Public Release Summary
on

Evaluation of the new active

CLOMAZONE

in the product

COMMAND 480 EC HERBICIDE

National Registration Authority
for Agricultural and Veterinary Chemicals

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FOREWORD

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

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

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

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

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

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

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

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List of Abbreviations and Acronyms

[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
d	Day
EC_{50}	concentration at which 50% of the test population are immobilised
Fo	original parent generation
h	Hour
HPLC	high pressure liquid chromatography *or* high performance liquid chromatography
id	Intradermal
ip	Intraperitoneal
im	Intramuscular
iv	Intravenous
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
kg	Kilogram
L	Litre
LC_{50}	concentration that kills 50% of the test population of organisms
LD_{50}	dosage of chemical that kills 50% of the test population of organisms
mg	Milligram
mL	Millilitre
MRL	maximum residue limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee
ng	Nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	no observable effect concentration/level
OC	Organic carbon
OM	Organic matter
po	Oral
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
s	Second
sc	Subcutaneous
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
T-Value	a value used to determine the First Aid Instructions for chemical products that contain two or more poisons
TGAC	technical grade active constituent
WHP	withholding period

SUMMARY

This publication outlines the regulatory considerations and provides a summary of the data evaluated for the proposed registration of *Command 480 EC Herbicide* (*Command*). *Command* is formulated as an emulsifiable concentrate containing 480 g/L of clomazone. It is proposed that the product will be used for weed control post-planting pre-emergence on cucurbits, green beans, navy beans, potatoes, tobacco, pre & post-emergence on rice and early post-emergence on poppies.

The NRA has assessed the data submitted by the applicant in support of the proposed use of clomazone. The following information is provided for public comment before the NRA determines whether to register the product in Australia. Comments should be submitted by **14 July 1999** to the NRA at the address indicated on page 1.

Public Health Aspects

Toxicology
Clomazone, the active ingredient of *Command*, has low acute oral, dermal and inhalational toxicity. It causes slight eye irritation, but does not cause skin irritation or sensitisation. The product, *Command*, has low oral, dermal and inhalational toxicity, and causes slight skin irritation and moderate eye irritation, but no skin sensitisation.

Following repeated oral administration of clomazone, increased liver weight and cellular alterations in the liver, consisting of enlarged liver cells, was consistently observed in mice and rats at moderate to high doses. Increased cholesterol levels were noted in rats and dogs at similar doses. There was no evidence of oncogenic potential following long-term dietary exposure to clomazone in mice or rats. Clomazone does not cause genetic damage in a number of *in vitro* and *in vivo* studies. No effects of clomazone treatment were noted on offspring development. Clomazone was not teratogenic in rats and rabbits when administered orally, but in rats there was evidence of treatment-related foetotoxicity at high doses.

Conclusion
Based on an assessment of the toxicology it was considered that there should be no adverse effects on human health from the proposed use of clomazone as a component of *Command* in accordance with label directions.

Residues in Food and Trade Aspects

Residues in food
In plants, clomazone was shown to be rapidly and extensively metabolised resulting in negligible residues of unchanged parent compound. The animal metabolism experiments conducted at exaggerated dose rates indicated that clomazone was extensively metabolised and rapidly excreted with negligible residues detected in tissues or milk.

As regards the residue definition, no one metabolite of clomazone was detected at levels >0.01 mg/kg. It is not appropriate to establish a complex residue definition as all metabolites present at harvest were at levels, below the level of detection of 0.01 mg/kg. The residue

definition should be parent compound. Validated analytical methods were capable of quantifying clomazone residues in rice to 0.01 mg/kg and other plants to 0.05 mg/kg.

The residue data from Brazil, the USA and Australia support the proposed MRLs of *0.05 mg/kg for beans, navy beans, poppy seed, cucurbits and potatoes, and *0.01 mg/kg for rice. The proposed use-pattern as a pre-planting or early post-emergent herbicide precludes the need for the establishment of harvest withholding periods.

Given the lack of detectable residues in plant material and rapid excretion and extensive metabolism by animals, it is not necessary to set animal MRLs for clomazone.

The registration of clomazone on green beans, navy beans, cucurbits, poppies, potatoes and rice does not pose a threat to human health or trade.

The following amendments to the *MRL Standard* are recommended:

Table 1

Compound	Food		MRL (mg/kg)
ADD:			
clomazone			
	VP 0061	Beans (except broad beans and soybeans)	*0.05
	VP 0526	Common bean (pod and/or immature seeds)	T*0.05
	VC 0045	Fruiting vegetables, cucurbits	*0.05
	SO 0698	Poppy seed	*0.05
	VR 0589	Potato	*0.05
	GC 0649	Rice	*0.01

T indicates a temporary Maximum Residue Limit and that the limit is subject to review of additional residue data. This limit should be withdrawn on 1 September 2001, unless consideration is made of a subsequent application prior to that date.

Table 3

Compound	Residue
ADD:	
clomazone	clomazone

Table 4

Compound	Animal Feed Commodity		MRL (mg/kg)
ADD:			
clomazone			
	AS 0649	Rice straw and fodder (dry)	*0.01
		Rice forage (green)	*0.01

The following WHPs are recommended in relation to the above MRLs for *Command*:

Harvest:
Green beans, cucurbits, navy beans, poppies, potatoes, rice:
Not required when used as directed
Grazing:
Rice: Do not graze or cut for stock food for 3 months after application
Other Crops: Do not graze or cut for stock food until after harvest

Trade Aspects

As no residues are expected in any produce or animal commodities related to the use of this product according to the label directions and Good Agricultural Practice, there is not expected to be any risk to Australian trade.

Occupational Health and Safety Aspects

The National Occupational Health and Safety Commission (NOHSC) has conducted a risk assessment on *Command* and found that it can be safely used by workers when handled in accordance with the control measures indicated in this assessment.

Clomazone and *Command* were determined to be hazardous according to NOHSC criteria. Hazardous substances are subject to the workplace controls outlined in NOHSC publications.

Command will be formulated overseas and will be imported only as the finished commercially packaged product.

Command will be applied as a ground spray for all crops, except rice. The application of *Command* into flooded rice bays will be made using the Soluble Chemical Water Injection In Rice Technique (or SCWIIRT). This technique involves the application of chemicals from a mounted tank on a specially converted motorbike, tractor or helicopter.

Workers may be exposed to *Command* during mixing and loading, ground spray application and during clean-up operations. The main hazards associated with *Command* are slight (if eye is washed) to moderate (if eye remains unwashed) eye irritation and slight skin irritation. The risk assessment indicates that adequate worker controls can be instituted to enable safe use of *Command.*

During mixing and loading operations, workers should wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) elbow length nitrile gloves and face shield or goggles. During application, workers should wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length nitrile gloves.

No re-entry period for *Command* is required.

Environmental Aspects

Hydrolysis of clomazone is very slow, with <1%, <2% and <10% hydrolysed at ph 5, 7 and 9 respectively after 30 days. Photolysis may provide a faster route of degradation in water (aqueous half-life of 67.5-87.7 days), but soil photolysis is very slow with a half-life of 996 days.

The main soil aerobic degradation half lives lie in the range of 28-56 days with mineralisation through both the carbonyl and aromatic rings shown to be relatively quick. There appears to be biological and temperature dependence on the rate of degradation although results with respect to soil moisture dependence on degradation was inconclusive. Anaerobic soils tests confirmed the parent compound degrades faster under anaerobic than aerobic conditions.

As with soils, aquatic systems saw much faster degradation of clomazone under anaerobic than aerobic conditions. Aerobic aquatic systems have half-lives for dissipation from the whole system between 71-78 days, while dissipation from the water layer was between 21-23 days. Results with respect of movement from water to sediments were variable, although up to 48% was extracted from sediments after 30 days. The major metabolite was formed in greater quantities under anaerobic conditions, and half-lives for the whole system ranged from 23-24 days.

Laboratory mobility studies showed varying results, with clomazone classed as having low to medium mobility under the Hellings system (no Koc values calculated), but having high to low mobility according to the McCall scale (based on Koc measurements from 19 soils, and company testing). Similarly, modelling provided varying results with PESTANS predicting low mobility in sand, while GUS predicted the chemical would range from a borderline leacher to a leacher.

Clomazone can be considered to have a relatively short half-life in the field, with the reported range of 6-117 days. The majority of the reported half lives were less than 2 months. Despite some laboratory tests and modelling predictions suggesting the chemical to be relatively mobile, field studies indicate limited mobility, with the chemical remaining in the top 30 cm of soil in a range of soil types at application levels greater than twice the maximum proposed rate for Australia.

Dissipation of clomazone from field systems appears to be influenced by a number of factors, such as temperature, tillage and incorporation effects. The general trend of results (even though some were inconclusive) were that soil incorporated treatments will persist longer than surface applied treatments, and conventional tillage plots had greater persistence than reduced and no tillage plots. However, on the issue of volatilisation (being distinct from overall persistence) bioassays left little doubt, that a greater amount of plant damage through volatilisation resulted in *pre-emergence* than pre-plant incorporated treatments, and in reduced or no tillage plots than conventional tillage plots. While the company accepts this, it has commented that the efficacy of the product precludes it from being used in a manner different to the recommended methods. When the product is incorporated, significantly higher rates (approximately double) are required to achieve the same level of control.

Temperature appeared to play a role in increasing degradation in laboratory studies. It was also shown to increase the rate of volatilisation with increasing temperature. However, this in effect allowed plants exposed at higher temperatures to recover faster, as at lower temperatures, clomazone persisted in the system longer, so adverse effects were noticed longer.
Similarly, with moisture content, bioassays showed the same level of adverse effects at all moisture contents for the first couple of weeks. However, in the systems where volatilisation would be expected to be faster (drier soils), clomazone was removed from the system faster, so these plants recovered earlier. There was no apparent effect of moisture content on the total dissipation rate of clomazone in the field.

Accumulation of clomazone is not expected due to the relatively short half-life and only one application per annum. The chemical can be considered as only slightly bioaccumulating.

Based on the tested environmental effects of this chemical, and its proposed use pattern, the environmental risk is predicted to be low. Exceptions may occur for aquatic plants and susceptible terrestrial plants. However, the company will be undertaking a strong stewardship program, and in the past, this has been shown to effectively limit the incidences of off target movement through application of clomazone. Observations have shown that plants damaged through clomazone exposure tend to recover.

Efficacy and Crop Safety Aspects

The registration of *Command* is keenly sought by the Australian horticultural, tobacco and poppy industries, as new products for use in these crops are rare. *Command* will provide a new herbicide with a different mode of action to those currently in use in these industries. It should help to overcome some serious weed problems that threaten the viability of these industries.

Data from 20 trials conducted from 1993-1996 have demonstrated that *Command* can be used post-planting pre-emergence (PPPE) in **cucurbits, green beans, navy beans, potatoes and tobacco** and early post-emergence in **poppies** for the control or suppression of a range of broadleaf weeds. In **rice** it has been demonstrated that *Command* can be used as a pre-emergence or early post-emergence herbicide applied either pre-sowing or early post-sowing, for control of Barnyard grass *(Echinochloa* spp.*)* and suppression of Silvertop grass *(Leptochloa fusca).*

Crop safety is acceptable. Some crops, particularly when the product is used at the higher rates, show minor transient bleaching however this is not commercially damaging.

INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of *Command 480 EC Herbicide (Command),* which contains the new active ingredient, clomazone.

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

Copies of full technical evaluation reports on clomazone, covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the NRA on request (see order form on page 33). They can also be viewed at the NRA library located at the NRA offices, Ground Floor, 22 Brisbane Avenue, Barton ACT 2604.

