Public Release Summary
on

Evaluation of the active

TERBUTHYLAZINE

in the product

SWIMCAREÒ T SWIMMING POOL ALGAECIDE

National Registration Authority for Agricultural and Veterinary Chemicals

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FOREWORD

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

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

The NRA has a policy of encouraging openness and transparency in its activities and of seeking community involvement in decision making. Part of that process is the publication of public release summaries for all products containing new active ingredients and for all proposed extensions of use 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 *Ag Manual: The Requirements Manual for Agricultural Chemicals* and *Ag Requirements Series.*

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

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

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

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LIST OF ABBREVIATIONS AND ACRONYMS

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
BBA	Biologische Bundesanalstalt fur Land – und forstwirschaft
bw	bodyweight
d	day
DAT	Days After Treatment
DT_{50}	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
E_bC_{50}	concentration at which the biomass of 50% of the test population is impacted
EC_{50}	concentration at which 50% of the test population are immobilised
EEC	Estimated Environmental Concentration
E_rC_{50}	concentration at which the rate of growth of 50% of the test population is impacted
EUP	End Use Product
Fo	original parent generation
g	gram
GAP	Good Agricultural Practice
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GVP	Good Veterinary Practice
h	hour
ha	hectare
Hct	Heamatocrit
Hg	Haemoglobin
HPLC	High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography
id	intradermal
im	intramuscular
ip	intraperitoneal
IPM	Integrated Pest Management
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
K_{oc}	Organic carbon partitioning coefficient
L	Litre
LC_{50}	concentration that kills 50% of the test population of organisms
LD_{50}	dosage of chemical that kills 50% of the test population of organisms
LOD	Limit of Detection – level at which residues can be detected
LOQ	Limit of Quantitation – level at which residues can be dquantified
mg	milligra m
mL	millilitre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee
ng	nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	No Observable Effect Concentration Level
OC	Organic Carbon
OM	Organic Matter
po	oral
ppb	parts per billion

PPE	Personal Protective Equipment
ppm	parts per million
Q-value	Quotient-value
RBC	Red Blood Cell Count
s	second
sc	subcutaneous
SC	Suspension Concentrate
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration
TGAC	Technical grade active constituent
T-Value	A value used to determine the First Aid Instructions for chemical products that contain two or more poisons
µg	microgram
vmd	volume median diameter
WG	Water Dispersible Granule
WHP	Withholding Period

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INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of SwimCare T Swimming Pool Algaecide, which contains the active constituent terbuthylazine.

Terbuthylazine is a triazine herbicide which is being proposed for use as an algaecide in swimming pools. It is not currently registered for use in Australia as a herbicide. It has properties and mode of action similar to other triazine herbicides such as atrazine and simazine. Its herbicidal/algaecidal action is through the inhibition of the Hill reaction and blocking electrons entering the PSII system in chloroplasts.

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.

Written comments are invited and should be submitted by **15 October 2001,** addressed to:

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Phone 02 6722 4850 Fax 02 6272 3218

Applicant:

BioLab Inc, through its Australian agent BioLab Australia Limited

Product details:

SWIMCARE® T SWIMMING POOL ALGAECIDE (SwimCare T) is an aqueous suspension concentrate containing 40g/L terbuthylazine. The product will be marketed to enhance the effectiveness of chlorine in controlling black, mustard and green algae in chlorine-containing swimming pools.

The active constituent is manufactured in the USA and the product will be formulated in the UK.

SwimCare T has not been registered for use in swimming pools overseas. Products containing terbuthylazine have been used widely overseas for broad-spectrum pre- and post-emergent weed control in a wide range of crops including maize, sorghum, vines, fruit trees and sugar cane plus forestry uses in tree nurseries and new plantings for control of a wide range of weeds.

