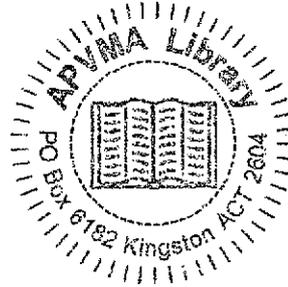




National Registration Authority

For Agricultural & Veterinary Chemicals

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Public Release Summary

pyriproxyfen

IN THE PRODUCT
SUMILARV INSECT GROWTH REGULATOR

This document is published by the
National Registration Authority for
Agricultural and Veterinary Chemicals.
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FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent Statutory Authority with responsibility for the assessment and approval of agricultural and veterinary chemical products prior to sale and use in Australia.

In undertaking this task, the NRA works in close cooperation with advisory agencies including the Department of Human Services and Health (Chemical Safety 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 products 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 products 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 Products" 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. Further more detailed technical assessment reports on occupational health and safety aspects, public health considerations and environmental impact are available from the NRA on request.

As a relatively new organisation, the NRA would welcome comment on the usefulness of this document and suggestions for further improvement. Comments should be forwarded to The National Registration Manager, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box 240, Queen Victoria Terrace, Parkes, ACT, 2600.

ABBREVIATIONS AND ACRONYMS WHICH MAY BE USED IN THIS DOCUMENT

ADI	Acceptable Daily Intake (for humans)
CSU	Chemical Safety Unit (of the Department of Human Services and Health)
d	Day
EC₅₀	Concentration at which 50% of the test population of fish are immobilised
EUP	End Use Product
F₀	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
m	Metre
mg	Milligram
mL	Millilitre
MRL	Maximum Residue Limit (a legal limit)
MSDS	Material Safety Data Sheet
ng	Nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	No Observable Effect Concentration/Level
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
po	Oral
ppb	parts per billion
ppm	parts per million
s	Second
sc	Subcutaneous
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
T-Value	A value used to determine the First Aid Instructions for chemical products that contain two or more poisons
TGAC	Technical Grade Active Constituent
WDG	Water Dispersible Granule
WHP	Withholding Periods

EXECUTIVE SUMMARY

Introduction

The purpose of this document is to provide a summary of the data reviewed and an outline of regulatory considerations for the proposed clearance and registration of the chemical pyriproxyfen in the product SUMILARV INSECT GROWTH REGULATOR, a growth regulator for the control of cockroaches and fleas in domestic, industrial and public health situations. Use in all States is proposed.

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) invites public comment before deciding whether to proceed to approve this product for use in Australia.

The NRA has completed an assessment of the data submitted by the applicant in support of these uses of pyriproxyfen and has provided the following information for public comment:

Environmental Aspects

Pyriproxyfen is a hydrolytically stable compound, with relatively low persistence in water and moderate persistence in soil to photolysis. When pyriproxyfen was degraded aerobically in one soil, it had a short half-life, but degradation appeared to slow considerably after ageing. Degradation products tend not to accumulate as the compound is mostly mineralised to CO₂. Any residue in soil appears to be immobile and the bound fraction associated with the humic material of the soil. However, even soils with low organic content retained pyriproxyfen in the top of a soil column after water was applied. The adsorption coefficient based on organic carbon content (K_{oc}) was very high which suggests that pyriproxyfen would not leach to groundwater. Further, pyriproxyfen and its metabolites appear not to accumulate in fish, and are readily excreted.

The ecotoxicity profile of pyriproxyfen suggests that the areas of concern are non-target insects and aquatic organisms, including fish. For non-target insects, it is expected to be highly toxic to very highly toxic, while for fish it could be highly toxic. Soil invertebrates (other than insects) and micro-organisms were noted to be less sensitive to pyriproxyfen.

Given the above, and its intended use for household and commercial control of fleas and cockroaches by professional operators, there would appear to be little likelihood of pyriproxyfen reaching and persisting in non-target natural areas, and the proposed use therefore represents a low hazard to terrestrial and aquatic fauna and flora.

Toxicology

The acute toxicity of pyriproxyfen, the active ingredient in Sumilarv, is low, with the only significant acute effect being slight irritation of the rabbit eye. Sumilarv, the 2% formulation of pyriproxyfen, may irritate the gastrointestinal tract if swallowed, or the

nasal mucosa if inhaled, and is slightly irritating to the eye, and may cause defatting of the skin.