Written comments should be submitted by **30 July 1999** and addressed to:

[redacted]

[redacted]

Applicant
FMC International A.G.

Product Details
Command is to be manufactured and packed in the USA as an emulsifiable concentrate containing 480g/L of clomazone.

It is proposed that the product will be will be registered in all Australian jurisdictions for post-planting pre-emergence control of certain annual grasses and broadleaf weeds in cucurbits, green beans, navy beans, potatoes, poppies, rice and tobacco.

Command inhibits the biosynthesis of photosynthetic pigments of both chlorophyll and carotenoids. Accordingly, clomazone can be classified in the pigment inhibitor group of herbicides (Group F). Entry into plants is through both shoots and roots. The movement of clomazone within the plant occurs upward with water in the xylem tissue (transpiration stream), and then diffuses within the leaf. The active ingredient does not appear to be downwardly systemic, or translocated from leaf to leaf.

Products which are comparable to *Command,* are registered in the following countries:

- Brazil
- China
- Korea
- Indonesia
- New Zealand
- Thailand
- USA

CHEMISTRY AND MANUFACTURE

The product proposed for registration in Australia is an emulsifiable concentrate formulation under the trade name *Command 480 EC Herbicide*.

The formulation storage stability and the physical and chemical properties of the formulated product and active constituent were evaluated by the NRA and found to be acceptable.

MSDS for the inactive ingredients/excipients were provided and are acceptable.

Formulated Product

Basic Chemical and Physical Properties

Colour:	straw yellow to tan colour
Odour:	aromatic solvent (xylene like)
Specific Gravity:	1.025 to 1.028 g/mL
pH:	5.1
Explodability:	based on an impact test, the formulated product is not explosive
Flash Point:	40°C
Corrosive Hazard:	non-corrosive to stainless steel and two types of polyethylene likely to be used in sprayer parts/spray tank manufacture

Packaging

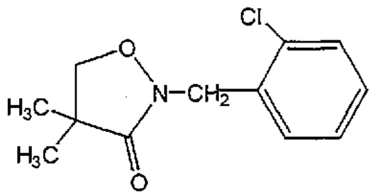
The formulated product will be packaged in 1, 5 and 10 litre high density polyethylene containers.

Active constituent

The chemical active constituent in *Command* is clomazone and has the following properties:

Common name (ISO):	clomazone
Chemical name (IUPAC):	2-(2-Chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one; 2-(2-Chlorobenzyl)-4,4-dimethylisoxazolidin-3-one
Chemical Group	Isoxazolidinones
CAS Registry Number:	81777-89-1
Empirical formula:	$C_{12}H_{14}Cl\,NO_2$
Molecular weight:	239.7 grams/mole
Physical form:	viscous liquid above room temp, white crystalline solid when cooled
Colour:	Liquid: clear colourless to very pale yellow; Solid:white, crystalline
Odour:	light fatty acid

Melting point:	25°C broad range
Octanol/water partition coefficient (K_{OW}):	350 (log Pow = 2.54)
Vapour pressure at 25°C:	1.44×10^{-4} mm Hg
Structural formula:	



Clomazone

TOXICOLOGICAL ASSESSMENT

Evaluation Of Toxicology

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

Toxicokinetics and Metabolism

Clomazone administered to rats is rapidly and extensively absorbed and metabolised, and subsequently excreted primarily in the urine, the majority within 24 h and > 90% within 7 days. Clomazone is metabolised predominantly to a number of derivatives of the parent compound. Low residues were observed in tissues and organs, with highest levels found in skin, hair, liver, lungs and heart.

Acute Studies

Clomazone exhibits low oral (LD_{50} 2077-2585 mg/kg male rats, 1369-1564 mg/kg female rats), dermal (LD_{50} > 2000 mg/kg in rabbits) and inhalational (LC_{50} 6520 mg/m^3 male rats, 4230 mg/m^3 female rats) toxicity. Clomazone is a slight eye irritant in rabbits in both washed and unwashed eyes, is not a skin irritant on either abraded or intact skin in rabbits and is not a skin sensitiser in guinea pigs.

Command has low oral (LD_{50} 2343 mg/kg males, 1406 mg/kg females) and inhalational toxicity in rats (LD_{50} 4470 mg/m^3 males, 4700 mg/m^3 females), low dermal toxicity in rabbits (LD_{50} > 2000 mg/kg with no deaths), is a slight skin irritant and a moderate eye irritant in unwashed eyes in rabbits, but a slight irritant in washed eyes, and is not a skin sensitiser in guinea-pigs.

Subchronic Studies

In mice treated with clomazone in the diet at concentrations of 20, 100, 500, 1000, 2000, 4000 and 8000 ppm (3 - 1200 mg/kg/day) for 13 weeks, significantly increased food consumption in animals administered 8000 ppm was noted. Increases in liver weight were observed in mice administered 4000 and 8000 ppm and clomazone treatment was associated with liver cell enlargement at 2000 and 8000 ppm. The NOEL was 1000 ppm (118 mg/kg bw/day for males, 263 mg/kg bw/day for females).

Rats treated with clomazone in the diet at concentrations of 20, 100, 500, 1000, 2000, 4000 and 8000 ppm (2 - 800 mg/kg/day) for 13 weeks ate less and gained less weight at 4000 ppm and 8000 ppm during the treatment period. Biochemical changes consisted of increased serums levels of cholesterol in animals administered 1000, 4000 ppm and 8000 ppm at 3 months, and increased serum levels of enzymes, indicative of liver damage, in animals given 8000 ppm at 3 months. Liver weight was increased in animals given 2000-8000 ppm and cellular alterations in the liver were present in rats administered 2000 ppm and 8000 ppm, reflecting liver cell damage. The NOEL was 500 ppm (35 mg/kg bw/day in males; 42 mg/kg bw/day in females).

Long Term Studies

Clomazone administered in the feed to mice for 24 months was associated with increased liver weights and enlargement of liver cells in male mice dosed with 1000 and 2000 ppm. Enlargement of the thymus was increased in 1000 and 2000 ppm females. Clomazone was not carcinogenic in mice. The NOEL was 500 ppm (73 mg/kg bw/day in males and 93 mg/kg bw/day in females).

In rats administered clomazone in the diet for 24 months, decreased body weight gain was observed in rats of both sexes at 2000 ppm. At 24 months, significantly increased liver weights were observed in females dosed at 2000 ppm. Clomazone was not carcinogenic in rats. The NOEL was 1000 ppm (approximately 44 mg/kg bw/day for males and 67 mg/kg bw/day for females).

Clomazone administration in the feed to dogs at 100, 500, 2500 and 7500 ppm (0.5 - 200 mg/kg/day) for 12 months produced dose-dependent anaemia in the early period of the study. The differences were most marked at 5000 ppm. Platelet numbers and serum cholesterol levels were increased in both sexes, platelets most markedly at 5000 ppm, with the largest differences observed for cholesterol at 2500 and 5000 ppm. Higher liver weights were observed in dogs administered 2500 and 5000 ppm. The NOEL was 500 ppm (14 mg/kg bw/day males and females).

Reproduction study

In rats administered clomazone at doses of 100, 1000, 2000 and 4000 ppm (10 - 400 mg/kg/day) in the diet for 2 generations, weight gains were significantly lower among parental females receiving 2000 or 4000 ppm during the pre-mating period. No significant differences were noted in progeny survival. Body weight was lower in pups on lactation days 0, 4, and 7 at 2000 ppm and on days 0, 7 and 21 at 4000 ppm. In the first generation, a treatment-related increase in liver/body weight ratio was observed in animals given 4000 ppm. Kidney/brain weight ratio was decreased and the liver/body weight ratio increased in males at 2000 and 4000 ppm of the second generation respectively, and an increase in the liver/body weight ratio was observed for females given 2000 and 4000 ppm. Ovary weight was decreased in the second generation progeny at 4000 ppm. There was no treatment-related effect on offspring development. The NOEL was 1000 ppm (M: 76 mg/kg bw/day; F: 86 mg/kg bw/day).

Developmental Studies

Pregnant rats administered clomazone at doses of 100, 300 and 600 mg/kg/day orally during the period of foetal organ development ate more at 300 mg/kg/day, and less at 600 mg/kg/day. Treatment-related decreased movement was observed at 600 mg/kg/day in most rats. At 600 mg/kg/day, female foetal body weights were reduced and higher incidences of abnormal thoracic vertebrae were noted. There was a slightly increased prevalence of delayed skeletal ossification observed among foetuses at 300 and 600 mg/kg/day. Abnormal distension of the ureter was the only minor visceral finding which occurred with a significant increase in animals given 600 mg/kg/day. Clomazone was not teratogenic in rats but there was evidence of treatment-related foetotoxcity at 300 and 600 mg/kg/day. The NOEL was 100 mg/kg/day.

In pregnant rabbits administered clomazone at doses of 30, 240 and 700 mg/kg/day orally, four rabbits died in the 700 mg/kg/day dose group. Two of these had multiple focal dark red areas of the stomach lining and rabbits were not eating or defecating prior to death. At 700 mg/kg/day, two rabbits exhibited awkward gait, four had red vaginal discharge and three of these four had abortions. Weight gain was low when dosed at 700 and 240 mg/kg/day. There were no differences in the number or percentage of litters or foetuses with malformations that could be considered treatment-related. clomazone was not teratogenic when administered orally in rabbits at doses of 700 mg/kg/day and less. The NOEL was 30 mg/kg/day.

Genotoxicity Studies

The results of *in vitro* and *in vivo* genotoxicity studies at the level of genes and chromosomes using bacteria (3 x AMES test using tester strains of *Salmonella typhimurium*), isolated mammalian cells (Chinese Hamster Ovary cells, CHO/HGPRT point mutation assay), a cytogenetic assay in rat bone marrow cells, and a Rat Hepatocyte Primary Culture/DNA Repair Test, were all negative.

PUBLIC HEALTH STANDARDS

Poisons Scheduling

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

The NDPSC recommended that formulations containing clomazone be placed in Schedule 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate warning statements and first-aid directions on the product label.

NOEL/ADI

The most sensitive species tested was the dog with a NOEL of 14 mg/kg bw/day in a 12 month study. In order to calculate an Acceptable Daily Intake (ADI) for humans, a safety factor is applied to the NOEL in the most sensitive species. The magnitude of the safety factor is selected to account for uncertainties in extrapolation from animal data to humans, variation within the human population, the quality of the experimental data, and the nature of the potential hazards. Using a safety factor of 100, an ADI of 0.1 mg/kg bw/day was established for clomazone.

RESIDUES ASSESSMENT

Extensive metabolism and residue data were supplied to allow the establishment of relevant MRLs in green beans, navy beans, cucurbits, potatoes, poppy seed and rice.

Metabolism Studies

Plant metabolism studies in soybeans, alfalfa and sweet potatoes were reviewed. When applied as a *pre-emergence* soil treatment to soybeans, the radioactive residues declined with plant growth with minimal residues detected in mature beans. Characterisation of the radioactive residue showed the levels of parent compound in foliage and beans were <0.001-0.002 mg/kg following *pre-emergence* treatment at 2.2 kg ai/ha (2.3× the maximum label rate for crops). Most of the radioactivity was present as very polar metabolites or bound to plant solids. Major metabolites identified were *o*-chlorobenzyl alcohol, *o*-chlorobenzoic acid as well as hydroxylated *o*-chlorobenzyl alcohols. None of the metabolites were present at levels > 0.01 mg/kg. Radioactive residues in sweet potato vines following *pre-emergence* soil treatment with ^{14}C-clomazone were slightly higher than in roots (tubers).