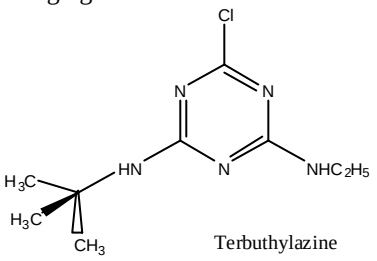
CHEMISTRY AND MANUFACTURE

ACTIVE CONSTITUENT

The active constituent terbuthylazine is manufactured by Novartis Crop Protection, Inc., River Road, St Gabriel, LA 70776-0011, USA.

Chemical Characteristics of the Active Constituent

Common Name:	Terbuthylazine (ISO/SA approved)
IUPAC Name:	N^2-tert-butyl-6-chloro-N^4-ethyl-1,3,5-triazine-2,4-diamine
Chemical Abstract Name:	6-chloro-N-(1,1-dimethylethyl)-N'-ethyl-1,3.5-triazine-2,4-diamine
CAS Number:	5915-41-3
Manufacturer's Code:	GS 13529, TK 12669/1
Minimum Purity	960 g/kg
Structure:	



Terbuthylazine
$C_9H_{16}ClN_5$
Mol. Wt.: 229.71

Molecular formula:	$C_9H_{16}ClN_5$
Molecular weight:	229.71 amu or dalton

Physical and Chemical Properties of Pure Active Constituent and TGAC

Physical state:	Solid	
Colour:	Off-white powder	
Odour:	Rancid, putrid	
Melting point:	178.0 – 179.3 °C	
Boiling point:	Not applicable	
Solubility in water:	11.5 mg/mL	
Bulk Density:	1.108 (at 20 °C)	
Solubility in organic solvents: (g/L at 20 °C)	Acetone	41.3
	Ethanol	15.0
	Toluene	10.4
	n-Octanol	12.5
	Ethylene glycol	2.36
Dissociation constant:	$pK_a = 1.9 \pm 0.1$	
pH	6.6 – 7.8	
Octanol/water partition coefficient:	Log $P_{O/W} = 3.21 \pm 0.0369$	
Vapour pressure:	5.8×10^{-7} mm Hg @ 25 °C	
Henry Constant:	4.1×10^{-4} Pa m^3 mol^{-1}	
Flash point:	> 150 °C	
Volatility:	Essentially non-volatile	
Explosive properties:	None	
Oxidising/reduction properties:	None	
Corrosion characteristics:	Not corrosive to stainless steel, polypropylene and high density polyethylene	
Storage stability:	No change in content over 12 months at 25 °C	

Summary of the NRA's Evaluation of Terbuthylazine TGAC

The Chemistry and Residues Evaluation Section of the NRA has evaluated the chemistry aspects of Terbuthylazine TGAC (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. On the basis of the data provided it is proposed that the following minimum compositional standard be established for Terbuthylazine TGAC:

Active constituent	
Terbuthylazine	Not less than 960 g/kg

FORMULATED PRODUCT

Distinguishing name:	SWIMCARE® T SWIMMING POOL ALGAECIDE
Formulation type:	Aqueous Suspension Concentrate (SC)
Active constituent concentration:	40 g/L Terbuthylazine

Physical and Chemical Properties of the Product

Appearance:	Off-white beige aqueous dispersion
Odour:	Slight
Boiling Point	Approximately 100 °C
Density or specific gravity:	0.95 – 1.05 (at 20 °C)
Acidity, alkalinity or pH value:	pH = 6 – 9
Viscosity:	400 – 1,000 cp (at 20 °C)
Flash point:	Not applicable
Volatility	No volatile components in the formulation
Storage stability:	Stability data provided by the applicant supports a shelf life of 1 year when the product is stored below 30 °C.

TOXICOLOGICAL ASSESSMENT

EVALUATION OF TOXICOLOGY

The toxicological database for terbuthylazine 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 acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

Acute Studies

Terbuthylazine has low acute oral toxicity in the rat (lowest LD_{50} 1503 mg/kg in females), and hamster (LD_{50} >3000mg/kg), low dermal toxicity in rats (LD_{50} >2000mg/kg) and rabbits (LD_{50} >4000mg/kg), and very low inhalation toxicity in rats. Terbuthylazine was a slight eye irritant in rabbits, but was not a skin irritant in rabbits, and did not induce skin sensitisation in guinea pigs.

