapes and wine), cotton, mammalian and poultry meat and offal, eggs, and dairy produce are considered to be major Australian export commodities.

Total exports of apples, pears, nashi pears, apricots, peaches, nectarines, plums, cherries, table grapes and dried vine fruits, obtained from the Australian Horticulture Statistics Handbook (2004)³ are tabulated below:

Australian apple exports in 2002/03

Destination	Value, \$ million
United Kingdom	8.494
Malaysia	6.984
India	7.635
Singapore	2.725
Sri Lanka	4.015
Bangladesh	1.361
Hong Kong	0.88
Taiwan	4.589
Indonesia	0.944
Japan	0.336
Other	3.411
TOTAL	41.374

Australian pear exports in 2002/03

Destination	Value, \$ million
Singapore	5.723
Malaysia	4.239
Indonesia	3.815
Hong Kong	0.874
New Zealand	2.143
Canada	2.635
Netherlands	0.181
Fiji	0.221
India	0.32
Switzerland	0.12
Other	2.135
TOTAL	22.406

Australian nashi pear exports in 2002/03

Destination	Value, \$ million
Singapore	0.39
Papua New Guinea	0.006
New Caledonia	0.003
French Polynesia	0.01
Other	0.019
TOTAL	0.428

Australian peach exports in 2002/03

Destination	Value, \$ million
Singapore	0.89
United Arab Emirates	0.771

³ *The Australian Horticulture Statistics Handbook 2004*, David Collins, Leo Cirillo, and Libby Abraham, Horticulture Australia Ltd.

Taiwan	2.065
Malaysia	0.219
United Kingdom	0.12
Hong Kong	0.423
Saudi Arabia	0.2
France	0.222
Thailand	0.015
Bahrain	0.051
Other	0.567
TOTAL	5.543

Australian nectarine exports in 2002/03

Destination	Value, \$ million
Taiwan	11.469
Hong Kong	8.762
Singapore	0.555
France	0.176
United Arab Emirates	0.378
Malaysia	0.362
Saudi Arabia	0.074
United Kingdom	0.292
Other	0.594
TOTAL	22.693

Australian apricot exports in 2002/03

Destination	Value, \$ million
Hong Kong	0.474
United Arab Emirates	0.128
Saudi Arabia	0.015
Thailand	0.005
Malaysia	0.004
Bahrain	0.018
Singapore	0.036
France	0.017
French Polynesia	0.004
Other	0.101
TOTAL	0.802

Australian plum exports in 2002/03

Destination	Value, \$ million
Hong Kong	12.112
Singapore	3.361
Malaysia	2.725
Taiwan	3.841
United Arab Emirates	0.831
United Kingdom	1.269
Saudi Arabia	0.049
Indonesia	0.179
India	0.1
Other	1.751
TOTAL	26.218

Australian cherry exports in 2002/03

Destination	Value, \$ million
Hong Kong	7.220
Taiwan	1.752
United Kingdom	0.638
Singapore	1.676
Thailand	0.555

Malaysia	0.096
United Arab Emirates	0.48
France	0.322
Indonesia	0.034
Netherlands	0.212
Other	0.751
TOTAL	13.736

Australian table grape exports in 2002/03

Destination	Value, \$ million
Hong Kong	36.426
Singapore	12.840
Malaysia	14.430
Indonesia	13.048
Bangladesh	1.969
Thailand	6.213
New Zealand	1.969
Vietnam	2.254
Sri Lanka	1.379
Other	4.844
TOTAL	95.372

Australian dried vine fruit exports in 2002/03

Destination	Value, \$ million
Germany	6.661
United Kingdom	4.760
New Zealand	1.993
Canada	1.887
Japan	1.564
Italy	1.125
Netherlands	0.513
Belgium and Luxembourg	0.461
Malaysia	0.305
Taiwan	0.173
Other	0.74
TOTAL	20.156

In 2006/07, 797.47 megalitres of Australian wine, worth \$2.991 billion, were exported. Details of the export destinations for wine are tabulated below.

Australian wine exports (2000/2001-2006/07)

	Unit	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07
Type								
Table wine	ML	329.81	406.31	498.16	568.74	646.73	719.92	779.31
Red	ML	179.79	233.23	307.09	364.09	417.97	454.81	496.89
White	ML	150.02	173.08	191.07	204.65	228.76	265.11	282.43
Sparkling wine	ML	6.60	6.93	7.26	9.31	11.35	13.68	16.15
Fortified wine	ML	2.27	1.86	1.79	2.11	1.89	1.85	1.78
Other wine	ML	0.22	1.51	0.75	0.58	0.86	0.27	0.22
Total	ML	338.90	416.61	507.96	580.74	660.83	735.72	797.47
Major destination								
Canada	\$m	91.2	123.9	174.0	205.1	247.4	249.2	266.3
China	\$m	2.2	2.4	3.4	5.9	9.9	20.8	49.0
Germany	\$m	50.1	47.9	58.0	70.9	71.7	75.6	65.6
Hong Kong, China	\$m	14.5	16.9	15.0	17.9	20.0	25.1	26.4
Ireland	\$m	40.1	42.5	39.7	49.4	54.0	54.0	68.7
Japan	\$m	29.5	30.1	31.7	35.7	48.7	44.1	48.9
Netherlands	\$m	33.9	33.6	38.6	39.3	45.9	45.3	65.3
New Zealand	\$m	77.3	84.7	99.0	98.0	94.0	92.0	101.4
Singapore	\$m	17.2	20.0	23.2	30.7	33.1	37.6	42.8
Sweden	\$m	18.6	24.7	33.6	39.2	36.2	49.6	51.1
Switzerland	\$m	31.1	30.0	36.0	23.9	19.6	19.1	18.1
Thailand	\$m	2.7	3.4	4.4	5.2	7.7	7.8	11.3
United Kingdom	\$m	689.9	840.4	859.4	860.3	966.8	960.3	974.6
United States	\$m	417.5	558.2	827.9	905.4	896.7	901.1	959.9
Other	\$m	98.3	111.3	142.0	158.1	196.6	217.7	241.9
Value	\$m	1 614.1	1 970.0	2 385.9	2 545.0	2 748.2	2 799.3	2 991.3
Unit value	\$/L	4.76	4.73	4.70	4.38	4.16	3.80	3.75

Sources: ABS, *Sales of Australian Wine and Brandy by Winemakers*, cat. no. 8504.0, Canberra; Australian Wine Export Council, *Wine Export Approval Report*, Adelaide.

In the 2006/07 financial year, 104.08 kilotonnes of cottonseed, 4.66 kilotonnes of cottonseed oil, and up to 9.04 kilotonnes of cottonseed meal (the figure is an upper limit as only a combined figure for cotton and sunflower seed meal was available) were exported. Cottonseed exports were worth \$31 million in 2006/07.

The total exports of Australian beef, veal and live cattle were 974 kilotonnes of meat and 638000 live cattle, at an estimated total value of \$5.071 billion, in the 2006/07 financial year.

The volume of dairy products (cheese, butter and butterfat, skim milk powder, casein, whole milk powder and other products) exported from Australia in 2006/07 was 792 kilotonnes at an estimated value of \$2.443 billion.

The volume of lamb, mutton and live sheep exported from Australia in 2006/07 was 312 kilotonnes of meat and 4138000 live animals at an estimated value of \$1.496 billion.

Poultry and pig meat are relatively minor export commodities, being worth \$26 million and \$142 million respectively in 2006/07. Egg exports in 2005/06 were worth \$4.27 million, mostly as processed egg products⁴.

The above figures for wine, cotton, and animal commodity exports (except eggs) have been obtained from the Australian Commodity Statistics⁵.

Overseas registration status

Codex MRLs have not been determined for chlorantraniliprole. It is included in the schedule of the 2008 JMPR.

Chlorantraniliprole products are registered in Romania, China, Indonesia, the Philippines, Korea, Ukraine and Pakistan. APVMA is not aware of any MRLs in these countries.

⁴ http://www.daff.gov.au/agriculture-food/meat-wool-dairy/ilg/industries/australian_egg_industry

⁵ *Australian Commodity Statistics 2007*, Australian Bureau of Agricultural and Resource Economics, Commonwealth of Australia.

The applicant has applied to register products containing chlorantraniliprole in apples, pears, apricots, peaches, non-bearing citrus, table grapes, wine grapes, tomatoes, eggplant, lettuce, broccoli, cabbage, cauliflower, Brussels sprouts, and potato in the European Union. Application has been made to register the use of chlorantraniliprole products in fruiting vegetables other than cucurbits, leafy vegetables, brassica vegetables including cabbage, cauliflower and broccoli, turf, ornamentals, cucurbits, pome fruit, grapes, potato, and stone fruit in the USA and Canada. Registration on cotton in the USA is also sought. The following MRLs are proposed for chlorantraniliprole in the EU, USA and Canada:

Country/status	Commodity	Tolerance, mg/kg
EU	Pome fruit	0.5
	Apricots	0.5
	Cherries	1
	Peaches	0.5
	Plums	0.1
	Grapes	1
	Cucurbits, edible peel	0.2
	Cucurbits, inedible peel	0.2
	Capsicum (including chilli peppers)	1
	Tomatoes	0.3
	Eggplant	0.3
	Potato	0.01
	Broccoli	1
	Head cabbage	2
	Lettuce and other salad plants including brassica leafy vegetables	10
	Spinach and similar leafy vegetables	20
	Celery	10
	Cottonseed	0.3
USA/Canada	Pome fruit	0.45
	Apricots	0.5
	Cherries	0.85
	Peaches	0.5
	Plums	0.08
	Grapes	1.7
	Cucurbits, edible peel	0.2
	Cucurbits, inedible peel	0.3
	Capsicum (including chilli peppers)	0.6
	Tomatoes	0.35
	Eggplant	0.35
	Potato	0.01
	Broccoli	0.9
	Head cabbage	4.5
	Lettuce and other salad plants including brassica leafy vegetables	10
	Spinach and similar leafy vegetables	16
	Celery	7
	Cottonseed	0.4

Potential risk to trade

USA/Canada: The proposed US/Canadian MRLs for chlorantraniliprole in pome fruit, grapes, and cottonseed are higher than the corresponding Australian MRLs. The proposed US/Canadian MRLs for apricots (0.5 mg/kg), cherries (0.85 mg/kg), peaches (0.5 mg/kg), and plums (0.08 mg/kg) are lower than the proposed Australian group MRL for stone fruit (1 mg/kg). However, based on the trial data, residues of chlorantraniliprole in Australian stone fruit are unlikely to exceed the proposed individual stone fruit MRLs for the USA and

Canada. Further, neither the USA nor Canada are significant export destinations for Australian stone fruit. An MRL has not been proposed for dried fruit.

European Union: The proposed EU MRLs for chlorantraniliprole in pome fruit, cherries, grapes and cottonseed are the same or higher than the corresponding MRLs for Australia. The proposed EU MRLs for apricots (0.5 mg/kg), peaches (0.5 mg/kg) and plums (0.1 mg/kg) are lower than the proposed Australian group MRL for stone fruit (1 mg/kg). Based on the trial data, residues of chlorantraniliprole in Australian stone fruit are unlikely to exceed the proposed individual stone fruit MRLs for the European Union. No MRL has been proposed for dried fruit.

Other major importing countries: There are currently no Codex MRLs or any other current or proposed MRLs that the APVMA is aware of. Malaysia, India, Singapore, Sri Lanka, Hong Kong, Bangladesh, Taiwan, and Indonesia are significant importers of Australian pome fruit. Hong Kong, Singapore, Malaysia, Taiwan, and the United Arab Emirates are significant importers of Australian stone fruit. Hong Kong, Singapore, Malaysia, Indonesia, Bangladesh, Thailand, Vietnam and Sri Lanka are significant importers of table grapes. China, Hong Kong, Japan, Singapore, New Zealand, Switzerland and Thailand are significant wine importers.

CONCLUSIONS

Pome fruit: The available residues trial data show that pome fruit from orchards treated with chlorantraniliprole may contain residues when harvested (range of residues from supervised Australian and New Zealand residues trials (n = 15) was 0.02-0.19 mg/kg). **The proposed Australian MRL of 0.3 mg/kg may potentially have an impact on the export of Australian pome fruit to the major importing countries. The APVMA welcomes comment on whether chlorantraniliprole residues will unduly prejudice Australian trade in pome fruit.**

Stone fruit: The available residues trial data show that stone fruit from orchards treated with chlorantraniliprole may contain residues when harvested (range of residues from supervised US/Canadian cherry residues trials (n = 12) was 0.072-0.61 mg/kg; from supervised US/Canadian plum trials (n =17) was <0.01-0.085 mg/kg,; from supervised US/Canadian peach trials (n = 23) was <0.01=0.35 mg/kg. **The proposed Australian MRL of 1 mg/kg may potentially have an impact on the export of Australian stone fruit to the major importing countries. The APVMA welcomes comment on whether chlorantraniliprole residues will unduly prejudice Australian trade in stone fruit.**

Grapes: The available residues trial data show that grapes from vineyards treated with chlorantraniliprole may contain residues when harvested (range of residues from supervised European wine grape residues trials (n = 15) was 0.02-0.15 mg/kg;; and from supervised European table grape residues trials (n = 9) was 0.02-0.23 mg/kg,). Processing studies gave processing factors of 1.2 for red wine, so finite residues of chlorantraniliprole may be found in wine. A separate MRL for wine is not required. A processing factor of 4.2 for dried grapes was determined. An MRL of 2 mg/kg for dried fruit is proposed. **The proposed Australian MRL of 0.3 mg/kg may potentially have an impact on the export of Australian table grapes and dried grapes to the major importing countries and Australian wine to some of the major importing countries. The APVMA welcomes comment on whether chlorantraniliprole residues will unduly prejudice Australian trade in grapes, including wine and dried grapes.**

Cottonseed: The available residues trial data show that cottonseed from crops treated with

chlorantraniliprole may contain residues when harvested (range of residues from supervised US residues trials (n = 14) was <0.01-0.23 mg/kg. Residues were <0.01 mg/kg in four Australian trials. **The proposed Australian MRL of 0.3 mg/kg may potentially have an impact on the export of Australian cottonseed to the major importing countries. The APVMA welcomes comment on whether chlorantraniliprole residues will unduly prejudice Australian trade in cottonseed.**

Animal commodities: Animal transfer data for lactating cattle, metabolism data in laying hens and the expected dietary burden in poultry and mammals feeding on commodities from crops treated with chlorantraniliprole show that quantifiable residues are unlikely to be found in mammalian and poultry meat and offal, and milk. MRLs are proposed for these commodities at the limit of quantitation. A finite MRL (0.03 mg/kg) is proposed for eggs, and there is a chance of low levels of residue being detected in eggs. Egg exports are relatively small (<\$5 million in 2005/06). **There is not expected to be any significant risk to Australian trade in meat, milk and eggs, however the APVMA welcomes comment on the proposed MRLs.**

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Formulation, packaging, transport, storage and retailing

DuPont Coragen Insecticide, Dupont Altacor Insecticide and DuPont Acelepryn Insecticide will be formulated overseas and imported into Australia.

Use pattern and exposure profile

DuPont Coragen Insecticide (SC) will be used to control insects in vegetable crops (broccoli, brussel sprouts, cabbage, cauliflower, lettuce, tomato capsicum, egg plant peppers, celery rhubarb and potatoes). It will be applied either by groundboom or hand held spray.

DuPont Acelepryn Insecticide (SC) will be used to control insect pests in turf grass. It will be applied either by groundboom or hand held spray.