Minimal levels of radioactivity were detected in mature corn, oats, sugar beet or cabbages planted as rotational crops following application of ^{14}C-clomazone at 2.2 kg ai/ha some 10 months earlier. Characterisation of radioactivity in sugar beet tops and oat straw detected negligible levels of parent compound (0.001-0.002 mg/kg). Individual metabolites were present at levels <0.01 mg/kg.

Following foliar treatment of alfalfa plants with ^{14}C-clomazone at 280 g ai/ha (to simulate spray drift) the radioactive residues declined rapidly. Non-conjugated metabolites declined from 3.7 mg equiv./kg at day 0 to be <0.1 mg equiv./kg by 3 days post-application. This indicates clomazone is rapidly metabolised following foliar application with residues of parent compound <0.1 mg/kg by 3 days post-application.

Six studies were provided on the animal metabolism and toxicokinetics of clomazone in rats and one for lactating goats. Following oral administration to rats, clomazone is rapidly and extensively metabolised. The majority of the radioactive dose was excreted within the first 24 hours with >90% excreted at 7 days post-dose. No sex related differences in excretion patterns were observed. The metabolites formed were predominantly hydroxylated derivatives and those formed by oxidation and heterocyclic ring opening. The levels of radioactive residues detected in tissues were low with highest levels found in skin, hair, liver, lungs and heart. For lactating goats, the majority of the dose was excreted in urine and faeces with negligible residues in any tissue and only small amounts in milk.

Collectively, the submitted metabolism studies indicated that clomazone is rapidly metabolised by both plants and animals.

Residue Definition

Given the extensive metabolism of clomazone by both plants and animals, and that individual metabolites are present at levels <0.01 mg/kg, it is appropriate to make the parent compound the residue definition.

Analytical Methods

Detailed descriptions of analytical methods for crops and milk were provided. In crop samples were acid hydrolysed and the clomazone recovered by hexane extraction. The hexane extract wash washed with sodium bicarbonate with clean up on a Florisil column before gas chromatographic quantitation.

Residue Trials

Green (French) beans (480-960 g ai/ha)
The eight Australian residue trials on green beans using a *pre-emergence* application of clomazone were conducted at 0.25, 0.5, 0.75, 1 and 1.5× the maximum Australian rate (960 g ai/ha). In all the trials the residues in green beans at normal commercial harvest were less than the LOQ of 0.05 mg/kg. An MRL of *0.05 mg/kg is recommended for green beans.

Navy beans (240-480 g ai/ha)
A temporary MRL would allow use of *Command* on navy beans pending the results of a confirmatory residue trial. Navy beans are a minor crop and it is argued that the data provided from 3 Brazilian and USA 24 trials on the related crop soybeans (residues <LOQ) are sufficient to grant a temporary MRL. It is recommended that a temporary MRL of *0.05 mg/kg be set for navy beans with the provision that additional data be generated.

Cucurbits (480-960 g ai/ha)
The applicant has requested a group MRL for fruiting vegetable, cucurbits. The maximum label rate for clomazone on cucurbits is 960 g ai/ha. Seven Australian trials on pumpkins (0.25-1.5× the maximum label rate) and 3 on zucchini (0.5, 1, 1.5×). The results of USA trials on pumpkin (13 trials, 7 states, 1.15×), cucumber (15 trials, 7 states, 0.3-1.2×), summer squash (11 trials, 4 states, 0.3-1.2×) and winter squash (9 trials, 4 states, 1.2×) were also presented. In all trials, the residues of clomazone were less than the LOQ of 0.05 mg/kg. On the basis of the data, a MRL of *0.05 mg/kg is recommended for cucurbits.

Poppy seed (120-480 g ai/ha)
The results of 9 Australian trials of clomazone applied 3-4 weeks after planting (2-4 leaf stage) showed no residues (<0.05 mg/kg) when treated at 0.5-2× the maximum label rate of 480 g ai/ha. In Australia, poppies (*Papaver somniferum*) are grown primarily for the production of pharmaceutical alkaloids from the seed capsules. The seed, once separated, is sold as a by-product for culinary and baking purposes. A MRL of *0.05 mg/kg is recommended for poppy seed.

Potatoes (240-480 g ai/ha)
Eight Australian residue trials for clomazone on potatoes were conducted over a period of 2 seasons and in 2 states (Tasmania and Queensland). The application rates (*pre-emergence*) used were 0.5-2× the maximum label rate of 480 g ai/ha. Residues of clomazone in trials,

measured as parent compound, were all less than the LOQ for the analytical method of 0.05 mg/kg. An MRL of *0.05 mg/kg is recommended for potato.

Rice (180-300 g ai/ha)
Two residue trials on rice grain were conducted at two sites in Australia (Vic, NSW) at rates ranging from 0.6 to 1.6× the label rate. Residues in the grain were all less than the LOD for the analytical technique (0.01 mg/kg). Additional results for residues of clomazone in rice grain from 51 trials conducted in 5 states of the USA with application rates 2.2× the Australian rate showed the residues were all <0.01 mg/kg. A MRL of *0.01 mg/kg is recommended for rice.

Animal Feed Commodities

Rice is an irrigated crop with high input costs (seed, fertiliser, and water) such that a totally failed crop is an unusual occurrence. Potential grazing of rice crops is not expected until after flowering and 100-130 days after sowing (usual time for crop assessment). Residues of clomazone in plants collected 52-122 days post-treatment (before and during flowering) did not have any detectable residues. No residues of clomazone were detected in rice forage or straw (<0.01 mg/kg). To allow the grazing of failed rice crops it is recommended the MRL for rice forage, straw and fodder be set at *0.01 mg/kg. The following WHP is recommended in relation to the animal feed MRLs for rice:
DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 3 MONTHS AFTER APPLICATION

The magnitude of residues on foliage was not addressed for other crops (green beans, navy beans, cucurbits, poppies or potatoes). However, the use of clomazone as a pre-emergence or early post-emergence herbicide gives ample time for residues to be reduced by metabolism and diluted by plant growth resulting in negligible residues at harvest. This is confirmed by the results of the plant metabolism studies. The following WHP is therefore appropriate for these crops:
DO NOT GRAZE OR CUT FOR STOCK FOOD UNTIL AFTER HARVEST

Animal MRLs

Although the applicant has requested animal feed MRLs be set for rice straw, forage and fodder, the maximum residues expected in these commodities are <LOD (0.01 mg/kg) and unlikely to result in significant residues in the tissues of animals. Lactating goats dosed orally with radiolabelled clomazone at 0.5 or 5 mg/kg in the feed for 7 days had negligible residues in tissues and milk. The maximum total radioactive residue in milk was 0.115 and 2.03 mg equiv/kg for the 0.5 and 5 mg/kg feeding groups respectively. Assuming the residues scale with dose and are similar for lactating goats and cattle, the maximum clomazone residue in milk resulting from feeding rice forage, straw or fodder to dairy cattle would be 2.03 mg equiv/kg/(5 mg/kg/0.01 mg/kg) = 2.03/500 = 0.004 mg equiv/kg. This is much less than the limit of analytical determination for milk (0.02 mg/kg). In the case of tissues, the only tissues for which low levels of radioactivity were detected 24 hours after the last dose were kidney and liver with residues in liver (0.045 mg equiv/kg) greater than in kidney (0.016 mg equiv/kg). Scaling these residues for dose shows the anticipated residues in tissues from feeding rice forage, straw and fodder will be less than 0.045/500 = 0.00009 mg equiv/kg. It should be noted that the anticipated residues of clomazone in milk and animal tissues would be much lower than those estimated above from total radioactive residues due to the extensive

metabolism of clomazone by animals. From the above discussion it is apparent that it is not necessary to set animal MRLs to cover feeding of clomazone treated crops.

Crop Rotation

When a herbicide is persistent in the soil there is a possibility that sufficient chemical remains in the soil to be taken up by a subsequent crop, leading to phytotoxicity and/or residues in that crop. Residues of clomazone were detected in soil some 10-12 months after application. However, plants rapidly metabolise clomazone and although residues were detected in soil, no residues were detected in crops grown on treated plots. The applicant has recommended minimum re-cropping intervals to avoid potential phytotoxic effects on certain rotational crops. The re-cropping intervals are supported by rotational crop residue trials.

Spray Drift

Clomazone is an inhibitor of photosynthesis. As its action is by inhibition of pigment synthesis, any spray drift will be easily detected as chlorosis of the leaves. In trials designed to simulate drift or volatility, various crops (in early stages of growth) were sprayed directly with clomazone at 250 g ai/ha. Residues of clomazone were all $\leq$0.02 mg/kg at harvest, some 38-112 days after treatment. Further, after foliar application of ^{14}C-clomazone at 280 g ai/ha to alfalfa, non-conjugated radioactive residues (including parent clomazone) declined from 3.7 mg equiv/kg at day 0 to be <0.1 mg equiv/kg by 3 days. This study demonstrates that clomazone is rapidly metabolised by plants with a half-life less than 15 hours. It is concluded that the risk of residue detection in crops from spray drift is small.

Maximum Daily Intake Calculations

The risk to human health from the use of clomazone is considered to be small. The chronic dietary risk is estimated by the theoretical daily maximum intake (TMDI) calculation. The TMDI calculation shows that the intake is equivalent to 0.14% of the ADI for clomazone (Appendix II). As it is widely recognised this calculation is a gross overestimate of actual dietary intake, we conclude that the chronic dietary exposure is small and the risk is acceptable.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Trade

The trade risk arising from the use of clomazone is estimated to be small. Clomazone is registered on various crops in Brazil, China, Indonesia, South Korea, Latin America, NZ, Philippines,Thailand and USA. Of these only Brazil, Philippines and the USA decided to establish MRLs, as residues at harvest are <LOD. The table below summarises the registrations and MRLs set for clomazone internationally.

Country	Crop	MRL (mg/kg)
Brazil	Soybeans	0.05
	Rice	NE
China	Soybeans	NE
Indonesia	Soybeans	NE
	Rice	NE
South Korea	Soybeans	NE
Latin America	Rice	NE
New Zealand	Pumpkins	NE
	Buttercup squash	NE
	Potatoes	NE
	Dwarf green beans	NE
Philippines	Rice	0.001 (LOD)
Thailand	Soybeans	NE
USA	Beans, snap	0.05
	Cabbage	0.1
	Cottonseed	0.05
	Cucumber	0.1
	Peas (succulent)	0.05
	Peppers	0.05
	Pumpkin	0.1
	Soybeans	0.05
	Squash, summer	0.1
	Squash, winter	0.1
	Sweet potato	0.05
	Watermelons	T0.1 (expires 30 May 1999)

NE = no MRL established

As no residues are expected in any produce, there is not expected to be any risk to Australian trade.

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Introduction

The active ingredient clomazone has been determined to be a hazardous substance by FMC International AG according to the National Occupational Health and Safety Commission (NOHSC) *Approved Criteria for Classifying Hazardous Substances.*

Clomazone is not classified as dangerous goods under the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG Code). *Command* is hazardous according to NOHSC Approved Criteria.

Both active ingredient and product will be formulated overseas and imported only as the finished commercially packaged product. *Command* Herbicide will be available in 1, 5 and 10 L containers.

Transport, storage and retailing

Sea transport employees, dockworkers, road transport workers and store persons will handle the packaged product only. Exposure of these workers will only occur if packaging is breached.

Advice on safe handling and storage of *Command* is provided on the label and Material Safety Data Sheet (MSDS).

Use

Command is proposed for the control of pre-emergence broadleaf weeds in cucurbits, green beans, navy beans, potatoes, rice and tobacco. It will also be used as an early post-emergence herbicide in poppies and rice.