Based on the acute toxicity of the components of the product which contains 40 g/L terbuthylazine, the product is expected to possess low acute oral and dermal toxicity, and very low inhalation toxicity; it may be a slight eye irritant, but is unlikely to cause skin irritation or skin sensitisation.

Short-Term Studies

Rats fed terbuthylazine in the diet at doses up to 65 mg/kg/day for 28 days showed reduced body weight gain and decreased food and water intake at doses of 8 mg/kg/day. At 25 mg/kg/day in males and 63 mg/kg/day in females, findings included serum biochemistry changes suggestive of liver toxicity, reduced thymus weight, and slightly increased testes weight in males. Male rats were more sensitive than females to the effects of terbuthylazine.

Rabbits administered oral doses of up to 5 mg/kg/day terbuthylazine 28 days showed slight changes in blood levels of haemoglobin (increased) and glucose (decreased), but no other adverse effects.

Application of terbuthylazine to the skin of rabbits at 500 mg/kg/day terbuthylazine for 28 days produced slightly reduced weight gain, sedation, coldness, unsteadiness, diarrhoea, ruffled fur, tremors, wasting, and slight skin irritation at the application site. There were slight decreases in blood clotting time, serum biochemistry changes suggestive of liver toxicity, a slight increase in serum glucose levels, and kidney and ovary weights were reduced in females. Animals recovered one week after stopping treatment.

Chronic Studies

Mice fed terbuthylazine in the diet for a period of 24 months lived longer than control animals. Body weight gain and food consumption were slightly decreased at 87 mg/kg/day. No signs of systemic toxicity were noted in any of the treatment groups. The NOEL was 17 mg/kg/day.

Rats fed terbuthylazine in the diet for a period of 24 months lived as long as, or longer than, control animals. Body weight gain was suppressed at doses of 1.3 mg/kg/day and above. There was a slight decrease in the weight of adrenals of males at 52 mg/kg/day. In females, a higher incidence of mammary carcinoma and a lower incidence of fibroadenomas of the mammary gland (compared

with controls) were noted but the incidence was not related to the dose of terbuthylazine. Members of this class of chemical are known to produce this effect in rats, and it is considered that the finding is not relevant to humans. In males at 52 mg/kg/day and females at 41 mg/kg/day, the incidence of foam cells in lung alveoli was higher, and the incidence of nodular hyperplasia of Leydig cells in the testes was increased in males. The NOEL was 0.35 mg/kg/day.

Dogs fed terbuthylazine in the diet for a period of 12 months at concentrations of 1.7 mg/kg/day and above showed decreased food consumption and body weight loss, which was severe at the highest dose level (15 mg/kg/day). Apart from transient anaemic responses in 15 mg/kg/day females, no specific target organ toxicity was found. The NOEL was 0.4 mg/kg/day.

Reproduction and Developmental Studies

In a two generation reproduction study, rats were given terbuthylazine in the diet at doses up to about 20 mg/kg/day. In adults of both generations, reduced water and food consumption, and reduced body weight gain occurred at doses of about 4 mg/kg/day and above. At 20 mg/kg/day, infertility of females, and a higher death rate and retarded development of offspring were noted. The NOEL was 0.5 mg/kg/day.

Female rats were administered terbuthylazine at oral doses up to 30 mg/kg/day, throughout the period of foetal development. There were no significant clinical signs related to treatment. Maternal body weight gain was reduced at 30 mg/kg/day, but there were no significant adverse effects on the foetuses at this dose level.

Terbuthylazine was administered to rabbits at oral doses up to 4.5 mg/kg/day, throughout the period of foetal development. There was no evidence of maternal or foetal toxicity at 4.5 mg/kg/day, the highest dose level.