DuPont Altacor Insecticide (WG) will be used to control insects in orchards (grapes, apples, pears, nashi pears, apricots, cherries, nectarine, peaches and plums) as well as on cotton. The product will be applied using a groundboom sprayer in all cases except for cotton, where it will be applied aerially.

The maximum application rate is for DuPont Acelepryn Insecticide when used on turf, where it can be used up to 300 g ai/ha in 200-200 L/ha of water. The products are generally used up to three times per season with a seven day interval between applications.

Farmers and contract spray workers will be the main users of the product. These workers may become contaminated with the product/spray during opening of the containers, mixing/loading, application, cleaning up spills, and maintaining equipment. The main routes of exposure to the product/spray will be dermal and inhalational. Post application activities are likely to include re-application, thinning, pruning and harvesting for the vegetable and fruit crops. Post application for turf is likely to include activities such as mowing and weeding.

A Pesticide Handlers Exposure Database (PHED) Surrogate Exposure estimation was conducted to estimate potential exposure to workers when applying each product by ground boom and for Altacor insecticide by aerial application. Regardless of the application method, the greatest contribution to exposure was from mixing and loading the product. The highest exposures were estimated for the aerial application of Altacor insecticide and groundboom application of Acelepryn Insecticide on turf, in each case when gloves were not worn. In all scenarios tested wearing gloves reduced workers exposure to negligible levels.

Risks to workers during use and recommended PPEs

Chlorantraniliprole and its products have very low overall toxicity. The most appropriate NOEL for OHS risk assessment, given the intermittent nature of likely exposure, is taken from the 28-day dermal toxicity study. The NOEL in this study was 1000 mg/kg bw/d, the highest dose tested. Dermal penetration studies were also performed on both products and showed that the dermal penetration of chlorantraniliprole for both formulations is between 0.32-1.09% for the undiluted concentrates and 2.10-2.79% for 0.75 g/L aqueous dilutions of the concentrates.

The OCS utilised the Margin of Exposure (MOE) approach in the calculation of risks to workers exposed chlorantraniliprole and determined that no particular personal protection equipment was required.

Hazardous classification

With the available toxicology information, OCS classified chlorantraniliprole according to the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004) and determined that chlorantraniliprole required no risk labels.

ENVIRONMENTAL ASSESSMENT

ENVIRONMENTAL FATE

Hydrolysis

The hydrolytic stability of chlorantraniliprole was investigated in three buffer solutions at pH 4, 7 and 9 at 25°C. Chlorantraniliprole is stable at pH 4 and 7. At pH 9, chlorantraniliprole was unstable and underwent cyclisation followed by irreversible dehydration to form IN-EQW78 which accounted for 86.7% AR at day 30. This metabolite was stable in strongly acidic environments, as demonstrated in the soil extraction procedures used in the field dissipation studies. Therefore, IN-EQW78 is considered stable to hydrolysis and is not expected to revert back to the parent compound. No other hydrolysis product was detected at greater than 10% of the applied radiolabel (AR). The DT50 of chlorantraniliprole in pH 9 buffer solution at 25°C was 10 days. The rate of degradation was also influenced by temperature, with DT values of 50 and 0.3 days at 15 and 50°C, respectively.

Soil photolysis

The phototransformation of chlorantraniliprole was investigated on a non-sterile Marietta sandy loam using a filtered xenon arc lamp as a light source. Samples were irradiated under continuous light for 15 days at 25°C. The parent compound degraded more rapidly than in the corresponding dark control, accounting for 72.1% AR by 15 DAT. By contrast, chlorantraniliprole accounted for 90.4% AR by study termination in the control samples. The decline of chlorantraniliprole in irradiated soil was due to extensive degradation of the parent molecule into numerous components, each of which accounted for less than 3% of the applied radioactivity, and the metabolites IN-ECD73 and IN-E5F18 were the only ones identified. In the irradiated test systems, approximately 17 minor products were formed that accounted for a combined maximum of 14.2% AR by Day 15 (maximum in the non-irradiated soils was approximately 5% AR). The DT50 and DT90 values of chlorantraniliprole were 43 and 144 days, respectively, compared to 416 and 1380 days in the non-irradiated (dark) control soil. Under natural sunlight (midday at latitude 30 to 50°N) conditions a DT50 of 129 days is predicted. Therefore, the laboratory studies demonstrate that chlorantraniliprole will degrade in soil by multiple pathways, but, as noted previously, the degradation will be limited by sequestration in soil.

Aqueous photolysis

The aqueous phototransformation of chlorantraniliprole was studied at 25°C in a sterile pH 7 buffer solution and natural water. Following continuous irradiation (Xenon arc light) for up to 21 days, rapid degradation was observed with DT50 values of 0.37 and 0.31 days in the buffer and natural water samples, respectively. The respective DT50 values in natural sunlight equivalent days were 0.7 and 0.6 days. Significantly slower degradation was observed in the dark controls, with respective DT50 values of 467 and 240 days.

Three major degradation products (shown in Figure 1) were observed in the buffer, namely IN-LBA22 (maximum of 52.8% AR on Day 1), IN-LBA23 (maximum of 40.8% AR on Day 5) and IN-LBA24 (maximum of 90.2% AR on Day 15). IN-LBA22 rapidly hydrolysed to

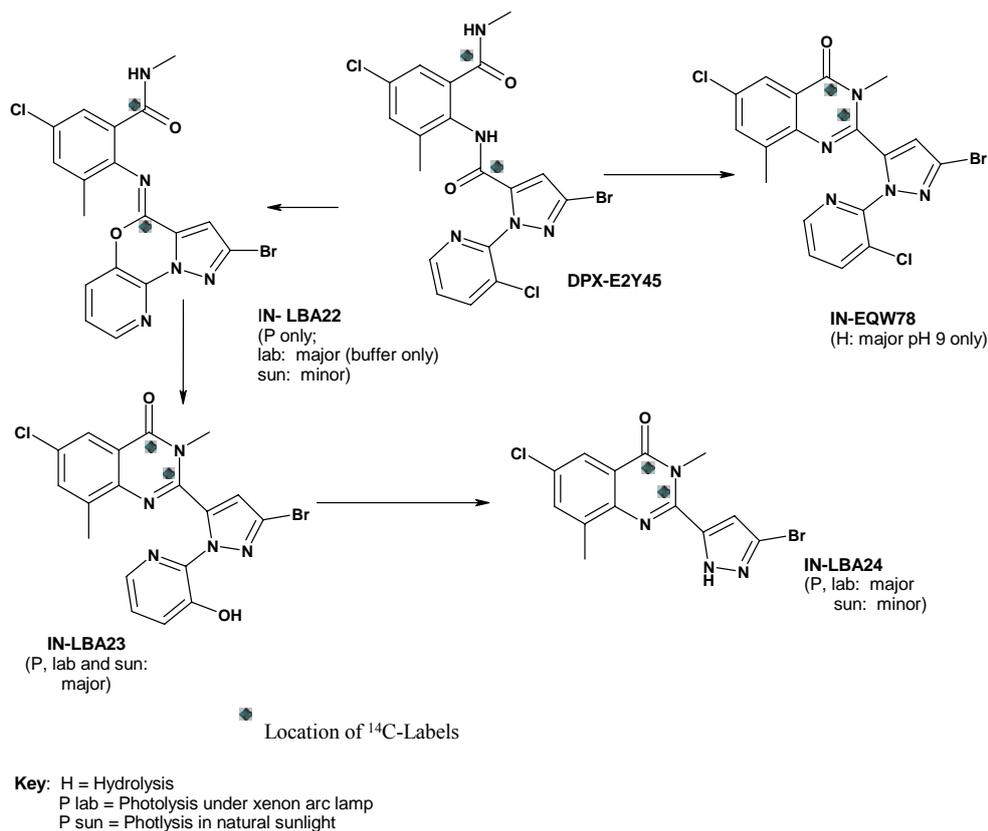


Figure 1. The proposed degradation pathway for aqueous photolysis.

form IN-LBA23 (as observed in the hydrolysis study), which then photolysed to yield IN-LBA24. The DT50 values for IN-LBA22 and IN-LBA23 in irradiated buffer were 0.9 and 1.5 days, respectively. IN-LBA24 was stable under these conditions. IN-LBA23 (maximum of 51.4% AR at 12 hours) and IN-LBA24 (maximum of 94.4% AR on Day 5) were the 2 major degradation products observed in natural water. IN-LBA22 was minor (maximum of 3.4% AR) and this was attributed to a rapid initial rearrangement to IN-LBA23. The DT50 values of IN-LBA23 and IN-LBA24 were 0.5 and 129 days in irradiated natural water, respectively. The latter metabolite is by far the most persistent in aqueous environments and has a DT90 value in natural water of 430 days.

An additional experiment conducted with the pH 7 buffer solution showed slower degradation of the parent compound (DT50 of 33 days) under natural summer sunlight (latitude and longitude of 39°N41', 75°W45'). Only one photoproduct (IN-LBA23) was detected at a maximum of 11% AR, while all other products were less than 4% AR.

Aerobic soil metabolism

Five aerobic soil metabolism studies with chlorantraniliprole were presented in support of the application. The first study investigated soil metabolism in a Marietta sandy loam at two temperatures (25 and 35°C) for up to one year of incubation. A second study was performed on three additional soils (Tama silty clay loam, Sassafras loam and Lleida clay loam) at the same temperatures for up to 120 days of incubation. Two temperatures were used in order to understand the effect of temperature on degradation under relevant environmental conditions. Chlorantraniliprole was observed to degrade slowly at 25°C with aerobic soil transformation half-lives ranging from 210-493 and 233-886 days for readily and total extractable residues,

respectively, depending on soil type. Degradation was more rapid at 35°C with respective half-lives ranging from 98-227 and 137-443 days. The concentration of the parent compound in readily extractable residues ranged from 59-79% and 36-74% of the applied radiocarbon by termination of the 25°C and 35°C studies, respectively. The ranges in total extractable residues were 68-83% and 46-82% at the 2 respective temperatures. The results showed that faster degrading soils (e.g. Lleida) have a higher proportion of readily extractable chlorantraniliprole, which are more inherently degradable than the sequestered residues.

Chlorantraniliprole primarily degrades via abiotic cyclisation followed by dehydration (as shown in Figure 2) to form IN-EQW78, with subsequent demethylation forming IN-GAZ70. Alternative pathways include abiotic rearrangement followed by cleavage to form IN-F6L99 and IN-ECD73. The major metabolites detected were identified as IN-EQW78 (all soils), IN-ECD73 (Marietta, Tama and Sassafras soils) and IN-GAZ70 (in Lleida soil only). IN-EQW78 was the only metabolite exceeding 10% AR (maximum of 9.54% at 25°C on the sandy loam at 365 DAT and 33.3% at 35°C on the clay loam at 120 DAT), with levels of IN-ECD73 (maximum of 4.93 and 8.22% on the sandy loam at 365 and 180 DAT, respectively, for the 2 temperatures), IN-F6L99 (maximum of 2.19 and 5.15% on the sandy loam at 240 DAT for both temperatures) and IN-GAZ70 (maximum of 4.35 and 7.38% on the clay loam at 120 DAT for both temperatures) exceeding 5% only at 35°C. IN-F9N04 was less than 5% AR. Metabolites were generally observed at increasing concentrations.

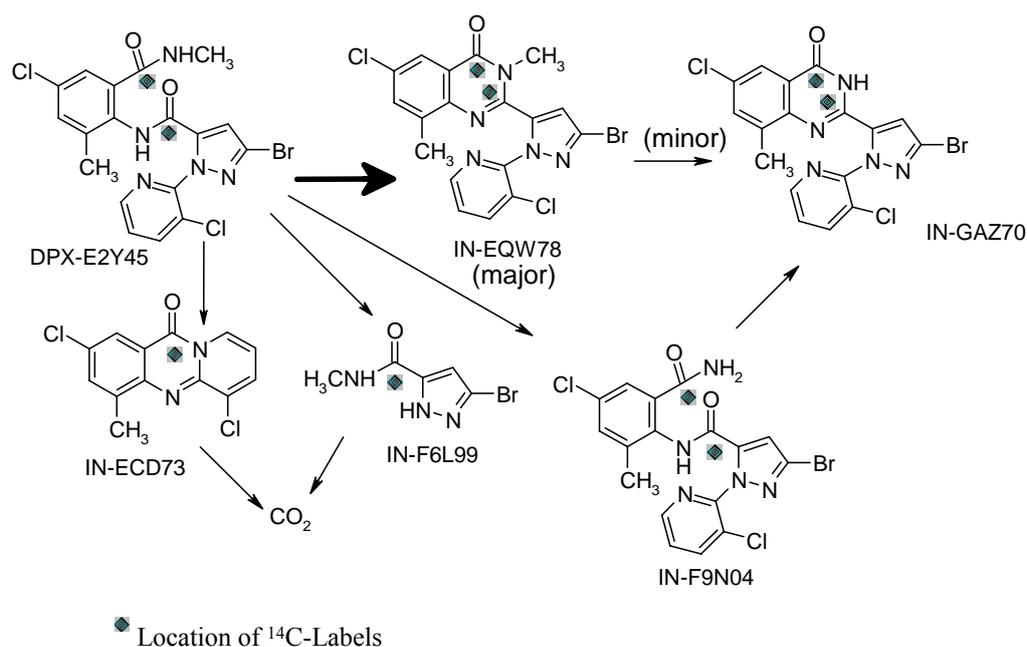


Figure 2. The proposed degradation pathway in soil under laboratory and field conditions.

The extractability of radioactivity from all samples decreased gradually over the period of the study but remained greater than 88% throughout. Non-extractable residues (NER) gradually increased to a maximum of 9% by study termination and a maximum of ~5.3% of applied radiocarbon was identified as CO₂.

In another study, the effect of temperature and soil viability on the rate of degradation of ¹⁴C-radiolabelled chlorantraniliprole was investigated over 120 days under sterile conditions at 3 temperatures (25, 34 and 49°C) in a Cajon sandy loam soil and a Lleida silty clay loam soil.

Similarly to the previous studies, slow degradation was observed in the parent compound, with DT50 values in non-sterile soil of 323, 125-234 and 20-21 days at the 3 respective temperatures. Half-lives under sterile conditions at 34°C were 103-118 days. At lower temperatures, Arrhenius extrapolation predicts a reduced degradation rate. At 10°C the DT50 for chlorantraniliprole was 1589 and 2234 days in the Cajon sandy loam and Lleida silty clay loam, respectively, compared to 125 and 234 days at 34°C. The lower temperature DT50 for the Cajon soil may be somewhat unreliable as only two data points were used to construct the Arrhenius equation. Under non-sterile conditions, chlorantraniliprole declined to 78-93, 51-74 and 3.4-4.8% of AR at the 3 respective temperatures by study termination, demonstrating the dependence of degradation on temperature, and the persistence expected at environmental temperatures. Under sterile conditions at 34°C, levels of the parent at study termination ranged from 41-48% of AR.

The route of degradation was similar between sterile and non-sterile soils, indicating that abiotic degradation was the major degradation mechanism for chlorantraniliprole in soil. Temperature did not affect the route of degradation, but degradation was more rapid with the proportion of the various metabolites increased with increasing temperature. Apart from IN-EQW78, which reached maximum levels of >10% AR at all temperatures, IN-ECD73 reached 10% AR only at 49°C. Other minor metabolites were generally less than 6% AR and included IN-F6L99, IN-F9N04 and IN-GAZ70. The new metabolite IN-EVK64 (from degradation of IN-F6L99) was observed at high temperatures, but only reached amounts greater than 10% AR at 49°C. IN-EVK64 has not been detected in other studies conducted at more representative temperatures and is not a significant product arising from degradation of DPX-E2Y45.