Command will be applied to all crops except rice by ground spray. The application of *Command* into rice bays will be made using the Soluble Chemical Water Injection In Rice Technique (or SCWIIRT). This technique involves the application of chemicals from a mounted tank on a specially converted motorbike, tractor or helicopter. *Command* will be mixed with water and applied at a rate of 0.375-0.625 L/ha for rice and 0.25-2L product/ha for other crops. The spray volume recommended for all crops except rice is 150-400 L/ha resulting in a maximum product concentration of 1.33% (0.64% clomazone). For rice, the volume recommended is 5 L/ha resulting in a maximum product concentration of 12.5% (6% clomazone).

Exposure to users will be predominantly through the dermal route: during mixing and loading and when using the spray because of spray mist. Eye exposure may occur during mixing and loading. Due to the high proportion of hydrocarbon liquids in *Command*, inhalation exposure to the product vapour should be avoided during mixing and loading.

The main hazards associated with *Command* are slight to moderate eye irritation and slight skin irritation. There is concern of prolonged or repeat exposure to clomazone by the dermal route. The dermal absorption of clomazone is not known. A default value of 10% absorption was used in the risk assessment.

No relevant exposure studies were available. Based on the UK Predictive Operator Exposure Model (UK POEM), estimates of exposure and risk for workers involved in ground boom application were calculated. The risk assessment indicated that *Command* is safe for use at the proposed rates, provided overalls and gloves are worn during mixing/loading operations and ground application.

Entry into treated areas

Command is applied to bare soil or to seedlings. The applicant has indicated that workers would only re-enter 1-2 weeks after application to determine the effectiveness of the herbicide application. A re-entry period is not required for *Command.*

Recommendations for safe use - all workers

Users

Users should follow the instructions and Safety Directions on the product label. During mixing/loading operations with *Command*, workers should wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length nitrile gloves and face shield or goggles.
During ground applications with *Command*, workers should wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length nitrile gloves.

Personal Protective Equipment

The personal protective equipment worn by all workers should meet the relevant *Standards Australia* standards specified below:

Gloves - AS 2161-1978, Industrial Safety Gloves and Mittens (Excluding Electrical and Medical Gloves)
Goggles - AS 1337-1992, Eye Protection for Industrial Applications
Overalls and aprons - AS 3765-1990, Clothing for protection against hazardous chemicals

MSDS

The MSDS for *Command* was provided by FMC International AG as part of the submission for registration.

Manufacturers and importers should produce an MSDS for all hazardous products, including *Command.* The MSDS should contain information relevant to Australian workers, as outlined in NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets.* Employers should obtain the MSDS from the supplier and ensure that their employees have ready access to it.

Conclusions

NOHSC supports the registration of *Command* (480 g/L clomazone and 450 g/L hydrocarbon liquid) for pre-emergence use on cucurbits, potatoes, green beans, navy beans, tobacco, rice and post-emergence use on poppies and rice.

ENVIRONMENTAL ASSESSMENT

Environmental Fate

Abiotic Degradation

Hydrolysis of clomazone in the laboratory was shown to be very slow. With hydrolysis testing being carried out in excess of 30 days at 25°C, hydrolysis rates were <1% (pH 4.65), <2% (pH 7), and <10% (pH 9.25). Similarly, the chemical can only be considered slightly degradable from laboratory photolysis testing. Photolysis using natural and simulated light was conducted in both aqueous and soil systems. In natural sunlight, a half-life of 67.5-87.7 days in aqueous conditions, and 996 days in soil was found. However, acetone sensitisation increased photolysis greatly in aqueous solution (half-lives ranged from 0.77-11.9 days).

Degradation in Soil and Sediment

Aerobic soils

Four company laboratory studies on three aerobic soils provided a range of half-lives from 28 days for sandy loams to 137 days for a silt loam. The main results lie in the range of 28-56 days. It is not possible to say whether %Organic Matter (OM) has an influence on degradation; one study showed shorter half lives in soils with higher %OM and higher sand content, while another study showed shorter half lives with higher sand content, but the %OM were similar. The laboratory studies did not demonstrate any dependence on soil pH for degradation. Mineralisation through both the carbonyl and aromatic rings was shown to be relatively quick, although the carbonyl ring seemed to initially mineralise faster than the aromatic ring. One study showed 48% CO_2 evolution after nine months when labelled in the aromatic ring, while 77% CO_2 evolved after nine months when labelled in the carbonyl ring. Rapid mineralisation through the carbonyl ring was replicated in another study where 62.5% CO_2 evolved after 90 days. One test indicated that mineralisation was much slower. However, the duration was less than one month.

A literature report provides evidence of biological dependence on clomazone mineralisation. Temperature dependence was demonstrated, with an increase in volatilisation and degradation rates along with increasing temperatures only up to 25°C. Increases of temperature above this level were not accompanied by an increase in degradation rate, leading to the hypothesis that microbes responsible for degradation of clomazone were not more active at higher temperatures. A non first-order reaction calculated the half-life in aerobic soils to be 154 days at 35°C. In this laboratory test, the results were inconclusive with respect to degradation dependence on soil moisture content. No demonstration of moisture dependence on volatilisation was demonstrated. This is discussed in more detail below.

A single metabolite was formed containing aromatic ring carbons and representing up to 4% of applied ^{14}C prior to dissipation. In contrast, no metabolite peak was detected where radioactivity was on the carbonyl carbon. Absence of this in the metabolite in addition to more rapid initial mineralisation of the carbonyl carbon suggests that clomazone metabolism in this soil initially involved cleavage of the isoxazolidinone ring and subsequent loss of the carbonyl carbon as CO_2. It was also concluded that the heterocyclic ring, while it is metabolised and incorporated into soil bound residues, is not rapidly mineralised to carbon dioxide after 28 days.

Anaerobic soils

Two studies in a total of two soils were done in conjunction with aerobic tests, and both confirmed that the parent compound degrades faster under anaerobic conditions. This was the case when labelling was in both the carbonyl and aromatic ring. The major metabolite, FMC 65317, is produced as a result of reduction of the N-O bond. In both tests, several other minor metabolites were detected, but none exceeded 0.7% of total radioactivity. In both studies, little CO_2 was produced after conditions were made anaerobic.

Aquatic systems

One test in aerobic aquatic conditions indicated a greater movement of radioactivity from water to sediment where the sediment had a higher %OM (7% in the low OM sediment and 12% in the high OM sediment after 100 days). A maximum of 10.6% CO_2 was found in ethanolamine traps. However, a second study conducted in an aerobic aquatic system over 30 days showed around 48% radioactivity being extracted from the sediment at the end of the test despite the sediment only having 1% OM. This test suggests relatively quick movement from water to sediment. Testing under aerobic aquatic conditions again saw FMC 65317 being the major metabolite at levels around a maximum of 11%, indicating a degradation route similar to the anaerobic route. Half lives for dissipation from the whole system (sediments and water) were calculated to be between 71.5-78.4 days, while dissipation from the water layer had a half life calculated between 21.5 and 23.5 days. Volatiles reached a maximum of 3.1% after 30 days. The shortness of this study means the results should be treated with some caution, although they are in the range determined in aerobic soil testing.

Much more major metabolite was formed under aquatic anaerobic conditions (70%). As with soils, the anaerobic conditions resulted in much faster dissipation, although not as dramatic as soils, with a half-life between 22.7-23.8 days for the whole system and 15.5-16.4 days for the water layer. Low levels of radioactivity were found in volatility traps indicating clomazone is not extensively mineralised or volatilised under these conditions.

Mobility

Adsorption/desorption

Company testing showed clomazone to exhibit low to medium mobility in a range of soils, with Koc's of 130-608. It appeared from this study that once adsorbed, the chemical was not readily desorbed. Two literature reports provide information on adsorption/desorption. Testing on 19 soils, with pH ranging from 4.2-8.3 and %Organic Carbon (OC) ranging from 0.3-3.4 resulted in Koc values ranging from 60-573. However, disregarding the highest value of 573 (which was more than twice the next highest value), the mean Koc was 150 (with a range of 60-262). These results indicate high to medium mobility in soils according to the McCall scale. There appeared to be some positive correlation between %OC and adsorption although the r^2 value (0.62) for this regression indicates %OC is not the sole factor determining adsorption. A second paper obtained by Environment Australia on a single soil gave a Koc of 94. It indicated equilibrium sorption is not temperature dependent, but the maximum sorption occurs faster with increasing temperature. This paper also determined that desorption increases with increasing time and temperature. No effect of soil moisture content on sorption was demonstrated. It is possible this minimal effect of soil moisture and clomazone desorption may be the result of the water solubility and volatile properties of clomazone.

TLC/Column studies

Two TLC/column studies were provided by the company addressing soil mobility, one on fresh clomazone and one on aged residues. The former study on 4 soils showed low to intermediate mobility based on Hellings system (no Koc values calculated). Nonetheless, in one of the soils over 37% of the parent compound was found in eluate (30 cm depth), and 18.6% parent remained in the 25-30 cm layer showing movement of the compound through the soil layer was significant. The study on 60 day aged residues demonstrated that these have lower mobility than fresh clomazone, although significant amounts were still found down to the 13-18 cm soil layer.

Modelling

PESTANS modelling provided by the company predicted low soil mobility in high sand loamy sand (<30 cm) based on field study data. Good correlation with field results saw the model extended to predict mobility in four other soil types (sand, sandy loam, silt loam and clay loam). Using a worst case scenario, the model predicted movement between 30-40 cm for these soils. Groundwater Ubiquity Scores (GUS) generated by Environment Australia contrast to the PESTANS predictions and class clomazone as ranging from a non-leacher to a leacher. Scores ranged from 1.5 (non leacher, Koc=608, half-life=16 days) to 3.8 (leacher, Koc=139, half-life=117 days).

Field Dissipation

Mobility

Two company studies were presented for this section. While the major metabolite was tested for in one study, it was not detected at any sampling point. No movement of clomazone beyond 30 cm was observed, which contrasted to the laboratory mobility studies. The half life was determined to be 10 days. A second field study on four soils confirmed the result of no movement past 30 cm depth. However, sampling periods were a long time after initial application (271-320 days), by which time, most of the parent compound would have been expected to dissipate. Additionally, the soils used in this second study all had higher clay and OM contents, and lower sand contents than that in the first study.

Persistence

Four company reports were provided in this section, although two were disregarded for the purpose of assessment. Environment Australia located a further four literature papers outlined in this section.

Both company data and literature studies showed an effect of incorporation on dissipation of clomazone, with the general result showing increased dissipation with pre-emergence (PRE) treatments compared with pre-plant incorporated (PPI) treatments. In one company study, marginal movement to 15-30 cm layer was demonstrated with no chemical detected 1 year after application in this layer (except in a sandy loam where 0.02 ppm was detected, which was below the limit of quantitation). Field half lives were determined for PPI and PRE treatments, and were 19-36 days and 16-24 days respectively, indicating faster dissipation with the PRE regime. While faster dissipation in PRE plots was shown in the literature, the results were less conclusive on occasions. In one instance, PRE treatments clearly gave faster dissipation rates (69 days compared to 117 days for the PPI treatment), but at another time, there was no difference between the two treatments, with a half life of 59 days each).

Effects of tillage on dissipation were investigated in two of the literature reports, and gave conflicting results. Quick dissipation was observed with both conventional and reduced tillage plots, with half-lives ranging from 6-34 days, although the effects of tillage were unclear. In one season in the second study, faster dissipation was observed in the first in reduced tillage plots (52 days compared with 58 days in the conventional tillage plot), but the opposite occurred in another season with half-lives of 83 days and 91 days in the conventional and reduced tillage plots respectively. Various reasons are provided by the authors including differences in soil moisture, and air temperatures affecting volatilisation in the second year which may have influenced results. A more detailed discussion on volatilisation is found below.