Genotoxicity

Terbuthylazine was negative in tests for mutation in bacteria, chromosomal aberrations in human lymphocytes, tests for DNA repair in rat hepatocytes and human fibroblasts; and for chromosome damage in mouse bone marrow.

PUBLIC HEALTH STANDARDS

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 terbuthylazine be listed in Schedule 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), except in preparations containing 5 per cent or less of terbuthylazine. The product SwimCare T will therefore be labelled as including a Schedule 5 poison. There are provisions for appropriate warning statements and first-aid directions on the product label.

METABOLISM AND TOXICOKINETICS ASSESSMENT

Toxicokinetics and Metabolism

Terbuthylazine was almost completely absorbed into the circulation after oral administration to rats; after application to the skin, about 30% of the dose was absorbed. Terbuthylazine was almost completely excreted within 48 hours; about 2/3 was excreted in the urine and the rest in faeces. There was no evidence of accumulation in organs. Thirteen metabolites were identified, representing about 65% of an administered dose, indicating that terbuthylazine is extensively metabolised in the body.

RESIDUES ASSESSMENT

As this product is not intended for use in any situation which might give rise to residues in food this aspect was not further assessed.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

As this product is not intended for use in any situation which might give rise to residues in food this aspect was not further assessed.

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Terbuthylazine is not listed on NOHSC *List of Designated Hazardous Substances*. It is considered to be a hazardous substance, according to NOHSC *Approved Criteria for Classifying Hazardous Substances*, based on its acute oral toxicity in the rat.

Terbuthylazine will be manufactured overseas as an off-white powder. It has low to moderate acute oral toxicity and low acute dermal and inhalation toxicity. It is a slight eye irritant, but not a skin irritant nor a skin sensitiser.

SwimCare® T Swimming Pool Algicide (SwimCare T) is an aqueous suspension concentrate formulation containing 40 g/L terbuthylazine. Based on the available information, SwimCare T is not classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances.*

Formulation, repackaging, transport, storage and retailing

SwimCare T will be formulated overseas and imported into Australia in bulk quantities. It will be re-packed locally in 200 L HDPE drums. Workers packing the product into smaller containers can be exposed to the product. Transport and storage workers and retailers will be exposed to the product only if the packaging is breached.

Use and exposure

SwimCare T is indicated for use in swimming pools for the control of black, mustard and green algae. It will be applied to skimmer baskets or other areas in the swimming pools where adequate mixing can be achieved. Initially, a dose of 125 – 250 mL SwimCare T per 10, 000 L pool water will be applied followed by maintenance doses of 32 mL product/10, 000 L pool water, every 5 to 7 days.

Considering the proposed use-pattern, workers may be exposed to SwimCare T only when opening containers and adding SwimCare T to pool water. The main route of exposure will be dermal. Ocular exposure may occur in the event of splashing during pouring.

Toxicological data on SwimCare T is not available. Based on the toxicity of the active constituent, the product is likely to be a slight eye irritant. However, the degree of irritation does not warrant eye protection. On the basis of this information, no personal protective equipment is recommended. However, as a general protection against chemicals used repeatedly, workers are advised to wear rubber gloves when repeated use of the product is required.

SwimCare T may be used in public and private swimming pools. The final concentration of terbuthylazine in the pool water will be very low (around 1ppm). Re-entering treated pools is not expected to pose any health risk.

Recommendations for safe use

Users should follow the instructions and Safety Directions on the product label. Safety Directions include the use of rubber gloves when opening the container and using the product. The recommended personal protective equipment should conform to the relevant standards specified by *Standards Australia*.

Information provision

Labels
SwimCare T will be formulated overseas; therefore a label for terbuthylazine is not required. A draft label for SwimCare T was provided by BioLab Inc.

Material safety data sheet
The Material Safety Data Sheet for SwimCare was provided by BioLab Inc as part of the submission for registration. The accuracy of this information remains the responsibility of BioLab Inc.

Occupational controls

Exposure standards
NOHSC has not established an exposure standard for terbuthylazine. NOHSC does not recommend that an exposure standard be established for terbuthylazine at this stage.

