PUBLIC RELEASE SUMMARY
of the evaluation by the NRA of
the new active constituent:

Pyrimethanil

in the product:

SCALA 400 SC FUNGICIDE

1996

(Published on the APVMA website on 26 September 2011 with a complete table of contents added)
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**FOREWORD**

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent Statutory Authority with responsibility for the assessment and approval of agricultural and veterinary chemical product prior to 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 Policy Assessment Unit), the Environment Protection Agency (EPA), the National Occupational Health and Safety Commission (Worksafe Australia) and State Departments of Agriculture and Health.

The NRA has a policy of encouraging openness and transparency in its activities and seeking community involvement in decision making. The publication of Public Release Summaries for all product containing new active ingredients is a part of that process.

The information and technical data required by the NRA in order to assess the safety of new chemical product and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the document "Interim Requirements for the Registration of Agricultural and Veterinary Chemical Product" which can be obtained from the NRA.

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

The NRA welcomes comment both on the usefulness of this document and on suggestions for further improvement. Comments should be forwarded to the National Registration Manager, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box E240, Queen Victoria Terrace, Parkes, ACT, 2600.
ABBREVIATIONS AND ACRONYMS WHICH MAY APPEAR IN THIS DOCUMENT

ac  Active constituent
ADI  Acceptable Daily Intake (for humans)
AHMAC Australian Health Ministers Advisory Council
ai  Active ingredient
CPAU Chemicals Policy Assessment Unit (Department of Health and Family Services)
d  Day
DT50 Half life
EC50 Concentration at which 50% of the test population are immobilised
EUP End Use Product
Fo  Original Parent Generation
h  Hour
HPLC 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
LC50 Concentration that kills 50% of the test population of organisms
LD50 Dosage of chemical that kills 50% of the test population of organisms
mg  Milligram
mL  Millilitre
MRL Maximum Residue Limit (a legal 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
Pow Partition Coefficient, octanol/water
po  Oral
ppb parts per billion
PPE Personal Protective Equipment
ppm parts per million
s  Second
sc  Subcutaneous
SC Suspension Concentrate
SUSDP Standard for the Uniform Scheduling of Drugs and Poisons
<table>
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>T-Value</td>
<td>A value used to determine the First Aid Instructions for chemical product that contain two or more poisons</td>
</tr>
<tr>
<td>TGAC</td>
<td>Technical Grade Active Constituent</td>
</tr>
<tr>
<td>WDG</td>
<td>Water Dispersible Granule</td>
</tr>
<tr>
<td>WHP</td>
<td>Withholding Period</td>
</tr>
<tr>
<td>WSA</td>
<td>Worksafe Australia</td>
</tr>
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</table>
1. EXECUTIVE SUMMARY

INTRODUCTION

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has before it an application for registration of the product SCALA 400 SC FUNGICIDE and now invites comment from any person on whether this product should be registered. This invitation is being made as the active constituent contained in SCALA 400 SC FUNGICIDE (Pyrimethanil) is new to agriculture in Australia.

The purpose of this document is to provide a summary of the data evaluated and of the regulatory considerations reached during the evaluation, by the NRA of SCALA 400 SC FUNGICIDE for the control of grey mould (Botrytis cinerea) in grapevines.

Having completed its evaluation of the proposed use of Pyrimethanil in SCALA 400 SC FUNGICIDE, the NRA provides the following description of that evaluation for public comment:

AGRICULTURAL ASPECTS

SCALA 400 SC FUNGICIDE contains the active constituent Pyrimethanil, a contact and translaminar type fungicide, which is effective against fungal strains of Botrytis spp that have developed resistance to most commercially available fungicides. It is to be applied to grapevine at early flowering, 80 to 100% cap-fall and pre-bunch closure and at veraison (commencement of berry ripening phase) and pre-harvest if infection is favoured by wet weather. Pyrimethanil is a new chemical not previously contained in agricultural chemical products in Australia.

Pyrimethanil has been trialed in Australia on commercial vineyards and conditions were applicable to use of the fungicide under commercial conditions. Data was supplied from 14 trials done in Australia for three consecutive seasons (1992/93 to 1994/95) to evaluate the efficacy against grey mould (Botrytis cinerea) in grapevines. The data presented has very well substantiated the claim of SCALA 400 SC FUNGICIDE for the control of grey mould (Botrytis cinerea) in grapevine. No phytotoxic effects were noted in any of the trials.

SCALA 400 SC FUNGICIDE (Pyrimethanil) is presently registered in many wine producing countries and has been found effective against Botrytis infections in trials by several Australian wine companies.
ENVIRONMENTAL ASPECTS

Pyrimethanil applied by air blast or boom sprayers to grapevines during spring-summer is likely to result in significant contamination of soil, and volatilisation from soil and particularly plant surfaces is also likely to be significant. Spray drift is likely to be the main means of off-site contamination.

The major route for degradation of pyrimethanil reaching soil and water is microbial degradation. A proportion of applied pyrimethanil may volatilise, but is unlikely to persist in the atmosphere due to indirect photodegradation. Photolysis on surface soil, in water (particularly if highly acidic), and presumably on plant surfaces, may also hasten degradation. Hence pyrimethanil has low persistence in soil and water and moderate persistence in sediment. As it should only be used 1-2 times per annum, there should be sufficient time for degradation to near completion between years. While laboratory studies indicate that pyrimethanil can potentially leach, field studies suggest that except in extreme situations, pyrimethanil and its major metabolite are unlikely to leach deeply into soil and are unlikely to contaminate groundwater.

Tests indicate that pyrimethanil TGAC and 40% SC has slight acute and moderate prolonged toxicity to rainbow trout (Onchorynchus mykiss), slight acute toxicity to carp (Cuprinus carpio), moderate acute and prolonged toxicity to aquatic invertebrates (Daphnia magna) and moderate to slight toxicity to the green alga Selenastrum capricornutum. Pyrimethanil TGAC is practically non-toxic to birds and mammals, not evidently inhibitory to soil or sewage sludge microbial activity, and virtually non-toxic to bees. Pyrimethanil 40% SC formulation was found to have relatively low toxicity to earthworms. In laboratory studies, pyrimethanil 40% SC caused slight to high mortality to some insect and mite predators and no mortality in others, while field and semi-field studies showed no harmful effects on populations of various arthropods. The 40% SC applied at field rates caused no harm in the majority of plant species tested, but phytotoxicity was evident in some ornamental plant species.