Both company and literature reports considered the residual effects on crops planted in the following year to clomazone applications. Bioassays were used to detect injury levels. Company data showed no correlation between injury levels in these crops and residue levels in the soil up to 0.4 ppm. It also showed no significant differences between injury levels from PPI and PRE treatments after 1 year. These results indicate only small amounts of clomazone are necessary to damage developing tissue, and injury being random in nature, may not be a function of residues in the soil, but more a function of volatilisation. The literature differs somewhat in these findings. One paper showed a significant difference in injury levels to crops planted a year later between application methods, with PPI treatments giving higher injury levels than PRE treatments, suggesting that more parent was still available in the former system due to slower dissipation.

Using bioassays, two literature reports demonstrated rapid dissipation from fields. One report indicated less herbicide availability in soils with higher clay and OM content, which is likely through increased adsorption. In one year, little dissipation was observed over 5 months, and was attributed to a lack of soil moisture. However, other studies indicate soil moisture is not a limiting factor in clomazone dissipation. Half-lives from this study ranged from 22-58 days. A second literature report also showed rapid dissipation from two soils with half-lives between 32.9 and 37.4 days. Faster dissipation was observed from the field with lower %OM, which is in agreement with other results.

Aquatic field dissipation

When applied to dry rice paddies, no movement below 15 cm in soil was detected. Rapid dissipation was initially detected from soil, with a half life of around 1-3 weeks (assuming first order kinetics). Slight desorption was observed when paddies were flooded some 28 days later, but never more that 7 ppb was found in the water layer. The half life from the sediments was calculated at 23-51 days, while for water, it was 12-13 days.

An Australian study where application was directly to flooded bays showed a degree of application rate dependence on dissipation rate with half lives of 3-5 days and 5-10 days at application rates of 180 and 360 g ai/ha respectively. In this study there was no measurement of movement from the water column to sediments, although anaerobic aquatic tests suggest this could be slow. Rapid dissipation from water was confirmed with a second test in flooded rice bays showing half-lives of less than 6 days.

Volatilisation

An internal document from the company outlining a study comparing volatility from soil and water was provided. This study showed significantly lower volatilisation from water than soil. Soil measurements indicate in the order of 3.7% of applied chemical will leave the field in the first day, with less than 1% per day volatilising after that.

Environment Australia located literature papers dealing with volatilisation in a response to a number of incidents of off target movement in Tasmania following application of clomazone to poppies under permit. Calculations made by Environment Australia of the Henry's law constant ($4.13X10^{-8}$ atm.m^3/mol) are suggestive of low volatility from water. A paper provided by the company has shown volatilisation from soil is greater than that for water (3.7% during the first day, easing to less than 1% thereafter). No data on volatilisation from plants has been provided.

Reports from the literature considered the effects of a number of variables on volatilisation including temperature, soil moisture, soil incorporation, tillage and application rates. While these factors were shown to largely influence volatilisation, it was also apparent that damage of the same magnitude to susceptible plants may occur regardless of the quantity of clomazone moving off site. This is because developing tissue is so susceptible, that movement of a little or a lot of clomazone will cause the same level of damage.

Temperature was shown to influence volatilisation. The fasted recovery of chlorophyll in bioindicator species was at the highest temperature, with the slowest in the lowest temperature. There was no significant difference between the level of chlorophyll at all temperatures during the first three weeks of the experiment, indicating that even though volatilisation was higher in the higher temperature, sufficient volatilisation was occurring from the lower temperatures to cause the same adverse effect. Plants seemed to recover faster in the higher temperature test because clomazone volatilised faster leaving less available as the experiment progressed.

Soil moisture content was demonstrated to influence volatilisation. Air dried soil unexpectedly saw volatilisation being sustained for 20-30 days. The air dried soil was a silt clay loam with 2% moisture content, and even this may have been sufficient to enable the water surface in the soil to exceed a monomolecular layer (see below). Chlorophyll contents appeared to recover faster with lower soil moisture content, and maximum inhibition occurred in the first two weeks of the experiment at all moisture levels. This result was obtained by use of bioassay and again demonstrates that the same level of injury can occur with different levels of clomazone.

Some papers presented in this assessment have indicated no effect of soil moisture content on dissipation (not specifically volatilisation). One demonstrated a lack of influence of soil moisture stating that in the study, the range of soil water content may not have been large enough to yield differences in volatilisation because the thickness of water surfaces within the soil at the lowest moisture content probably exceeded a monomolecular layer. This may result in vapour density of the compound in the soil air being greatly increased, so additional soil water does not influence the tendency of the compound to leave its sorbed site.

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Testing was also conducted on the effects of application rate, carrier and carrier volume on volatilisation. Using bioassays on sunflowers and wheat, it was shown that higher application rates led to increased off site movement, with the highest rate tested of 1.4 kg ai/ha moving the furthest distance of 32 m. Carrier volume did not appear to be a factor in the distance of movement. Where clomazone was impregnated onto dry fertiliser, results consistently showed the least off site movement.

Incorporation could be expected to influence volatilisation. One bioassay test gave inconclusive results of incorporation on volatilisation. However, in another test, PRE treatments consistently exhibited more chlorosis, that is, increased effects of volatilisation than PPI treatments. This experiment indicated the effects of volatilisation were starting to diminish after 24 days.

Tillage was shown to have a direct influence on volatilisation with increased tillage resulting in decreased off site movement. This is possibly a result of increased surface area for volatilisation or higher soil moisture resulting in greater volatilisation.

Australian observations indicate volatilisation can be significant, with plants a distance of up to 150 m being affected. However, careful management and strict application conditions enforced during 1998 permit applications seem to have largely limited off target movement through drift and volatilisation.

Accumulation/Bioaccumulation

Accumulation of clomazone is not expected as a result of it only being applied once per annum, and the relatively short field half life of the chemical. Testing for bioaccumulation resulted in a maximum bioaccumulation factor of 75X in fish viscera indicating the chemical can be considered as only slightly bioaccumulating. Within 2 weeks, 99% depuration had been observed.

Environmental Toxicity

Avian Toxicity

Acute and dietary studies were conducted on two bird species and clomazone was demonstrated to be practically non-toxic to birds.

Aquatic Toxicity

Clomazone can be regarded as slightly toxic to fish (3 species tested for acute exposure, and 1 species for chronic), and moderately to highly toxic to aquatic invertebrates (4 acute, 1 chronic). Testing on aquatic plants is very limited, with only one full algal test conducted, and a paper provided on clomazone effects to four aquatic marine weed species. This latter test did not determine inhibition concentrations so it is of limited value in assessing toxicity. It did observe 50-60% chlorosis at 24 mg/L (the highest concentration tested). Because of the mode of action of clomazone, toxicity to aquatic plants is of major concern. Further testing on algae is highly desirable, and testing on duckweed (*Lemna gibba*) is considered essential to be able to more accurately predict the potential hazard of this chemical to aquatic plants.

However, this is not available so Environment Australia has applied an assessment factor to the algae result in order to predict the environmental hazard to aquatic plants.

Non-target invertebrates
Clomazone demonstrated only slight toxicity to earthworms and low toxicity to mammals when tested for oral and dermal toxicity.

Non-target plants
Clomazone has been demonstrated to injure non target plants through off target movement as a result of drift or volatilisation. Injury levels differ among species. Some plants only exhibit chlorotic leaves as symptoms, while in others, necrosis is observed. It does appear that damage is not long lived, and plants will not die from non-target exposure through lift-off. However, damage can persist, still being observed in some sensitive species at 30 days after exposure. Phytotoxicity testing has shown a high variation in tolerance levels of different plants to clomazone. This variability in tolerance is observed in both monocotyledons and dicotyledons. The results suggest that in the event of off target movement, patterns of damage may be difficult to establish as some plants may not be affected at all while others may be quite susceptible even at very low concentrations.

Metabolite
Tests provided for the main metabolite, FMC 65317, saw rainbow trout, *Daphnia*, and *Selanastrum capricornutum* exposed to 20, 5 and 3 mg/L respectively. No firm conclusions can be drawn from these studies, as exposure for each organism was to only one concentration. However, it can be claimed that at worst, this metabolite is only slightly toxic to fish and moderately toxic to daphnia and algae as no toxicity was demonstrated at the tested levels.

Prediction Of Environmental Hazard

Cucurbits, Green beans Tobacco, Potatoes, Navy bean and Poppies.
All applications in the submission are for pre-emergence to bare ground with the exception of poppies, where application can either be pre or post-emergence up to the 8-leaf stage (expected to be 5 to 6 weeks after emergence).

The application of this chemical to the above crops is by use of ground boom sprayers fitted with flat fan nozzles using low pressure (280 kPa) and high volumes (150-400 L/ha) and the lowest possible boom height. During the 1998 permit, the company provided Turbo Teejet Nozzles for poppies, which are designed to allow larger droplets thereby minimising drift, while maintaining uniformity of distribution. The label prohibits application by aircraft.

Terrestrial Hazard
Clomazone is practically non-toxic to birds and mammals. Terrestrial organisms will not undergo significant exposure to clomazone, as it will be applied no more than once a year.

Residues in the order of 116 mg/kg have been predicted through modelling in both leaf matter and small insects exposed to an effective application of 960 g ai/ha. This means, a 200 g insectivorous bird with the sensitivity of a bobwhite quail (LD50>5620 mg/kg) would need to consume in excess of 10 kg of insects exposed to clomazone application confirming a low expected hazard to birds.

With application at the maximum rate of 960 g ai/ha, a concentration in the top 10 cm soil (assuming a density of 1.2 g/cm) of 0.8 ppm is predicted. This is several orders of magnitude lower than the LC50 of 156 ppm and two orders of magnitude lower than the NOEC of 41 ppm to earthworms.

The potential hazard to terrestrial organisms is considered to be low.

Aquatic organisms

Clomazone can reach the aquatic compartment through either drift or run off mechanisms. With ground application methods there is little possibility of direct overspray and significant drift, however, clomazone is known to move off site through volatilisation.

Drift

As a worst case, it is pertinent to conduct an environmental hazard to the aquatic compartment based on 10% drift. However, data indicates that spray drift from applications of herbicides using conventional rigs, would be about 1% 5 m downwind so both these rates of drift are considered.

The highest proposed rate of clomazone in Australia is 960 g ai/ha in cucurbits, tobacco and green beans. A worst case of 10% and more realistic estimate of 1% drift from a 1 ha field to an adjacent 1 ha pond with a depth of 15 cm is assumed and result in an estimated environmental concentration (EEC) of 0.064 and 0.006 ppm respectively.

Based on the most sensitive aquatic species from fish, invertebrates and aquatic plants (subject to an assessment factor of 100 due to the lack of testing in this area), Q values of <0.01, 0.11 and 1.73 respectively were obtained in the 10% drift scenario, and <0.01, 0.01 and 0.17 respectively for the 1% drift scenario.

This indicates that in the event of 10% drift, an unacceptable hazard exists for aquatic plants. A potential hazard exists for aquatic invertebrates, although this is only marginal, and may be readily mitigated.

However, the nature of application, with use of large droplet sizes and boom settings close to the surface, and with the use of Turbo Teejet Nozzles in poppies, designed to further reduce drift, Environment Australia is satisfied that the assumption of 1% drift, 5 metres down wind should be realistic, provided the strict conditions of spraying as outlined on the label are adhered to. In this case, only a marginal hazard is predicted for aquatic plants. However, with an assessment factor of 100 being used to estimate an EC50 for these organisms, and a further factor of 10 being built in to the Q value (giving an overall factor of 1000), the assumed toxicity to aquatic plants can be described as very conservative, and the strong stewardship proposed for this product should mitigate this risk.