Health surveillance
NOHSC has not placed terbuthylazine on the Schedule for Health Surveillance (Schedule 3 Hazardous Substances for which Health Surveillance is Required; NOHSC *Control of Workplace Hazardous Substances*; 1994).

NOHSC does not consider placing terbuthylazine on this schedule at this stage.

Conclusion

SwimCare® T Swimming Pool Algicide can be used safely if handled in accordance with the instructions on the product label. Additional information is available on the product MSDS.

Environmental Aspects

Terbuthylazine is an older triazine herbicide proposed for a new, narrow use as an algacide in swimming pools and spas. The environmental exposure to terbuthylazine should only occur when waste pool water requires disposal, during pool cleaning or more rarely when pools are emptied.

Terbuthylazine is fairly degradable in laboratory and field soil studies, but degradation is dependent on microbial activity and is notably slower if soils are cold. While it shows a potential to leach, the field trials indicate it remains in or near the soil surface where it is has been applied, except perhaps in sandy soils with low organic matter. Accumulation in soils is considered to be unlikely.

Terbuthylazine photo-degrades in water and in this use pattern in pools this is likely to be the main degradation pathway. Any residues entering water from disposal of waste water are expected to partition with some preference for the sediment. Residues in aquatic systems (water/sediment) are expected to be fairly degradable where temperatures are relatively warm (20^{o}C). The fate of residues in aerobic and anaerobic aquatic conditions is similar and bio-accumulation is not expected to be a problem.

The major metabolites of terbuthylazine are the de-chlorinated and N-dealkylated products, which are more mobile than the parent, and exhibit some herbicidal activity when they retain the chlorine atom on the triazine ring plus one alkyl group.

The ecotoxicity profile of terbuthylazine is typical for a herbicide, with toxic effects mostly apparent towards plants/algae. However, terbuthylazine shows slight toxicity towards fish and shellfish, and variable toxicity towards aquatic crustaceans, from very highly toxic to practically non-toxic. Tests for birds, mammals, soil micro-organisms, bees and earthworms all indicated terbuthylazine is likely to be practically non-toxic towards these groups.

Hazard calculations for disposal of terbuthylazine treated pool water give residues above the the EC_{50} value for the most sensitive organisms tested (green alga). This concentration is unlikely to adversely effect fish or daphnia. Direct application to desirable plants is considered unlikely, apart from unadvised disposal. There should be no toxic effects in mammals or birds.

Summary of Environmental Fate Data

Terbuthylazine is a slightly basic, slightly water soluble triazine herbicide or algacide which adsorbs to soil organic matter. It will be applied initially to swimming pools to attain a pool water concentration at around 1ppm, but will be used on a weekly basis at a lower maintenance rate at around 0.5ppm. Following application to pools, terbuthylazine is expected to break down by aquatic photolytic mechanisms and is susceptible to microbial breakdown. Due to this narrow use pattern terbuthylazine is only expected to be associated with the general environment if treated pool water is disposed onto soils or into drains (waterways).

- *Degradation rates and routes*

The principal route for degradation appears to be aquatic photolysis or aerobic microbial degradation in soil. Under laboratory conditions, aquatic photolytic half-lives ranged from around 3 hours (attenuated) to a more realistic ~1.5-5 days under more usual test conditions that seem to be reflected in the recommended use pattern. Usually, the main degradation product was hydroxy-terbuthylazine, although with an attenuator N-dealkylation is favoured.

Laboratory studies in two soils (sandy loam) gave half-lives of 73-138 days at 20-25^{o}C, but this extended to 456 days at 10^{o}C, with hydroxy-terbuthylazine and desethyl-terbuthylazine as the main degradation products. Field degradation data gave half-lives of 11-36 days for a range of three soils.

The field data suggests that the degradation rate slows in soils high in clay, possibly as binding to clay particles reduces the availability of terbuthylazine to microbes.