Birds, mammals, bees and earthworms exposed to pyrimethanil in vineyards are unlikely to be adversely affected. Testing of insects and mites under laboratory conditions where exposure to residues is maximised indicated potential for harm in some cases. However, field or semi-field studies indicated that normal field rates did not harm the populations of beneficial arthropods under field conditions, including the species where laboratory tests indicated some toxicity. Mite studies show that Scala® can be recommended as safe for use in disease control within biological control programs for grapevine mites.

Calculations show that direct overspray at normal rates to shallow water could pose a hazard to algae and aquatic invertebrates. However, environmental risk analysis of the more likely situation of a 10% spray drift worst case (15 cm deep lentic water) contamination situation indicates that there is little risk of harm to fish, algae or Daphnia, based on the toxicity of either the TGAC or 40 SC formulation. Phytotoxicity to native plants is highly unlikely, as exposure is most likely to be at relatively low rates in spray drift.
PUBLIC HEALTH AND SAFETY ASPECTS

Toxicology

*Pyrimethanil*, the active ingredient in the product, has low acute oral, dermal and inhalation toxicity, and is not a skin or eye irritant, or skin sensitizer in animal studies. SCALA 400 SC FUNGICIDE, the 400 g/L formulation of *pyrimethanil*, has low acute oral, dermal and inhalation toxicity, and is a slight skin irritant, but is not an eye irritant or skin sensitizer, in animal studies.

The main effects in short and long-term studies with *pyrimethanil* in laboratory species were in the thyroid gland and urinogenital system in mice and rats, and the liver in rats. Dogs showed vomiting and reduced bodyweights, and some moderate haematological effects. A long-term study in rats showed slightly increased incidences of benign tumours in the thyroid gland, only at very high dietary levels of *pyrimethanil*. Other studies in rats showed that *pyrimethanil* indirectly stimulates the thyroid gland, by increasing liver enzyme activity. The thyroid tumours occurred at doses which would greatly exceed any anticipated dietary intake, and were not considered to be a significant indicator of human health risk associated with the use of SCALA 400 SC FUNGICIDE.

*Pyrimethanil* did not adversely affect genetic material (DNA), nor reproduction, nor did it cause birth defects in animals when administered during pregnancy.

Conclusion

Based on an assessment of the toxicology and the potential dietary intake of residues, it was considered that there should be no adverse effects on human health from the proposed use of SCALA 400 SC FUNGICIDE.

RESIDUES IN FOOD AND TRADE ASPECTS

Residues in Food

Residue data from Australia and overseas were generated from trials conducted on grapevines with use patterns equivalent to that proposed for Australia. The data indicate that finite residues of *pyrimethanil* were detected, with little change in levels over 21 days. In accordance with the recommended use pattern, a MRL of 5 mg/kg has been established for grapes with a withholding period of 7 days. Animal metabolism studies have shown that the potential for residues in animal commodities is low, due to rapid excretion of *pyrimethanil* and the low exposure of the compound to animals. A feeding restraint has been included on the label to reduce the likely incidence of animals being fed treated vine trash or vine by-products.

Trade

Data from residue trials conducted in Australia indicate that finite residues will be detected in grapes, when the product is used in accordance with the proposed use pattern. Upon consultation, the wine industry has stated that when wine from treated grapes is destined for countries where there are no established MRLs for chemicals which are used in Australia, it is the current practice...
of the industry to either extend the withholding period of the pesticide or restrict its use. In the case of SCALA 400 SC FUNGICIDE, as the product has not previously been used on grapes in Australia, the use would be restricted to before fruit-set, resulting in non detectable residues in wine. Therefore, with the full cooperation of the wine industry, the proposed use of SCALA 400 SC FUNGICIDE will not unduly prejudice Australian trade.

**OCCUPATIONAL HEALTH AND SAFETY ASPECTS**

Worksafe Australia has conducted a risk assessment on SCALA 400 SC FUNGICIDE containing *pyrimethanil* at 400 g/L as a suspension concentrate for use on grapevines to control grey mould and concludes that it can be safely used by workers.

Both *pyrimethanil* and SCALA 400 SC FUNGICIDE are determined not to be hazardous substances.

SCALA 400 SC FUNGICIDE will be imported fully formulated and re-packaged in Australia in the first year of registration. Subsequently, it will be imported fully packed and ready for use. The product is of very low oral, acute dermal and inhalation toxicity. It is a slight skin irritant, but is not an eye irritant or skin sensitiser.

The risk of accidental contact with the product during routine transport, storage and retailing is expected to be negligible.

Safety directions are established to enable end users to minimise contamination with the product. They include the use of cotton overalls buttoned to the neck and wrist and washable hat and elbow-length PVC gloves for workers opening the container, preparing the spray and using the prepared spray. Respiratory protection is not considered necessary for end users.

Workers should not re-enter treated areas until the spray deposits have dried. When prior entry is necessary, they should wear cotton overalls buttoned to the neck and wrist and elbow-length PVC gloves. Clothing must be laundered after each day's use.

*Pyrimethanil* and SCALA 400 SC FUNGICIDE can be used safely with the control measures indicated on the product label. Additional information is provided in the Material Safety Data Sheet for the product.
2. INTRODUCTION

The purpose of this document is to provide the public with a summary of the data evaluated, and of the regulatory considerations reached, in the evaluation by the NRA of SCALA 400 SC FUNGICIDE.

The use of SCALA 400 SC FUNGICIDE is proposed as a control for grey mould (*Botrytis cinerea*) on grapevines in all States and Territories of Australia. The NRA now invites comment from any person on whether SCALA 400 SC FUNGICIDE should be registered.

Comments should be sent by 3 September 1996 to:

Ranjit Gajanayake  
Product Evaluator  
National Registration Authority  
PO Box E240 Queen Victoria Terrace  
PARKES ACT 2600

Tel: 06 272 5567 Fax: 06 272 3218

APPLICANT

The applicant, Hoechst Schering AgrEvo Pty Ltd, has applied for the registration of SCALA 400 SC FUNGICIDE, which contains a new active constituent, *Pyrimethanil*.

PRODUCT DETAILS

SCALA 400 SC FUNGICIDE will be formulated by Hoechst Schering AgrEvo GmbH of Germany, and will be imported as a fully formulated product. It is a suspension concentrate formulation containing 400 g/L of *Pyrimethanil*.