The main toxic effects in repeat-dose studies were on the liver. Kidney toxicity occurred in mice, but not in rats or dogs. Slight anaemia occurred in rats and dogs. Pyriproxyfen did not cause tumours or birth defects in laboratory animals, and was not toxic to genetic material (DNA).

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

Occupational Health and Safety Aspects

Pyriproxyfen and its product SUMILARV INSECT GROWTH REGULATOR, are of low toxicity. They are not classified as hazardous substances or dangerous goods.

The main acute hazards of contamination with SUMILARV INSECT GROWTH REGULATOR are skin and eye irritation. The probability of workers developing adverse health effects following long term use is low.

Safety directions on the product label state that users should wear elbow-length PVC gloves when preparing the working strength spray. All workers should maintain good personal hygiene practices.

Adequate information is available to workers on the product label and in the material safety data sheets for pyriproxyfen and the product, to enable their safe use under routine and emergency conditions.

Residues in Food Commodities

SUMILARV INSECT GROWTH REGULATOR is recommended for use by licensed pest control operators only. Adequate warning statements have been included in the product label to prevent any contamination of food with the chemical.

Implications For Trade

The proposed use for SUMILARV INSECT GROWTH REGULATOR preclude the opportunity for residues to arise in agricultural commodities. Consequently there will be no implications for trade.

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INTRODUCTION

The purpose of this document is to provide the public with a summary of the data reviewed and an outline of the regulatory considerations for the proposed chemical pyriproxyfen as an insect growth regulator for the control of cockroaches and fleas in domestic, industrial and public health situations and to seek public comment prior to the chemical product being approved for use in Australia.

Comments should be sent to:

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Applicant

Hoechst Schering AgrEvo Pty Ltd has applied for registration of a new end-use product containing a new active constituent, pyriproxyfen. It is to be used in conjunction with an adulticide to control fleas and cockroaches in domestic, industrial and public health situations.

Product Details

Pyriproxyfen is imported as a solid. It will be formulated in Australia as SUMILARV INSECT GROWTH REGULATOR, as an aqueous concentrate containing 2% by weight of the active.

Hoechst Schering AgrEvo Pty Ltd intends to market the end use product SUMILARV INSECT GROWTH REGULATOR in all States.

Overseas Registration Status

Products containing pyriproxypen are not registered anywhere overseas.

PROPERTIES OF THE CHEMICAL ACTIVE INGREDIENT

The chemical active ingredient pyriproxyfen is manufactured in Japan and has the following properties:

Common name:	pyriproxyfen
Chemical name:	2-[1-methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine
Product name:	SUMILARV INSECT GROWTH REGULATOR
CAS Registry Number:	95737-68-1
Molecular formula	$C_{20}H_{19}NO_3$
Molecular weight	321.37
Appearance:	pale yellowish solid with faint characteristic odour
Melting point:	47.4 °C
Specific gravity:	1.24
n-Octanol/water partition coefficient	5.37 @ 25° ± 1° C
Vapour pressure:	<1 x 10 ⁻⁷ mm Hg @ 22.8 °C

Structural Formula:

AGRICULTURAL ASSESSMENT

Justification for Use

Pyriproxyfen is not a conventional insecticide. It acts as an Insect Growth Regulator (IGR). Insect Growth Regulators can make a positive contribution, not only towards improved population control but, due to their completely different mode of action from the conventional insecticides acting on the nervous system, IGRs can be used in the resistance management of these pests.

Proposed Use Pattern

SUMILARV INSECT GROWTH REGULATOR is proposed to be used to control fleas and cockroaches in domestic, industrial and public health situations. The initial treatment with SUMILARV would be in conjunction with the label rate of any commercially available adulticide. For cockroaches, 50 mL of SUMILARV per 5L of water will be used (200 mg ai/L), while for fleas it would be half this rate. Any maintenance treatment to control nymphs and larvae hatched from eggs surviving the initial treatment, would involve the application of SUMILARV alone. These maintenance treatments would be at the same rates as initial treatment.

Evaluation of Efficacy

The applicant has provided convincing efficacy data for use of SUMILARV individually and in combination for fleas, but only for the latter category for German cockroach. On its own, Sumilarv led to apparent reductions in cockroach populations 40.4% after 1 month, 58.3% after 2 months, and 79.1% after 6 months. This product does not incorporate an adulticide in its formulation, hence it should be used in combination with a registered adulticide.