Terbuthylazine was also observed to undergo transformation in hydro-soil systems, but where sediment was a low proportion (1%) of the systems, half-lives were much longer (463 & 579 days). When soil was a significant proportion (33%) the half-life was much shorter (38.8 days) and under anaerobic conditions this test system produced a somewhat slower degradation rate with a half-life of 69 days.

- *Metabolites*

The structures of the several major metabolites in water and soil were investigated. The main degradation pathways for the triazine group of herbicides are well known (Hassall, 1990) and those found for terbuthylazine fitted this pattern. The main degradates were hydoxy-terbuthylazine formed by the de-chlorination of the triazine ring and de-alkylated products (eg desethyl-terbuthylazine) formed when the alkyl side chains are cut.

- *Mobility*

While terbuthylazine is potentially mobile in soils the proposed use pattern in swimming pools should not allow it to enter the surrounding soil and water compartments of the environment. Movement of the chemical into the atmosphere will be unlikely due to its low vapour pressure.

Although the calculated K_{OC} values for terbuthylazine indicate it could be mobile in the sandy and loamy soils, the desorption test results indicate that terbuthylazine is relatively tightly bound in soils, presumably a function of organic matter and clay content. Application of the Groundwater Ubiquity Score (GUS) for the sandy loam soil (3.2-3.6) used in laboratory degradation studies also confirms the chemical's potential mobility in soil (Gustafson, 1989). The leaching studies further support the influence of organic matter on the movement of terbuthylazine through the soil profile. All soils tested had moderate to high levels of OM and the majority of terbuthylazine was retained in the top 10 cm of soil. Using aged residues, leaching on soil columns was slightly greater, with some degradation products (~5% radio-label) appearing in the leachate.

Under field conditions the environmental fate of terbuthylazine was mainly determined by the influence of biotic factors. Terbuthylazine may be mobile in some soils, but its use in swimming pools means that it should not come into contact with soil to any extent. The existence of microbial degradation pathways in aerobic soils mean that significant residues are unlikely to occur if terbuthylazine were occasionally disposed of onto soils.

- *Accumulation in soils*

Soil accumulation and bioaccumulation of terbuthylazine are not expected with this use pattern.

Summary of Environmental Toxicity

- *Avian Toxicity*

Results indicate that terbuthylazine will be practically non-toxic to birds, based on acute oral and dietary testing in mallard ducks and bobwhite quail (LD_{50} >2510 mg/kg and LC_{50} >5620 ppm).

- *Aquatic Toxicity*

Acute studies on five fish species indicate that is moderately toxic to fish (LC_{50}s between 3.6 and 7.6 mg/L) and a similar toxicity level observed for oysters. Acute toxicity to daphnia and mysid shrimp differed significantly (LC_{50}s 39.4 mg/L and 0.092 mg/L, respectively), but the chronic life-cycle tests reported for these species were more comparable (daphnia 21 d NOEC = 0.21 mg/L and mysid life-cycle MATC = 0.13 mg/L), and terbuthylazine can be rated as slightly to very highly toxic. Aquatic

plant toxicity tests with terbuthylazine using a green alga and an aquatic plant gave an EC_{50} value of 0.02 mg/L and 0.23 mg/L respectively, showing this herbicide/algacide exhibits very high toxicity to this group.

A series of tests using four separate terbuthylazine metabolites in trout, daphnia and the alga showed all metabolites exhibited lower toxicity than the parent, being at worst only slightly toxic to fish and daphnids. However, for green algae the range was greatest (LC_{50}s were 0.2->100 mg/L) with one rated highly toxic, one moderately toxic, one slightly toxic, and the last as practically non-toxic. Algal toxicity of these metabolites clearly depends on retention of the chlorine atom on the triazine ring plus one alkyl group.

- *Non-target Invertebrates*

Standard test results for bees show that terbuthylazine is practically non-toxic (oral and contact LD_{50} >100 µg/bee) and also for earthworms (LC_{50}s 210 & >1000 mg/kg). As well, the effect of terbuthylazine on soil micro-organisms was studied and there was no effect on the soil respiration and nitrification activity of the soil micro-organisms at either treatment rate (1 and 5 times maximum field rates). In sewage sludge terbuthylazine did not affect oxygen consumption nor microbial digestion.