A pilot study was performed on 3 acidic soils at 2 temperatures to further explore the effect of pH on degradation in soil determined that there was no effect of soil pH on degradation.

Degradation was limited by sequestration or aging of the chlorantraniliprole residues in soil, which became progressively more difficult to extract with age, protecting the residues from degradation, while limiting their mobility in soil. The initial sorption may involve the surfaces of various soil constituents such as the mineral (clay) fraction or the organic matter fractions, with possible binding mechanisms occurring with humic substances or the interlayer of 2:1 expandable clays (smectitic clays) amongst others. Part of the sequestration behaviour of chlorantraniliprole may be explained by the smectite clays (2:1 expandable clays) present in the Tama soil (which has one of the longer DT values), into which diffusion by chlorantraniliprole can occur, thereby becoming less available for extraction and degradation.

Four aerobic soil metabolism studies with the metabolites were also presented in support of the application. IN-EQW78 degraded slowly in soil incubated in the dark at 25°C, with DT50 and DT90 values ranging from 646-785 and 2150-2610 days, respectively. Unextractable residues and ¹⁴CO₂ were <5% AR in all soils. IN-ECD73 degraded slowly in soil with DT50 and DT90 values ranging from 752-2870 and 2500-9540 days, respectively. There was no apparent degradation in one of the soils tested (Cajon sandy loam) and these values were excluded. Unextractable residues reached a maximum of 13% AR and ¹⁴CO₂ was less than 1% AR. In four soils, IN-GAZ70 degraded slowly, with DT50 and DT90 values ranging from 741-3690 and 2460-12200 days, respectively. Unextractable residues remained less than 5% AR in all soils and ¹⁴CO₂ remained below the limit of quantitation during the course of the study. No degradation was noted in the Cajon sandy loam soil. IN-F6L99 degraded rapidly in soil with DT50 and DT90 values ranging from 7.6-29 and 38-132 days, respectively. ¹⁴CO₂ ranged from 17-59% AR in all soils at study termination, with unextractable residues ranging

from 14-27% AR. Therefore, IN-F6L99 would degrade rapidly in the environment.

Anaerobic soil metabolism

The anaerobic biotransformation of chlorantraniliprole was studied on a Marietta sandy loam at 25°C. The parent compound was incubated under dark, aerobic conditions 30 days, at which point IN-EQW78 accounted for 1.86-2.09 %AR compared to 6.21-6.71 % in the aerobic metabolism study on the same soil. Following flooding (to obtain anaerobic conditions) and incubation in the dark for an additional 120 days, the parent compound degraded to 54.9-58.9% AR, with DT50 and DT90 values of 208 and 692 days, respectively. The lower DT50 value in anaerobic conditions was due to increased formation of IN-EQW78, which reached a maximum concentration of 26.7% AR at 120 DAT. The other degradation products seen in the aerobic soil metabolism studies were also detected but in concentrations of less than 5% AR. The average pH was 6.6 (\pm 0.6) in the water layer and 6.8 (\pm 0.6) in the soil during the course of the study, showing that degradation was promoted by reducing conditions and not by changes in pH. Mineralisation after 120 days ranged from 0.17-0.66%. Corresponding amounts of non-extractable residues were between 2.8-4.9 %.

Terrestrial field dissipation

A total of 26 field studies have been initiated in the United States, Canada and Europe to evaluate the behaviour of chlorantraniliprole under field conditions.

Soil dissipation trials in the USA using radiolabelled chlorantraniliprole

Field dissipation of an emulsifiable concentrate containing radiolabelled chlorantraniliprole was conducted on a Cajon sandy loam over 18 months, and on a Hidalgo clay for 2 consecutive 12 month periods following 2 autumn applications. In both soils about 10-15% of the applied material became sequestered in soil, which slowed down the rate of degradation. This is reflected in a higher DT50 value of 188 days for total extractable residues in the Cajon sandy loam compared to a DT50 value of 108 days for readily extractable residues. A similar trend was observed on the Hidalgo clay, with DT50 values of 184-188 and 222-239 days for the readily and total extractable residues, respectively. Total extractable residues of the parent compound declined to 20-29% AR by study termination. The major transformation product detected was IN-EQW78 at a maximum level of 42% AR in the Hidalgo clay. Other metabolites included IN-F6L99 (maximum of 10.2% AR in the Hidalgo clay), IN-ECD73 (maximum 9.5% AR in the Cajon sandy loam), while the maximum amount of IN-GAZ70 was 7.3% AR in the Cajon sandy loam. Unidentified radioactivity reached a combined maximum concentration of 7.2 to 10% AR for the 2 soils, with no single component exceeding 2% AR. The pattern of the unidentified radioactivity was similar to that seen in the irradiated test system, suggesting that photolysis was contributing to the decline of chlorantraniliprole in the field.

No radioactivity was detected below 15 cm in the Cajon sandy loam. No radioactivity was detected below 60 cm for the benzamide carbonyl-labelled material (1.3% AR in the 45-60 cm segment by Day 379). However, for the pyrazole carbonyl-labelled material, 2.7% AR was found in the 75-90 cm segment. After Application 2, 0.9% AR was detected in the same segment by Day 741.

Eight bare soil dissipation trials in Europe

Eight terrestrial field dissipation studies using either SC or WG formulations were initiated on bare soil (single broadcast application) under field conditions in Northern and Southern Europe. Generally biphasic degradation of the parent compound was observed until approximately one year after application. In addition, the decline of chlorantraniliprole appeared to accelerate during the summer/autumn period following a lull during winter/spring. The kinetic data was recalculated according to recent FOCUS kinetics guidance. DT50 values ranged from 49-248 and 82-540 days for the readily and total extractable parent compound residues, respectively. DT90 values ranged from 404-5628 days. The majority of soil residues were found above 15 cm depth. At the end of the study period, parent compound residues degraded to 23.6-59.8% (mean 40.4%) of the day 0 residues. In Northern European sites the DT50 values of total extractable residues ranged from 82-489 and 117-540 days at the Northern and Southern European sites, respectively. Maximum levels of IN-EQW78 ranged from 2.4-29.3% (mean 17.3%) of the day 0 residues. Maximum residues levels of IN-ECD73 ranged from 2.5-10.3% (mean 5.5%). Residues of IN-GAZ70 were only reported for four of the eight European residue trials, ranging from 0.6-3.6 (mean 1.8%). The lower levels of metabolite were observed in Poland, with the higher levels in Italy. In general < 1% of the day 0 amount was observed in the 70-90 cm soil layer.

Eight bare soil dissipation trials in the United States

Four terrestrial field dissipation studies using an SC formulation of chlorantraniliprole were initiated on bare soil under field conditions in the United States. Application was in April/May, apart from an October application for the Texas site (Hidaglo clay). Soils included 2 silt loams (Cajon & Penn), a Hidalgo clay and a Tifton sand. DT50 values ranged from 34-444 and 45-1130 days for the readily and total extractable residues, respectively. In both cases the highest values were recorded in the Tifton sand. Rapid initial decline during the first 2 months to half the applied was observed at the Texas site. Degradation slowed down during the winter months but increased again after this period. Degradation to 15-16% of day 0 levels was observed in this and the Cajon silt loam by 540 DAT. Degradation was slower at the 2 other sites with 64-73% of Day 0 levels remaining as parent by 540 DAT. The difference may be related to the very high sand content and low organic content of the latter test soils. Maximum concentrations of IN-EQW78 and IN-ECD73 ranged from 9-21% and 2-6%, respectively. These residues showed generally low potential for mobility, with essentially no detects below the 45 cm soil depth in the Cajon silt loam and Tifton sand. Slightly more downward mobility was observed in the Penn silt loam and Hidaglo clay, but detections were generally at a low concentration (less than or equal to 1% of Day 0 residues) below 60 cm.

In a field study conducted in Washington using a WG formulation, chlorantraniliprole degraded during summer, slowed during winter, but continued to decline the following spring as temperatures increased again. Between 36-48 % (~530 DAT) of the applied amount was carried over into the following cropping season. The DT50 values ranged from 335-411 days.

Further studies using chlorantraniliprole as a WG formulation were initiated in Minnesota (Estherville loam), and Prince Edward Island (Alberry sandy loam). The DT50 values ranged from 210 days (Minnesota) to 274 days (Prince Edward) for the total extractable residues. Degradation to ~50% of day 0 residues was observed at both the Minnesota (539 DAT) and Prince Edward Island (Day 468) sites. Parent degradation was accompanied by an increase in the amounts of degradation products, with IN-EQW78 detected at maximum levels of 4-5% of the Day 0 residues. IN-ECD73 and IN-GAZ70 were generally <5%. Additional

metabolites, known to contribute to the material loss were not monitored because they were not anticipated to show >5% of the applied material. Parent and metabolite residues showed a generally low potential for mobility, with detections at both sites $\leq 1\%$ of day 0 residues at lower depths (~38 cm).

Four dissipation trials in the presence of a cover crop in the USA

Additional field trials were performed at or near the sites with the longest DT50 values to determine the effect of crop cover on the degradation of chlorantraniliprole in soil. The New Jersey test site contains smectite clays (2:1 expandable clays), whilst the Georgia site may contain metal oxides, both of these soil components can enhance sequestration (OECD 2007a).

Application to turf

Turf dissipation trials were conducted with the 200SC formulation of chlorantraniliprole applied directly to a turf-covered plot. Run-off was minimal, accounting for approximately 1-4% of the applied mass. The New Jersey test site had higher run-off due to a significant rainfall event (~406 mm). Chlorantraniliprole degraded faster than in the comparable bare soil study, with higher amounts of IN-EQW78 (7-14% of day 0 residues) observed in the turf dissipation trials compared to 4-6%. The parent half-lives in all matrices (sum of grass, thatch and soil) were 150 and 258 days in the New Jersey and Georgia trial sites, respectively. The respective DT50 values for IN-EQW78 were 181 and 233 days. Extractable parent residues declined over the 6-month study period to 49 and 73% of the applied amount in the New Jersey and Georgia sites, respectively.

Application to a pre-emergent grass and post-emergent pepper trial

Dissipation in crop covered field sites was further investigated at the New Jersey trial site. Chlorantraniliprole was applied as two post-emergent applications to pepper plants or a single application to bare soil seeded to grass. For both studies, the DT50 values of the readily and total extractable residues were much shorter than those measured in the bare soils studies. In the presence of plants, DT50 values ranged from 59-114 and 85-232 days (lower values were peppers), respectively. Higher amounts of IN-EQW78 and IN-ECD73 (respectively 6.5 and 2.3 % of day 0 residues) were observed in these trials relative to those with the pepper plants. No detectable residues of chlorantraniliprole were observed below 60 cm.

Soil accumulation trials in the presence of crop cover in Europe.

In addition, the potential of chlorantraniliprole to accumulate in soil was investigated in four European field trials. Parent compound levels in soil ranged from 1/4 to 2/3 of the cumulative applied parent compound after 2-4 applications, when applied to crops under normal agronomic conditions. This suggests that approximately 1/3 to 3/4 of applied amount had either degraded, been intercepted by a crop or otherwise dissipated over the 1.5-2 years since the initial application. The interim results do not permit a definitive assessment of the accumulation potential of chlorantraniliprole, however, results from one test site suggest residues are approaching the plateau concentration following 4 applications.

Mobility studies

Chlorantraniliprole

The adsorption/desorption of chlorantraniliprole was conducted on 5 soils from the US and Europe. The average K_d was 3.17 (range 0.8-7.88) mL/g and the corresponding average KOC was 329 (range 152-535) mL/g. Along with the average $1/n$ of 0.952 (range 0.85-1.04) moderate sorption of chlorantraniliprole to soil is indicated. There was a strong correlation between K_d and percent of organic carbon (OC), which was inversely related to desorption. Total desorption levels ranged from 23-65%. A weak inverse relationship between the Freundlich adsorption parameter K_{FOC} and soil pH was observed. However, it is not apparent if there is a physical explanation for this observation. Based on the classification system of McCall (1980), chlorantraniliprole can be considered to have medium mobility in soil.

In a supportive study on 22 soils from Europe, North and South America, and Asia using the batch equilibration method, chlorantraniliprole showed a wide range of sorption behaviour, ranging from 24.53-90.68% (average 61.94 %). Adsorption was inversely related to desorption, which ranged from 9.7-63.8%. The average K_d value was 5.3 (range 0.7-20.2), and the associated KOC value was 315 (range 115-1343) mL/g. K_d was generally related to %OC but not pH. There was some correlation between K_d and %, however, clay type appeared important, with soils containing 2:1 expandable clays (smectitic) showing higher sorption. The same method was used on 3 Brazilian soils, with K_d and KOC values ranging from 3.4-28.7 and 170-226 mL/g, respectively. The study confirmed no correlation between soil pH and adsorption.

Aged sorption of radiolabelled chlorantraniliprole was studied in 3 US soils at 25°C for 120 days. Similar Day 0 desorption values were observed in the Cajon (57%) and Hidaglo (52%) soils, with a lower value in the Penn soil (27.6%). Aging increased KOC by 2-4× in 30 days, with the Day 0 range of 162-328 mL/g increasing to 519-1361 mL/g by study termination, suggesting movement of the solute deeper into soil solids (clays, humic substances, micropores, etc.), where it becomes sequestered and removed from the solution phase, thereby increasing the amount of sorption. The largest increase in KOC was seen in the Penn soil, which contains smectite clays. In a supporting study using the batch equilibrium method, highest sorption was observed in Na⁺ rich smectite clay (2:1 expandable clays) as compared to Ca²⁺ rich smectite, kaolinite clays (1:1 non expanding clays) or a natural soil known to contain kaolinite clay. The highest sorption in Na⁺ rich smectite clay was attributed to possible movement of chlorantraniliprole into interlayer spaces saturated with K⁺ ions, which have lower hydration energies than Ca²⁺.

A further aged residue study of radiolabelled chlorantraniliprole in Myakka sand columns (0.4% organic matter) was conducted in 3 soils obtained from Europe and the US. The column leachates were analysed either on fresh spikes, on aged soil (90 days), or on aged soil after extraction of the readily extractable residues. Greatest mobility was observed in the fresh spiked sample for each soil. The Penn fresh spike soil showed the greatest mobility, with 9.6% AR in the column leachate and 27.7% AR remaining in the soil layer. For the Goch and Lleida fresh spike soils, >60% AR remained in the soil layer after elution. The aged soil columns had more radioactivity retained in the applied soil layer, with less in the column sand and the column leachates (< 2% AR). Lower levels of extractable residues were observed in the Penn soil (a 2:1 expandable clay) with ~49%, compared to 72-77% for the other soils. Metabolites were detected in the soil residues, with IN-EQW78 and IN-ECD73 accounting for

4.1-6.3 and 1.6-3.2% AR, respectively. Unidentified components accounted for <4% AR. The post-extraction soils demonstrated the lowest mobility potential of all the soil treatments, with >95% AR remaining in the applied soil layer. These data demonstrate that the aged residues of chlorantraniliprole in soil have decreased mobility. Furthermore, once the readily extractable residues are removed from soil, the remaining (sequestered) residues are essentially immobile.

