

**Public Release Summary
on**

Evaluation of the new active

ZINC PHOSPHIDE

in the product

MOUSEOFF ZINC PHOSPHIDE BAIT

**National Registration Authority
for Agricultural and Veterinary Chemicals**

May 2000

**Canberra
Australia**

©NRA 2000
ISBN 1443-1335

This work is copyright. Apart from any use permitted under the *Copyright Act 1968*, no part may be reproduced without permission from the National Registration Authority for Agricultural and Veterinary Chemicals. Requests and inquiries concerning reproduction and rights should be addressed to the Manager, Communication and Secretariat, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box E240, Kingston ACT 2604 Australia.

This document is published by the National Registration Authority for Agricultural and Veterinary Chemicals. In referencing, the NRA should be cited as both the author and publisher of this document. For further information, please contact:

Gavin Hall
National Registration Authority for Agricultural and Veterinary Chemicals
PO Box E 240
KINGSTON ACT 2604

Ph: (02) 6272 3194
Fax: (02) 6272 3218

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 (Agricultural and Veterinary Chemicals Section) and relevant State departments of agriculture and environment.

The NRA has a policy of encouraging openness and transparency in its activities and of seeking community involvement in decision making. Part of that process is the publication of Public Release Summaries for all products containing new active ingredients and Trade Advice Notes for all proposed major extensions of use to new crop/animal situations for existing products.

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

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

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

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

CONTENTS

Foreword	iii
List of Abbreviations and Acronyms	vii
Summary	ix
Introduction	1
Chemistry and Manufacture	2
Toxicological Assessment	4
Residues Assessment	7
Assessment of Overseas Trade Aspects of Residues in Food	9
Occupational Health and Safety Assessment	10
Environmental Assessment	13
Efficacy and Safety Assessment	20
Labelling Requirements	21
Glossary	24
Suggested Further Reading	25
NRA Order Form	26

LIST OF ABBREVIATIONS AND ACRONYMS

ac	active constituent
ADI	acceptable daily intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
d	Day
EC₅₀	concentration at which 50% of the test population are immobilised
EUP	end use product
F₀	original parent generation
h	Hour
HPLC	high pressure liquid chromatography <i>or</i> high performance liquid chromatography
id	Intradermal
ip	Intraperitoneal
im	Intramuscular
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
iv	Intravenous
kg	Kilogram
L	Litre
LC₅₀	concentration that kills 50% of the test population of organisms
LD₅₀	dosage of chemical that kills 50% of the test population of organisms
LOQ	Limit of Quantitation
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
NOHSC	National Occupational Health and Safety Commission
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
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 *Mouseoff Zinc Phosphide Bait (Mouseoff)*. Mouseoff is a grain bait containing 25 g/kg zinc phosphide. It is proposed the product will be used to control heavy infestations of mice in certain agricultural crops and crop stubble.

The NRA has assessed the data submitted by the applicant in support of the proposed use of zinc phosphide. The following information is provided for public comment before the NRA determines whether to register the product in Australia. Comments should be submitted by **20 July 2000** to the address given on page 1.

Public Health Aspects

Toxicology

Zinc phosphide is a metallic phosphide, with some similarities to aluminium or magnesium phosphide. It does not appear to release phosphine gas as readily as aluminium phosphide, and appears to have less explosive potential than other metallic phosphides.

Zinc phosphide has high acute oral toxicity, with signs apparently related to the production of phosphine gas in the stomach. The initial signs of poisoning following an oral dose include lethargy, an increase in the respiratory rate and in a loss of interest in food. These signs progressed to include coma, followed by death. Phosphine gas also has high toxicity.

In repeat dose feeding studies, the main effects seen were decreased body weight gain, difficulty in walking, paralysis of the hind limbs, damage to the cells of the liver and congestion in the lungs. Deaths were seen at high doses. At lower doses recovery was seen after a few weeks of treatment. Exposure to phosphine gas at low levels resulted in decreased food consumption and decreased body weight gain. Deaths and kidney damage were seen at higher doses.

Phosphine gas did not produce any effects on the foetus in rats at doses below those producing signs of maternal toxicity. At high doses, zinc phosphide produced some chromosome changes and sperm abnormalities in one study in mice. These effects were not seen at lower doses and no mutagenicity was seen in bacteria.

Conclusion

Zinc phosphide is a highly acute toxic compound. The proposed use, to control heavy infestations of mice in agricultural situations, should not result in adverse effects on human health, provided it is used strictly in accordance with all label directions.

Residues in Food

In both plants and animals zinc phosphide is hydrolysed to phosphine. In animals, the phosphine formed is either expired or slowly oxidised to hypophosphite, phosphite and phosphoric acid.

Zinc phosphide releases phosphine on hydrolysis. As the analytical methods employed to measure residues of metallic phosphides in plant and animal tissues are based on the determination of phosphine, the residue definition for zinc phosphide should be the same as for other metal phosphides, *viz.*,

Zinc phosphide, see phosphine and
Phosphine All phosphides, expressed as hydrogen phosphide (phosphine)

Validated analytical methods were capable of quantifying zinc phosphide residues in crops at 0.01 mg/kg.

Residue data from a variety of USA trials following aerial or furrow application of zinc phosphide (2% baits) to agricultural crops including alfalfa, corn, snap beans, peas, tomatoes, sugarbeet and sugarcane gave residues which, when scaled to the proposed Australian use rate, would be <0.01 mg/kg. The results of field trials indicate that the residues of zinc phosphide in crops will be <LOQ (0.01 mg/kg) when applied at the Australian rate of 25 g ai/ha.

In addition, “worst case” estimates of residues of phosphine in grains, calculated by assuming retention of 5% of the product by leaf axils and no decomposition with time, indicate that residue levels at harvest will be much lower than the current MRL of 0.1 mg/kg for cereal grain.

The results of actual residue trials indicate residues in crops and animal feed commodities should be <LOQ (0.01 mg/kg). At low concentrations, phosphine is metabolised in mammals to a variety of non-toxic oxidation products such as phosphite and phosphate.

No residues of zinc phosphide (or phosphine) are expected in animals as a result of feeding treated crops. The registration of zinc phosphide as a rodenticide for agricultural use will not pose a threat to human health or trade.

The following amendment to the *MRL Standard* is recommended:

Table 1

Compound	Food	MRL (mg/kg)
ADD: Zinc phosphide see Phosphine		
Phosphine ADD:	VD 0070 Pulses	*0.01

Note: Phosphine MRL’s for all other commodities to be treated (e.g., cereals and oilseed) have already been included in the MRL Standard due to other approved uses of phosphine (e.g., from aluminium phosphide and phosphine gas).

Residues and Trade

The use of zinc phosphide does not present a risk to Australian trade as no detectable residues are expected in exported commodities.