- *Mammals*

The limited summary data indicates that terbuthylazine is likely to be practically non-toxic to wildlife mammals and the use pattern is unlikely to be hazardous to these mammals.

- *Phytotoxicity*

Terbuthylazine has herbicidal activity against a broad range of plants and is used overseas for broad-spectrum pre- and post-emergent weed control. This group of herbicides (triazines) act through the inhibition of the Hill reaction by blocking electrons entering the PSII system in chloroplasts. No specific data were presented for terbuthylazine's toxicity to terrestrial vegetation. However, based on its extreme toxicity to freshwater algae and its similar herbicidal activity to other triazines, terbuthylazine is predicted to be highly toxic to a large range of terrestrial and aquatic plants.

Hazard arising from use

- *Terrestrial birds, mammals and other vertebrates*

Terrestrial wildlife species are not likely to be affected by the proposed use pattern in swimming pools due to low exposure. Even if birds and mammals were to drink from treated swimming pools (containing up to 1 ppm) they should not be adversely affected.

- *Aquatic Organisms*

The exposure of aquatic fauna and flora (fish, invertebrates, plants and algae) to terbuthylazine is likely to occur mainly from disposal of treated pool water, either from back-flushing filters or less frequently when pools are emptied, either directly to sewers or to drains/waterways. Although the label prohibits this there seem to be few other options. There would appear to be little risk from sewer disposal, apart from handling the extra water volumes if large pools are emptied, due to inherent dilution factors and likely degradation. Furthermore, the tests conducted on sewage and soil microflora indicate there are unlikely to be adverse effects from terbuthylazine at levels 100 times greater than the use level (in pools) and there is an even greater safety margin when dilution in sewers is considered.

Direct release of treated pool water to drains that inevitably lead to waterways would seem to present more of a hazard since reasonable dilution factors might not apply, especially for private home use where disposal via storm water drains seems highly probable. A worst case disposal of pool water assuming a 10-fold dilution would result in receiving water containing 0.1 ppm. This is near the LC_{50}

and MATC for the most sensitive invertebrate tested (mysid), and still 5 times greater than the corresponding LC_{50} for green algae. The company has agreed to provide information on the label to users/householders on disposal options and non-treatment periods to avoid adverse effects on the environment.

These considerations indicate potential damage to algal communities, but aspects of the proposed use may moderate the hazard. Residues in pool water (maximum 1 ppm) should be readily lowered due to photo-degradation and ceasing routine treatment several weeks before disposal.

- *Non-Target Terrestrial Invertebrates and Micro-organisms*

Significant hazard to terrestrial invertebrate fauna is not expected due to the use pattern, rate of use and lack of toxicity in laboratory tests.

- *Non-Target Vegetation*

In terrestrial ecosystems, exposure of non-target vegetation would only arise through disposal of swimming pool waters to soil surfaces, and while this is not prohibited on the label there is a statement to avoid use of treated water on plants/lawns. As noted above for sewers, any disposal to soil surfaces would also require cessation of pool treatments some time before disposal.

Conclusions

In view of the high algal/plant toxicity, every precaution should be taken to avoid aquatic contamination especially disposal of treated pool water to storm water drains that inevitably lead to waterways. The label is proposed to carry cautions to address this issue.

Registration for the proposed use pattern is supported.

EFFICACY AND SAFETY ASSESSMENT

JUSTIFICATION FOR USE

Standard chlorination of swimming pools is known to be effective in controlling bacteria but has relatively poor activity against algae. If chlorine levels are allowed to fall strains of algae resistant to chlorine can proliferate and further reduce chlorine levels. Control of algae in pools frequently involves "shock" additions of chlorine where the level of chlorine is raised to high levels for a short time. These high levels are undesirable as they can result in irritation of the eyes and skin of swimmers if they enter the water before the levels subside and the formation of chlorine disinfection by-products.