Volatilisation

Internal testing provided by the company has shown in the order of 3.7% applied clomazone can volatilise from soil during the first day following application, with less than 1% per day thereafter. For the purposes of this hazard assessment, worst case volatilisation of 5% in the first day will be assumed.

Using the highest proposed application rate, and a worst case of 5% volatilisation from a 1 ha field to an adjacent 1 ha pond with a depth of 15 cm, Q values of <0.01, 0.06 and 0.87 were derived for fish, invertebrates and aquatic plants (subject to an assessment factor of 100) respectively.

These outcomes predict that a low environmental hazard exists to fish and aquatic invertebrates. The case with aquatic plants is a little more difficult to consider in the absence of suitable test results. There seems little doubt that contamination of the aquatic system will result in chlorosis to aquatic plants based on tests. However, testing showed a pattern of delayed injury, and suggested plants do recover. Because there will only be one application per annum, it may be stated that the short term effects will not pose a significant environmental hazard.

While we can not make this claim with certainty, the predicted hazard above is not unmanageable (Q=0.87). The highest level of volatilisation may be expected within the first day of application. Previous field permits have shown that strong product stewardship can result in low incidences (0.5%) of off target movement. Additionally, it is very unlikely all the material volatilised will deposit in the one water body (see also discussion on the assessment factor on the previous page).

Nonetheless, without these additional data, a hazard from clomazone to aquatic plant communities can not be ruled out. One potential mechanism for reducing any potential hazard will be to use suitable buffer zones. This issue is also relevant to desirable vegetation and is discussed further below.

Desirable vegetation

As with aquatic plants, there is little doubt that off target movement of the chemical from fields will lead to non-target plants being exposed to clomazone. Bioassay work has shown damage to developing tissue is from even very small amounts of clomazone. It is also apparent from field work that injury may result during the first two weeks following application regardless of planting techniques designed to limit volatilisation.

It is Environment Australia's experience that volatilisation from plant surfaces can be significantly higher than for soil and may be an issue when the chemical is applied post emergent to poppy crops. The company has advised that, even at the 8-leaf stage for poppies, the leaves are not elongated, so biomass surface area is still relatively low. While weed growth may be more established, it is commercially better if spraying is conducted earlier rather than later for efficacy of the product, so generally, spraying will occur prior to the 8-leaf stage. It is the company's field experience that off target movement can be effectively controlled through good grower education and stewardship.

An internal experiment has shown significantly less volatilisation of clomazone from water than soil. Testing on non-target crop species showed these to be susceptible, and Australian observations showed chlorotic effects on plants such as chestnut trees and rose bushes, with no particular pattern of injury suggesting it was a result of volatilisation and not direct drift. It was apparent from testing and observational work that affected plants did not die, although the affected part of the plant may have resulted in necrotic tissue forming. However, similar to comments relating to aquatic plants, we are not aware of sensitivities of Australian native terrestrial plants to clomazone.

Buffer zones and other measures to control off target movement.
Suitable buffer zones may be an effective tool in reducing injury from clomazone off target movement. Australian observations application to poppies under permit in 1997 and 1998 saw off target movement as far as 800 m from the point of application. Damage was generally attributed to direct drift, but on occasions volatilisation could not be discounted due to the position of damaged plants.

Labelling for products used in the United States prescribe a buffer zone of 1500 feet (500 m) from desirable plants when applying *pre-emergence*. Based on the evidence seen in Australia, this distance for a buffer zone would not be excessive, although it should be noted that rates of use in the United States can be significantly higher than Australia, with a maximum label rate of 1400 g ai/ha compared to 960 g ai/ha in Australia.

Wind speed at the time of application will be an important factor in controlling direct drift. The draft label currently recommends application only when the wind speed is less than 12 km/h. While it may be appropriate to reduce this further, it is not advisable to apply when there is the possibility of inversion layers forming, which is likely at wind speeds less than 2-3 km/h, although this phenomenon would not be expected to apply with tractor drawn boom spray equipment. Therefore, the window of opportunity of application will be very low if wind speeds at the time of application are restricted much lower than 12 km/h and greater than 3 km/h. As such, the 12 km/h or less wind speed is considered acceptable on the label.

Other factors resulting in lower volatilisation found from the literature include incorporation of the chemical in the soil at the time of application, increasing tillage, and lowering application rate. Currently, all applications with the exception of rice is proposed to be surface applied. Environment Australia suggested the company should consider the possibility of altering application to be pre-plant incorporated where possible. Additionally, the lowest possible rates of application should be used, and fields should be tilled.

The company has commented that the use of micro-encapsulation formulations does not provide a total solution, and strong stewardship is still required. In Australia, the ME formulation has proved inferior in terms of efficacy to the EC formulation with respect to poppies. Impregnation of clomazone onto dry fertiliser is not seen as a viable option as the foliar use pattern in poppies is not addressed. The company also claims that the adoption of the clomazone impregnated fertiliser granule for the soil applied market would be restrictive due to the granule needing to be incorporated or watered in, and as such, needing an increase in the active rate to achieve the same level of control.

Rice
Rice is a crop where application using helicopters may occur. In this crop, the SCWIIRT system will be used with either with motorbikes or helicopters with application very close to

the surface, thus minimising drift potential. The maximum application rate in rice is proposed to be 300 g ai/ha.

Terrestrial Hazard
Clomazone is practically non-toxic to birds and mammals, and with application once per annum, directly to water, terrestrial organisms will not undergo significant exposure.

Aquatic studies indicated movement of between 25-50% of radioactivity from the water to the sediment. Assuming 50% of the applied compound initially moves to the sediment, a concentration of 0.15 ppm could be expected to be found in the top 10 cm. After 6 months when the fields are drained, even with the maximum half-life of 79 days, the concentration in the top 10 cm of soil will not be expected to exceed 0.06 ppm. This supports a conclusion of low environmental risk to terrestrial organisms with respect to parent compound.

Few insects would be expected to be found in the soil at the point of draining. One form of exposure may be to birds drinking the bay water. A 200 g bird with the sensitivity of bobwhite quail (LD50 >2510 mg/kg bw) would need to drink well over 1000 L of water which indicates a low hazard.

Aquatic organisms
The half life in water was shown from Australian rice studies to be less than 2 weeks. Assuming 7 cm water depth in the rice bays, maximum application of 360 g/ha results in a concentration in the rice bay water of around 500 µg/L (ppb). Application will be early in the season, so in excess of six months will pass prior to water being discharged from the bays. Often, no water is available for discharge as bay top-up will cease in time for the bays to be dry prior to harvesting.

With a two week half life, in six months, 13 half lives will occur. Therefore, even if the bays did contain water and this was discharged directly to an aquatic environment, the concentration of clomazone in the water would not be expected to exceed 0.06 ppb. With the most sensitive species tested, mysid shrimp (LC50=566 ppb), the Q value is <<0.01 indicating a low environmental risk to aquatic species. This conclusion can be drawn for aquatic plants also, as the EC50=37 ppb (based on an assessment factor of 100 applied to the algal test results in a Q value <0.01).

Environmental effects testing of the major metabolite, FMC 65317 indicates that at worst, it can only be considered moderately toxic to aquatic plants with an EC50>3 ppm for *Selenastrum*. No herbicidal effect of this metabolite is stated to have been documented, and the environmental hazard from this metabolite is predicted as low.

Desirable vegetation
Hazard to terrestrial vegetation may be expected to result from volatilisation of clomazone from rice bay water leading to exposure of surrounding vegetation. Environment Australia has calculated the Henry's law constant to be $4.13X10^{-8}$ atm.m^3/mol, which is suggestive of low volatility from water, and is supported by company testing. However, it is known that only a minor amount of clomazone needs to volatilise to effect developing tissue.

The company has provided a summary of feedback received from growers during the time of the rice permit. The response rate from growers was 36% (32 respondents). Of these, 6 growers reported off site movement with all claiming only weeds and native grasses on the bay banks as being affected. One grower reported weeds and grass on an adjacent roadway (5 metres from the water) as affected. Two growers claimed full recovery within 2 weeks, and one grower observed no effect to an adjacent wheat crop.

Monitoring of surrounding areas to *Command* treated rice bays failed to show signs of any off target movement on native shrub or tree species.

Conclusions

Environment Australia has assessed data in support of *Command* and believes that the application contains adequate environmental fate and toxicity data to demonstrate that the use of this product for control of weeds in cucurbits, green beans, tobacco, potatoes, navy beans, poppies and rice according to the label and Good Agricultural Practice is unlikely to result in harmful effects on environmental organisms. The greatest environmental hazard from use of the product is to aquatic plants and desirable vegetation as a result of off target movement either during or after application, but aerial application is forbidden except in rice and suitable label warnings have been included on the product label to minimise the likelihood of aquatic contamination. The company intends to undertake a comprehensive product stewardship program with respect to this herbicide, which should result in limited occurrences of off target movement.

EFFICACY AND SAFETY ASSESSMENT

Data from a wide range of trials conducted from 1993-1996 have demonstrated that *Command* can be used post-planting pre-emergence (PPPE) in **cucurbits, green beans, navy beans, potatoes and tobacco** and early post-emergence in **poppies** for the control or suppression of Apple of Peru *(Nicandra physalodes)*, Amaranth *(Amaranthus powellii)*, Blackberry nightshade *(Solanum nigrum)*, Fat hen *(Chenopodium album)*, Pigweed *(Portulaca oleracea)*, Potato weed *(Galinsoga parviflora)*, Hogweed *(Polygonum aviculare)*, Wild Radish, *(Raphanus raphanistrum)* and Stagger Weed *(Stachys arvensis)*. In **rice** it has been demonstrated that *Command* can be used as a pre-emergence or early post emergence herbicide applied either pre-sowing or early post-sowing, for control of Barnyard grass *(Echinochloa* spp.*)* and suppression of Silvertop grass *(Leptochloa fusca* syn*: Diplacne fusca)*.

Cucurbits

Most cucurbit crops (cucumbers, melons, pumpkins, squash and zucchini) are mechanically cultivated to control weeds during the early growth stages of the crop prior to running. This is reasonably successful, although it does contribute to moisture loss, and stimulates another flush of seeding weeds and represents another additional cost of production.

Currently, fluazifop-P and sethoxydim are registered in cucurbits for post-emergent grass weed control. Bensulide and naptalam, both effective broadleaf herbicides in cucurbits, have recently been withdrawn from sale. Problems with broadleaf and to some extent grass control confront the cucurbit industry. *Command* has good broadleaf weed activity.

Command is registered for use in pumpkins in the USA and for both pumpkins and buttercup squash in New Zealand. The treatment is applied before both weed and crop emergence.

The proposed use for Australia is Post-Planting Pre-Emergence (PPPE) with *Command* being applied directly to the bare ground, from planting to up to a week after planting.

Green beans

Green beans *(Phaseolus vulgaris)* are grown in Australia for both the fresh market and for processing. French (or dwarf) beans are the predominant types grown in most of Australia. While green beans is not a major crop on a nation-wide basis and the size of the market is small, there is nevertheless a need for effective weed control in this minor crop, for growers to continue to produce viably.

One particular weed that is proliferating, spreading and proving difficult to control in green bean crops, is Amaranth. Adequate data has been presented to show that *Command* is effective against this weed. The proposed use is PPPE as for cucurbits.

Navy Beans

The navy bean industry, while well established in Australia, is small with only 7000 to 15,000 hectares grown each year. The bulk of the crop is used for canning as "baked beans" with the remainder being sold to the health food market.