In an additional study using the batch equilibration method, the sorption of chlorantraniliprole was found to be related to the % OC in turf, soil and thatch. K_d values were highest in grass (43.1-49.4) followed by thatch (3.0-12.6) and soil (1.4-5.3).

Chlorantraniliprole metabolites

Four batch equilibrium studies with Freundlich isotherm data were conducted for IN-EQW78, IN-ECD73, IN-F6L99 and IN-GAZ70. For IN-EQW78, IN-ECD73 and IN-GAZ70 sorption was correlated to the % OC in the soils, with no apparent correlation to soil pH. However, for IN-F6L99 the correlation with organic carbon was poor. For IN-EQW78, the average K_d value was 143.5 (range 38.6-345.1), with an associated mean KOC of 14851 (range 7468-22,196) and mean $1/n$ value of 0.92. For IN-ECD73, the average K_d value was 412 (range 152-1053), with a mean KOC of 44,073 (range 25,925-58,495) and mean $1/n$ value of 0.88. For IN-F6L99, the average K_d value was 1.46 (range 0.64-2.61), with an associated mean KOC of 237 (range 51-698) and mean $1/n$ value of 0.90. For IN-GAZ70, the average K_d value was 216 (range 51-584), with an associated mean KOC of 23,165 (range 6396-35,583) and mean $1/n$ value of 0.98. Based on the Freundlich adsorption constants, low potential for mobility of IN-EQW78, IN-ECD73 or IN-GAZ70 is expected. While IN-F6L99 is potentially more mobile the metabolite in soil is degraded rapidly relative to other soil metabolites. In general desorption was inversely proportional to the organic matter content of the soil.

Aerobic aquatic metabolism

The fate of chlorantraniliprole was studied in the dark at 25°C in two water/sediment (one sand, one loam) systems over 100 days. In both systems, the parent compound partitioned preferentially (but slowly over 100 days) to the sediment, where it underwent further degradation. Numerous minor degradation products (-F6L99, IN-F9N04, IN-GAZ70, IN-EQW78, and IN-ECD73) were identified at <5% AR in the water phases. However, in the sediment phase of both systems, IN-EQW78 was identified as a major metabolite with maximum concentrations of 34.7% AR (day 75) in the loam sediment. IN-F6L99, IN F9N04, IN GAZ70, and IN-ECD73 were identified as minor metabolites (<5% AR). Unextractable residues in the sand and loam sediment reached maximum values of 7.4 and 5% AR, respectively. Evolved $^{14}\text{CO}_2$ was <1% AR in both test systems. The degradation of chlorantraniliprole and IN-EQW78 was generally faster in the loam sediment than in the sand sediment. Whole system DT50 values were 125 and 231 days for the loam and sand systems, respectively, with DT90 values of 414 and 768 days, respectively. IN-EQW78 had a comparable rate of degradation (DT50 and DT90 of 121 and 402 days, respectively) to the parent substance in the loam system. However, in the sand system degradation was much slower (DT50 and DT90 values of 680 and 2260 days, respectively).

The degradation of chlorantraniliprole was also studied in two water sediment systems (one loamy sand, one sandy loam) exposed to natural sunlight (summer latitude 39° N41') and incubated at approximately 20°C. The whole system DT50 values ranged from 10-22 days (irradiated) and 43-91 days (non-irradiated). Lower half-lives of 5-11 days were experienced

in the water compartment, indicating longer persistence of chlorantraniliprole in sediment. Photolysis was not considered to be the main degradation process, primarily because typical photoproducts (IN-LBA22, IN-LBA23 and IN-LBA24) were not found in significant amounts (>5%). Fluctuations in pH enhanced formation of IN-EQW78 in both the water (maximum of 6.4% AR on Day 7 at pH 9.7 as consistent with the hydrolysis study) and sediment (maximum of 38.1% AR on Day 14 at pH 8.1 as consistent with the aerobic aquatic metabolism study) layers in irradiated sandy loam systems. These data demonstrate that pH variations occurring in natural aquatic systems can enhance the degradation of chlorantraniliprole in the aquatic environment.

Anaerobic aquatic metabolism

The fate of chlorantraniliprole in an anaerobic aquatic loam sediment system was studied in the dark at 25°C for 365 days. Loss of the parent compound from the overlying water to the sediment was rapid with a DT50 value of 17 days. IN-EQW78 was the major metabolite in both water (maximum 19.5% AR on Day 21) and sediment (maximum 67.8% AR on Day 181) and was also lost to sediment with a water phase DT50 value of 17 days. With an average water phase pH of 7.8±0.4, anaerobic conditions, not pH, were responsible for formation of IN-EQW78 in this phase. Numerous other metabolites were observed in both phases, with IN ECD73 being the only other metabolite >5% AR (sediment only). IN F6L99, IN-F9N04 and IN GAZ70 were observed as minor metabolites. Non-extractable residues reached a maximum of 4.93% AR in the sediment and no significant amount of ¹⁴CO₂ was observed (<1%). The whole system DT50 values for chlorantraniliprole and IN-EQW78 were 42 and 701 days, respectively.

Bioaccumulation

A bioaccumulation study was conducted with the bluegill sunfish (*Lepomis macrochirus*) exposed over 14 days to ¹⁴C-chlorantraniliprole at 0.0132 and 0.138 mg ac/L in high and low level studies, respectively, followed by a 21-day depuration period. The uptake and depuration rate constants appeared dependent on the concentration of the active substance, with higher and depuration rates observed in the low and high level studies, respectively. Fish tissue concentrations reached steady-state equilibrium within 11 days. The average 50% and 90% depuration times (CT50 and CT90) for whole fish were 1.5 and 8.9 days, respectively. The whole fish steady-state Bioconcentration factors (BCF) were 13 and 15 for the low and high level studies, respectively. Chlorantraniliprole degrades rapidly in fish to IN-ECD73 and polar metabolites.

ENVIRONMENTAL EFFECTS

Fish

There were 7 acute toxicity studies conducted with fish, 3 with chlorantraniliprole, and 2 for each of the formulations. Two chronic early life stage studies with the active substance were also conducted.

In 96 hour static toxicity tests, rainbow trout (*Oncorhynchus mykiss*), bluegill sunfish (*Lepomis macrochirus*) and sheepshead minnow (*Cyprinodon variegatus*) exposed to chlorantraniliprole showed no mortality or sublethal effects, with 96 hour LC50 values of >13.8, >15.1 and >12 mg ac/L, respectively. No compound related toxic effects (mortality and

sublethal) were observed in the channel catfish (*Ictalurus punctatus*) exposed to the active substance in a 96 hour static limit test, resulting in a 96 hour LC50 value >13.4 mg ac/L. Chlorantraniliprole was classified as at most slightly toxic to fish on an acute exposure basis.

Rainbow trout exposed to the 200SC formulation of chlorantraniliprole in a 96 hour static limit test resulted in 10% mortality, with a 96 hour LC50 value >2.16 mg ac/L. No mortality was observed in rainbow trout exposed to the 350WG formulation conducted under identical test conditions. Sublethal effects were observed in 3 of the remaining 27 fish exposed to the 200SC formulation. No compound related toxic effects (mortality and sublethal) were observed in bluegill sunfish exposed to the 200SC and 350WG formulations, resulting in respective LC50 values of 1.84 and 1.19 mg ac/L. The 200SC and 350WG formulations of chlorantraniliprole were considered to be moderately toxic to fish on an acute exposure basis.

The 90 day chronic toxicity of chlorantraniliprole to the early life stage of rainbow trout was studied under flow-through conditions. No treatment related effects on survival, wet weight, length or hatching were observed. However, significant effects of larval abnormalities resulted in a NOEC value of 0.110 mg ac/L. In a 32 day early life-stage study with the sheepshead minnow under intermittent flow-through conditions, significant toxic effects on survival at test termination, length and wet weight were observed. However, the most sensitive endpoint was survival at end of hatch, resulting in a NOEC value of 1.28 mg ac/L. Chlorantraniliprole was considered to be slightly toxic to fish from chronic exposure, based on the rainbow trout study.

Aquatic invertebrates

There were 15 acute toxicity studies conducted with daphnids (*Daphnia magna*), 3 with the active substance, 2 with the 200SC and 350WG formulations, and 10 tests to evaluate the effects of 8 metabolites observed in the environmental fate studies.

Chlorantraniliprole was very highly toxic to daphnids under static conditions, with a 48 hour EC50 value of 0.0116 mg ac/L for neonates. Sublethal effects included lethargic and floating daphnids, resulting in a NOEC value of 0.00139 mg ac/L. In another 48 hour study under static conditions, older daphnids were found to be less sensitive than neonates, however, 28 day old daphnids were more sensitive than those 14 days old, with 48 hour EC50 values of 0.0166 and 0.0260 mg ac/L, respectively. Signs of lethargy were observed in both groups at the higher test concentrations. In a further study, it appears that immobility in daphnids exposed to the active substance for variable time periods followed by a 48 hour recovery period, was dependant on the length of the initial exposure, with EC50 values of >0.0183, 0.0171 and 0.0161 mg ac/L following exposure for 6, 12 and 24 hours, respectively. The respective EC50 values were >0.0183, >0.0183 and 0.0098 following recovery. In a 96 hour static study with the mysid shrimp (*Americamysis bahia*), time-dependent mortality was observed at the highest test concentration, resulting in an LC50 = 1.15 mg ac/L.

The two formulations of chlorantraniliprole, also investigated under static conditions for 48 hours, were similar to the technical active ingredient in their toxicity to daphnid neonates, with 48 hour EC50 values of 0.0071 and 0.011 mg ac/L for the 200SC and 350WG formulations, respectively. Signs of floating and lethargy were observed at the 3 highest dose concentrations.

No compound related toxic effects (mortality or sublethal) were observed in daphnids

exposed to the metabolites IN-EQW78, IN-ECD73 and IN-GAZ70 in static limit tests over 48 hours, with EC50 values of >0.138, >0.0138 and >0.00987 mg metabolite, respectively. Dose responsive mortality effects were observed in daphnids exposed to IN-F6L99 and IN-F9N04 under static non-limited conditions, with EC50 values of 46.8 and 0.030 mg metabolite/L. In addition, sublethal effects were observed in surviving daphnids, particularly those exposed to IN-F6L99. No daphnid mortality was observed in daphnids exposed to the metabolites IN-LBA22, IN-LBA23 and IN-LBA24 in non-GLP screening tests. The 24 hour EC50 values were >0.24, >0.1 and >10 mg metabolite/L, respectively.

The acute toxicity of chlorantraniliprole was conducted on 12 additional aquatic invertebrate species under static conditions over 48 hours, with the exception of the eastern oyster, which was assessed under flow-through conditions over 96 hours. Five of the additional species were sensitive to chlorantraniliprole, with the most sensitive species were mayflies (*Centroptilum triangulifer*) and caddisflies (*Chimarra atterima*), with 48 hour LC50 values of 0.0116 and 0.0117 mg ac/L, respectively. Amphipods (*Gammarus pseudolimnaeus*) and midges (*Chironomus riparius*) were also sensitive, with 48 hour LC50 values of 0.0351 and 0.0859 mg ac/L, respectively. Mortality effects were not observed in oysters (*Crassostrea virginica*), however effects on shell growth were observed, with a 96 hour EC50 value of 0.0399 mg ac/L. The remaining species showed negligible responses at exposures approaching or exceeding the water solubility limit of approximately 1 mg/L.

There were 3 chronic exposure tests for aquatic invertebrates, one each with daphnids, mysids and chironomids. Chlorantraniliprole was highly chronically toxic to daphnids under static renewal conditions over 21 days. Significant effects on adult length, reproduction, and young immobility resulted in a 21 day NOEC value of 0.00447 mg ac/L. Under flow-through conditions over 28 days, the active substance was slightly toxic to the mysid shrimp (*Americamysis bahia*) resulting in a 28 day NOEC of 0.695 mg ac/L, based on complete adult mortality at the highest test concentration. No dose-dependant significant effects were observed in surviving adults or young. The toxicity of radiolabelled chlorantraniliprole to the sediment dwelling phase of midges was assessed in two studies with static test systems (sediment spiking and water spiking). Adult emergence and development time were the most sensitive endpoints in the water spiked test, resulting in a 28 day NOEC value of 0.0025 mg ac/L. In the sediment spiked system, emergence ratio was the most sensitive endpoint, resulting in a 28 day NOEC value of 0.005 mg ac/kg sediment.

Algae

There were 7 studies conducted to evaluate the effects on growth and growth rate in algae and aquatic plants, 5 with the active substance and 2 with the formulations.

No significant effects on growth and growth rate were observed in the green alga (*Selenastrum capricornutum*) when exposed to chlorantraniliprole (EC50 > 2 mg ac/L; NOEC = 2 mg ac/L) and its 200SC (EC50 > 4 mg ac/L; NOEC = 4 mg ac/L) and 350WG (EC50 > 1.78 mg ac/L; NOEC = 1.78 mg ac/L) formulations in 76-120 hour limit tests without test medium renewal. Similarly, the growth and growth rate of the blue-green algae (*Anabaena flos-aquae*), marine diatom (*Skeletonema costatum*) and the freshwater alga (*Navicula pelliculosa*) were not significantly inhibited from exposure to chlorantraniliprole over 120 hours, with EC50 values >2, >14.6 and >15.1 mg ac/L, respectively. The respective NOEC values were 2, 14.6 and 15.1 mg ac/L. Growth and growth rate in aquatic plants was not affected from exposure to chlorantraniliprole in a 14 day static limit test, with an EC50 value

>2 mg ac/L, and a NOEC value of 2 mg ac/L for duckweed (*Lemna gibba*).

Terrestrial invertebrates

Studies were conducted on a range of terrestrial invertebrates. There were 15 studies conducted to evaluate the toxicity of chlorantraniliprole and its 200SC and 350WG formulations to honey bees. The acute oral and contact toxicity of chlorantraniliprole in water (solubility limit) or acetone was conducted over 48 hours. Oral exposure of the test substance resulted in negligible mortality (EC50 >0.0274 and >104.1 µg ac/bee for water and acetone, respectively), however, a dose dependent response was observed in the contact test, with 32% mortality (EC50 >0.005 and >4 µg ac/bee for water and acetone, respectively) at the highest test concentration. Sublethal effects were observed in the treatments with test substance and acetone, and included apathy, slow and unco-ordinated movements, inability to climb the wall to reach food, and apparent paralysis. Most bees recovered within 48-72 hours. Similar to the effects of chlorantraniliprole, negligible mortality was observed during and following oral exposure of bees to the 200SC formulation over 48 hours. Higher levels of mortality were observed from contact exposure, but no dose-response relationship was apparent. The 48 hour LD50 values were 114.1 and 100 µg ac/bee for oral and contact exposure, respectively. Similar sublethal effects were observed, with apparent recovery within 48 hours, except for contact exposed bees at the highest treatment rate. Although exposure to the 350WG formulation resulted in 48 hour oral and contact LD50 values of 119.2 and 100 µg ac/bee, respectively, which are comparable to the 200SC formulation results, the significantly lower levels of mortality in the contact test and lack of any reportable sublethal effects must be noted.