OVERSEAS REGISTRATION STATUS

Countries having registrations of product containing *Pyrimethanil* are shown below –

<table>
<thead>
<tr>
<th>Country</th>
<th>Crop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>apples, strawberries</td>
</tr>
<tr>
<td>Chile</td>
<td>vines, apples, strawberries, tomatoes, vegetables</td>
</tr>
<tr>
<td>Country</td>
<td>Products</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>Cyprus</td>
<td>vines, apples, pears, strawberries,</td>
</tr>
<tr>
<td></td>
<td>tomatoes, potatoes, vegetables</td>
</tr>
<tr>
<td>France</td>
<td>vines, strawberries, fodder peas,</td>
</tr>
<tr>
<td></td>
<td>ornamentals</td>
</tr>
<tr>
<td>Israel</td>
<td>strawberries, tomatoes, cucumber,</td>
</tr>
<tr>
<td></td>
<td>roses</td>
</tr>
<tr>
<td>New Zealand</td>
<td>vines, apples</td>
</tr>
<tr>
<td>Netherlands</td>
<td>apples, strawberries, bulb dip</td>
</tr>
<tr>
<td>Poland</td>
<td>apples, pears &amp; strawberries</td>
</tr>
<tr>
<td>South Africa</td>
<td>vines</td>
</tr>
<tr>
<td>Spain</td>
<td>vines, strawberries, tomatoes</td>
</tr>
<tr>
<td>Switzerland</td>
<td>vines, pomefruit, ornamentals</td>
</tr>
</tbody>
</table>
### 3. PROPERTIES OF THE CHEMICAL ACTIVE CONSTITUENT

The chemical active constituent Pyrimethanil is manufactured in Germany and has the following properties:

#### CHEMICAL IDENTITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common name</td>
<td>Pyrimethanil</td>
</tr>
<tr>
<td>Chemical Abstracts name</td>
<td>N-(4,6-dimethylpyrimidin-2-yl) aniline 2-anilino-4,6-dimethylpyrimidine (IUPAC)</td>
</tr>
<tr>
<td>Product Name</td>
<td>SCALA 400 SC FUNGICIDE</td>
</tr>
<tr>
<td>CAS Registry Number</td>
<td>53112-28-0</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>C12H13N3</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>199.26</td>
</tr>
<tr>
<td>Appearance (colour)</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>almost odourless</td>
</tr>
<tr>
<td>Physical state</td>
<td>crystalline powder</td>
</tr>
<tr>
<td>Melting Point</td>
<td>96.3°C</td>
</tr>
<tr>
<td>Vapour Pressure</td>
<td>1.1 x 10^-3 Pa at 20°C</td>
</tr>
<tr>
<td></td>
<td>2.2 x 10^-3 Pa at 25°C</td>
</tr>
<tr>
<td></td>
<td>4.1 x 10^-3 Pa at 30°C</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>0.121 g/L at 25°C and pH 6.1</td>
</tr>
<tr>
<td></td>
<td>0.099 g/L at 20°C and pH 9.9</td>
</tr>
<tr>
<td></td>
<td>0.160 g/L at 20°C and pH 4.2</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>log n-octanol/water: 2.84 at 25°C</td>
</tr>
<tr>
<td>Structural Formula</td>
<td></td>
</tr>
</tbody>
</table>
4. AGRICULTURAL ASSESSMENT

JUSTIFICATION FOR USE

Grey mould (*Botrytis cinerea*) is a serious disease of grapevine, occurring in vineyards throughout the world which affects the quality and the quantity of the crop. Pyrimethanil is a contact and translaminer fungicide with a particular role against resistant strains of *Botrytis* in grapevine disease control programs.

PROPOSED USE PATTERN

SCALA 400 SC FUNGICIDE is proposed for use in all States and Territories and to be applied at the rate of 1.5 to 2.0 L/ha (0.6 to 0.8 kg/ha active ingredient). Sprays should be applied at early flowering, 80-90% cap-fall and pre-bunch closure, and at verasion (commencement of berry ripening phase) and pre-harvest if infection is favoured by wet weather. SCALA can be applied using suitable high or low volume ground application equipment. Equipment should produce a spray that ensures penetration of the canopy and coverage of the flowers and branches.

EVALUATION OF EFFICACY

The applicant, Hoechst Schering AgrEvo Pty Ltd, provided efficacy data to support the claims of SCALA 400 SC FUNGICIDE. The reviewers of this data were satisfied that the claim for SCALA 400 SC FUNGICIDE was supported by the data presented.

SCALA 400 SC FUNGICIDE has been trialed in Australia for 3 consecutive seasons (1992/93 to 1994/95) to evaluate its efficacy against grey mould (*Botrytis cinerea*) in grapevines in vineyards in Australia.

Fourteen trials have been conducted. All trials included controls, and in general had an appropriate level of replication and included randomisation or blocking of treatments and controls.

The spray application times reflected the current recommended treatment times (growth stages) for control of *Botrytis* in vineyards in Australia.

Trials have been conducted using an adequate range of varieties and vineyard locations.

PHYTOTOXICITY

In all trials, SCALA 400 SC FUNGICIDE has demonstrated a high level of crop safety. No phytotoxicity has been reported to either target or non target crops from the use of SCALA.

CONCLUSION

SCALA 400 SC FUNGICIDE has been shown in trials to be effective for the control of grey mould on grapevines with no observed adverse effects on crop yield.
ENVIROMENTAL ASSESSMENT

ENVIRONMENTAL FATE

*Pyrimethanil* will be applied by air blast or boom sprayers to grapevines during spring-summer, at one or at most two occasions only per annum, to minimise the chances of fungal resistance to it developing. Significant contamination of soil is likely from spray missing foliage and from run-off. Volatilisation from soil and particularly plant surfaces is also likely to be significant. Spray drift is likely to be the main means of off-site contamination.

- Degradation rates and routes

- **Hydrolysis**

 *Pyrimethanil* only hydrolyses slightly in water (DT$_{50}$ = 2-3 years), but is subject to aerobic microbial degradation and may be subject to direct or indirect photolytic degradation.