Like most minor crops, navy beans suffer from lack of registered products for weed control. The navy bean industry (Bean Growers Australia) identified, as a priority, the need to develop alternative herbicides and has funded their own efficacy trial work in an attempt to get new products registered.

The proposed use for *Command* in navy beans, PPPE, is identical to that for green beans and cucurbits and will provide alternative herbicide options for the navy bean industry.

Potatoes

In Australia, potatoes are an important horticultural crop with annual production of approximately 1,100,000 tonnes.

Chemical weed control in potatoes is limited by the number of herbicides registered and the weed spectrum each herbicide controls. Some potato growers, who are not satisfied with the weed control or crop safety from currently registered herbicides, have returned to cultivation for weed control. This practice has been shown to reduce crop yield considerately when compared to herbicide use. Cultivation caused direct damage to potato roots and tops and indirect damage due to increased soil compaction.

The use of metribuzin for weed control in potatoes is widespread. However, metribuzin does not control certain commercially important weeds such as blackberry nightshade *(Solanum nigrum)* and hogweed *(Polygonum aviculare)*. *Command* has been shown to be effective against these and other broadleaf weeds when applied PPPE.

Tobacco

Despite increasing community health consciousness and the strong move to reduce smoking in the community, tobacco continues to be an important minor crop in Australia, with an annual product value of approximately $80 million. The major growing areas are in North Qld (Mareeba) and North-eastern Victoria at Myrtleford.

Tobacco, like most small crops, suffers from a lack of registered products for weed control. Currently, trifluralin is the most commonly used herbicide. However it does not control certain commercially important weeds - potato weed *(Galinsoga parviflora)* or blackberry nightshade *(Solanum nigrum)*.

Command is registered and widely used in the USA for weed control in tobacco. It is applied either post-plant pre-mergence or post-transplanting pre-emergence to weeds.

In Australia, tobacco seed is planted into separate and specifically prepared "nursery" seed beds, where it is allowed to grow to approximately 10 - 20 cm in height. The seedlings are tipped to reduce moisture loss and planted into the prepared fields. It has been demonstrated that *Command* can be applied either to bare ground just prior to transplanting or over the seedling within a couple of days of transplanting, prior to weed emergence.

Pre and post transplant application is by ground boom sprayers fitted with flat fan nozzles. *Command* is not recommended for use in "nursery" seed beds.

Poppies
The opium poppy *(Papaver somniferum)* is the only plant species to synthesise morphine, which is used in the production of codeine and other pharmaceutical alkaloids. Growth of the opium poppy is restricted to a relatively small number of countries. In Australia, this crop is only grown commercially in Tasmania, an island state, where control of any illegal practises involving this drug can be managed relatively easily, and where the climatic conditions are ideal.

In recent times the poppy industry in Tasmania has grown significantly and currently about 10,000 hectares are planted each year. The future of the crop appears to be very positive.

Weed control in this crop is generally quite a complex exercise and may involve the use of up to six different herbicides and four separate spray applications.

Weed populations are shifting towards combinations that are increasingly difficult to control. In particular the following weeds are becoming more dominant and control less consistent: - fat hen *(Chenopodium album),* wild radish *(Raphanus raphanistrum),* hogweed *(Polygonum aviculare)* and in some areas, thistles *(Cirsium vulgare).*

As poppies do not compete well with weeds, the early use of herbicides is important. However, poppies are also very susceptible to herbicides in the very early growth stage. Results with currently available herbicides have been extremely variable from paddock to paddock and season to season. Crop tolerance is often marginal and overkill on weeds has also meant death of poppies.

Control of early germinating weeds is a major problem, as herbicide use is limited until poppies are large enough to prevent excess herbicide damage to the crop. Weed competition can seriously restrict poppy growth at these early stages. As weeds get larger they are also much harder to control. An added problem occurs when split germinations of weeds or crop make herbicide timing impossible to optimise without damage to crop or loss of weed control. Such split germinations are common.

Early trial results indicated that *Command* applied early post-emergence provided excellent crop safety and more useful efficacy than the pre-emergence application. Subsequent testing of *Command* in poppies was therefore focussed on the post-emergence uses of this product.

Thus poppy seed should be sown into a well prepared seed bed, and both crop and weeds allowed to emerge before the post-emergence application of *Command.* Application is recommended when weeds are at the cotyledon to 8 leaf stage, which is approximately 3 to 6 weeks after planting.

Application is by ground boom sprayers via a strict product stewardship program aimed at minimising potential drift/volatilisation problems. The program has been very successful during product evaluation trials on this crop and tobacco.

Rice
The introduction of *Command* to the rice industry will provide a number of benefits to growers. These benefits include, flexibility in their herbicide program for the management of

barnyard grass and silvertop grass, different mode of action to reduce likelihood of grass weed resistance, lower odour and improved crop safety compared to current herbicides and low use rate.

Command is currently registered for use in rice in Brazil, Latin America, Indonesia and the Philippines and is under review in a number of other overseas countries, including the U.S.A. and Europe. Commercial development of clomazone in drill sown rice for grass weed control in Latin America prompted evaluation in water seeded rice culture in New South Wales.

Barnyard grasses *(Echinochloa* spp*)* and Silvertop grass *(Leptochloa fusca)* are the predominant grass weeds infesting water seeded rice in New South Wales. Molinate and thiobencarb are the commercial standards used to control these weeds.

Data from field trials has demonstrated pre and early post efficacy and crop safety when *Command* is applied in water sown rice, equal to or better than the industry standards molinate (2400 to 3600g ai/ha) or thiobencarb (3000g ai/ha).

Conclusion
The data presented supports the claims for this product with suitable label wording and the product stewardship program addressing potential problems with off target damage and minimum recropping intervals.

The registration of *Command* is keenly sought by the Australian horticultural, tobacco and poppy industries, as new products for use in these crops are rare. *Command* will provide a new management tool with a different mode of action to help overcome some serious weed problems that threaten the viability of these industries.

Proposed Draft Label

Main Panel

POISON

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

COMMAND® 480 EC

HERBICIDE

ACTIVE CONSTITUENT: 480 g/L CLOMAZONE
SOLVENT: 450 g/L LIQUID HYDROCARBONS

GROUP	F	HERBICIDE

For the control of certain broadleaf weeds in Cucurbits, Green Beans, Navy Beans, Potatoes, Poppies and Tobacco and the control of certain annual grasses in Rice as per the Directions for Use Table.

IMPORTANT: READ THE ATTACHED LEAFLET BEFORE USE.

1, 5 & 10 Litres

FMC International AG., Suite 7, 36 Bryants Road, Loganholme, QLD 4120

STORAGE AND DISPOSAL

Do NOT store near (or allow to contact) fertilisers, fungicides or pesticides. Store in the closed, original container in a well ventilated area, as cool as possible. Do not store for prolonged periods in direct sunlight. Store in a locked room or place away from children, animals, food, feed stuffs, seed and fertilisers. FLAMMABLE : Store away from naked lights, heat sources and oxidising agents.

Spillage - In case of spillage, confine and absorb spilled product with absorbent material such as sand, clay or cat litter. Dispose of waste as indicated below or according to Australian Standard 2507 - Storage and Handling of Pesticides. Do NOT allow spilled product to enter sewers, drains, creeks or any other waterways.

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.

SAFETY DIRECTIONS

Harmful if inhaled or swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale vapour. When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow length nitrile gloves and face shield or goggles. When using the prepared spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length nitrile gloves. If product in eyes, wash out immediately with water. Wash hands after use. After each day's use, wash gloves, face shield or goggles and contaminated clothing.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 131126.

MATERIAL SAFETY DATA SHEET

Additional information is available in the Material Safety Data Sheet (MSDS FMC/COM/1) which can be obtained from the supplier.

WARRANTY

FMC makes no warranty express or implied, concerning the use of this product other than that indicated on the label. Except as so warranted the product is sold as is. Buyer and user assume all risk of use and/or handling and/or storage of this material when such use and/or handling and/or storage is contrary to label instructions.

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* Other trademarks

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BATCH No. **DATE OF MANUFACTURE**

NRA Approval No. 49604/

POISON

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

COMMAND® 480 EC

HERBICIDE

ACTIVE CONSTITUENT: 480 g/L CLOMAZONE
SOLVENT: 450 g/L LIQUID HYDROCARBONS

GROUP	F	HERBICIDE

For the control of certain broadleaf weeds in Cucurbits, Green Beans, Navy Beans, Potatoes, Poppies and Tobacco and the control of certain annual grasses in Rice as per the Directions for Use Table.

IMPORTANT: READ THIS LEAFLET BEFORE USE.

1, 5 & 10 Litres

FMC International AG., Suite 7, 36 Bryants Road, Loganholme, QLD 4120

COMMAND 480 EC HERBICIDE

Directions for use
RESTRAINTS:
DO NOT apply by aircraft for all crops except rice, or through irrigation equipment.
DO NOT apply more than once per year.
DO NOT apply in foggy conditions or conditions conducive to fog.

CROP	WEEDS CONTROLLED	STATE	RATE	CRITICAL COMMENTS
Cucurbits (Pumpkins, squash, rockmelons, watermelon, cucumber & zucchini) **Green Beans** (French beans)	Blackberry Nightshade (*Solanum nigrum*), Fat hen (*Chenopodium album*), Amaranth (*Amaranthus powellii*), Potato Weed (*Galinsoga parviflora*), Pig Weed (*Portulaca oleracea*) & Apple of Peru (*Nicandra physalodes*).	All states	1-2 L/ha	Apply post plant pre-emergence before weeds emerge. Use higher rates when high weed pressure is expected or in heavier soil types. Use lower rates on sandy, low organic matter soils.
Navy Bean	Blackberry nightshade, Fat hen, Amaranthus, Potato Weed, Pig Weed & Apple of Peru	All States	1 L/ha	Apply post plant pre-emergence before weeds emerge.
			0.5 to 1 L/ha	Command is compatible with other bean herbicides. Use lower rates in combination with other bean herbicides to broaden weed spectrum.

COMMAND 480 EC HERBICIDE

Directions for use (Cont)

CROP	WEEDS CONTROLLED	STATE	RATE	CRITICAL COMMENTS
Poppies		Tas only		Apply post emergence to actively growing weeds as early as the 2 leaf stage of the crop through to the 6 and 8 leaf stage. Command 480 EC is compatible with other poppy herbicides. To broaden weed spectrum, Command 480 EC can be used in tank mixes or in a multiple spray strategy with other poppy herbicides. Use higher rates on heavier soil types and lower rates on sandy, low organic matter soils. Use in accordance with advise from contracting Company's Advisory Officers.
	Fat Hen		0.5 - 1 L/ha	Use the lower rate for small weeds cotyledon to 2 leaf in size. Use the higher rate for high weed pressure or weeds 4-6 leaf in size
	Amaranth			Use the lower rate for small weeds cotyledon to 2 leaf in size. Use the higher rate for high weed pressure or weeds 2-4 leaf in size.
	Hogweed (*Polygonum arvensis*)		0.25 - 0.5 L/ha	
	Wild radish (*Raphanus raphanistrum*)		1 L/ha (Suppression only)	Apply at the cotyledon to 4 leaf stage. Useful suppression only may be achieved. If weed population is high or weeds are greater than 4 leaf in size, use a dedicated Wild radish herbicide.
	Stagger Weed (*Stachys arvensis*)		0.5 L/ha	Apply at the cotyledon to 4 leaf stage.
Potatoes	Blackberry Nightshade, Fat hen, Amaranth, Potato Weed, Pig Weed & Apple of Peru.	All States	1 L/ha	Apply post plant pre-emergence before weeds emerge. Do not apply to emerged potatoes as crop injury may occur.
			0.5 L - 1 L/ha	Use higher rates on heavier soil types and lower rates on sandy, low organic matter soils. Command 480 EC is compatible with other potato herbicides. Use lower rates in combination with other potato herbicides to broaden weed spectrum.