Occupational Health and Safety

National Occupational Health and Safety Commission (NOHSC) has conducted a risk assessment on Mouseoff containing zinc phosphide at 25g/kg as a grain bait for the control of heavy mouse infestations in agricultural situations. Mouseoff can be safely used by workers when handled in accordance with the control measures indicated in this assessment.

Zinc phosphide is included on the NOHSC *List of Designated Hazardous Substances*, and is assigned a cut-off value of 7.0% w/w for very toxic effects, 1.0% w/w for toxic effects, and 0.1% w/w for harmful effects. NOHSC has determined that Mouseoff is a hazardous substance, based on the concentration of zinc phosphide present in the formulation.

Zinc phosphide TGAC is manufactured overseas and imported into Australia in 1kg cans. Stevedoring, warehouse and transport workers will be exposed to zinc phosphide only in the event of a breach of packaging. Mouseoff is formulated in Australia and packaged into 15kg (20L) polypropylene pails, or 125kg (200L) epoxy lined steel drums. Chemical formulators and packagers will potentially be exposed to zinc phosphide and the finished bait. Chemical formulators and packagers will operate using enclosed cabinets or with extraction ventilation during formulation. Personal protection equipment will be worn by formulators and packagers.

Zinc phosphide is a metallic phosphide of high acute oral toxicity. It generates phosphine gas of high acute inhalation toxicity upon contact with water and acids. The acute dermal LD₅₀ is low as dermal absorption does not appear to be significant. No information has been provided on irritant effects or sensitisation potential. The toxicity profile of the formulated product is expected to be similar in nature to zinc phosphide.

The product is to be applied by ground or aerial methods at the rate of 1kg/ha.

Instructions and safety directions are provided on the product label to minimise exposure to the product. End-users need to wear elbow-length PVC gloves and full facepiece respirator with combined dust and gas cartridge, or supplied with an air respirator when opening the container and using the product. Re-entry statements were not considered necessary for Mouseoff.

Environmental Aspects

Mouseoff will be used for control of heavy infestations of mice in cropping areas. Baits will be broadcast applied at 1kg/ha, using aerial or ground based methods, when monitoring of mouse numbers indicates a need for control.

Application into areas with high mouse populations should ensure rapid bait consumption. Untaken baits gradually lose their potency in the field, apparently through physical weathering processes and hydrolysis by atmospheric moisture, but can persist indefinitely when conditions are dry. Degradation delivers zinc and phosphate ions to the soil, or small amounts of phosphine gas to the atmosphere. Ingestion by rodents or other animals does not alter the ultimate fate of the toxicant.

Zinc phosphide is very highly toxic (LD₅₀ < 10 mg/kg) for sensitive bird species such as geese and galliforms and highly toxic (LD₅₀ < 50 mg/kg) to many other bird species. Pen

and field studies show that bird kills can occur, but that some species are not attracted to zinc phosphide baits. Reported mammalian LD50s range from 5.6 mg/kg in nutria to 93 mg/kg in kit fox. Most LD50s are in the 20-40 mg/kg range, indicative of high toxicity. Zinc phosphide is also highly toxic to fish (LD50s from 0.3 to 0.8 mg/L).

Birds are the non-target organisms most likely to be exposed to or poisoned by zinc phosphide baits when used to control mice in Australia. Recent Australian monitoring data, generated when zinc phosphide was used under permit, indicate that non-target mortalities from zinc phosphide baiting appear relatively low. When baiting was conducted in crops or stubble with strict observance of buffer zones near native vegetation, only a few dead birds were recovered. These included clusters of small pigeons and parrots, apparently casualties of baiting near native vegetation. Suggested reasons for the low non-target impact include the black colour of the baits, which appears to makes them hard to find by birds, especially at the low bait densities recommended for mouse control.

Much of the target selectivity apparently offered by zinc phosphide can be attributed to its application at a relatively low rate. This is insufficient to attract feeding birds, into areas where hungry mice have quickly depleted food resources and where mice will search for and rapidly consume baits on the ground. It should be noted, however, that the non-target risks of baiting over open ground, as may be needed to protect newly planted crops from invading mice, do not appear to have been investigated. Avian exposure in such situations would be expected to be much higher than where the baits are obscured by a maturing crop or other ground cover such as stubble, and more prolonged as mice are likely to be less abundant than when resident in crop.

Available data indicate that baiting in mature crops or into stubble may give rise to isolated avian mortality, but does not appear likely to incur broadscale avian impacts. Registration in these situations only is supported, subject to conditions as outlined in the full assessment report (p12), and close monitoring of use. Any adverse impacts that may occur must be immediately reported to the National Registration Authority. In the absence of monitoring data where baiting occurred over open ground, there is insufficient justification to demonstrate the use would not cause adverse impacts on bird populations. Therefore, the proposed label does include a restraint not to use the product on bare ground.

Efficacy and Crop Safety Aspects

Mouseoff has been used under permit since 1997 in a number of states and a variety of farming situations. Data was presented from a variety of sources including CSIRO Rodent Research Group, Victorian Department of Natural Resources and Environment and the Grains Research and Development Corporation.

The data provided adequately demonstrate that Mouseoff was effective in causing very large reductions of mice numbers in crops and crop stubble. However it was also noted that the presence of alternative feed often resulted in reduced effectiveness of the bait. In addition, the data demonstrated that in a number of situations where mouse numbers were high, sufficient mice survived to be considered a potential economic threat, despite moderately high mortality. The proposed label includes statements warning users of this effect.

No crop injury was observed in any trials and none are expected as there is little contact with the crops. Neither zinc phosphide nor phosphine is expected to cause crop phytotoxicity.

INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of *Mouseoff Zinc Phosphide Bait* (*Mouseoff*), which contains the new active ingredient, zinc phosphide.

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 zinc phosphide, covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the NRA on request (see order form on last page). 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 **20 July 2000** and addressed to:

Gavin Hall
AgVet Chemicals Evaluation Section
National Registration Authority
PO Box E240
Kingston ACT 2604

Phone (02) 6272 3194
Fax (02) 6272 3218

Applicant

Animal Control Technologies Australia Pty Ltd.

Product Details

The NRA proposes to register *Mouseoff* containing zinc phosphide at 25g/kg as a bait formulation. *Mouseoff* will be formulated in Australia and packed into 15 & 125 kg containers.

The proposed use of *Mouseoff* will be for the control of heavy infestations of mice in agricultural situations such as grain crops, legume crops, canola, safflower, nut crops, and pasture. Currently there are no registered products for the control of mice in crop and therefore this product is seen as a very useful addition to the management options for persons requiring control of heavy mice infestations.

The applicant has indicated that zinc phosphide is registered in a number of different products in the USA, Canada and certain European countries. In addition the US Environmental Protection Agency have recently (1998) completed a Re-registration Eligibility Decision on zinc phosphide.