ENVIRONMENTAL ASSESSMENT

Environmental Fate

Sumilarv will be used in household, commercial and industrial situations and applied to walls and floors, and their fixtures and crevices and cracks, to control fleas and cockroaches. The initial treatment with Sumilarv would be in conjunction with a commercially available adulticide to break the breeding cycle, with maintenance sprays using only Sumilarv. There should be little environmental exposure from its intended use and low volume of use.

Hydrolysis

Pyriproxyfen proved stable (half-lives greater than 367 d) in sterile aqueous buffers (pH 4, 7 and 9) incubated at 50°C for 7 days in the dark. Unidentified hydrolysis products amounted to <2% of the applied ¹⁴C throughout the experiment.

Photolysis

Solutions of pyriproxyfen (0.2 ppm) in distilled water and river water had half-lives of 17.5 and 21 d, respectively, when exposed to sunlight. No significant degradation was observed when the solutions were kept in the dark. Using a model, it was estimated that the half-life of pyriproxyfen at a latitude of 40° would be 15.8 d, which agreed with the observed values. Pyriproxyfen mainly degraded via cleavage of the ether bond to form 2-(2-pyridyloxy)propyl alcohol, with ultimate mineralisation to CO₂.

A sandy loam soil and silt loam soil was fortified to 100 mg.m⁻² with pyriproxyfen and exposed to natural sunlight. The half-lives for the sandy and silt soils were 11.3 and 13.2 weeks, respectively, while pyriproxyfen persisted under dark conditions (>87% of applied labelled pyriproxyfen recovered after 8 weeks). Photolysis of pyriproxyfen was by cleavage of all three ether bonds. The major product was CO₂.

Metabolism in soils and aquatic systems

Radiolabelled pyriproxyfen was applied to a sandy clay loam soil to assess the degree of aerobic degradation in a 30 d study. The half-life of pyriproxyfen was 6.3 d, with any degradation product tending not to accumulate because of mineralisation to CO₂. While this implies that the study was followed for about 5 half-lives, after the 30 d ageing 24-27% of the label remained as the parent compound; degradation appears to slow considerably after the first half-life.

No studies were submitted for metabolism in water.

Mobility in Soils

The adsorption/desorption characteristics of pyriproxyfen were assessed in water-soil suspension systems. Four types of soil with different physico-chemical properties were used for the study. Equilibrium of adsorption and desorption was reached within 2 to 9 hours. Both processes were described by the Freundlich isotherm equation. The adsorption coefficients (K_{ads}) ranged from 25.1 to 637, while the desorption coefficients (K_{des}) ranged from 35.9 to 925. The adsorption coefficients based on organic carbon content of soils (K_{oc}) were calculated to be 13×10^3 to 58×10^3 from the K_{ads} values. Since pyriproxyfen has K_{oc} values estimated to be > 1000 , it suggests that it is likely to be immobile in soils.

The possible extent of leaching was investigated using a soil column method. Results indicated that pyriproxyfen would be immobile in soils, even those with low organic matter content. Greater than 88% of the applied radioactivity remained in the treated fraction and 0-5 cm fraction of the column, while $<3\%$ of the applied radioactivity was found in any elutriate. It is concluded that pyriproxyfen is unlikely to leach through soil and contaminate groundwater.

Field Dissipation Studies

No studies were submitted. Since Sumilarv has no claims for field use, this is acceptable.

Accumulation and bioaccumulation

Carp were exposed to pyriproxyfen in a flow-through system for 14 d. The nominal aqueous concentration was $2 \mu\text{g.L}^{-1}$. Both the label and pyriproxyfen reached equilibrium in the fish body after three days of exposure. The bioaccumulation ratios for the radiolabel and pyriproxyfen were about 1500 and 400, respectively. The concentrations of the radiolabel and pyriproxyfen decreased rapidly when fish were transferred to fresh water, with biological half lives of about 1 and 0.5 d, respectively.

No studies were submitted for accumulation potential in soils. Since Sumilarv has no claims for field use, this is allowable.

Environmental Effects

Birds

Five-day dietary (acute) tests with Bobwhite quails and Mallard ducks gave LC₅₀'s greater than 5200 ppm. This data suggests that pyriproxyfen is practically nontoxic to birds.

Aquatic organisms

The aquatic toxicity of pyriproxyfen was tested only with rainbow trout (*Oncorhynchus mykiss*), which gave an LC₅₀ of 850 µg.L⁻¹ and a NOEC of

56 µg.L⁻¹. This suggests that pyriproxyfen is highly toxic to fish.