- **Aqueous and soil photolysis**

The protonated form of *pyrimethanil*, present in significant quantities at about pH 5 and lower, is subject to direct photolysis in water, with an estimated DT$_{50}$ of 1.5-5 days in Australian latitudes (29 hours in continuous light). Photolysis in water at neutral and basic pH is very slow in buffered distilled water (DT$_{50}$ = 8-13 months in Australian latitudes), but was found to be much faster in synthetic natural waters, where the presence of humic acid reduces the DT$_{50}$ at pH 7 to approximately 48 hours continuous irradiation, presumably due to indirect photolysis. Thus photolytic degradation may hasten dissipation from water. However, the extent to which this occurs is likely to be limited by turbidity, which is common in waters such as farm dams and channels. Photolysis and volatilisation may both hasten dissipation from soil, the DT$_{50}$ for soil photolysis having been estimated as approximately 5 days.

- **Laboratory soil and water metabolism**

In the absence of light, the DT$_{50}$ of *pyrimethanil* in aquatic situations (aerobic water and partially anaerobic sediment) was found to be 40-121 days for water + sediment, but dissipation from free water is more rapid (9-24 days), presumably due to adsorption to sediment. *Pyrimethanil* has low persistence (2-6 weeks) in water, but moderate persistence (6 weeks-6 months) in sediment. Aerobic soil degradation DT$_{50}$ in the absence of light was found to range from 25-82 days in laboratory studies, with an initial lag phase consistent with a build-up of micro-organisms adapted to *pyrimethanil* degradation. A two-compartment model for degradation time was more satisfactory, and is consistent with binding of *pyrimethanil* and metabolites to organic matter from which it must be released to be fully accessible to degradation. Aquatic and soil degradation was shown to be due to microbial degradation, but interestingly, *pyrimethanil* was not degraded during incubation with activated sludge and failed the "ready biodegradability" and "inherent biodegradability" tests.
- field dissipation

$DT_{50}$ in field dissipation studies ranged from 25-54 days, with an average of 28 or 35 days depending on the degradation model used, indicating that pyrimethanil has low (2-6 weeks) to moderate (6 weeks-6 months) persistence in soil under field conditions. The field $DT_{50}$ is only marginally faster than laboratory studies in the dark.

-bioaccumulation

*Pyrimethanil* is unlikely to bioaccumulate in fish, as the log n-octanol/water coefficient (log $P_{ow}$) value for this substance < 3 and bioconcentration factor (BCF) estimated by the EPA from this value is <100.

- Metabolites

Significant production of CO2 from both the anilino and pyrimidine parts of the molecule and extraction or detection of various unidentified metabolites, including polar substances, indicates a high degree of mineralisation of the molecule can occur. *Pyrimethanil* and its metabolites may also become strongly bound to soil organic matter, but these residues are at least partially accessible to further microbial attack. 2-amino-4,6-dimethylpyrimidine has been identified as a major *pyrimethanil* metabolite in aerobic soil and aquatic metabolism studies (~10% up to 58% applied *pyrimethanil*). Laboratory studies showed it to be slightly more persistent than the parent molecule. The major proposed route for aerobic soil degradation is production of 2-amino-4, 6-dimethylpyrimidine, which reacts to produce 2-hydroxy-4,6-dimethyl-pyrimidine, followed by hydrolysis to produce aliphatic ketones, ammonia and CO2.

- Mobility

- laboratory

Evaluations of the $K_{oc}$ of *pyrimethanil* in conventional flask adsorption/desorption studies indicated that it had low to moderate mobility in soil, and estimation of the Gustafson Ubiquity Score (GUS) from $K_{oc}$ and soil degradation half life data indicated that *pyrimethanil* is a transitional leacher. Laboratory leaching studies showed significant movement down soil columns ($\geq 24$ cm depth in 3 tests) from heavy irrigation, but $\leq 1.7\%$ of applied *pyrimethanil* emerged in the percolate from the columns during the test period. With a lower $K_{oc}$ and longer $DT_{50}$, the *pyrimethanil* metabolite 2-amino-4,6-dimethylpyrimidine ranks according to GUS as a probable leacher and is more likely to move downwards in soil.

- field

However, *pyrimethanil* and known major metabolites were not detected in leachate from a field lysimeter study. This study and a field dissipation study showed that *pyrimethanil* and its residues were largely confined to the surface 10 cm of soil, with little or no detectable movement below 20 cm. Thus, while laboratory studies indicate potential for *pyrimethanil* to leach downwards in the soil, significant downward movement has not been confirmed in field studies.
The vapour pressure of pyrimethanil indicates it is slightly volatile, and laboratory studies found that 27% and 10% respectively of applied pyrimethanil volatilised from leaf and soil surfaces after 24 hours. Thus significant volatilisation may occur in the field from plant and soil surfaces, but the Henry's Law Constant indicates very slight volatilisation from water surfaces. Volatilised pyrimethanil is likely to be degraded with an estimated DT$_{50}$ $\sim$1.8 hours by reaction with photolytically produced OH radicals.

ENVIRONMENTAL TOXICITY

The majority of toxicity studies with pyrimethanil formulated as a suspension concentrate (40% SC) were conducted with a formulation differing from the final formulation used for Scala® only in minor details. Hence toxicity studies based on either formulation have been accepted for assessment of the EUP Scala®.

- Aquatic

Tests indicated that pyrimethanil TGAC has slight acute (96 h) toxicity (LC$_{50}$ = 10.6 mg.L$^{-1}$) and moderate prolonged (21 d) toxicity (LC$_{50}$ = 7.2 mg.L$^{-1}$) to rainbow trout (Onchorynchus mykiss), slight acute toxicity to carp (Cupinus carpio), and moderate acute (48 h) and prolonged (21 d) toxicity (EC$_{50}$ = 0.97-2.9 mg.L$^{-1}$) to aquatic invertebrates (Daphnia magna). Acute and prolonged toxicity of pyrimethanil 40 % SC was less than that of the TGAC by approximately 2-3 fold, but still generally had a similar toxicity rating. Using the same toxicity scale, pyrimethanil TGAC was moderately toxic (LC$_{50}$ = 1.20 and 5.84 mg.L$^{-1}$ for biomass and growth rate respectively) to the green alga Selenastrum capricornutum and the 40 % SC formulation was 6 X (growth rate) to 16 X (biomass production) less toxic, having slight toxicity.

- Avian and terrestrial

Tests indicated that pyrimethanil TGAC is practically non-toxic to birds (LD$_{50}$ > 2,000 mg.kg$^{-1}$) and mammals, not evidently inhibitory to soil or sewage sludge microbial activity, and virtually non-toxic to bees (LD$_{50}$ > 100 μg per bee). Pyrimethanil 40 % SC formulation was found to be relatively low toxicity to earthworms (Eisenia fetida, TGAC - 14-day LC$_{50}$ =~625 mg.kg$^{-1}$ dry soil).