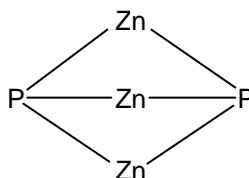
CHEMISTRY AND MANUFACTURE

Active constituent

The active constituent zinc phosphide is manufactured in India by United Phosphorus at 3-11 GIDC, VAPI-396 195, Gujarat, and has been approved by the NRA (Approval No.: 48824).

Chemical Characteristics of the Active Constituent

Common name (SA or ISO common name):	Zinc phosphide
Synonyms and code number:	65811
Chemical name	
(IUPAC):	trizinc diphosphide
(CA):	zinc phosphide
CAS Registry Number:	1314-84-7
Molecular formula:	Zn ₃ P ₂
Molecular weight:	258.09 g/mole
Chemical structure:	



Physical and Chemical Properties of Pure Active Constituent

Physical state:	Crystalline solid
Colour:	Dark grey
Odour:	Garlic-like
Melting point or range (for solids):	420 °C
Boiling point or range (for liquids):	Not applicable
Density/specific gravity:	4.55 g/cm ³
Solubility in water:	Insoluble in water. Reacts with acidified water to form phosphine gas (PH ₃).
Solubility in fat and organic solvents:	Soluble in benzene and carbon disulfide. Insoluble in ethanol.
Vapour pressure:	Not applicable
Dissociation constant:	Not applicable
Octanol/water Partition Coefficient:	Not applicable
pH:	Not applicable
Storage stability:	When stored dry in unopened containers, zinc phosphide is stable for at least 5 years. However, the active decomposes slowly in moist air.
Corrosion characteristics:	Potentially corrosive. Liberates volatile phosphine gas (PH ₃) upon decomposition.
Chemical type:	Rodenticide
Chemical family:	Metallic phosphide

Product

Distinguishing name:	Mouseoff Zinc Phosphide Bait
Formulation type:	Grain bait (sterilised)
Active constituent[s] concentration:	25 g/kg zinc phosphide
Mode of Action:	Zinc phosphide is used as a rodenticide where, upon ingestion, it reacts with stomach acids to liberate the potent mammalian poison, phosphine. Phosphine gas enters the blood and results in damage to the liver, kidneys and heart.

Physical and Chemical Properties of the Product

Physical state:	Coated wheat grains
Colour:	Grey/black
Odour:	Slight sesame odour
Density/specific gravity:	690 kg/m ³
Acidity, alkalinity or pH value:	Not applicable
Viscosity and surface tension:	Not applicable
Flash point:	Not applicable
Flammability:	Not applicable
Explodability:	Not applicable
Corrosion Characteristics:	Not corrosive while kept dry
Storage Stability:	Stability data provided by applicant support a shelf life of 2 years when the product is stored below 40 °C in sealed polypropylene pails (20 L) or epoxy-lined steel drums (125 kg).

TOXICOLOGICAL ASSESSMENT

The toxicological database for zinc phosphide, which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses which are high compared to likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur.

Toxicokinetics and Metabolism

Studies in rats showed that oral dosing with zinc phosphide resulted in phosphine levels in the liver shortly after dosing. At a later stage, phosphine was bound in the liver tissue and was no longer detectable. Phosphine reacted to produce phosphinic and phosphonic acids and will further oxidise to hypophosphite, phosphite and phosphoric acid.

Acute Studies

Zinc phosphide has high acute oral toxicity. In mice a dose which resulted in the deaths of half of the females was 39 mg/kg bw, and of the males was 73 mg/kg bw. In rats, a dose of 41 mg/kg bw resulted in the death of half of the tested animals. In dogs, it was found that the presence of acid in the stomach, either as a result of eating food or by dosing with a mild acid, increased the toxicity of zinc phosphide. The signs of poisoning following an oral dose included a decrease in activity, an increase in the respiratory rate and in a loss of interest in food.

Inhalation studies using phosphine gas (generated from zinc phosphide) showed that it had high toxicity, with a four hour exposure to between 27 and 33 ppm resulting in the deaths of half the mice tested. A two-hour exposure produced weight loss and damage to the lining of the nose. Rats were more sensitive to phosphine gas than mice, with an exposure to 11 ppm resulting in the deaths of half the rats tested.

Short-Term Studies

Rats fed diets with 10 mg zinc phosphide/kg bw/day for up to 68 days survived, with decreased body weight gain, while all rats fed diets with 15 mg zinc phosphide/kg bw/day died within 31 days. Examination of the tissues of the body showed damage to the cells of the liver and congestion in the lungs.

Mice survived exposure to phosphine gas at 10 ppm for 6 hours/day over 4 days, while all rats exposed in this way died. Damage to the kidneys and liver was seen following this exposure, as was damage to the heart muscle. An exposure of 5 ppm for 2 weeks did not produce any deaths, and the extent of kidney and liver damage was much less than at 10 ppm.

Rats were fed diets containing zinc phosphide at 0, 2.5, 5, 10 or 25 mg/kg bw/day for 13 weeks. Deaths were seen at 10 and 25 mg/kg bw/day. Signs of poisoning, including difficulty in walking and paralysis of the hind limbs were seen in all treatment groups, but rats at 2.5 or 5 mg/kg bw/day recovered after the first few weeks. At 10 and 25 mg/kg bw/day there was decreased body weight and some changes in the liver and kidney. When rats were fed rice fumigated with phosphine at up to 50 g/tonne there were no significant effects seen.

Rats were exposed to phosphine gas for 6 hours/day for 13 weeks at 0, 0.3, 1, 3, 5 or 10 ppm. All treated groups had decreased food consumption, with decreased body weight gain from 1 ppm. Deaths and kidney damage were seen at 10 ppm, with other doses producing no significant effects. In another study, rats tolerated exposure to 2.5 ppm for 24 weeks, while deaths were seen at 5 ppm. A range of species were able to tolerate 2.5 ppm when exposed daily over a long period.

Long-Term Studies

In a two-year study, rats were fed diets treated with aluminium phosphide, with an average level of 0.05 mg phosphine/kg bw/day for most of the study. This dose did not produce any adverse effects.

Reproduction and Developmental Studies

A developmental study was done in pregnant rats using inhalational doses of 0.03, 0.3, 3, 5 or 7.5 ppm of phosphine gas for 6 hours/day during the period of foetal organ formation. No adverse clinical signs were seen at doses up to 5 ppm; at 7.5 ppm deaths occurred, and treatment of this group was stopped early. Treatment with phosphine gas did not produce any effects on the number of live foetuses or on foetal weight. There was no increase in the number of malformations related to treatment. Phosphine gas did not produce any adverse foetal or maternal effects at exposures up to 5 ppm.