A study in the USA demonstrated that bees exposed to dried residues of the 350WG formulation aged on alfalfa foliage for 3-48 hours after a field application of 112.5 g ac/ha resulted in no treatment related mortality or behavioural abnormalities. A further 9 studies evaluated field applications of chlorantraniliprole 200SC. Exposure to spray solutions either by direct overspray onto foraging honey bees or via spray deposits on plant surfaces from the previous day had no effects on mortality, behaviour, flight intensity or development of honey bee colonies, when applied at 52.5-75 g ac/ha. Two studies with the 200SC formulation were conducted to evaluate the possibility of exposure to honey bees from soil residues that may carry over from previous applications to crops, and subsequently be translocated to blossoms. No substance related mortality, behavioural changes or impact on the colonies were observed in these studies following soil incorporation of up to 313.6 g ac/ha. Based on the available data set it can be concluded that the insecticide chlorantraniliprole generally demonstrated low intrinsic toxicity for honey bees.

There were 16 studies conducted to evaluate the toxicity of chlorantraniliprole to non-target arthropods. No compound related toxic effects (mortality and reproduction) were observed in parasitic wasps (*Aphidius rhopalosiphi*) exposed to fresh-dried deposits of the 200SC and 350WG formulations on glass plates in Tier 1 dose-response tests, resulting in a 48 hour LR50 and ER50 values were >750 g ac/ha in both tests. Predatory mites (*Typhlodromus pyri*) exposed to the formulations in Tier 1 toxicity tests showed some adverse effects on mortality and reproduction, but the only dose-responsive effect observed was for mortality in mites exposed to the 350WG formulation, resulting in a 7 day LR50 and 14 day ER50 of >750 g ac/ha for both formulations. Maximum mortality effects of 17.65 and 29.92% (significant) were observed in mites exposed to 2 repeat applications (47.5-52.5 and 52.5 g ac/ha) of the 200SC and 350WG formulations with 13-15 day intervals. Mortality and reproduction levels recovered to non-significant levels by study termination. No adverse effect of >50% were

observed in the tests. Further Tier 1 tests were conducted using the 200SC formulation. Green lacewings (*Chrysoperla carnea*) were exposed to treated test units (120 g ac/ha) and/or were fed treated aphids (120 g ac/ha). Significant mortality effects (24 and 50%) were observed in lacewings exposed to the treated test units only and to both test units and aphids. Reductions in fecundity by 39.5 and 47.5% were also observed in these groups. Exposure to treated aphids only had no significant effects on mortality or reproduction, indicating that effect levels (LR50 >120 g ac/ha based on no exposure to test units only) may be compared directly with predicted levels of exposure in the field. In identical tests conducted with the ladybird (*Coccinella septempunctata*) and hoverfly (*Episyrphus balteatus*), magnified levels of mortality (90.3-100%) were observed in the same treatment groups, however, effects on reproduction could not be evaluated due to the high mortality levels. The resultant LR50 value, based on mortality only was <120 g ac/ha. A corrected mortality of 36.1% was also observed in the hoverfly only exposed to treated aphids.

Based on the results of the Tier 1 tests, further tests were conducted under extended conditions. In an extended dose-response study with exposure by the predatory bug (*Orius laevigatus*) to fresh-dried residues of the 200SC formulation on dwarf bean leaves, there was no dose-responsive effect or effect >50% on mortality and reproduction, resulting in a 9 day LR50 and ER50 value of >120 g ac/ha. Significant effects on the ladybird beetle were observed, with a 15 day LR50 value of 79.5 g ac/ha, and a reproduction NOEC value of 4.4 g ac/ha. An LR50 value of 12.6 g ac/ha and a dose-responsive effect on mortality was obtained in a similar study conducted with hoverflies exposed to residues of the 200SC formulation on winter rape leaves. Hoverflies were more sensitive to the 350WG formulation, with an LR50 value of 4.64 g ac/ha. No effects on reproduction were observed, with respective ER50 values >13.3 and >4.4 g ac/ha. When exposed to 21 day aged residues of the 200SC formulation applied at 120 g ac/ha on rape leaves, 93% corrected mortality was observed in the hoverflies, resulting in an LR50 <120 g ac/ha.

No adverse effects on mortality or reproduction >50% were observed in ladybird beetles exposed to 28 or 78 day old aged residues (SC formulation) on apple leaves from two 60 g ac/ha treatments with a 7 day interval. In the same way, hoverflies were exposed for 11-12 days to residues of the 200SC and 350WG formulations aged for 28 and 42 days, but mortality did not exceed 50% (respectively 33.5-43.8% and 3.6-25%) and no effects on reproduction were observed.

Dose-responsive effects in the mortality and reproduction in collembolans (*Folsomia candida*) exposed to chlorantraniliprole over 28 days was observed, with LR50, EC50 and NOEC values of 0.85, 0.48 and 0.39 mg ac/kg soil, respectively. No compound related toxicity was observed in collembolans exposed to the metabolites IN-EQW78, IN-ECD73 and IN-GAZ70, with LR50, EC50 and NOEC values of >100, >100 and 100 mg/metabolite/kg soil. Soil mites were similarly unaffected to chlorantraniliprole. The 200SC (2 applications of 156 and 150 g ac/ha over 8 days) and 350WG (2 applications of 2028 and 1022 g ac/ha over 17 days) formulations of chlorantraniliprole had no effects on leaf litter decomposers, with no significant differences >10% in litter breakdown over 12 months between the control and treated areas. Soil metabolites have no effects on soil arthropods or leaf litter decomposers.

There were 11 studies conducted with earthworms exposed to the active substance, 350WG formulation and metabolites. No compound related toxic effects (mortality and reproduction) were observed in earthworms exposed over 14 days to chlorantraniliprole and the metabolites IN-EQW78, IN-ECD73 and IN-GAZ70 (LC50 >1000 mg metabolite/kg soil) and to the 200SC and 350WG formulations (LC50 >200 and >350 mg ac/kg dry soil). However, dose

dependent toxic effects were from exposure to the IN-F6L99 metabolite, with LC50 and NOEC values of 632.5 and 250 mg metabolite/kg dry soil, respectively. Longer exposure (56 days) resulted in no adverse effects on reproduction in earthworms exposed to the 350WG formulation (NOEC = 350 mg ac/kg soil) and the metabolites IN-EQW78, IN-ECD73 and IN-GAZ70 (NOEC = 1000 mg metabolite/kg soil).

Soil microorganisms

There were 6 studies conducted to evaluate effects on soil microbial activity – one with chlorantraniliprole, one each with the 200SC and 350WG formulations, and 3 with the metabolites IN-EQW78, IN-ECD73 and INGAZ70.

No dose-dependant effects on nitrogen formation soil and respiration were observed over 28-42 days in soil exposed to chlorantraniliprole at 0.7 mg ac/kg soil. Significant effects were observed to nitrogen formation in soil following exposure to the 200SC and 350WG formulations (0.88 and 0.8 mg ac/kg dry soil, respectively), however, these were not dose-responsive. In addition, the effects compared to the control were not >25%. Significant effects on nitrogen formation and soil respiration observed in soil exposed to the metabolites, but these were not dose responsive, except for respiration rate following exposure to IN-ECD73. However, no observed effect was >25% compared to the control. In addition, chlorantraniliprole had no effect on activated sludge respiration following a 3 hour exposure period (EC50 >100 mg ac/L).

Terrestrial plants

There were 2 studies conducted with the 200SC formulation of chlorantraniliprole applied at a rate of 300 g ac/ha. No effects on seedling emergence and early growth in 9/10 common plant species were observed, with an EC25 >300 g ac/ha. Ryegrass was the most sensitive species, with a 34% reduction in dry shoot weight. The same species were less sensitive to foliar applications, with lower effects on vegetative vigour, resulting in an EC25 >300 g ac/ha for all species. The most sensitive species were onions and peas, with 12% reductions in shoot dry weight and shoot height, respectively.

RISK ASSESSMENT

Chlorantraniliprole will be applied using ground equipment or aircraft to a range of crops. Environmental exposure is expected to primarily involve the crop and the underlying soil, with aquatic exposure also possible through spray drift and runoff. Chlorantraniliprole is highly persistent in soils and aquatic sediments, where residues deposited to water will partition.

Chlorantraniliprole is a new insecticide with a novel mode of action (ryanodine receptor agonist) that confers good specificity for the target pests. The toxicity to birds and mammals is low. The toxicity to terrestrial and aquatic vertebrates and plants is also low, but chlorantraniliprole can be toxic to some invertebrates, as may be expected of an insecticide.

In terrestrial environments, there are likely to be some harmful effects on ladybirds and hoverflies present when crops are treated with chlorantraniliprole, but with recovery to be expected within the season and only transient effects if any on integrated pest management systems. Chlorantraniliprole does not harm other beneficial arthropods (parasitic wasps,

predatory mites, pirate bugs and green lacewings) that have been tested.

Control of subterranean pests of turf entails intentional application to the soil. Although calculations based on toxicity data for collembolans indicate that harm to these organisms is unlikely, it is probably unrealistic to expect that non-target soil arthropods within the treated soil will not occasionally be affected to some extent by such treatment. However, such effects would not contravene the Australian legislative criterion that use of the product “would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment” given the intentional application to the soil and the restriction of any effects to the treated area with no lasting effects expected on overall populations.

Aquatic risk assessment indicates that some aquatic invertebrates are likely to be harmed by spray drift exposures in shallow water. The draft labels acknowledge this, and include some appropriate instructions to minimise the risk of aquatic exposure, including the recommendation that a spray drift strategy be employed at all times when aerially applying Altacor Insecticide, and prohibits application under weather conditions, or from spraying equipment, that may cause spray to drift onto nearby plants/crops, cropping lands and pastures. The draft label also warns that the product is dangerous to aquatic invertebrates, and that drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent areas. However, a requirement for buffer distances to protect against such harm has been identified.

EFFICACY AND SAFETY ASSESSMENT

The submission included 102 trials in total, 20 in cotton, 28 in vegetables, 34 in fruit and 20 in turf.

COTTON - DuPont Altacor Insecticide (350g/kg chlorantraniliprole)

In total twenty trials were presented which included seventeen small plot replicated trials which were reported on the evaluation of DuPont Altacor Insecticide (350g/kg chlorantraniliprole) against *Helicoverpa* spp. in conventional cotton varieties (ie. non Bt-transgenic) in three Australian states (NSW, Queensland and Western Australia) and three trials reported against *Earias* spp. in Australia (Western Australia – 1 trial) and Pakistan (2 trials). The three later trials also reported performance against *Helicoverpa* spp.

Trials involved randomised complete block designs with four replications and plots of various sizes (2 to 7 rows and 7 to 20 m in length with additional buffers). Pest assessment methods used standard protocols and multi-entry assessments. Trials compared the product with untreated controls and in most cases at least one registered industry standard insecticide treatment applied at label rates was also compared. Treatments were applied using calibrated hand-held spray booms operating at appropriate pressures (180 to 360 kPa) and delivering suitable spray volumes (100 to 300L/ha). The two trials from Pakistan used back-pack sprayers.

All trials were conducted against moderate to very high infestations of the target species on cotton crops at suitable stages of development that reflect commercial conditions.

In the seventeen Australian trials against *Helicoverpa* spp. the product significantly reduced larval numbers and crop damage. In most cases there was no significant dose response, although some trials indicated that the lowest dose tested (20 g ai/ha) was inadequate and the higher doses (70 and 105 g ai/ha) provided no benefit over 52.5 g ai/ha. Limited data showed activity of the product against *Earias* spp. at the highest rate proposed for registration (52 g ai/ha). However noting that *Earias* spp. is a difficult to control pest because of its entrenched feeding habits of the larvae it was concluded that the product performed well against this pest. The degree of control afforded by rates proposed for the product was in all cases at least equivalent of the registered industry standard against which it was compared.

No phytotoxicity was reported in any of the trials presented.

The data presented support the registration of the product against *Helicoverpa* spp. when used at 90 g (31.5 g ai/ha) or 150 g (52.5 g ai/ha) and *Earias* spp. at 150 g (52.5 g ai/ha). Trials also included the use of non-ionic surfactants, where one trial also reported a significant positive response and no reduction in performance in other trials. On this basis the use of a non-ionic surfactant is supported.

VEGETABLES - DuPont Coragen Insecticide (200g/L chlorantraniliprole)

In total twenty-eight trials were presented including fourteen in Brassica vegetables (targeting one or several of diamondback moth, cabbage white butterfly, cabbage centre grub, cabbage cluster caterpillar, cluster caterpillar, soybean looper, cotton bollworm and native budworm), four in lettuce (targeting cotton bollworm and native budworm), five in tomatoes (targeting cotton bollworm, native budworm and tomato leaf miner), three in potato (targeting potato tuber moth) and two in pumpkins (targeting *Helicoverpa* spp.).

The trial locations, spray application methods, plot size, trial design (including number of replicates) and statistical analyses presented were acceptable.

Brassica vegetables and Brassica leafy vegetables

Of the fourteen trials eleven were conducted in various Australian states (Queensland, NSW, South Australia and Victoria) and three were conducted in New Zealand. Ten trials were conducted on European cabbage varieties, two were conducted on broccoli, and two were conducted on Chinese cabbage.

The results, in aggregate, support the claims for the efficacy of 100 mL/ha of the product in controlling larvae of the seven lepidopteran pests in Brassica vegetables. There was no clear evidence of ovicidal action by the product against eggs of these pest species.

No phytotoxicity was observed in any of the trials.

The data are also supportive for extrapolation to registration of those minor use crops classified as Brassica leafy vegetables, due to similar pest complex and data provided in traditional Brassica vegetables and trials conducted on lettuce (reported below).

Leafy vegetables and Stalk and Stem Vegetables

Four trials were conducted in Queensland. Trials conducted at 150 mL/ha gave statistically similar control and marketability outcomes to other registered industry standards, however, with the high pest pressure that prevailed in trials no treatment provided commercially acceptable percentages of marketable heads. It is acknowledged that there is extreme difficulty in achieving high percentages of marketable heads when high-density *Helicoverpa* spp. infestations are encountered and that this was also demonstrated in trials for currently registered industry standards.

No phytotoxicity was observed in any of the trials.

Therefore based upon the similar level of control achieved with the product to registered industry standards and noting that trials included high-density *Helicoverpa* spp. infestations the results support registration of the product on lettuce at 150mL/ha.

The data presented in lettuce in combination with data presented for other vegetable crops such as Brassica vegetables, Fruiting vegetables, Cucurbits and Potatoes is also supportive for extrapolation to registration of minor use crops classified as Leafy vegetables and Stalk and Stem vegetables against *Helicoverpa* spp. at a rate of 100mL/ha.

Fruiting vegetables including cucurbits

Five trials were conducted in tomato crops in Queensland and Victoria (processing tomatoes) against *Helicoverpa* spp. and Tomato leaf miner (*Phthorimaea operculella*) and two trials from Pakistan were presented for use on pumpkins against *Helicoverpa* spp..

In tomatoes trials 100 mL/ha provided good to significant *Helicoverpa* spp. control and reduced fruit damage compared to the control and a registered industry standard. For leaf miner trials provided significant suppression to significantly reducing levels of leaf miner infestation and fruit damage compared to the control, and to a similar degree to that of registered industry standards.

No phytotoxicity was observed in any of the trials.

The results from tomato trials in combination with other data presented for various vegetables crops has also been considered for the registration of several minor use crops by way of extrapolation. It is noted that both the feeding behaviour of *Helicoverpa* spp. and the tolerance for economic damage in crops such as cucurbits and other solanaceous fruiting vegetables are similar and the data is relevant for extrapolation and in doing so is supportive for registration of the product for the control of both *Helicoverpa* spp. in all Fruiting vegetables (including cucurbits) and tomato leaf miner in Fruiting vegetables (excluding cucurbits) at 100mL/ha.