- Arthropod predators and parasites

In laboratory studies, pyrimethanil 40 % SC caused 99% mortality to the parasitic wasp Trichogramma cacoeciae and 85% mortality to predatory ladybird larvae (Coccinella septempunctata) at 1.0 kg.ha$^{-1}$ a.i.. It was rated as slightly toxic to the predatory mite Typhlodromus pyri at 400 g.ha$^{-1}$ a.i. and to lacewing (Chrysoperla carnea) larvae at 1.0 kg.ha$^{-1}$ a.i. However, field studies with the SC found no harmful effects on Typhlodromus pyri numbers in German vineyards, even with repeated spraying, and laboratory studies in with other predatory mite species collected from Australian vineyards indicated that they were not affected at field rates of Scala®. Ladybird and lacewing populations were also unaffected by field spraying in a Dutch and an English apple orchard.
The SC caused some toxicity to the parasitic wasp *Aphidius rhopalopsiphi* in a preliminary laboratory study, but no toxicity in an extended study treating wasps on plants in pots rather than in small arenas. The SC was not toxic in laboratory studies at 1.0 kg.ha\(^{-1}\) a.i. to hoverfly or the Heteropteran bug *Orius laevigatus*, and in strong contrast to its toxicity in the laboratory to the parasitic wasp *Trichogramma cacoeciae*, pyrimethanil resulted in zero mortality to the parasitic wasp *Coccogymimus turionellae* at 1.0 kg.ha\(^{-1}\) a.i. Field studies also indicate low toxicity to various other beneficial and non-target arthropods (predator bugs, earwigs, wasps).

- **Plants**

No data are available regarding phytotoxicity to non-target native plants. However, the absence of significant phytotoxicity to grapes, or to many of the ornamental plant species tested, suggests that *pyrimethanil* is unlikely to cause serious phytotoxicity to non-target species, at least at the lower rates which might be expected from spray drift.

**PREDICTION OF ENVIRONMENTAL HAZARD**

*Pyrimethanil* residues would be expected on plant surfaces, including the grapevine canopy, grapes and interrow plant cover, soil, invertebrates exposed to spray and grapevine trellises. Surface water, uncultivated land and nearby non-target plants (e.g. trees and grasses) may be contaminated through overspray, spray drift and/or run-off.

- **Birds and animals**

Birds and mammals exposed to field concentrations of *pyrimethanil* by direct contact or ingestion are unlikely to be adversely affected, as the rates of application are well below the exposure rates required to cause toxicity.

- **Non target invertebrates**

Earthworms are likely to be exposed when they move into the upper horizons of the soil to feed. The estimated environmental concentration (EEC) calculated assuming incorporation of the maximum rate of application into the top 5 cm of soil is \(~1.07\) mg.kg\(^{-1}\), which is well below LC\(_{50}\) estimates based on laboratory studies. Pyrimethanil has also been shown to cause no harm to soil microflora at rates of \(~1\) and 10 mg.kg\(^{-1}\) soil.

While laboratory studies indicate that the predatory mite *Typhlodromus pyri* may be harmed to some extent by exposure to pyrimethanil at field rates, field investigations show no evidence of toxicity. The results indicating no toxicity at field rates with the predatory mites *Typhlodromus doreenae*, *T. dossei* and *Amblyseius victoriensis* are particularly pertinent to mite pest management in Australian vineyards, where they provide biological control of pest mites in grapes. Scala® can be recommended as safe for use in disease control within biological control programs for grapevine mites.

Testing of insects to *pyrimethanil* 40 % SC or TGAC on two-dimensional substrates under controlled laboratory conditions where exposure to residues is maximised indicated potential for harm in some cases. However, all the field or semi-field studies indicated that normal field rates did not harm the populations of beneficial arthropods under field conditions, including the species where laboratory tests indicated some toxicity.
Aquatic organisms

Using US EPA methodology a worst case scenario can be estimated for a direct overspray on to 15 cm deep lentic water of the formulated product at the maximum label rate (800 g.ha$^{-1}$ active ingredient). This results in an estimated environmental concentration (EEC) of 533 μg.L$^{-1}$ pyrimethanil.

Environmental risk analysis using this EEC and toxicity data from laboratory studies indicates there is a potential hazard from a direct overspray to aquatic organisms (the invertebrate Daphnia magna and green algae Selenastrum capricornutum, but not rainbow trout or carp). The hazard is significantly lower with the formulated product than with technical pyrimethanil, nonetheless there is still a potential hazard from direct overspray with Scala® to Daphnia, based on prolonged exposure data.

A much more likely situation in practical use of this product in vineyards is contamination of surface waters by spray drift and run-off of material sorbed to soil and organic matter particles, where the amounts of pyrimethanil in water would be expected to be considerably lower than the estimated EEC of 533 μg.L$^{-1}$. The US EPA estimates that for pesticides applied by air or mist blower, approximately 10% of the amount sprayed will reach the aquatic environment via spray drift. Assuming this as a worst case, an EEC of 53 μg.kg$^{-1}$ would result. Under a 10% spray drift worst case (15 cm deep lentic water) contamination situation, there is little risk of harm to fish, algae or Daphnia, based on the toxicity of either the TGAC or 40 % SC. The risk from spray drift is further ameliorated by the fact that water bodies are likely to average >15 cm in depth, and that spray drift with good management practices should be < 10%. Therefore, with good agricultural practices, the hazard to aquatic organisms from the use of Scala® should be low.

Non target plants

Phytotoxicity to native plants is highly unlikely, especially as exposure is most likely to be at relatively low rates in spray drift.

CONCLUSIONS

The submission contains good, comprehensive data and the EPA believes that overall, a low hazard to the environment is indicated and that the use of pyrimethanil according to label recommendations and good agricultural practice should not result in environmental contamination or acute poisoning of wildlife.
6. PUBLIC HEALTH AND SAFETY ASSESSMENT

EVALUATION OF TOXICOLOGY

The toxicology database for *pyrimethanil*, which consists 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. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse effects in humans would be expected.

**Toxicokinetics and Metabolism**

A single oral dose of *pyrimethanil* in mice or rats was well absorbed, metabolised, and rapidly excreted, mainly in urine, with the remainder excreted in faeces. A single oral dose in dogs was well absorbed, and rapidly excreted, mainly in faeces, with the remainder excreted in urine. In dogs, some of the dose was excreted in bile.