Further, literature results suggest that it is very highly toxic to other aquatic life, such as invertebrates, which might be expected from its mode of action. In one study, laboratory results showed a 90% inhibition of emergence of the chironomid, *Polypedilum nubifer*, exposed to 10 µg.L⁻¹. The same study, in field tests also with a nominal water concentration of 10 µg.L⁻¹, showed significantly reduced emergence of *P. nubifer*, and another chironomid, *Kiefferulus intertinctus* 24 days after application. In another study, also using 10 µg.L⁻¹, there was a significant reduction in the reproductive capacity of cladocera and induced morphometric aberrations in emergent dragonflies.

Non-target Invertebrates

No studies were submitted for predators, parasites or bees. Since Sumilarv has no claims for field use, this is acceptable.

An LC₅₀ of greater than 1000 mg.kg⁻¹ (dry weight) was determined for earthworms in an artificial soil system. The effect of pyriproxyfen on ammonification, nitrification and respiration in a humic sand soil and loam soil (amended with lucerne meal) concluded that it had no effect on these processes to any significant extent.

Plants

No studies were submitted. Since Sumilarv has no claims for field use, this is acceptable.

Environmental Hazard

Pyriproxyfen is for use in domestic, industrial and public health situations on surfaces of walls and floors and associated fixtures, and any cracks and crevices in these

surfaces. Its use is therefore for mainly interior purposes. If pyriproxyfen is used for the claims as indicated, then there should be little risk of aquatic ecosystems being contaminated.

Similarly, significant hazard to terrestrial macro-fauna is not expected in view of Sumilarv's use, rapid excretion of any ingested residues, and lack of acute toxicity in laboratory tests.

Hazard to non-target insects will be more significant, but for household and commercial purposes, insects exposed are likely to be considered pests anyway.

Hazard arising from formulation, handling and disposal is low as formulation takes place in a controlled area with recycling of spills, and the magnitude of any spills which may occur will be limited by the small pack sizes and the low production volume.

PUBLIC HEALTH AND SAFETY ASSESSMENT

Evaluation of Toxicology

The toxicological database for pyriproxyfen, 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. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop appropriate standards for exposures at which no adverse effects in humans would be expected.

Pharmacokinetics and Metabolism

Following single or repeated oral doses in rats, most of the pyriproxyfen (81-96%) was excreted in the faeces, with only small amounts (5-12%) in urine. Accumulation of pyriproxyfen in tissues was low, except for fat. Pyriproxyfen was metabolised extensively; the main faecal metabolite was 4'-hydroxy-pyriproxyfen.

Acute Studies

The acute oral toxicity of pyriproxyfen was very low, in rats ($LD_{50} > 5000$ mg/kg bw) and dogs and dermal ($LD_{50} > 2000$ mg/kg bw) and inhalation toxicities in rats were low ($LC_{50} > 1300$ mg/m³). No skin irritation was observed in rabbits, although it was a slight irritant to rabbit eyes. No skin sensitisation was observed in guinea pigs.

The Sumilarv formulation, containing 2% pyriproxyfen, may irritate the gastrointestinal tract if swallowed, is slightly irritating to the eye, may cause defatting of the skin, and may irritate the nasal mucosa if inhaled.

Repeat-Dose Studies

With repeat-dosing of pyriproxyfen in animals, the main effects were on the liver; however, apart from some liver damage in dogs at very high doses, other liver

changes could be regarded as detoxifying adaptations to pyriproxyfen administration. Chronic exposure to pyriproxyfen also produced toxicity in the kidneys of mice, but not in rats or dogs. High doses of pyriproxyfen produced slight anaemia in rats and dogs.

Carcinogenicity Studies

Pyriproxyfen administered in the diet for 18 months to mice and for 2 years to rats did not cause tumours in either species.

Reproduction and Developmental Studies

Pyriproxyfen did not cause birth defects in rats or rabbits and did not affect fertility in a 2-generation rat study following oral administration.

Genotoxicity

Pyriproxyfen was not genotoxic (DNA-damaging) in two in vitro assays, a mutation test in bacterial systems and a chromosomal aberration test in Chinese hamster ovary cells in culture.

Public Health Standards

Poisons Scheduling

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

The NDPSC recommended that pyriproxyfen be listed in Appendix B of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate warning statements and first-aid directions on the product label.

NOEL/ADI

The most sensitive species was the rat, in which the NOEL was 7mg/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 0.07 mg/kg/day for pyriproxyfen was established.