Potatoes

Three trials were conducted in potatoes in South Africa and Brazil against potato tuber moth (*Phthorimaea operculella*).

The body of data presented for potato tuber moth control in the South African and Brazilian trials in combination with three Australian tomato trials support the Potato tuber moth claim. Additionally data presented for *Helicoverpa* spp on tomatoes is also suitable to support registration on potatoes by extrapolation where there is similarity in (i) foliage/canopy architecture between tomatoes and potatoes and (ii) the foliage feeding behaviour of *Helicoverpa* larvae in both these crops. The data presented support registration of 100 mL/ha for Potato tuber moth and *Helicoverpa* spp. control in potatoes.

FRUIT - DuPont Coragen Insecticide (200g/L chlorantraniliprole)

In total thirty-four trials were presented including nineteen in pome fruit (targeting Codling moth and Light brown apple moth), eight in stonefruit (targeting Oriental fruit moth) and six in grapes (targeting Light brown apple moth and Grapevine moth).

Pome fruit

Twenty trials were conducted, eighteen in apples and two in pear. Twelve trials were conducted in Australia (NSW, Queensland, Victoria, South Australia and Tasmania) and eight trials were conducted in New Zealand and were conducted during different seasons and environmental conditions. A number of the trials (9) involved the use of a different formulation (200SC) to that proposed for registration (350WG).

Trials involved randomised complete block design with four or more replicates, sample size and pest level assessments consisted of a single or two tree plot. An untreated control and comparisons with registered industry standards were used in trials. All treatments were applied with a powered hand lance as dilute spray to the point of run-off.

Against Light brown apple moth the proposed product in a number of trials at low pest pressure demonstrated similar or superior and significant control of Light brown apple moth to that of the registered industry standards. Against Codling moth the product in a number of trials including those with high pest pressure provided significant and highly effective control.

It is noted that a number of trials (9) involved a different formulation (200SC) to that proposed for registration (350WG). In these trials control was achieved to significant levels (complete control in some cases for LBAM) under low pest pressure for Light brown apple moth and high pest pressure for Codling moth.

Stone fruit

Eight trials were conducted in peaches in Victoria against Oriental fruit moth including untreated controls and comparisons to registered industry standards. The product under moderate to extreme pest pressure demonstrated significant control of Oriental fruit moth at

the proposed label rate equal to that of a currently registered industry standard. Similarly with pome fruit trials discussed above a number of trials (2) involved a different formulation (200SC) to that proposed for registration (350WG). In one of these trials under very high pest pressure significant control of Oriental fruit moth was achieved.

In addition to the data presented it is noted through an OECD Workshare assessment that the Canadian Pest Management Regulatory Agency (PMRA) has also supported the registration of the product for the control of Oriental fruit moth in all stone fruits. In summary six field trials were assessed from Canada (5 Ontario) and the United States (1 Michigan), which demonstrated efficacy against Oriental fruit moth at rates similar to those proposed for use in Australia.

Data as presented for Light brown apple moth control in other fruit crops in this submission has been considered and is accepted based upon the high level of control demonstrated in other fruit crops as relevant for the purposes of extrapolation for the control of this pest in stone fruit.

Grapes

Six trials were conducted in grapes in Victoria, South Australia, New South Wales and New Zealand against Light brown apple moth (*Epiphyas postvittana*) and Grapevine moth (*Phalaenoides glyciniae*) including untreated controls and comparisons to registered industry standards.

The product under light to high pest pressure demonstrated significant control of Light brown apple moth at the proposed label rate equal to that of currently registered industry standards. Against Grapevine moth the product provided a significant level of control under low pest pressure and whilst the product was observed as slower in activity to a registered industry standard the level of control was not significantly different.

TURF - DuPont Acelepryn Insecticide (200g/L chlorantraniliprole)

Twenty trials were conducted in turf in New South Wales and the United States against African black beetle (*Heteronychus arator*), *Cyclocephala* spp., *Listronotus* spp. and *Sphenophorus* spp.. Trials included controls and comparisons against registered industry standards.

The product was evaluated against the specific pests nominated and/or closely related species. Trials demonstrated under moderate to high-pressure significant control of African black beetle, *Cyclocephala* spp., *Listronotus* spp. and *Sphenophorus* spp. similar to that of currently registered industry standards for the majority of trials presented.

There was no phototoxicity observed in trials.

PRODUCT LABELS

**READ SAFETY DIRECTIONS BEFORE OPENING OR
USING**

DRAFT

**DuPont™
Altacor®
insecticide**



ACTIVE CONSTITUENT: 350 g/kg CHLORANTRANILIPROLE

GROUP	28	INSECTICI DE
-------	-----------	-----------------

For the control of Lepidopteran species of insect pests in certain fruit crops, as per the Directions for Use

IMPORTANT: READ THIS LEAFLET BEFORE USE

DIRECTIONS FOR USE

RESTRAINTS:

DO NOT apply if rainfall is expected within 2 hours of application.

EXPORT STATEMENT: Import tolerances for produce treated with DuPont™ Altacor® insecticide may be pending in some countries. Consult with your exporter or DuPont before applying Altacor® to export crops.

For use in all States where appropriate for the crop and/or insect pest.

CROP	PEST	RATE/100 L	WHP	CRITICAL COMMENTS
ALL CROPS				
Apply by dilute or concentrate spraying equipment. Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. Refer to Application section of the label.				
Thorough fruit coverage is essential.				
Use in accordance with AIRAC Insecticide Resistance Management Strategy guidelines.				
Pome fruit including Apples, Nashi Pears, Pears	Codling Moth (<i>Cydia pomonella</i>) Budworms (<i>Helicoverpa</i> spp). Oriental fruit moth (<i>Grapholita molesta</i>)	<u>Dilute spraying:</u> 9 g + non ionic surfactant @ 15 gai/100 L <u>Concentrate spraying:</u> Refer to Mixing/ Application section	14 days	DO NOT make more than three (3) applications per crop per season. <u>Codling moth:</u> A maximum of three (3) applications of Altacor® are to be applied at 14 – 21 day intervals commencing at petal fall (or before 110 Degree Days after Codling Moth are detected in traps) until late December. Further treatments should be made with an alternate mode of action insecticide. <u>Or</u> a maximum of three (3) applications can be applied commencing from the end of December at 14 - 21 day intervals following treatments with an alternate mode of action product. <u>Oriental fruit moth:</u> When treating the first generation, apply the initial treatment before 110 Degree Days after Oriental fruit moths are detected in traps. The above programme, when commenced at petal fall, will also control budworms.
	Lightbrown apple moth (<i>Epiphyas postvittana</i>)			<u>Lightbrown apple moth:</u> A maximum of three (3) applications of Altacor® are to be applied at 14 - 21 day intervals commencing at petal fall or apply at 140 Degree Days after Lightbrown apple moths are detected in traps. Further treatments should be made with alternative mode of action insecticides.
Stone fruit including Apricot, Cherries, Nectarines, Peaches, Plums	Oriental fruit moth (<i>Grapholita molesta</i>)	<u>Dilute spraying:</u> 12 g + non ionic surfactant @ 15 gai/100 L <u>Concentrate spraying:</u> Refer to Mixing/ Application section		DO NOT make more than two (2) applications per crop per season. When treating the first generation, apply the initial treatment before 110 Degree Days after Oriental fruit moths are detected in traps. A maximum of two (2) applications of Altacor® (minimum of 14 days between applications) to each crop. Target sprays against eggs and newly hatched larvae before they become entrenched. Further treatments should be made with alternative mode of action insecticides.

CROP	PEST	RATE/100 L	WHP	CRITICAL COMMENTS
	Lightbrown apple moth (<i>E. postvittana</i>)	<u>Dilute spraying:</u> 9 g + non ionic surfactant @ 15 gai/100 L <u>Concentrate spraying:</u> Refer to Mixing/ Application section		A maximum of two (2) applications of Altacor® are to be applied with a minimum spray interval of 14 days commencing at 140 Degree Days after Lightbrown apple moths are detected in traps. Further treatments should be made with alternative mode of action insecticides.
Grapes	Lightbrown apple moth (<i>E. postvittana</i>) Grapevine moth (<i>Phalaenoides glycinæ</i>)	<u>Dilute spraying:</u> 9 g + non ionic surfactant @ 15 gai/100 L <u>Concentrate spraying:</u> Refer to Mixing/ Application section	8 weeks	DO NOT make more than two (2) applications per crop per season. Applications to be timed for egg hatch (140 Degree Days after a detected moth flight). DO NOT retreat within fourteen (14) days. A final application may be applied up to bunch closure. DO NOT apply after bunch closure. Concentrated spray: DO NOT apply in volumes less than 250 L/ha. This low water volume is dependent on the suitability of concentrated spray application equipment. More reliable application may be gained through increased water volumes.

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

WITHHOLDING PERIODS

HARVEST

POME & STONE FRUIT: DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION.

GRAPES: DO NOT HARVEST FOR 8 WEEKS AFTER APPLICATION.

**GRAZING – ALL TREATED CROPS
DO NOT GRAZE OR CUT FOR STOCK FOOD.**

GENERAL INSTRUCTIONS

DuPont™ Altacor® insecticide has been specifically designed for use in Integrated Pest Management (IPM) schemes. Altacor® is an anthranilic diamide insecticide in the form of a water dispersible granule. Altacor® is particularly active on Lepidopteran insect pests, primarily as a larvicide. Before application monitor insect populations to determine whether or not there is a need for application of Altacor® based on locally determined economic thresholds. More than one treatment of Altacor® may be required to control a population of pests.

INSECTICIDE RESISTANCE WARNING



For insecticide resistance management DuPont™ Altacor® insecticide is a Group 28 insecticide. Some naturally occurring insect biotypes resistant to Altacor® and other Group 28 insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Altacor® and other Group 28 insecticides are used repeatedly. The effectiveness of Altacor® on resistant individuals could be significantly reduced. Since the occurrence of resistant individuals is difficult to detect prior to use DuPont accepts no liability for any losses that may result from the failure of Altacor® to control resistant insects.

Altacor® may be subject to specific resistance management strategies. To help prevent the development of resistance to Altacor®, use Altacor® in accordance with the current Insecticide Resistance Management (IRM) strategy for your region. For further information contact your farm chemical supplier, consultant, local Department of Agriculture or Primary Industries, or local DuPont Representative.

MIXING

Fill spray tank to $\frac{1}{4}$ to $\frac{1}{2}$ full of water. Measure the amount of Altacor[®] required for the area to be sprayed. Add Altacor[®] directly to the spray tank with the agitation engaged. Mix thoroughly to disperse the insecticide. Once dispersed, the material must be kept in suspension at all times by continuous agitation. Use mechanical or hydraulic means, **DO NOT** use air agitation, premix or slurry.

If spray solution is left standing, ensure thorough re-agitation of the spray mix until fully resuspended. **DO NOT** allow spray mix to sit overnight, as resuspension may be difficult.

SURFACTANT/WETTING AGENT

Use a non-ionic surfactant/wetting agent at 15 g active/100 L, (e.g. Agral 600 @ 25 mL/100 L). **DO NOT** use BS1000[†] or Activator-90[‡] as it may cause crop phytotoxicity.

DO NOT add a non-ionic surfactant/wetting agent if:

- mixing with another product which already contains a surfactant and/or the product label advises not to add a surfactant.
- mixing with a liquid fertiliser

APPLICATION

Minimising Spray Drift

The interaction of many equipment and weather-related factors determines the potential for spray drift. The applicator must consider all these factors when making application decisions.

The most effective way to reduce drift potential is to apply large droplets (volume mean diameter (VMD) > 250 - 300 microns). The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. **APPLYING LARGER DROPLETS REDUCES DRIFT POTENTIAL, BUT WILL NOT MINIMISE DRIFT IF APPLICATIONS ARE MADE IMPROPERLY OR UNDER UNFAVOURABLE ENVIRONMENTAL CONDITIONS.** When making applications in hot and dry conditions, set up equipment to produce larger droplets to reduce effects of evaporation.

DO NOT apply in orchards or vineyards when wind speed is less than 3 or more than 20 kilometres per hour are measured 15 metres outside of the orchard/vineyard on the upwind side.

DO NOT apply when there are aquatic and wetland areas including aquacultural ponds or surface streams and rivers downwind from the application area and within the mandatory no-spray zone of 50 metres.

Ground application

Use a sprayer fitted with high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. Use the lower spray pressures recommended for the nozzle. Higher pressure reduces droplet size, **DOES NOT** improve canopy penetration and may increase drift potential. **WHEN HIGHER FLOW RATES ARE NEEDED, USE A HIGHER-CAPACITY NOZZLE INSTEAD OF INCREASING PRESSURE.** Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. For orchard/vineyard sprayers avoid directing spray above trees and always turn-off outward pointing nozzles at row ends and outer rows.

Dilute Spraying

- Use a sprayer designed to apply high volumes of water up to the point of run-off and matched to the crop being sprayed.
- Set up and operate the sprayer to achieve even coverage throughout the crop canopy. Apply sufficient water to cover the crop to the point of runoff. Avoid excessive run-off.
- The required water volume may be determined by applying different test volumes, using different settings on the sprayer, from industry guidelines or expert advice.
- Add the amount of product specified in the Directions for Use table for each 100 L of water. Spray to the point of run-off.
- The required dilute spray volume will change and the sprayer set up and operation may also need to be changed, as the crop grows.
- Always apply sufficient water to cover the crop to the point of runoff, otherwise under dosing will occur and disease control may be inadequate.

Concentrate Spraying

- Use a sprayer designed and set up for concentrate spraying (that is a sprayer which applies water volumes less than those required to reach the point of run-off) and matched to the crop being sprayed.
- Set up and operate the sprayer to achieve even coverage throughout the crop canopy using your chosen water volume.
- Determine an appropriate dilute spray volume (see Dilute Spraying above) for the crop canopy. This is needed to calculate the concentrate mixing rate.
- The mixing rate for concentrate spraying can then be calculated in the following way:

Example Only

1. Dilute spray volume as determined above: For example 1500 L/ha
 2. Your chosen concentrate spray volume: For example 500 L/ha
 3. The concentration factor in this example is : 3 times (i.e. 1500 L divided by 500 L = 3)
 4. If the dilute label rate is 150 g/100 L, then the concentrate rate becomes 3 x 150, that is, 450 g/100 L of concentrate spray.
- The chosen spray volume, amount of product per 100 L of water, and the sprayer set up and operation may need to be changed as the crop grows.
 - For further information on concentrate spraying, users are advised to consult relevant industry guidelines, undertake appropriate competency training and follow industry Best Practices.

Compatibility

Since formulations may be changed and new ones introduced, it is recommended that users premix a small quantity of the desired tank mix and observe possible adverse changes (settling out, flocculation etc). Avoid complex tank mixtures of several products or very concentrated spray mixtures. Altacor[®] is compatible with Captan*, Dextrolac*, Delan*, Fulasin*, Manzate[®] DF[®], Nustar[®], Omite*, Polyram* and Systhane*.

The mixing sequence recommended is: water soluble bags, dry flowable or water dispersible granules (Altacor[®]), wettable powders, water based suspension concentrates, water soluble concentrates, oil based suspension concentrates, emulsifiable concentrates, adjuvants and surfactants, soluble fertilisers.

Spray Equipment Cleanout

Prior to application, start with clean, well-maintained application equipment. Immediately following application, thoroughly clean all spray equipment to reduce the risk of forming hardened deposits which might become difficult to remove. Drain spray equipment. Thoroughly rinse sprayer and flush hoses, boom, and nozzles with clean water.