**Acute Studies**

*Pyrimethanil* has low acute oral (LD$_{50}$ = 4150 mg/kg bw), dermal (LD$_{50}$>5000 mg/kg bw), and inhalation (LC$_{50}$ > 1980 mg/m$^3$, the highest attainable concentration) toxicity in rats, and is not a skin or eye irritant in rabbits, or a skin sensitizer in guinea pigs.

SCALA 400 SC FUNGICIDE has low acute oral (LD$_{50}$ > 5000 mg/kg bw), dermal (LD$_{50}$ > 4000 mg/kg bw) and inhalation (LC$_{50}$ > 1260 mg/m$^3$, the highest attainable concentration) toxicity in rats, and is not an eye irritant in rabbits, or a skin sensitizer in guinea pigs, but is a slight skin irritant in rats.

**Repeat Dose Studies**

The thyroid gland, liver and urinary system were the main targets in 28-day and 13-week dietary studies in mice and rats, with increased liver weights, cell death in kidney tubules and larger thyroid follicular cells occurring in the 13-week studies from 139 mg/kg bw/d in mice, and 54 mg/kg bw/d in rats. Rats in the 13-week study showed complete recovery within 4 weeks after cessation of treatment. Dogs showed vomiting and bodyweight loss, increased white blood cells, and reduced blood clotting times in 28-day and 90-day studies, at the very high oral dose of 800 mg/kg bw/d.

**Carcinogenicity studies**

An 80-week dietary study in mice showed no effects on the types and incidences of tumours. There were increased incidences of urinogenital lesions in males, which included distension of the urinary bladder, seminal vesicles, and coagulating gland, mainly at the high-dose of 240 mg/kg bw/d.
A 2-year dietary study in rats showed increased liver weights, enlargement of liver cells, increased depletion of colloid, and pigmentation and enlargement of the follicular epithelium in the thyroid gland. There was a slight increase in benign tumours of the thyroid gland, only at the high-dose of 221 mg/kg bw/d. Pyrimethanil was shown to indirectly stimulate the thyroid gland, by increasing liver enzyme activity.

Reproduction and Developmental Studies

*Pyrimethanil* had no effects on reproduction parameters in a 2-generation rat study. The development of pups, in terms of bodyweight gain and performance of the righting reflex, was slightly retarded only at the highest dose (500 mg/kg bw/d), which was also toxic to the parents.

Genotoxicity

*Pyrimethanil* was not mutagenic in bacteria, did not cause chromosomal aberrations in human lymphocytes *in vitro*, did not cause unscheduled DNA synthesis in rat liver cells *in vivo*, and did not cause mutations in Chinese hamster ovary cells *in vitro*. These studies indicate that pyrimethanil dose not cause damage to genetic material (DNA).

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 that it was not necessary to include *pyrimethanil* in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate warning statements on the product label.

NOEL/ADI

The most sensitive species was the rat, with a NOEL of 17 mg/kg bw/d. In order to calculate the 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 of 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 0.2 mg/kg bw/d for *pyrimethanil* was established.
7. RESIDUES IN FOOD AND TRADE ASSESSMENT

Background

Pyrimethanil is the active ingredient of Scala 400 SC Fungicide which may be applied as a spray to apples, pears, grapes, strawberries and tomatoes for the control of a range of fungal diseases. Its mode of action is unusual in that it inhibits the secretion of fungal enzymes required for the infection process. It is effective against all strains of Botrytis. Temporary MRLs were previously established.

Appropriate residue and metabolism studies were presented, in accordance with the Requirements for Clearance of Agricultural and Veterinary Chemical Products, to support the use of pyrimethanil on grapes in Australia.

Residues in Food Commodities - Grapes

There were six Australian trials (2 in Vic, 2 in SA and 2 in NSW) and of these three incorporated wetting agent and three did not. All trials used applications at the recommended maximum rate and at double that rate (800 and 1600 g ai/ha), and four grape varieties were used. In four trials there was a single treatment plus two treatments at a range of intervals likely to occur in practice. In the other trials there were three or five applications.

Residues were determined at intervals 0-91 days after the final application. It appeared that there was little change in residue level over the first 14-21 days and this was followed by a slow decline with residues still 0.1-0.6 mg/kg after 60-90 days. Maximum residue detected following recommended application was 2.0 mg/kg at 14 days while after double application 3.8 mg/kg was the maximum.

Overseas trials on many varieties of grapes were conducted in Germany (two trials involving five sites), Italy and Greece. Application rates varied from 600 to 2000 g ai/ha and some intervals between applications were as short as 12 days. Residue levels were higher when the treatment interval was shorter. The maximum residue detected was 7.2 mg/kg, 0 days following three treatments at 800 g ai/ha, final interval 14 days. This dropped to 3.8 mg/kg at 14 days. In the same trial, when the final interval was 22 days, residues at 0 days were 2.4 mg/kg. Residue decline patterns were similar to those found in Australian trials.

Overseas studies on residues in wine and other grape commodities were also provided. While these studies were not definitive, wine residues were considerably less than those in the original grapes, but did not change much during storage. In one report, grapes at 0.51 mg/kg gave juice at 0.37 mg/L, raisins at 0.80 mg/kg, wet pomace at 1.2 mg/kg, dry pomace at 3.8 mg/kg and raisin waste at 9.25 mg/kg.

The residue data indicate that, in accordance with the recommended pattern of use the withholding period should be:

Grapes 7 days
Reports of two plant metabolism trials (grapes and apples) showed that metabolites are almost identical. The primary pathway is hydroxylation of the methyl groups of the pyrimidine ring followed by conjugation with sugars. Studies on mice, rats, dogs and a cow showed that pyrimethanil was absorbed, metabolised and excreted rapidly. There were only small amounts of parent compound in faeces. Metabolism was extensive mostly involving oxidation to OH in both aromatic rings. A minor pathway was oxidation of methyl groups to the alcohol. Metabolites were excreted mainly as glucuronide or sulphate conjugates. The significant residue in both plants and animals is the parent pyrimethanil.

Detailed descriptions of two analytical methods were presented. These varied slightly in the extraction and clean-up procedures. Determination was by HPLC with UV detection at 268 nm. The limit of determination was 0.02-0.05 mg/kg.