Genotoxicity

Genotoxicity studies using phosphine were negative in a bacterial mutagenicity (Ames) test and in a chromosomal aberration study in rats and mice. Zinc phosphide at high doses produced some chromosome changes and changes in sperm in mice. In workers using phosphine for fumigation there was no increase in chromosome damage in comparison to controls, and there was no increase in mutagens present in the urine.

Other studies

In humans, a number of poisonings with zinc phosphide have been reported. The signs associated with acute poisoning included shock and signs of liver, kidney and heart damage. Less severe poisonings produced vomiting and difficulty in breathing, followed by muscle weakness, inability to stand and an inability to breathe. Poisoning with either aluminium phosphide or phosphine gas produced similar signs, with phosphine also damaging the lining of the nose.

Public Health Standards

Acceptable Daily Intake

No Acceptable Daily Intake for zinc phosphide was established. This was not an impediment to registration of the product, as the proposed method of use (broadcast of treated seed in crops to provide protection against excessive mouse numbers) should result in little or no contamination of harvested grain.

Poisons Schedule

The current entry in schedule 7 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), for metallic phosphides remains appropriate. Appendix J entry of the SUSDP requires that only authorised or licensed persons as determined by the relevant state or territory poisons authorities, have access to this product. The label includes a statement informing of this requirement. In addition, there are provisions for appropriate warning statements and first-aid directions on the product label.

Special Concerns

One of the major concerns with zinc phosphide is that it has the potential to release phosphine gas slowly in moist air or immediately if it becomes wet. This hazard is specifically highlighted in the safety directions, along with warnings not to inhale the vapour and to keep the product away from water and liquids. This concern has also been addressed in a recommendation in the assessment that there should be adequate measures during transport and storage to ensure that stocks of the product are not allowed to become wet.

RESIDUES ASSESSMENT

Residue Evaluation

Metabolism studies

In both plants and animals zinc phosphide is hydrolysed to phosphine. In animals, phosphine is either expired or slowly oxidised to hypophosphite, phosphite and phosphoric acid.

Residue definition

Zinc phosphide, in common with aluminium and magnesium phosphides, releases phosphine on hydrolysis. As the analytical methods employed to measure residues of all three phosphides in plant and animal tissues are based on the determination of phosphine, the residue definition for zinc phosphide should be the same as for other metallic phosphides.

The proposed residue definition is:

Zinc phosphide, see phosphine and

Phosphine All phosphides, expressed as hydrogen phosphide (phosphine)

Analytical methods

Detailed descriptions of analytical methods for crops were provided. In crops, samples were acid hydrolysed and the phosphine gas recovered for analysis by gas chromatography with flame photometric or nitrogen/phosphorous detection. The Limit of Quantitation (LOQ) was 0.01 mg/kg for a variety of crops.

Residue trials

Residue data from a variety of USA trials following the aerial application of zinc phosphide (2% baits) to agricultural crops were presented. Crops treated included alfalfa, snap beans, peas, tomatoes, sugarbeet and sugarcane. The application rates employed were 2× - 18× the maximum Australian rate. When the residue levels in crops are scaled to the proposed Australian use rate of 25 g ai/ha, the residues are all <0.01 mg/kg.

A report on residues in corn grain, forage (silage) and fodder from test sites located in the five major corn growing states in the USA found residue levels <LOD (0.0005 mg/kg for grain; 0.0007 mg/kg for forage and 0.0008 mg/kg for fodder). Samples of grain and fodder were collected 115-117 days after application and forage at 80-113 days after application (application of zinc phosphide baits was by in-furrow, planter-slot or mechanical broadcast). The USA approved rate for corn is 224 g ai/ha, 9× the proposed Australian rate.

The results of field trials indicate that the residues of zinc phosphide in crops will be <0.01 mg/kg when applied at the proposed Australian rate of 25 g ai/ha. An MRL is recommended for pulses (dry) at *0.01 mg/kg.

A “worst case” estimate for zinc phosphide in crops at harvest can be calculated by making some simple assumptions. By assuming that harvested crops retain 5% of the applied bait and

that there is no breakdown of the zinc phosphide in the interval between application and harvest a worst case estimate can be made of crop residues. In the following calculations it is assumed that the 2.5% zinc phosphide baits are applied at 1 kg/ha (25 g ai/ha). The conversion factor for zinc phosphide to phosphine is simply the molecular weight of phosphine (2PH_3) divided by the molecular weight of zinc phosphide (Zn_3P_2), $68 \div 258.1 = 0.26$. Maximum estimated residues in crops = $(25000 \text{ mg ai/kg} \times 1 \text{ kg/ha} \times 0.05 \div \text{crop yield in kg/ha}) \times 0.26$.

Using the above formula the maximum residue in grains for typical crop yields of 4, 6 and 8 tonnes/ha are estimated to be 0.08, 0.06 and 0.04 mg/kg respectively. The “worst case” estimates of residues of phosphine in grains indicate that the residue levels will be much lower than the current MRL of 0.1 mg/kg for phosphine in cereal grain.

Animal feed commodities

Residues in crops and animal feed commodities are expected to be <LOQ (0.01 mg/kg). At low concentrations, phosphine is metabolised in mammals to a variety of non-toxic oxidation products such as phosphite and phosphate. No residues of zinc phosphide (or phosphine) are expected in animals as a result of feeding treated crops.

Maximum Daily Intake Calculations

No residues are expected in any commodity consumed by humans. The risk to human health from the use of zinc phosphide is considered to be small.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

The trade risk arising from the use of zinc phosphide is estimated to be very low if not negligible. Zinc phosphide is registered as a rodenticide able to be used in various crops in many countries including the USA. Only the USA decided to establish MRLs, as residues at harvest are expected to be <LOQ. The table below summarises the MRLs set by the USA for zinc phosphide.

Commodity	Tolerance (mg phosphine/kg)
Grapes	0.01
Grasses (rangeland)	0.1
Sugarcane	0.01
Artichoke (globe)	0.01
Sugar beet (roots)	0.04
Sugar beet (tops)	0.02
Alfalfa (forage)	0.1 (15/1/98)
Alfalfa (hay)	0.1 (15/4/98)
Clover (forage)	0.1 (15/4/98)
Clover (hay)	0.1 (15/4/98)
Potatoes	0.05 (15/10/97)
Sugar beet (roots)	0.05 (15/10/97)
Sugar beet (tops)	0.05 (15/10/97)
Timothy (forage)	0.1 (15/4/98)
Timothy (hay)	0.1 (15/4/98)
Timothy (seed)	0.1 (15/4/98)

No CODEX MRLs exist for phosphine, however, no residues are expected at harvest. Further, phosphine has been used as a fumigant for many years without any trade problems arising. Therefore as no detectable residues are expected the use of zinc phosphide does not present an unacceptable risk to Australian trade.

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Zinc phosphide is listed as a hazardous substance on the NOHSC *List of Designated Hazardous Substances* and has been assigned a cut-off value of 7.0% w/w for very toxic effects, 1.0% w/w for toxic effects, and 0.1% w/w for harmful effects.