Clean all other associated application equipment. Take all necessary safety precautions when cleaning equipment. **DO NOT** clean near wells, water sources or desirable vegetation. Dispose of waste rinse water in accordance with local regulations.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Dangerous to aquatic invertebrates. Drift and run off from treated areas may be hazardous to aquatic organisms in neighbouring areas. **DO NOT** contaminate streams, rivers or waterways with the chemical or used containers.

STORAGE AND DISPOSAL

KEEP OUT OF REACH OF CHILDREN.

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

The method of disposal of the container depends on the container type. Read the 'Storage and Disposal' instructions on the label that is attached to the container.

SAFETY DIRECTIONS

May irritate eyes. Avoid contact with eyes.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

<p style="text-align: center;">IN A MEDICAL EMERGENCY CALL 1800 674 415 ALL HOURS</p>

MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet.

NOTICE TO BUYER

To the extent permitted by law all conditions and warranties and statutory or other rights of action which buyer or any other user may have against DuPont or Seller are hereby excluded. DuPont hereby gives notice to buyer and other users that it will not accept responsibility for any indirect or consequential loss arising from reliance on product information or advice provided by DuPont or on its behalf unless it is established that such information or advice was provided negligently and that the product has been used strictly as directed. DuPont's liability shall in all circumstances be limited to replacement of the product or a refund of the purchase price paid therefor.

The DuPont Oval Logo, DuPont™ and Altacor® are trademarks or registered trademarks of DuPont or its affiliates.

Du Pont (Australia) Ltd
A.C.N. 000 716 469
7 Eden Park Drive
Macquarie Park NSW 2113
(02) 9923 6111 or 1800 257 169
<http://www.dupont.com.au/ag/>

APVMA Approval Number: 61824/0608

*READ SAFETY DIRECTIONS BEFORE OPENING OR
USING*

DRAFT

DuPont™

Altacor®

insecticide



ACTIVE CONSTITUENT: 350 g/kg CHLORANTRANILIPROLE

GROUP	28	INSECTICI DE
-------	-----------	-----------------

For the control of Lepidopteran species of insect pests in
Cotton, as per the Directions for Use

IMPORTANT: READ THIS LEAFLET BEFORE USE

DIRECTIONS FOR USE

RESTRAINTS:

DO NOT apply if heavy dew is present on crops, or if rainfall is expected within 2 hours of application.

DO NOT make more than 3 applications per crop per season, and no more than 2 consecutive sprays per field per season. Applications must be a minimum of 7 days apart.

EXPORT STATEMENT: Import tolerances for produce treated with DuPont™ Altacor® insecticide may be pending in some countries. Consult with your exporter or DuPont before applying Altacor® to export crops.

For use in all States where appropriate for the crop and/or insect pest.

CROP	PEST	RATE/HA	WHP	CRITICAL COMMENTS
Cotton	Cotton bollworm (<i>Helicoverpa armigera</i>) Native budworm (<i>H. punctigera</i>)	90 or 150 g + non ionic surfactant @ 125 gai/100 L	28 days	Target brown eggs and hatchling (neonates or 1 st instar) to small larvae (2 nd instar) when they reach the economic spray threshold and before they become entrenched in squares, flowers and bolls. Use the low rate on threshold larvae pressure (2 larvae per metre row) and low egg pressure. Use the high rate with high egg and/or larvae pressure (where potential for >3-5 larvae per metre row produced) and so as to achieve longer residual control of <i>Helicoverpa</i> spp.
	Northern rough bollworm (<i>Earias vittella</i>) Rough bollworm (<i>Earias huegeliana</i>)	150 g + non ionic surfactant @ 125 gai/100 L		Target eggs and hatchling (neonates or 1 st instar) to small larvae (2 nd instar) when they reach the economic spray threshold and before they become entrenched in terminals or bolls.

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

WITHHOLDING PERIODS

HARVEST

DO NOT HARVEST FOR 28 DAYS AFTER APPLICATION.

GRAZING

DO NOT ALLOW LIVESTOCK TO GRAZE CROPS, COTTON STUBBLE OR GIN TRASH TREATED WITH ALTACOR® INSECTICIDE.

GENERAL INSTRUCTIONS

DuPont™ Altacor® insecticide is an anthranilic diamide insecticide in the form of a water dispersible granule. Altacor® is particularly active on Lepidopteran insect pests, primarily as a larvicide.

Altacor® should be applied after careful field monitoring of pest populations of eggs and larvae to determine the need for application, the correct timing of the initial application and of any subsequent applications. Subsequent applications are dependent on economic thresholds, as well as the growth rate of new unprotected cotton terminals.

For *Helicoverpa* species, spray applications should be timed to coincide with egg hatching and before larvae are entrenched in protected feeding sites.

Altacor® has been specifically designed for use in Integrated Pest Management (IPM) schemes. Altacor® enters larvae primarily by ingestion of treated foliage, or through penetration of the insect cuticle. **After ingesting Altacor®, the larvae cease feeding and die four to five days later.** Altacor® does not give traditional larval “knockdown” control, but controls nominated larvae species giving superior square, flower and boll protection in cotton.

INSECTICIDE RESISTANCE WARNING

GROU	28	INSECTICI
P		DE

For insecticide resistance management DuPont™ Altacor® insecticide is a Group 28 insecticide. Some naturally occurring insect biotypes resistant to Altacor® and other Group 28 insecticides may exist through

normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Altacor[®] and other Group 28 insecticides are used repeatedly. The effectiveness of Altacor[®] on resistant individuals could be significantly reduced. Since the occurrence of resistant individuals is difficult to detect prior to use DuPont accepts no liability for any losses that may result from the failure of Altacor[®] to control resistant insects.

Strategies to minimise the risk of insecticide resistance are available. To help prevent the development of resistance to Altacor[®] observe the following instructions:

- Use Altacor[®] in accordance with the current Insecticide Resistance Management (IRM) strategy for your region.
- Cultivate all cotton fields as soon as possible after picking to destroy over-wintering pupae of *Helicoverpa armigera*.

For further information contact your farm chemical supplier, consultant, local Department of Agriculture or Primary Industries, or local DuPont Representative.

MIXING

Fill spray tank to ¼ to ½ full of water. Measure the amount of Altacor[®] required for the area to be sprayed. Add Altacor[®] directly to the spray tank with the agitation engaged. Mix thoroughly to disperse the insecticide. Once dispersed, the material must be kept in suspension at all times by continuous agitation. Use mechanical or hydraulic means, **DO NOT** use air agitation, premix or slurry.

If spray solution is left standing, ensure thorough re-agitation of the spray mix until fully resuspended. **DO NOT** allow spray mix to sit overnight, as resuspension may be difficult.

SURFACTANTS

Use a non-ionic surfactant/wetting agent at 125 g active/100 L, (e.g. BS1000 @ 125 mL/100 L).

DO NOT add a non-ionic surfactant/wetting agent if:

- mixing with another product which already contains a surfactant and/or the product label advises not to add a surfactant.
- mixing with a liquid fertiliser

APPLICATION

Application equipment should be calibrated to apply at least sixty (60) droplets per cm² of target foliage. Droplet VMD should be of medium spray quality according to ASAE S572 definition for standard nozzles.

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour at the application site.

DO NOT apply where there are aquatic and wetland areas including aquacultural ponds or surface streams and rivers downwind from the application area and within the mandatory no-spray zone shown in the Table below.

FOR AERIAL APPLICATION				
Usage	Applications per season	Spray quality	Wind speed conditions (km/h)	Downwind No-Spray Zone
Cotton	3	Medium	3-8	140 metres
			8-14	240 metres
			15-18	350 metres
FOR GROUND APPLICATION				
Usage	Applications per season			Downwind No-Spray Zone
Cotton	3			70 metres

Ground application

Apply as a *blanket* spray or as a *banded* spray. Ensure thorough spray coverage on the foliage, using appropriate fan nozzles. Apply in a minimum spray volume of 100 L/ha and keep the boom low to avoid spray drift. A minimum spray pressure of 275 kPa (40 psi) should be used with fan nozzles applying insecticides. **Higher**

pressure reduces droplet size, DOES NOT improve canopy penetration and may increase drift potential. WHEN HIGHER FLOW RATES ARE NEEDED, USE A HIGHER-CAPACITY NOZZLE INSTEAD OF INCREASING PRESSURE. For band spraying, increase the number of fan nozzles per crop row as the plant size increases.

Aerial application

Altacor® must only be applied with aircraft fitted with accurately calibrated equipment. Apply a minimum total spray volume of 30 L/ha with with nozzles (e.g. Micronaire® rotary atomisers, CP nozzles or conventional hydraulic nozzles) set to medium spray quality according to ASAE S572 definition for standard nozzles. A spray drift minimisation strategy, should be employed at all times when applying this product. **DO NOT apply Altacor® using Ultra Low Volume (ULV) methods.**

Compatibility

Since formulations may be changed and new ones introduced, it is recommended that users premix a small quantity of the desired tank mix and observe possible adverse changes (settling out, flocculation etc). Avoid complex tank mixtures of several products or very concentrated spray mixtures. Altacor® is compatible with Ovasyn* (amitraz) and Pix* (mepiquat chloride). Altacor® is not compatible with Ultra Low Volume (ULV) formulations.

Spray Equipment Cleanout

Prior to application, start with clean, well-maintained application equipment. Immediately following application, thoroughly clean all spray equipment to reduce the risk of forming hardened deposits which might become difficult to remove. Drain spray equipment. Thoroughly rinse sprayer and flush hoses, boom, and nozzles with clean water.

Clean all other associated application equipment. Take all necessary safety precautions when cleaning equipment. **DO NOT** clean near wells, water sources or desirable vegetation. Dispose of waste rinse water in accordance with local regulations.

Entry into treated areas

DO NOT allow entry into treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Dangerous to aquatic invertebrates. Drift and run off from treated areas may be hazardous to aquatic organisms in neighbouring areas. **DO NOT** contaminate streams, rivers or waterways with the chemical or used containers.

DO NOT apply under weather conditions, or from spraying equipment, that may cause spray to drift onto near-by non-target plants/crops, cropping lands or pastures.

STORAGE AND DISPOSAL

KEEP OUT OF REACH OF CHILDREN.

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

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

PRECAUTION

DO NOT use human flaggers/markers unless they are protected by engineering controls such as vehicles with enclosed cabs.

SAFETY DIRECTIONS

May irritate eyes. Avoid contact with eyes.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

**IN A MEDICAL EMERGENCY CALL
1800 674 415 ALL HOURS**

MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet.

NOTICE TO BUYER

To the extent permitted by law all conditions and warranties and statutory or other rights of action which buyer or any other user may have against DuPont or Seller are hereby excluded. DuPont hereby gives notice to buyer and other users that it will not accept responsibility for any indirect or consequential loss arising from reliance on product information or advice provided by DuPont or on its behalf unless it is established that such information or advice was provided negligently and that the product has been used strictly as directed. DuPont's liability shall in all circumstances be limited to replacement of the product or a refund of the purchase price paid therefore.

The DuPont Oval Logo, DuPont™, and Altacor® are trademarks or registered trademarks of DuPont or its affiliates.

Du Pont (Australia) Ltd

A.C.N. 000 716 469

7 Eden Park Drive

Macquarie Park NSW 2113

(02) 9923 6111 or 1800 257 169

<http://www.dupont.com.au/ag/>

APVMA Approval No: 61892/B/0608

DRAFT

DuPont™ Coragen®

insecticide



ACTIVE CONSTITUENT: 200 g/L CHLORANTRANILIPROLE

GROUP	28	INSECTICI DE
-------	-----------	-----------------

For the control of Lepidopteran species of insect pests in certain vegetables, as per the Directions for Use

IMPORTANT: READ THIS LEAFLET BEFORE USE

DIRECTIONS FOR USE

RESTRAINTS:

DO NOT apply if rainfall is expected within 2 hours of application.

DO NOT use on container or hydroponic grown crops.

EXPORT STATEMENT: Import tolerances for produce treated with DuPont™ Coragen® insecticide may be pending in some countries. Consult with your exporter or DuPont before applying Coragen® to export crops.

For use in all States where appropriate for the crop and/or insect pest.

CROP	PEST	RATE/HA	WHP	CRITICAL COMMENTS
CRITICAL COMMENTS - ALL CROPS				
Regularly scout crops to monitor for eggs and larvae. Target sprays against eggs and newly hatched larvae before they become entrenched. Apply as egg and larvae reach threshold numbers.				
A maximum of three (3) applications are to be applied to any one crop. No more than two (2) consecutive sprays per crop, with a minimum spray interval of 7 days (unless stated otherwise). Further treatments should be made with alternative mode of action insecticides.				
Use enough water to ensure thorough coverage of the crop. Adjust water volumes to crop stage (200 – 1000 L/ha).				
Refer to Surfactant/Wetting agent section.				
Use in accordance with AIRAC Insecticide Resistance Management Strategy guidelines. As part of an Insecticide Resistance Management programme for Cotton bollworm, it is important to plough crops immediately after harvest.				
Brassica vegetables including; Broccoli, Brussels Sprout, Cabbage, Cauliflower	Cabbage-centre grub (<i>Hellula hydralis</i>) Cabbage cluster caterpillar (<i>Crocidolomia pavonana</i>)	100 mL + 75 gai/100 L of non-ionic surfactant	7 days	
Brassica leafy vegetables including; Bok choy, Chinese broccoli (Gai lum/Gai lan/Kai lan), Chinese cabbage (Pet sai/Wombok/Haksukai), Choy sum, Gai choy/Am soy, Kai choy, Kale, Mibuna, Leafy mustard including Indian mustard and Mustard spinach (Komatsuma), Pak choy, Tat soy	Cabbage white butterfly (<i>Pieris rapae</i>) Cluster caterpillar (<i>Spodoptera litura</i>) Cotton bollworm (<i>Helicoverpa armigera</i>) Diamondback moth (<i>Plutella xylostella</i>) Native budworm (<i>Helicoverpa punctigera</i>) Soybean looper (<i>Thysanoplusia orichalcea</i>)		3 days	
Stalk & Stem vegetables, including; Celery, Rhubarb	Cotton bollworm (<i>Helicoverpa armigera</i>) Native budworm (<i>Helicoverpa punctigera</i>)	100 mL + 15 gai/100 L of non-ionic surfactant		
Leafy vegetables (excluding lettuce), such as; Cress, Endive, Silverbeet, Spinach				
Lettuce (leaf and closed head varieties)		150 mL + 15 gai/100 L of non-ionic surfactant		

CROP	PEST	RATE/HA	WHP	CRITICAL COMMENTS
Fruiting vegetables (excluding Cucurbits), including; Capsicum, Egg plant, Peppers, Tomato (trellis and field)	Cotton bollworm (<i>Helicoverpa armigera</i>) Native budworm (<i>Helicoverpa punctigera</i>) Tomato leaf miner (<i>Phthorimaea operculella</i>)	100 mL or 10 mL/100 L (dilute)		
Fruiting vegetables (Cucurbits), including; Cucumbers, Melons, Pumpkin, Squash, Zucchini	Cotton bollworm (<i>Helicoverpa armigera</i>) Native budworm (<i>Helicoverpa punctigera</i>)	100 mL or 10 mL/100 L (dilute)	3 days	Apply with a minimum spray interval of 5 days.
Potatoes	Cotton bollworm (<i>Helicoverpa armigera</i>) Native budworm (<i>Helicoverpa punctigera</i>) Potato moth (<i>Phthorimaea operculella</i>)	100 mL	Not required	Only target foliar infestations of Potato moth. Moth larvae in the soil or within stems will not be controlled. Apply with a spray interval of 10 - 14 days.