**MRL Standard**

The following additions have been recommended to the MRL Standard:

<table>
<thead>
<tr>
<th>Table 1</th>
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<table>
<thead>
<tr>
<th>Compound</th>
<th>Food</th>
<th>MRL (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add: Pyrimethanil</td>
<td>FB 0269 Grapes</td>
<td>5</td>
</tr>
</tbody>
</table>

and

<table>
<thead>
<tr>
<th>Table 3</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>Residue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add:</td>
<td>Pyrimethanil</td>
</tr>
</tbody>
</table>

Since data on residues following feeding to animals was not provided the label will include the restriction:

DO NOT FEED TRASH OR BY-PRODUCTS RESULTING FROM TREATED GRAPES TO LIVESTOCK
Trade

Data from residue trials conducted in Australia indicate that finite residues will be detected in grapes, when the product is used in accordance with the proposed use pattern.

The wine industry has been consulted on the issue of the proposed use of SCALA 400 SC FUNGICIDE and the likelihood of trade implications. The Australian Wine Research Institute has stated that when wine is destined for countries where there are no established MRLs or registrations for chemicals which are used in Australian viticulture, it is the current practice of the industry to either extend the withholding period of the pesticide (export harvest interval) or restrict its use. In the case of SCALA 400 SC FUNGICIDE, as the product has not previously been used on grapes, use would be restricted to before fruit-set, resulting in non-detectable residues in wine. If data becomes available showing the degradation of pyrimethanil residues through the wine making process, then the industry will revise its current recommendation.

Therefore in summary, upon consultation with the wine industry, the Residues Evaluation Section is satisfied that with the appropriate regulation by industry as outlined above, the proposed use of SCALA 400 SC FUNGICIDE will not unduly prejudice Australian trade.
8. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

*Pyrimethanil* is determined not to be a hazardous substance by Hoechst Schering AgrEvo Pty Ltd according to National Occupational Health and Safety Commission (NOHSC) Approved Criteria for Classifying Hazardous Substances.

*Pyrimethanil* is an off white to light beige to light yellow, almost odourless crystalline powder.

SCALA 400 SC FUNGICIDE is determined not to be a hazardous substance by Hoechst Schering AgrEvo Pty Ltd according to NOHSC Criteria. The product is of very low oral, low acute dermal and inhalation toxicity. It is a slight skin irritant, but is not an eye irritant or skin sensitiser.

SCALA 400 SC FUNGICIDE will be imported fully formulated and re-packaged in Australia in 5L and 10L high density polyethylene containers in the first year of registration. Subsequently, it will be imported fully packed and ready for use.

*Pyrimethanil* and SCALA 400 SC FUNGICIDE are not classified as Dangerous Goods under the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code).

**Transport, storage and retailing**

Australian workers involved in transport, storage and retailing of the product will not be exposed to the product unless the packaging is breached.

Advice on safe handling of the product during routine transport and storage is provided in the Material Safety Data Sheet (MSDS) for SCALA 400 SC FUNGICIDE.

**End use**

SCALA 400 SC FUNGICIDE will be used as a high volume or low volume ground spray to control grey mould in grapevines. It may be applied from early flowering till harvest by owner operators or contract workers, using suitable (eg. air assisted) ground application equipment. The number of repeat applications is restricted under the resistance management strategy.

End users may become contaminated with SCALA 400 SC FUNGICIDE when making up the working strength solution and applying the spray. The concentration of product in the spray will be: < 0.4% for low volume spray and < 0.2% for high volume spray, corresponding to < 0.16% and < 0.08% *pyrimethanil*, respectively. Workers will also need to clean up spills and maintain and clean spray equipment. The main routes of exposure for end users will be by skin contamination and breathing in of spray mist.

Potential exposure during use was estimated, as worker exposure studies were not available for this product. This indicated that predicted exposure to the product or working strength spray is not expected to result in short-term or long-term health effects in workers. To enable end users to avoid any unnecessary contamination with the product or spray, personal protective equipment (PPE) is prescribed on the product label. Respiratory protection is not considered necessary for end users.
SCALA 400 SC FUNGICIDE can be tank mixed with a number of other pesticides. When using SCALA 400 SC FUNGICIDE with Bayfidan, workers need to use a different glove type, namely butyl rubber gloves.

**Entry into treated areas or handling treated crops**

There is a 7-day withholding period prior to harvest.

Workers may need to enter treated areas to carry out routine grapevine maintenance. Plants may become quite wet with spray as the foliage needs to be thoroughly covered. Therefore the potential exposure to product residues is high. Workers should not re-enter treated areas until the spray deposits have dried. When prior entry is necessary, they should wear cotton overalls buttoned to the neck and wrist and elbow-length PVC gloves. Clothing must be laundered after each day’s use.

**Recommendations for safe use - all workers**

End users should follow the instructions and Safety Directions on the SCALA 400 SC FUNGICIDE label. Safety Directions include the use of cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves for workers opening the container, preparing the spray and using the prepared spray.

The PPE recommended should meet the relevant Standards Australia standard specified below:

- AS 2161-1978 Industrial Safety Gloves and Mittens (Excluding Electrical and Medical Gloves)
- AS 3765-1990 Clothing for protection against hazardous chemicals

Workers tank mixing SCALA 400 SC FUNGICIDE and Bayfidan should use butyl rubber gloves. This information is included on the SCALA 400 SC FUNGICIDE label.

Workers should comply with re-entry statement on the label.

Manufacturers and importers should produce a MSDS for any future hazardous products containing *pyrimethanil*. 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**

SCALA 400 SC FUNGICIDE can be used safely if handled in accordance with the instructions on the product label and other control measures described above. Additional information is available on the product MSDS.