Residues in Food Commodities

SUMILARV INSECT GROWTH REGULATOR is to be used by licensed commercial pest control operators only, in domestic, industrial and public health

situations. As a precautionary measure the following warning statements are included in the product label.

AVOID CONTACT WITH FOOD, FOOD UTENSILS, OR PLACES WHERE FOOD IS PREPARED OR STORED.

BEFORE USE- REMOVE OR COVER ALL EXPOSED FOODSTUFFS; COVER ALL DISHES AND UTENSILS, AND PLACES WHERE FOOD IS PREPARED OR STORED.

AFTER USE-THOROUGHLY VENTILATE TREATED AREA. CLEAN UP THOROUGHLY BEFORE PROCESSING/SERVING RESUMES.

Implications for Trade

The proposed use for SUMILARV INSECT GROWTH REGULATOR preclude the opportunity for residues to arise in agricultural commodities. Consequently there will be no implications for trade.

OCCUPATIONAL HEALTH AND SAFETY

Pyriproxyfen is not a hazardous substance according to the National Occupational Health and Safety Commission (NOHSC) Approved Criteria for Classifying Hazardous Substances.

After considering the available data, Worksafe Australia does not believe Sumilarv Insect Growth Regulator is a hazardous substance under NOHSC criteria.

Pyriproxyfen is imported as a solid. It will be formulated in Australia as Sumilarv Insect Growth Regulator, an aqueous concentrate and packed in one litre containers.

Pyriproxyfen and Sumilarv Insect Growth Regulator are not dangerous goods under the Australian Code for the Transport of Dangerous Goods by Road and Rail.

Formulation, packaging, transport and sale

Australian workers engaged in formulation and packaging should be protected by engineering controls such as local and general exhaust ventilation. Workers should wear long sleeved overalls, safety boots, PVC gloves and chemical splash goggles.

Workers involved in transport, storage and retailing could only become contaminated with the product during accidental spillage. These workers should refer to the label instructions and precautions for use and safe handling information in the material safety data sheet. These contain adequate information to enable workers to deal with accidental spills.

End-Use

End users will handle Sumilarv Insect Growth Regulator when preparing and using the working strength spray, cleaning up spills and maintaining application equipment. The main routes of exposure will be via the skin and respiratory tract.

The diluted product (25 mL/5 L or 50 mL/5 L depending on the pest to be treated) will be applied inside buildings as a coarse spray. It is to be applied at the rate of 5 L/100 m² or to the point of run off, depending on the nature of the surface. The working strength concentration of the product is 0.5% or 1.0%.

Inhalation of the product may cause respiratory irritation. However, as pyriproxyfen should not vaporise and the product is to be applied as a coarse spray, substantial inhalational exposure is considered unlikely.

End users may experience skin contamination with normal use of the product. The main short term hazards are eye and skin irritation.

Considering the low toxicity of pyriproxyfen, long term use of the product should not result in workers experiencing health effects.

In the Safety Directions on the product label, end users are advised to avoid contact with eyes and skin and not to inhale spray mist. They are instructed to wear elbow-length PVC gloves when preparing the spray. Personal protective equipment is not necessary for workers applying the spray. Workers should maintain good personal hygiene practices.

Entry into treated areas

Workers entering treated areas are not expected to experience any health effects from contacting product residues. Worksafe Australia does not recommend any restrictions on entering treated areas.

Recommendations for safe use - all workers

Workers involved in formulation and packing should be protected by engineering controls, such as exhaust ventilation, safe work practices and training. They should wear long sleeved overalls (AS 3765-1990, Clothing for Protection Against Hazardous Chemicals), safety boots (AS 2210, Safety Footwear), PVC gloves (AS 2161-1978, Industrial Safety Gloves and Mittens) and chemical splash goggles (AS 1337-1984, Eye Protectors for Industrial Applications).

End users should follow the instructions on the product label and wear elbow-length PVC gloves when preparing the spray.

On the basis of this assessment, no occupational health and safety regulatory standards, such as Health Surveillance or an Exposure Standard, are considered necessary for pyriproxyfen.

Labelling

The proposed label for SUMILARV INSECT GROWTH REGULATOR is at Appendix 1.

SUGGESTED FURTHER READING

Interim Requirements for Registration of Agricultural and Veterinary Chemical Products (available from the NRA)

Code of Practice for Labelling Agricultural Chemical Products (available from the NRA)