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

WITHHOLDING PERIODS

HARVEST

POTATOES: WITHHOLDING PERIOD NOT REQUIRED WHEN USED AS DIRECTED.

BRASSICA LEAFY VEGETABLES, STALK & STEM VEGETABLES, LEAFY VEGETABLES (INCLUDING LETTUCE): DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION.

BRASSICA VEGETABLES (including BROCCOLI, BRUSSELS SPROUT, CABBAGE, CAULIFLOWER): DO NOT HARVEST FOR 7 DAYS AFTER APPLICATION.

GRAZING

DO NOT GRAZE OR CUT FOR STOCK FOOD.

GENERAL INSTRUCTIONS

DuPont™ Coragen® insecticide has been specifically designed for use in Integrated Pest Management (IPM) schemes. Coragen® is an anthranilic diamide insecticide in the form of a suspension concentrate. Coragen® is particularly active on Lepidopteran insect pests, primarily as a larvicide. Before application monitor insect populations to determine whether or not there is a need for application of Coragen® based on locally determined economic thresholds. More than one treatment of Coragen® may be required to control a population of pests.

INSECTICIDE RESISTANCE WARNING



For insecticide resistance management DuPont™ Coragen® insecticide is a Group 28 insecticide.

Some naturally occurring insect biotypes resistant to Coragen® and other Group 28 insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Coragen® and other Group 28 insecticides are used repeatedly. The effectiveness of Coragen® on resistant individuals could be significantly reduced. Since the occurrence of resistant individuals is difficult to detect prior to use DuPont accepts no liability for any losses that may result from the failure of Coragen® to control resistant insects.

Coragen® may be subject to specific resistance management strategies. To help prevent the development of resistance to Coragen®, use Coragen® in accordance with the current Insecticide Resistance Management (IRM) strategy for your region. For further information contact your farm chemical supplier, consultant, local Department of Agriculture or Primary Industries, or local DuPont Representative.

MIXING

Fill spray tank to $\frac{1}{4}$ to $\frac{1}{2}$ full of water. Measure the amount of Coragen[®] required for the area to be sprayed. Add Coragen[®] directly to the spray tank with the agitation engaged. Mix thoroughly to disperse the insecticide. Once dispersed, the material must be kept in suspension at all times by continuous agitation. Use mechanical or hydraulic means, **DO NOT** use air agitation, premix or slurry.

If spray solution is left standing, ensure thorough re-agitation of the spray mix until fully resuspended. **DO NOT** allow spray mix to sit overnight, as resuspension may be difficult.

SURFACTANT/WETTING AGENT

For celery, lettuce, rhubarb and other leafy vegetables use a non-ionic surfactant/wetting agent at 15 g active/100 L, (e.g. Agral 600 @ 25 mL/100 L).

For broccoli, Brussels sprout, cabbage, cauliflower a use a non-ionic surfactant/wetting agent at 75 g active/100 L, (e.g. Agral 600 @ 125 mL/100 L).

DO NOT use BS1000* or Activator-90# as it may cause crop phytotoxicity.

DO NOT add a non-ionic surfactant/wetting agent if:

- mixing with another product which already contains a surfactant and/or the product label advises not to add a surfactant.
- mixing with a liquid fertiliser.

APPLICATION

Minimising Spray Drift

The interaction of many equipment and weather-related factors determines the potential for spray drift. The applicator must consider all these factors when making application decisions. The most effective way to reduce drift potential is to apply large droplets (volume mean diameter (VMD) > 250 - 300 microns). The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. **APPLYING LARGER DROPLETS REDUCES DRIFT POTENTIAL, BUT WILL NOT MINIMISE DRIFT IF APPLICATIONS ARE MADE IMPROPERLY OR UNDER UNFAVOURABLE ENVIRONMENTAL CONDITIONS.** When making applications in hot and dry conditions, set up equipment to produce larger droplets to reduce effects of evaporation.

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour at the application site.

DO NOT apply when there are aquatic and wetland areas including aquacultural ponds or surface streams and rivers downwind from the application area and within the mandatory no-spray zone of 20 metres.

Ground application

Use a boom sprayer fitted with high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. Use the lower spray pressures recommended for the nozzle. Higher pressure reduces droplet size, **DOES NOT** improve canopy penetration and may increase drift potential. **WHEN HIGHER FLOW RATES ARE NEEDED, USE A HIGHER-CAPACITY NOZZLE INSTEAD OF INCREASING PRESSURE.** Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. When applying Coragen[®] by ground application, keep the boom low to avoid spray drift.

Compatibility

Since formulations may be changed and new ones introduced, it is recommended that users premix a small quantity of the desired tank mix and observe possible adverse changes (settling out, flocculation etc). Avoid complex tank mixtures of several products or very concentrated spray mixtures. Coragen[®] is compatible with Captan*, Dextrolac*, Delan*, Fulasin*, Manzate[®], Nustar[®], Omite*, Polyram* and Systhane*.

The mixing sequence recommended is: water soluble bags, dry flowable or water dispersible granules, wettable powders, water based suspension concentrates (Coragen[®]), water soluble concentrates, oil based suspension concentrates, emulsifiable concentrates, adjuvants and surfactants, soluble fertilisers.

Spray Equipment Cleanout

Prior to application, start with clean, well-maintained application equipment. Immediately following application, thoroughly clean all spray equipment to reduce the risk of forming hardened deposits which might become difficult to remove. Drain spray equipment. Thoroughly rinse sprayer and flush hoses, boom, and nozzles with clean water.

Clean all other associated application equipment. Take all necessary safety precautions when cleaning equipment. **DO NOT** clean near wells, water sources or desirable vegetation. Dispose of waste rinse water in accordance with local regulations.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Dangerous to aquatic invertebrates. Drift and run off from treated areas may be hazardous to aquatic organisms in neighbouring areas. **DO NOT** contaminate streams, rivers or waterways with the chemical or used containers.

STORAGE AND DISPOSAL

KEEP OUT OF REACH OF CHILDREN.

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

The method of disposal of the container depends on the container type. Read the 'Storage and Disposal' instructions on the label that is attached to the container.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

IN A MEDICAL EMERGENCY CALL 1800 674 415 ALL HOURS

MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet.

NOTICE TO BUYER

To the extent permitted by law all conditions and warranties and statutory or other rights of action which buyer or any other user may have against DuPont or Seller are hereby excluded. DuPont hereby gives notice to buyer and other users that it will not accept responsibility for any indirect or consequential loss arising from reliance on product information or advice provided by DuPont or on its behalf unless it is established that such information or advice was provided negligently and that the product has been used strictly as directed. DuPont's liability shall in all circumstances be limited to replacement of the product or a refund of the purchase price paid therefor.

The DuPont Oval Logo, DuPont™ and Coragen® are trademarks or registered trademarks of DuPont or its affiliates.

Du Pont (Australia) Ltd
A.C.N. 000 716 469
 7 Eden Park Drive
 Macquarie Park NSW 2113
 (02) 9923 6111 or 1800 257 169
<http://www.dupont.com.au/ag/>

APVMA Approval No: 61519/0608

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

DRAFT

**DuPont™
Acelepryn®**

INSECTICIDE

ACTIVE CONSTITUENT: 200 g/L CHLORANTRANILIPROLE

GROUP	28	INSECTICI DE
-------	-----------	-----------------

For the control of African black beetle, Argentinian scarab, Argentine stem weevil, Billbug and other insect pests in turf as per the Directions for Use

IMPORTANT: READ THIS LEAFLET BEFORE OPENING OR USING THIS PRODUCT.



The miracles of science™

DIRECTIONS FOR USE

RESTRAINTS:

DO NOT apply more than 2.8 L per hectare per year in broadcast applications to turfgrass.

For use in all States where appropriate for the crop and/or insect pest.

CROP	PEST	RATE/HA	CRITICAL COMMENTS
Applications should not be made when the soil is saturated with water because adequate distribution of the active ingredient vertically in the soil profile cannot be achieved under this condition. As is the case with any insecticide applied to turfgrass for beetle larvae control, optimal results will be achieved if the product is irrigated into the turf immediately after application.			
Golf courses	Beetle larvae including;	750 mL – 1.5 L	Apply before or at peak egg hatch for maximum control (typically mid-Sept). Apply the higher rate for early season (mid-Sept) applications where long residual protection is required, or in later season applications (mid-Dec onwards) when less sensitive mid-instar grubs are present at the time of application, or in cases of high pest pressure.
Lawns, including commercial and residential lawn areas	African black beetle (<i>Heteronychus arator</i>)		
Sports grounds	Argentinian scarab (<i>Cyclocephala signaticollis</i>)		Apply before or at peak egg hatch for maximum control (typically mid-Dec). Use the higher application rates for later season applications when less sensitive mid-instar grubs are present at the time of application or in cases of high pest pressure.
Other sport and recreational turfgrass areas	Argentine stem weevil larvae (<i>Listronotus bonariensis</i>), Billbug larvae (<i>Sphenophorus brunnipennis</i>)		Apply early season (mid-Sept) applications when overwintered adults are first observed, to prevent damage and population build up. Early application is essential to prevent grass damage due to feeding. Use the higher application rates when extended residual performance is required or for later season applications (mid-Dec onwards) or in cases of high pest pressure.

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

WITHHOLDING PERIOD

DO NOT GRAZE OR CUT FOR STOCK FOOD.

GENERAL INSTRUCTIONS

DuPont™ Acelepryn® insecticide is an anthranilic diamide insecticide in the form of a suspension concentrate. DuPont™ Acelepryn® insecticide delivers excellent preventative performance, with optimal results achieved with application early in the season (mid Sept) with the appearance of overwintering adult pests. The long residual performance of DuPont™ Acelepryn® insecticide will provide up to 6 months protection at the higher application rates. Curative control with DuPont™ Acelepryn® insecticide on pest outbreaks later in the season (mid Dec onwards) can be achieved using the higher recommended application rates.

INSECTICIDE RESISTANCE WARNING

GROU P	28	INSECTICI DE
-------------------	-----------	-------------------------

For insecticide resistance management DuPont™ Acelepryn® insecticide is a Group 28 insecticide. Some naturally occurring insect biotypes resistant to Acelepryn® and other Group 28 insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Acelepryn® and other Group 28 insecticides are used repeatedly. The effectiveness of Acelepryn® on resistant individuals could be significantly reduced. Since the occurrence of resistant individuals is difficult to detect prior to use DuPont accepts no liability for any losses that may result from the failure of Acelepryn® to control resistant insects. Acelepryn® may be subject to specific resistance management strategies. To help prevent the development of

resistance to Acelepryn[®], use Acelepryn[®] in accordance with the current Insecticide Resistance Management (IRM) strategy for your region. For further information contact your farm chemical supplier, consultant, local Department of Agriculture or Primary Industries, or local DuPont Representative.

SPRAY TIMING

Beetle larvae;

DuPont™ Acelepryn[®] insecticide may be applied from Spring onwards for preventative control of larvae of all the major beetle species infesting turfgrass. The need for an application may be based on historical monitoring of the site, previous records or experiences, current season adult trapping or other methods.

Argentine stem weevil:

DuPont™ Acelepryn[®] insecticide should be applied when over-wintered adult Argentine stem weevils are observed in early Spring (mid Oct) to prevent damage in late Spring. An application at this time will also give excellent control of beetle larvae control.

Billbugs:

DuPont™ Acelepryn[®] insecticide should be applied when over-wintered adult billbugs are first observed (mid Oct). An application at this time will also give excellent beetle larvae control.

MIXING

Fill spray tank to ¼ to ½ full of water. Measure the amount of Acelepryn[®] required for the area to be sprayed. Add Acelepryn[®] directly to the spray tank with the agitation engaged. Mix thoroughly to disperse the insecticide. Once dispersed, the material must be kept in suspension at all times by continuous agitation. Use mechanical or hydraulic means, **DO NOT** use air agitation, premix or slurry.

If spray solution is left standing, ensure thorough reagitation of the spray mix until fully resuspended. **DO NOT** allow spray mix to sit overnight, as resuspension may be difficult.

APPLICATION

- Spray with at least 400 L of water/ha to ensure even coverage.
- The required water volume may be determined by applying different test volumes, using different settings on the sprayer, from industry guidelines or expert advice.
- Note that the amount of product specified in the Directions for Use table is per hectare of product. You will need to determine your spray rate per hectare before deciding on the amount of product to add to the tank.
- Irrigate with approx 6 mm of water after application.

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour at the application site.

DO NOT apply when there are aquatic and wetland areas including aquacultural ponds or surface streams and rivers downwind from the application area and within the mandatory no-spray zone of 90 metres.

Spray Equipment Cleanout

Prior to application, start with clean, well-maintained application equipment. Immediately following application, thoroughly clean all spray equipment to reduce the risk of forming hardened deposits which might become difficult to remove. Drain spray equipment. Thoroughly rinse sprayer and flush hoses, boom, and nozzles with clean water.

Clean all other associated application equipment. Take all necessary safety precautions when cleaning equipment. **DO NOT** clean near wells, water sources or desirable vegetation. Dispose of waste rinse water in accordance with local regulations.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Dangerous to aquatic invertebrates. Drift and run off from treated areas may be hazardous to aquatic organisms in neighbouring areas. **DO NOT** contaminate streams, rivers or waterways with the chemical or used containers.

DO NOT apply under weather conditions, or from spraying equipment, that may cause spray to drift onto near-by non-target plants/crops, cropping lands or pastures.

STORAGE AND DISPOSAL

KEEP OUT OF REACH OF CHILDREN.

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

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

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

IN A MEDICAL EMERGENCY CALL 1800 674 415 ALL HOURS

MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet.

NOTICE TO BUYER

To the extent permitted by law all conditions and warranties and statutory or other rights of action which buyer or any other user may have against DuPont or Seller are hereby excluded. DuPont hereby gives notice to buyer and other users that it will not accept responsibility for any indirect or consequential loss arising from reliance on product information or advice provided by DuPont or on its behalf unless it is established that such information or advice was provided negligently and that the product has been used strictly as directed. DuPont's liability shall in all circumstances be limited to replacement of the product or a refund of the purchase price paid therefor.

The DuPont Oval Logo, DuPont™ and Acelepryn® are trademarks or registered trademarks of DuPont or its affiliates.

Du Pont (Australia) Ltd

A.C.N. 000 716 469

7 Eden Park Drive

Macquarie Park NSW 2113

(02) 9923 6111 or 1800 257 169

APVMA Approval No: 63085/0608

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.
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
Leaching	Removal of a compound by use of a solvent.
Metabolism	The conversion of food into energy
Toxicokinetics	The study of the movement of toxins through the body.
Toxicology	The study of the nature and effects of poisons.

APVMA PUBLICATIONS ORDER FORM

To receive a copy of the full technical report for the evaluation of [active constituent] in the product [product name], please fill in this form and send it, along with payment of \$30 to:

Alan Norden
 Manager, Minor Use
 Pesticides Program
 Australian Pesticides and Veterinary Medicines Authority
 PO Box 6182
 Kingston ACT 2604

Alternatively, fax this form, along with your credit card details, to:
 Alan Norden at (02) 6210 4776

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 'National Registration Authority'.

___ Bankcard ___ Visa ___ Mastercard

Card number ____/____/____/____ Expiry date ____/____/____

Signature _____ Date _____