The following risk phrases are assigned:

R15/29	Contact with water liberates toxic, highly flammable gas.
R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.

Substances containing zinc phosphide are considered hazardous when it is present in concentrations above 0.1% w/w. NOHSC has classified Mouseoff as a hazardous substance based on the concentration of zinc phosphide present in the product.

Zinc phosphide is a grey-black crystalline powder, with a garlic-like or decaying fish odour. Zinc phosphide generates phosphine gas on contact with water and acids. It is of high acute oral toxicity and low acute dermal toxicity. No inhalational studies were provided on zinc phosphide. However phosphine gas released is of high acute inhalational toxicity. No information on irritant effects or sensitisation potential is available.

Mouseoff is formulated as a solid grain bait, with a black-grey colour and slight odour.

Formulation transport and storage

Zinc phosphide will be imported and Mouseoff will be formulated in Australia. Transport and storage workers will only be exposed to zinc phosphide in the event of package breaching. Chemical formulators and packagers will operate using enclosed cabinets or with extraction ventilation during formulation. Personal protection equipment will be worn by formulators and packagers.

Advice on safe handling of the product during routine use is provided in the Material Safety Data Sheet (MSDS) for Mouseoff.

End use

The product is intended to be used by either aerial or ground broadcast at the rate of 1 kg/ha for the control of plague mice in crops and crop stubble. The label does not include a re-entry statement, however monitoring of mice numbers could be expected the day after application.

End-users will be exposed primarily by inhalation when opening the containers, loading/unloading the bait and during clean-up procedures. The potential exposure to phosphine is considered to be greatest in moist conditions following rains and in close proximity to the product.

A qualitative risk assessment was performed, as a No-Observed-Effect-Level for zinc phosphide was not available. Assessments of worker exposure during manufacture, ground and aerial baiting trials and when opening containers were provided. The risk assessment showed that elbow-length PVC gloves and full facepiece respiratory protection are recommended when opening containers and using the product.

Entry into treated areas or handling treated crops

Workers are unlikely to enter treated areas immediately after applications. Given the fact that product will be applied in dry conditions, to the ground, and only at 2-3 grains per square metre (of which heavy populations of mice are expected to consume a significant portion), and that release of phosphine from the bait on soil is likely to be slow, no re-entry statement is recommended.

Recommendations for safe use

Workers involved in the formulation of the product should be protected with adequate processes or engineering controls, personal protective equipment and safe work practices and training. Workers involved in the transport, storage and retailing should be protected by safe work practices and training. End-users should follow the instructions and safety directions on the product label. Safety directions include the use of elbow-length PVC gloves and full facepiece respirator with combined dust and gas cartridge or supplied air respirator, when opening containers and using the product.

The personal protection equipment recommended should meet the relevant Standards Australia standards specified below:

AS/NZS 1715-1994	Selection, Use and Maintenance of Respiratory Protective Devices and
AS/NZS 1716-1994	Respiratory Protective Devices
AS 2161-1978	Industrial Safety Gloves and Mittens (Excluding Electrical and Medical Gloves)

Exposure standards

NOHSC has established an exposure standard of 0.3ppm (0.42mg/m³) TWA (time weighted average) and 1ppm (1.4mg/m³) STEL (short term exposure limit) for phosphine, as listed in the NOHSC *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*. Employers should ensure that exposure to phosphine is not greater than this standard.

MSDS

Manufacturers and importers should produce a MSDS for zinc phosphide and hazardous products containing zinc phosphide. These should contain information relevant to Australian workers, as outlined in the 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

Mouseoff Zinc Phosphide Bait can be used safely if handled in accordance with the instructions on the product label. Additional information is available on the MSDS for Mouseoff Zinc Phosphide Bait.

ENVIRONMENTAL ASSESSMENT

Environmental Exposure

Application of baits

The proposed label for Mouseoff allows use in any jurisdiction of Australia for control of heavy infestations of mice in cropping areas (grain growing areas, legume crops, canola, safflower and nut crops, pasture, and pasture adjoining cropping areas) where economically threatening populations of mice occur. However, the product is most likely only to be used in Queensland, NSW, Victoria, SA and WA. A single treatment will normally suffice, but there may be an occasional need to apply a second treatment, particularly where very heavy mouse populations occur. Baiting is expected to occur every 2-4 years, although 10 years may pass between treatments in some locations. Baits will be broadcast applied at 1 kg/ha, using aerial or ground based methods, when monitoring of mouse numbers indicates a need for control. Trail baiting is not permitted.

The use pattern has previously been authorised under a NRA, Emergency Use, Off-Label Permit, subject to a number of conditions. The permit required that baits must not be laid if the monitoring program does not indicate that mouse activity is at a sufficient level, application should achieve an even distribution of 2-3 grains/m², baits should preferably be placed late in the day when birds have finished feeding and not within 50 m of the crop perimeter or areas of native vegetation. It is considered necessary that these conditions be maintained as restraints or use requirements on the proposed approved label.

Fate of the toxicant

Baits gradually lose their potency in the field, apparently through physical weathering processes and hydrolysis by atmospheric moisture. Some losses also occur through mechanical abrasion during application. Residues that enter soil are expected to decompose rapidly, except in dry soils where degradation is retarded. Baits that enter water bodies are not expected to decompose readily through aquatic hydrolysis, but decomposition is expected to proceed slowly in sediments.

In summary, zinc phosphide will mainly remain associated with the bait material, where it may persist for some weeks or months, particularly if conditions are dry. Degradation will deliver zinc and phosphate ions to the soil, or small amounts of phosphine gas to the atmosphere. Ingestion by rodents or other animals will not alter the ultimate fate of the toxicant.

Environmental Effects

No standard laboratory toxicity tests were submitted with the application. Such reports are not considered necessary in this case as consistent results may be obtained from various sources in the published literature, including extensive reviews and the recent US EPA evaluation. Birds are the focus of most of the studies submitted as they are the non-target organisms most likely to be exposed to or poisoned by zinc phosphide baits used to control mice. Most of the information submitted relates to field studies and observations, both in Australia and overseas.

Avian Toxicity

Data available from various sources in the literature indicate that zinc phosphide is likely to be very highly toxic ($LD_{50} < 10$ mg/kg) for sensitive bird species such as geese and galliforms and highly toxic ($LD_{50} < 50$ mg/kg) to many other bird species. Avian casualties may be expected to occur where baits are consumed by birds.

US pen and field studies submitted in support of Australian registration show that bird kills can occur, but that some species are not attracted to zinc phosphide baits. Baiting of prairie dog colonies with poisoned grain gave rise to significant mortality of horned larks, but only where strychnine rather than zinc phosphide was used as toxicant. It was suggested that these birds may experience a negative sensory response to zinc phosphide which deters further bait consumption.