COMMAND 480 EC HERBICIDE

Directions for use (Cont)

CROP	WEEDS CONTROLLED	STATE	RATE	CRITICAL COMMENTS
Rice		NSW & Vic only		To achieve optimum control ensure seedbed is free of germinated grasses prior to flooding. Apply by SCWIIRT (Soluble Chemical Water Injection In Rice Technique) from motorbike or helicopter to permanent water from pre sowing up to 2 leaf rice stage. Floodwater must cover all ground and foliage at time of application. Lockup all bays to prevent water movement for at least 3 days after treatment.
	Barnyard Grass (*Echinochloa* spp.)		0.4 to 0.6 L/ha	Apply to weeds up to 3 leaf in size which have germinated since flooding. Use the lower rate for small weeds less than 2 leaf in size. Use the higher rate when high barnyard grass populations are expected or weeds are 3 to 4 leaf in size.
	(Suppression only) Silver top grass (*Leptochloa fusca*) (Syn: *Diplacne fusca).*		0.5 to 0.6 L/ha	Apply to weeds less than 2 leaf in size which have germinated since flooding. Use the higher rate when high silver top grass populations are expected or weed are 2 stage.

COMMAND 480 EC HERBICIDE

Directions for use (Cont)

CROP	WEEDS CONTROLLED	STATE	RATE	CRITICAL COMMENTS
Tobacco (Transplanted tobacco only, do not use on seedling beds)	Blackberry Nightshade, Fat hen, Amaranth, Potato weed, Pig Weed & Apple of Peru.	Qld, NSW & Vic only	1-2 L/ha	Apply pre transplant or up to 7 days post transplant before weeds emerge. If weeds have emerged before application can be made, cultivate shortly before or at the time of treatment, or if prior to planting use in a tank mix with a knockdown herbicide. Use higher rates when high weed pressure is expected or in heavier soil types. Use lower rates on sandy, low organic matter soils.

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

WITHHOLDING PERIODS:

HARVEST

Beans, cucurbits, navy beans, poppies, potatoes and rice:
Not required when used as directed

GRAZING

Rice:
Do not graze or cut for stock food for 3 months after application.
Do not drain rice water into regional drains as defined by the local irrigation authority and/or the nsw environmental protection agency.

Other crops:
Do not graze or cut for stock food until after harvest.

GENERAL INSTRUCTIONS

COMMAND 480 EC Herbicide is a soil applied herbicide for the control of certain annual grasses and broadleaf weeds. Plant uptake of Command occurs through both the roots and the shoots.

Except in poppies, best weed control by COMMAND 480 EC Herbicide is achieved by pre-emergence application. All emerged weeds should be controlled by application of a non-selective, non-persistent herbicide or by tillage. The soil surface should be left free of large clods of soil that might protect weed seedlings during emergence.

COMPATIBILITY

COMMAND 480 EC may be tank mixed with other herbicides to broaden the weed control spectrum compared to products applied alone. The lower rates of COMMAND 480 EC may be used when tank mixing.

POPPIES - Command 480 EC is compatible with Asulox* and Brodal*. Command is not compatible with Tramat* and efficacy can be reduced in tank mixes using Starane*. Other herbicide combinations should be used with caution and in accordance to advise from contracting Company's Advisory Officers.

RICE - COMMAND 480 EC is compatible with the herbicides Molinate*, Saturn*, Londax* and Taipan* the insecticide Chlorpyrifos.

RESISTANT WEEDS WARNING

COMMAND 480 EC Herbicide is a member of the Isoxazolidinone group of herbicides. COMMAND 480 EC has the inhibitors of carotenoid biosynthesis mode of action. For weed resistance management COMMAND 480 EC is a Group F herbicide.

Some naturally occurring weed biotypes resistant to COMMAND 480 EC and Group F herbicides may exist through normal genetic variability in any weed population if these herbicides are used repeatedly. These resistant weeds will not be controlled by COMMAND 480 EC or other Group F herbicides

Since the occurrence of resistant weeds is difficult to detect prior to use, FM International AG accepts no liability for any losses that may result from the failure of COMMAND 480 EC or other Group F herbicides.

MIXING:

Add half the required volume of water in spray tank and start agitation. If tank mixing with wettable powders or Water Dispersible Granules add these first, liquid suspensions (ie. Flowables) are added next, and COMMAND 480 EC is added last. Maintain good agitation at all times until spraying is completed.

APPLICATION:

COMMAND 480 EC can be applied as a broadcast or banded application. Use conventional sprayers with either mechanical or by-pass agitation. Flat fan nozzles producing medium to coarse droplets should be used. Spray equipment should be properly calibrated to ensure correct application. To minimise off target movement, use the lowest pressure and boom height which provides uniform coverage, using 150 to 400 litres per hectare. Do not apply to very wet soils or to soils with a rough surface.

In Rice apply as a SCWIIRT (Soluble Chemical Water Injection In Rice Technique) via motorbike or Helicopter. Dilute the required amount of COMMAND 480 EC in water and apply to flooded bay at a distance of 20 to 30 metres between runs. Alternatively Command 480 EC can be applied using a constant head siphon applied as a drip at inundation.

Band spray rate

The rate of COMMAND 480 EC for band spraying per hectare of crop is calculated from the broad area rates as follows

$$\frac{\text{Band width (cm)}}{\text{Row spacing (cm)}} \times \text{Broadcast Rate (L)}$$

= Band Rate (L) per hectare of crop for band spraying

CROP ROTATION RECOMMENDATIONS:

COMMAND 480 EC Herbicide treated area may be replanted to any of the specified crops after the interval indicated in the following table.

Minimum Recropping Intervals For Command 480 EC

	Minimum Recropping INTERVAL (months after application)					
Rate	**0**	**3**	**6**	**9**	**12**	**15**
0.5 L/ha or less (Or up to 0.625 L/ha in flood water - rice)	Poppies Potatoes Cucurbits Beans Tobacco Rice		Barley Oats Wheat Lucerne Rye grass Onions Canola Sub- clover	All other crops		
1 L/ha	Potato Cucurbits Beans Tobacco Rice	Poppies		Barley, Oats Wheat Lucerne Rye grass Onions Canola Sub-clover	All other crops	
2 L/ha	Cucurbits Beans Tobacco	Potato Poppies Rice			Barley Oats Wheat, Lucerne, Rye grass, Onions, Canola, Sub- clover	All other crops

Tolerance of other crops (grown through to maturity) should be determined on a small scale before sowing into larger areas.

Cover crops, however may be planted anytime but stand reductions may occur in some areas. Do not graze, or harvest for food or feed, cover crops.

Replanting: If initial seedlings fail to produce a stand, the crop maybe replanted in fields treated with COMMAND 480 EC alone. Do not retreat field with a second application of COMMAND 480 EC. Do not replant treated fields with any crop at intervals which are inconsistent with the rotational crop guidelines on this label. When tank mixing observe all application precautions, rotational guidelines and replanting instructions of each product label.

PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS:
DO NOT apply under meteorological conditions or from spray equipment which could be expected to cause spray drift onto nearby susceptible plants, adjacent crops, crop lands or pastures.

OFF TARGET WHITENING
Command 480 EC herbicide can cause whitening of sensitive plants (i.e. some species of trees, shrubs, flowers, agronomic crops, fruits and vegetables) by either spray drift or volatilisation. The application and recommendation for the use of this product should be undertaken only by persons adhering to the following requirements:

Precautions to be taken to minimise potential off-target effects:

- DO NOT spray within 100 metres of residential or industrial properties or homes on neighbouring properties,
- where it is proposed to spray within 100 metres of a neighbouring property which is used for primary production, the owner of the property must be given written notice of the intention to spray and information which includes the name of the product being sprayed and its effects on susceptible plant species,
- ensure that when the product is being diluted prior to application, that it is done away from desirable plants,
- DO NOT empty or clean sprayers near homes and sensitive plants,
- DO NOT apply by aircraft (for all crops except rice), or through irrigation equipment, and
- remove contaminated clothing before entering areas where sensitive plants exist e.g. homes, nurseries, greenhouses and other crops.

Application equipment/calibration:

- use coarse nozzles with pressure not exceeding 35 psi/250 kPa (2.5 bar) with boom height no greater than 60 cm above the target, and
- apply only with calibrated equipment.

Minimisation of product volatilisation:

- apply to dry soils in 150 - 400 L water per hectare,
- DO NOT apply to wet soils and/or wet plants,
- DO NOT spray poppy crops beyond the 8 leaf stage,
- DO NOT apply in wind gusts over 12 km/hr or when weather conditions favour the formation of inversion layers,
- weather resulting in warm, high moisture soils increase the volatility potential of Command 480 EC Herbicide. Sunlight may also heat the soil surface, evaporating soil moisture and causing an inversion effect. This inversion effect causes the product to move to the soil surface where it is subject to volatilisation, and
- DO NOT apply in fog or in conditions conducive to fog.

PROTECTION OF WILDLIFE, FISH, CRUSTACEA, AND ENVIRONMENT
DO NOT contaminate streams, rivers or waterways with COMMAND 480 EC or used container (except rice bays).

STORAGE AND DISPOSAL

Do NOT store near (or allow to contact) fertilisers, fungicides or pesticides. Store in the closed, original container in a well ventilated area, as cool as possible. Do not store for prolonged periods in direct sunlight. Store in a locked room or place away from children, animals, food, feed stuffs, seed and fertilisers. FLAMMABLE : Store away from naked lights, heat sources and oxidising agents.

Spillage - In case of spillage, confine and absorb spilled product with absorbent material such as sand, clay or cat litter. Dispose of waste as indicated below or according to Australian Standard 2507 - Storage and Handling of Pesticides. Do NOT allow spilled product to enter sewers, drains, creeks or any other waterways.

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.

SAFETY DIRECTIONS

Harmful if inhaled or swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale vapour. When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow length nitrile gloves and face shield or goggles. When using the prepared spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length nitrile gloves. If product in eyes, wash out immediately with water. Wash hands after use. After each day's use, wash gloves, face shield or goggles and contaminated clothing.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 131126.

MATERIAL SAFETY DATA SHEET

Additional information is available in the Material Safety Data Sheet (MSDS FMC/COM/1) which can be obtained from the supplier.

WARRANTY

FMC makes no warranty express or implied, concerning the use of this product other than that indicated on the label. Except as so warranted the product is sold as is. Buyer and user assume all risk of use and/or handling and/or storage of this material when such use and/or handling and/or storage is contrary to label instructions.

NRA Approval No. 49604/

GLOSSARY

Active constituent	The substance that is primarily responsible for the effect produced by a chemical product.
Acute	Having rapid onset and of short duration.
Carcinogenicity	The ability to cause cancer.
Chronic	Of long duration.
Codex MRL	Internationally published standard maximum residue limit.
Desorption	Removal of an absorbed material from a surface.
Efficacy	Production of the desired effect.
Formulation	A combination of both active and inactive constituents to form the end use product.
Genotoxicity	The ability to damage genetic material
Hydrophobic	Water repelling
Leaching	Removal of a compound by use of a solvent.
Log P_{ow}	Log to base 10 of octonol water partioning co-efficient.
Metabolism	The conversion of food into energy
Photodegradation	Breakdown of chemicals due to the action of light.
Photolysis	Breakdown of chemicals due to the action of light.
Subcutaneous	Under the skin
Toxicokinetics	The study of the movement of toxins through the body.
Toxicology	The study of the nature and effects of poisons.

References

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