Future products containing *pyrimethanil* at different concentrations, or with different formulations, use patterns or application methods will require a separate occupational health and safety risk assessment.
Products containing different non-active constituents or different concentrations of existing non-active constituents, will require an assessment in order to assign safety directions.
READ SAFETY DIRECTIONS BEFORE OPENING OR USING

SCALA®

400 SC FUNGICIDE

Active Constituent: 400 g/L PYRIMETHANIL

GROUP I FUNGICIDE

For Control of Grey Mould

(Botrytis cinerea) including

Fungal Strains Resistant to

Dicarboximides and

Benzimidazoles, in Grapevines

5 LITRES

AgrEvo  A company of Hoechst and Schering
SCALA 400 SC FUNGICIDE

DIRECTIONS FOR USE - (For Use in All States and Territories)

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE</th>
<th>APPLICATION RATE</th>
<th>CRITICAL COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grape vines</td>
<td>Grey mould (Botrytis cinerea)</td>
<td>Flowering 200 ml/100 L water *</td>
<td>Applications should be made at the critical timings for Botrytis control as indicated by the AVCARE Resistance Management Strategy. Refer to General Instructions for full details of the strategy. Scala should be included in a spray program in conjunction with products with a different mode of action. Refer to Application Frequency in General Instructions. Use a sufficient amount of water and/or adequate equipment to ensure penetration, of the canopy and coverage of the flowers or bunches. May be used with a non-ionic wetting agent. For low volume applications use the high rate at flowering on dense canopies or when conditions favour disease.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post-flowering 200 mL/100 L water * (maximum 2.0 L/ha)</td>
<td>* Refer to Instructions for details on water volumes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flowering 1.5 to 2.0 L/ha</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post-flowering 2.0 L/ha</td>
<td></td>
</tr>
</tbody>
</table>

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

WITHHOLDING PERIOD: DO NOT APPLY LATER THAN 7 DAYS BEFORE HARVEST. DO NOT FEED TRASH OR BY-PRODUCTS RESULTING FROM TREATED GRAPES TO LIVESTOCK.
GENERAL INSTRUCTIONS

**Fungicide Resistance Warning**

Scala is a member of the anilino-pyrimidine group of fungicides. For fungicide resistance management Scala is a Group I fungicide.

Some naturally-occurring individual fungi resistant to Scala, and other Group I fungicides may exist through normal genetic variability in any fungal population. The resistant individuals can eventually dominate the fungi population if these fungicides are used repeatedly. These resistant fungi will not be controlled by Scala and other Group I fungicides, thus resulting in a reduction in efficacy and possible yield loss.

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

**Resistance Management Strategy**

1. Apply fungicide sprays at early flowering, 80 to 100% cap-fall and pre-bunch closure. Further applications may be necessary at veraison and pre-harvest, if wet weather favours infection.
2. Do not apply more than two consecutive sprays of a benzimidazole or dicarboximide fungicide in this program.
3. Do not apply more than four benzimidazole or dicarboximide sprays in a season.

**Application Frequency**

Scala should not be applied more than once per season if four or less Botrytis applications are made in a spray programme. Where 5 or more sprays per season are made Scala should not be applied more than twice in the spray programme.

**Equipment**

NOT to be applied by aircraft.

Scala can be applied using suitable high or low volume ground application equipment.

Equipment should produce a spray that ensures penetration of the canopy and coverage of the flowers or bunches.

**Water Volume**

For high volume applications at flowering, use 750 to 1000 L of water/ha.
For application close to harvest, this would require a minimum of 1000 L/ha and often up to 1600 L/ha. If using more than 1000 L/ha of water, do not exceed 2 L of Scala per hectare.

**Mixing**

Add the required amount of Scala directly to the half filled spray vat with agitators in motion. Complete filling of spray vat under constant agitation. Do not allow the spray mixture to remain in the tank for long periods without agitation.
Rear panel continued

**Compatibility**

Scala is compatible with most commonly used fungicides and insecticides, including; *Bacillus thuringiensis*, Bavistin® FL, Bayfidan®, Blue Shield®DF, Lorsban®, mancozeb, Oxydul®, Perfekthion®, ProGibb®, Ridomil® Plus and Wetable Sulphur.

Do not mix Scala with products exhibiting alkaline reaction, including lime sulphur and Bordeaux mixtures. When mixing Scala with Bayfidan, use butyl gloves. Mixtures with Foli-R-Fos® may cause leaf damage.

**Protection of Wildlife, Fish, Crustaceans and Environment**

Do not contaminate streams, rivers or waterways with this product or used container.

**Drift Warning**

DO NOT apply under meteorological conditions or from spraying equipment which could be expected to cause spray to drift onto nearby susceptible plants, adjacent crops, crop lands or pastures.

**Storage and Disposal**

Keep out of reach of children.

Store in the closed, original container in a dry, well ventilated, secure area, as cool as possible. Do not store for prolonged periods in direct sunlight. Triple (or preferably) pressure rinse containers before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on-site.

Break, crush, puncture and bury empty containers in a local authority landfill. If not available, bury empty containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Empty containers and product should not be burnt.

**SAFETY DIRECTIONS**

Will irritate the skin. Avoid contact with skin. When opening the container and preparing spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves. Wash hands after use. After each day’s use, wash gloves and contaminated clothing.

**FIRST AID**
If poisoning occurs, contact a doctor or Poisons Information Centre.

**Material Safety Data Sheet**

Additional information is listed in the Material Safety Data Sheet available from Hoechst Schering AgrEvo Pty. Ltd.

**Re-entry Period**

Do not allow entry into treated areas until the spray deposits have dried. When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and elbow-length PVC gloves. Clothing must be laundered after each day's use.
Exclusion of Liability

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

NRA Approval No.: 46026/1

Scala® and Oxydu® are Registered Trademarks of Hoechst Schering AgrEvo GmbH

Blue Shield ® is a Registered Trademark of Hoechst Schering AgrEvo Pty Ltd

Bavistin® and Perfekthion® are Registered Trademarks of BASF

Bayfidan® is a Registered Trademark of Bayer

Foli-R-Fos® is a Registered Trademark of Dupont

Lorsban® is a Registered Trademark of Dow Elanco

ProGibb® is a Registered Trademark of Abbot

Ridomil® is a Registered Trademark of Ciba, Basle, Switzerland

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THIS PRODUCT IS NOT CLASSIFIED AS A DANGEROUS GOOD UNDER THE AUSTRALIAN CODE FOR THE TRANSPORT OF DANGEROUS GOODS BY ROAD OR RAIL

IN A TRANSPORT EMERGENCY:

DIAL 000

POLICE OR FIRE BRIGADE.

FOR SPECIALIST ADVICE, CONTACT UNITED TRANSPORT
SERVICES EMERGENCY RESPONSE

COORDINATOR:

008 024 973 (24 HOURS)

Hoechst Schering AgrEvo Pty. Ltd.  A.C.N. 062 299469
1731-1733 Malvern Road, Glen Iris Vic. 3146

Telephone (03) 9248 6666

Batch Number:
Date of Manufacture:

(5L) 053457/R1
(10 L) 055336/R1