Evidence that zinc phosphide baits are not attractive to some avian species does not infer their general safety to birds. For example, pheasants appear highly susceptible to zinc phosphide poisoning based on pen studies in California. Geese have also been killed by zinc phosphide baits spread at high rates in pen studies, although emetic and aversive effects appeared to prevent mortality at more moderate application rates. Large kills of geese have also been reported from the field where baits were laid at high rates, including one incident that occurred when crop cover was removed by burning 2 months after baiting.

In its recent evaluation of zinc phosphide, the US EPA concluded that incidents of primary poisoning by zinc phosphide are likely to occur, but that many bird species can distinguish and avoid zinc phosphide baits, or regurgitate the toxicant. Lethal secondary poisoning is less likely as toxic residues are mainly confined to the alimentary tract, but sub-lethal effects may occur in secondary consumers.

Recent Australian monitoring data are available from use authorised by permit in NSW, Victoria, Queensland, SA and WA. Similar data are available for strychnine, which was formerly the poison of choice for such applications but fell from favour because of concerns over residue in food. Available evidence indicates that strychnine gave rise to significant avian mortality, particularly where baits were not evenly laid. In contrast, non-target mortalities from zinc phosphide baiting appear low.

Detailed monitoring reports were completed in Victoria and Queensland. Monitoring of minimum tillage areas in the Victorian Central Mallee and Wimmera recovered only a few birds, including two cluster mortalities of pigeons and parrots. Mortalities appeared to reflect primary poisoning. Proximity to native vegetation appeared to be a risk factor. Casualties reported in Queensland following baiting into stubble were also low, but appeared to largely reflect secondary exposure of scavengers such as ibis and crows rather than primary bait consumption by granivores. Heavy mouse populations appeared to be a risk factor. No reports were received from landholders in WA, and carcass searches at a number of properties recovered no casualties. Similarly, searches of representative areas by NSW Rural Lands Protection Board officers in 1999 discovered no non target casualties, and no reports were forthcoming from landholders following a request for information by NSW Agriculture.

Suggested reasons for the low non-target impact include the black colour of the baits, which appears to makes them hard to find by birds, especially at the low densities recommended for

mouse control. Baiting was conducted where mouse populations were high, and such areas may not have attracted birds as mice would have depleted available food resources. Baits were laid in crops or stubble with strict observance of buffer zones near native vegetation. Only a few mouse carcasses were recovered above ground. The delayed onset of action, particularly compared with the formerly used strychnine, allows mice to seek cover in burrows prior to death. The gradual onset of symptoms may also offer sensory cues to birds that deter further bait consumption.

Much of the target selectivity apparently offered by zinc phosphide can be attributed to its application at a relatively low rate, insufficient to attract feeding birds, into areas where hungry mice have depleted food resources and will search for and rapidly consume baits on the ground. However, in the absence of monitoring data where baiting occurred over open ground, there is insufficient justification to demonstrate the use on bare ground would not be likely to exert adverse impacts on bird populations.

Aquatic organisms

Results are available for six fish species (rainbow trout, carp, channel catfish, black bullhead, bluegill and yellow perch) but without supporting details (the data are unpublished). The LC50s fell in a narrow range between 0.3 and 0.8 mg/L, indicative of high toxicity.

Mammals

Reported mammalian LD50s range from 5.6 mg/kg in nutria to 93 mg/kg in kit fox. Most LD50s are in the 20-40 mg/kg range, indicative of high toxicity. The recent US EPA review notes that zinc phosphide is highly to very highly toxic to small mammals on an acute oral basis (most LD50s below 50 mg/kg, with some below 10 mg/kg) and that chronic studies are not required because of the fatal outcome of acute zinc phosphide poisonings.

Prediction Of Environmental Hazard

The primary and secondary hazards of zinc phosphide to non-target wildlife have been extensively reviewed as part of the US EPA's Re-registration Eligibility Decision. The most sensitive birds appear to be waterfowl and galliforms, particularly geese. Primary toxicity may be modified by prior exposure to untreated food, nutritional condition, availability of alternative food, and regurgitation. Many birds appear to be able to discriminate in favour of uncontaminated food when a choice is available.

Secondary poisoning hazard is low because toxins do not accumulate in muscle tissue. Secondary incidents are really cases of primary poisoning by residues in the gastrointestinal tract. The secondary hazard to mammals is further reduced because mammalian predators appear to be less sensitive than rodents. Secondary consumers will generally refuse to eat the digestive tract of poisoned animals, and experience strong emetic reactions that reduce intake of zinc phosphide. The review reports that bald eagles fed on poisoned nutria regurgitated after eating stomach contents but otherwise showed no ill effect. Black vultures offered a similar diet avoided the gastrointestinal tract and showed no signs of poisoning. Yellow-billed kites were observed to feed daily on dead and dying gerbils in a control area but remained apparently unaffected during a 6 month monitoring period.

The review concludes that field studies have generally shown few risks to nontarget species when zinc phosphide baits are properly applied. Most non-target incidents from operational use have involved misuse or application rates and concentrations that were much higher than currently labelled rates. Large kills of geese occurred in Oregon and California some 30 years ago, in each case following application of 1% bait. The Oregon incident involved application at 22 kg/ha, and the California incident followed aerial application at 7-9 kg/ha to a barley field that was subsequently burnt, exposing large amounts of treated bait some 3 months after application. A similar large kill of geese occurred in the Netherlands in the 1950s but no details are available. A large kill of corvids (some 3000 birds) occurred in the former Czechoslovakia in 1988 following operational vole control in a winter wheat field using a wheat bait containing 2.5% zinc phosphide. Baits were exposed because the wheat crop was very sparse and there was no snow cover.

Hazard in the Australian context is further evaluated below.

Terrestrial organisms

The main non-target organisms to be exposed to zinc phosphide in baited areas will be birds. Cropping areas are not widely used by mammals other than pest rodents.

Exposure may occur through consumption of treated grain or of mice that have taken the baits and still retain toxic residues within their bodies. True secondary poisoning is not expected to occur as zinc phosphide does not leave toxic residues in animal tissue; rather, scavenging animals may be exposed to residues of zinc phosphide in the alimentary tract if they consume viscera.

Zinc phosphide is highly toxic to birds and mammals. Baits are formulated so that one grain of wheat will deliver an LD50 to a 15 g mouse. As rodents and birds share similar sensitivity, a single wheat grain may be expected to deliver a lethal dose to a small bird such as a house sparrow. Larger birds would need to consume more baits before receiving a toxic dose.

The application rate of 1 kg/ha equates to 3 grains/m², well short of the US EPA's screening level of concern (10 LD50s/m²), even for small birds. This evaluation suggests that primary avian risk is relatively low, but caution is warranted as pen studies indicate that some species will actively search for baits over large areas, at least when alternative food is not available. Higher bait concentrations may arise at start up, or when the plane turns steeply during aerial application, or through spillage.

Isolated avian casualties have been reported from local field trials, indicating that some risks remain even though the bait concentration on the ground is low, and its black colour may reduce the chance of avian consumption. The occurrence near native vegetation of cluster mortalities in small granivorous birds affirms the importance of careful baiting that avoids such areas.

Non-target deaths have also been recorded overseas. These are usually isolated incidents, even at higher treatment rates than will be used in Australia, but some major incidents involving hundreds or thousands of birds (geese and crows) have been reported. The incidents appear largely historical and involved high application rates in situations where baits were exposed and/or alternative food was in short supply, but the occurrence of a large bird

kill when baits were exposed some 3 months after being laid highlights the importance of ensuring rapid bait consumption by mice.

It does not appear likely that such incidents will be repeated in Australia when baits are laid in situations with at least some ground cover, particularly if baits are laid late in the day and only at sites with heavy mouse populations to consume them. However, the possibility of a significant bird kill can not be discounted, given the historical precedents overseas where baits are exposed, and the observation of cluster mortalities in pigeons and parrots in Victorian field studies conducted in minimum tillage areas with buffer zones around native vegetation. Detailed analyses of non-target impact have yet to be conducted in fallow or bare ground situations, where baits are likely to be more visible to birds, particularly if laid near areas of native vegetation. Non-target exposures would likely be prolonged in such situations because of lower mouse populations to consume the baits. Detailed monitoring of such use patterns is warranted. Any such incidents that may occur would need to be thoroughly investigated in order to determine contributing factors and avoid any recurrence.

Aquatic organisms

In a hypothetical worst case situation of direct bait application to 15 cm standing water, with immediate and complete dissolution of the zinc phosphide content (25 g/ha), the estimated environmental concentration would be 17 µg/L. This is less than 10% of the lowest known LC50 of 0.3 mg/L (for fish). Even in this unrealistic exposure situation, acute hazard to fish is low. Chronic exposure situations are not expected as zinc phosphide will only be used occasionally and does not persist in the environment.

No data are available to assist in predicting the hazard to aquatic invertebrates. However, any aquatic exposure will be at very low levels and occur infrequently. Adverse impacts to invertebrate organisms are not expected based on the low levels of exposure, but can not be discounted in the absence of toxicity test results. However, even if some impacts do occur, the limited persistence of zinc phosphide and phosphine mean that they would be transient. Isolated transient incidents are unlikely to affect invertebrate populations given the rapid regeneration times characteristic of these organisms.

Labelling

Labels approved for use under permit instructed users that baits must not be laid if the monitoring program does not indicate that mouse activity is at a sufficient level. Baiting when mouse populations are high reduces non-target risks by ensuring that a high proportion of the bait will rapidly be eaten by mice on the first night of baiting. It is considered necessary the approved label reflect this objective.

State government officers involved in use of Mouseoff under permit advised that a “sufficient level” of mice activity was determined to be when mouse populations were considered an economic threat. As the data collected under permit were used to demonstrate that the use was not an undue risk to the environment and because the concept of economic threshold is a great deal easier for users to appreciate, the use of economic threshold on the label is considered adequate to ensure adequate mouse activity exists, thereby minimising any remaining bait.

It is important that baits be laid evenly in order to minimise risks to birds. It is considered necessary for the application rate expressed on the proposed label, to include the statement “achieve an even coverage of 2-3 grains/m²” to require the user to apply the product in a manner that will further minimise the risk to granivorous birds.

The proposed label for approval instructs users that baits should be distributed so as to minimise exposure to birds. The applicant has agreed to include further guidance, such that the label now includes the following: “It is preferable to place baits late in the day when birds have finished feeding. Do not place baits within 50 m of the crop perimeter, over bare ground, or within 50 m of areas of native vegetation. Particular care should be taken when baits are applied near native vegetation using aircraft as high bait concentrations may occur on the ground beneath aircraft that need to climb steeply”.

Risks would be more significant where high concentrations of bait occur on the ground, as may occur in spill situations. The proposed label instructs users to collect any spilt bait. Spilt material, used containers, and excess or unused baits, should be buried beneath one metre in a disposal pit specifically marked and set up for this purpose.

Conclusions

The data package submitted in support of the registration of zinc phosphide lacks the usual guideline studies, but contains sufficient information to identify the main areas of concern. Zinc phosphide will not persist in the environment, unless conditions are very dry, or move significantly within it. Use to control mice in crops and crop stubble is not expected to lead to significant aquatic exposure, but some mammals and more particularly birds feeding in baited areas are likely to be poisoned if they consume enough of the baits. Such risks can be minimised by laying baits late in the day and only in areas of high mouse populations, as mice should consume a significant proportion on the first night. Avian risks can also be minimised by avoiding baiting near areas of remnant native vegetation. Similarly, risks can be reduced by avoiding baiting in situations where birds may see the baits, such as over bare ground or near fence lines from which birds may survey the treated area. High mouse populations would not be expected to occur where the ground is bare.

Much of the target selectivity apparently offered by zinc phosphide can be attributed to its application at a relatively low rate, insufficient to attract feeding birds, into areas where hungry mice have depleted food resources and will search for and rapidly consume baits on the ground. Higher rates of bait application, particularly where mice are present in low numbers, are likely to be more attractive to birds. It is vital that zinc phosphide baits be laid evenly, with no locally high concentrations, and only when mice are abundant. It is recognised that ground application of Mouseoff is likely to be more variable than aerial application. However, it is considered that ground application will not pose an unacceptable risk to granivorous birds if the user follows all label requirements (ie, by following label restraints and calibrating application equipment to ensure an even application of 2-3 grains per square metre).

Available data indicate that baiting in mature crops or into stubble may give rise to isolated avian mortality, but does not appear likely to incur broadscale avian impacts. Registration is supported in these situations, based on current data and subject to the conditions outlined above, and to close monitoring of use with immediate reporting of any adverse impacts that may occur to the National Registration Authority.

EFFICACY AND SAFETY ASSESSMENT

Justification for use.

Extremely high density mouse populations have been reported to be increasing in frequency (CSIRO Rodent Research Unit). The increasing frequency of severe mouse problems in cropping areas of Australia seems to be related to changes in farming practices. To compound the problem there is currently no registered in-crop rodenticide. Therefore an efficacious and publicly and environmentally acceptable rodenticide is crucial to the management options available to farmers with potential and existing mice problems.

Proposed use pattern

It is proposed that Mouseoff Zinc Phosphide Bait be used to control heavy infestations of mice in agricultural situations. The proposed rate is 1 kg/ha to achieve 2-3 grains per m². The product will be registered for all states and territories.

There are a number of restrictions on the application of the product to reduce the risk to the environment (non-target wildlife). See the proposed label following for full details. A 14 day Withholding Period for all crop uses is proposed.

Evaluation of efficacy

A number of reports on both Australian and overseas studies were provided to demonstrate efficacy of the product. Only the Australian data were considered relevant to the proposed use in Australia.

The Australian data consisted of a variety of trials (laboratory and field), in a number of States and a variety of farming situations. Data were presented from a variety of sources including CSIRO Rodent Research Group, Victorian Department of Natural Resources and Environment and the Grains Research and Development Corporation.

The data provided were found to be adequate in demonstrating that Mouseoff Zinc Phosphide Bait was effective in causing very large reductions of mice numbers in crops and crop stubble. However it was also noted that the level of efficacy was quite variable and that the presence of alternative feed often resulted in reduced effectiveness of the bait. In addition, data provided demonstrated that in a number of situations where mouse numbers were high and where moderately high mortality results were achieved in mice, sufficient mice survived to be considered an potential economic threat. Retreatment may be required under these circumstances. The proposed label includes statements warning users of this effect.

Phytotoxicity

No crop injury was observed in any trials and none are expected as there is little contact with the crops. Neither zinc phosphide nor phosphine is expected to cause crop phytotoxicity.

LABELLING REQUIREMENTS

DANGEROUS POISON
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING

M O U S E O F F
ZINC PHOSPHIDE BAIT

Active Constituent: 25 g/kg ZINC PHOSPHIDE

For the control of heavy infestations of mice in agricultural situations.

THIS PRODUCT IS NOT TO BE AVAILABLE EXCEPT TO PERSONS AUTHORISED
OR LICENSED UNDER THE RELEVANT STATE OR TERRITORY POISONS
CONTROLS FOR SCHEDULE 7 POISONS.

Net contents: 15 kg, 125 kg

Animal Control Technologies Pty Ltd.
46-50 Freight Drive
SOMERTON VIC 3062
AUSTRALIA

DIRECTIONS FOR USE

RESTRAINTS

DO NOT apply bait to bare ground (including fallow where there is no vegetative cover).

DO NOT apply bait in a trail.

DO NOT apply bait if heavy rain is imminent.

DO NOT apply bait inside 50 m of the crop perimeter or within 50 m of native vegetation.

DO NOT apply bait unless monitoring of mouse numbers indicate the potential for crop damage of economic significance.

Situation	Pest	Rate	Critical Comments
Grain crops, legume crops, canola, safflower, nut crops, and pasture. (Note: for all situations - only as a post emergent treatment, stubble of harvested crop prior to sowing seed, or when seed have been sown into crop stubble or other similar ground cover).	Mice	1 kg/ha to achieve an even coverage of 2-3 grains/m ²	Bait is only to be applied by aerial application or accurately calibrated ground application equipment to achieve 2-3 grains/m ² . It is imperative that all attempts are made to apply bait as evenly as possible to maximise product efficacy and minimise risks to non-target animals. Mouseoff Zinc Phosphide Bait will provide a high level of control in most situations. However in areas of extremely high mice densities or areas with significant amounts of alternative feed, sufficient mice may remain to cause damage to crops after treatment. Retreatment after 14 days may therefore be required in certain circumstances. It is recommended that pre-treatment estimations of the severity of the mouse problem are performed before applying bait and that post-baiting estimates are conducted to assess the effectiveness of the control operation. Bait may retain activity for several days after light rain or in damp conditions, and light showers can be tolerated. Maximum performance will however be expected under dry conditions.

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

THIS PRODUCT IS TOO HAZARDOUS FOR USE IN THE HOME GARDEN.
DO NOT USE THIS PRODUCT IN THE HOME GARDEN.

WITHHOLDING PERIOD

DO NOT harvest any crops or allow livestock to graze baited areas for 14 days after application.

PROTECTION OF WILDLIFE, THE ENVIRONMENT AND LIVESTOCK

Bait should be distributed to minimise exposure to non-target wildlife, especially birds and livestock. It is preferable to place baits late in the day when birds have finished feeding.

Particular care should be taken when baits are applied near native vegetation using aircraft as high bait concentrations may occur on the ground beneath aircraft that need to climb steeply. Spilt bait must be collected immediately and applied according to label directions or buried below one metre.

STORAGE AND DISPOSAL

The contents of each container should be used within 3 months of opening. Store in the closed original container in a dry cool well-ventilated area out of direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers. Store away from acids, water and any sources of heat or ignition.

Dispose of used containers by crushing and burying below one metre in a disposal pit specifically marked and set up for this purpose, clear of waterways, vegetation and roots.

Excess or unused baits must be buried below one metre. Empty containers and product must not be burnt.

SAFETY DIRECTIONS: Poisonous if swallowed. Releases dangerous phosphine gas slowly in moist air and immediately if wet. Do not inhale vapour. Avoid contact with eyes and skin. Keep away from water and liquids. Keep away from naked flames – forms toxic gas. When opening the container and using baits wear elbow-length PVC gloves and a full face respirator with combined dust and gas cartridge or supplied air respirator. Wash hands after use. After each days use wash gloves and respirator and if rubber wash with detergent and warm water.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre (phone: 13 11 26). Do not give direct mouth-to-mouth resuscitation if swallowed. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area.

MATERIAL SAFETY DATA SHEET: Additional information is listed in the MSDS which can be obtained from the supplier.

Batch Number:

Date of manufacture:

NRA Approval No. /

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.
Codex MRL	Internationally published standard maximum residue limit.
Efficacy	Production of the desired effect.
Formulation	A combination of both active and inactive constituents to form the end use product.
Leaching	Removal of a compound by use of a solvent.
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

- US EPA 1998, Reregistration Eligibility Decision (RED) Zinc Phosphide, July 1998.
- National Registration Authority for Agricultural and Veterinary Chemicals 1996, *Ag Manual: The Requirements Manual for Agricultural Chemicals*, NRA, Canberra.
- National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Requirements Series: Guidelines for Registering Agricultural Chemicals*, NRA, Canberra.
- National Registration Authority for Agricultural and Veterinary Chemicals 1996, *MRL Standard: Maximum Residue Limits in Food and Animal Feedstuffs*, NRA, Canberra.
- National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Labelling Code—Code of Practice for Labelling Agricultural Chemical Products*, NRA, Canberra.

NRA PUBLICATIONS ORDER FORM

To receive a copy of the full technical report for the evaluation of Zinc Phosphide in the product Mouseoff Zinc Phosphide Bait, please fill in this form and send it, along with payment of \$30 to:

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

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

Name (Mr, Mrs, Ms, Dr) _____
Position _____
Company/organisation _____
Address _____
Contact phone number (____) _____

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

Make cheques payable to 'National Registration Authority'.

___ Bankcard ___ Visa ___ MasterCard ___ Amex

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

Signature _____ Date _____