Additional products are often used specifically to control algae in pool water. These include quaternary ammonium compounds, copper compounds and bromine compounds. Many of these affect the water chemistry and may impact on the efficacy of chlorine. The addition of terbuthylazine increases the efficacy of chlorine against a broad spectrum of algae and does not appear to cause significant changes in water chemistry.

EFFICACY DATA

Data from both laboratory and field trials were supplied. The field trials provided good testing of the product under commercial conditions. The laboratory trials were not replicated and it is therefore not possible to draw statistically valid conclusions from these studies.

Substantial evidence of control of a range of algae is provided by field trials with the product. These trials were conducted in a range of climates in Australia, England, Germany and the USA. The field trial design depended largely on the reports from potential customers on their experiences in using the product. In most studies around an 80% success rate in controlling algae was achieved. The quality and control of these "customer" trials was variable and the data generated was qualitative rather than quantitative.

The validation data was obtained from genuine potential customers of the product under realistic conditions and is likely to be applicable under commercial conditions of usage.

The data supports the claim that SwimCare T enhances the algaecidal activity of chlorine on a wide range of algae. The data also demonstrates that the product has no significant effect on algae at the intended use concentrations in the absence of chlorine. The product will therefore be limited to use in chlorine-containing swimming pools.

The data support efficacy if maintained in the pool at 0.5-1.0 mg/L. The recommended dosage rate is 125-250mL/10000L water as an initial dose followed by 32mL/10000L water every 5-7 days. This will result in an effective concentration in the water of around 0.5 mg/L which should be effective in controlling algal growth.

There was not sufficient data available to indicate that the product will be effective when used in spas and hot tubs, so use will be limited to swimming pools only.

SAFETY

The major safety issue relevant to this section of the assessment is safety to various pool surfaces. (Safety to swimmers is addressed in earlier sections). The product was tested in pools with a variety of different surface materials, including pebble, plaster, marble sheen, vinyl, tiles, paint, concrete and fibreglass. There were no reports of damage to any surfaces due to use of the product.

LABELLING REQUIREMENTS

The draft label proposed for the product is as follows:

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

SwimCare® T
Swimming Pool Algaecide

ACTIVE CONSTITUENT: 40 g/L TERBUTHYLAZINE

Enhances the effectiveness of chlorine in controlling black, mustard and green algae in chlorine-containing swimming pools

Logo

Contents 200 L

BioLab Australia Limited
61-63 Canterbury Road
MONTROSE VIC 3765

Ph: (03) 9728 2599

DIRECTIONS FOR USE

RESTRAINTS

Do not backwash for 24 hours after product application.
Do not super chlorinate (i.e. shock - raise the free chlorine level above 100 ppm) in your pool for one week after product application.

BEFORE YOU BEGIN

- Ensure that all pool equipment is working in accordance with manufacturers' recommendations.
- All skimmers should be free of debris and/or any obstructions that may interfere with the skimmer operation.
- Vacuum all leaves and other foreign matter in the pool.
- Check water pH, alkalinity and calcium hardness with a test kit. Adjust pH to 7.2 – 7.6. Adjust calcium hardness to 200-400 ppm by adding calcium hardness increaser.

HOW TO USE

- SwimCare T is compatible with those chemicals normally used to treat pools and effectively reduces the required level of chlorine needed in the pool to keep it free from algae. When using other products in combination with this product, follow label directions for those products exactly.
- Determine the dose required to treat your pool from the table below. Do not exceed recommended dose.
- This product functions by enhancing the sanitising activity of the chlorine already present in the pool water. Before adding this product to the pool, test the pool water for free chlorine concentration. Make the appropriate additions if the pool water does not contain at least 1 ppm free chlorine.
- **Shake well before use.** Add this product slowly through the skimmer of the pool. If the pool does not have a skimmer, dilute in 8 litres of water and broadcast directly into the pool along the walls. This product may cause temporary cloudiness that will clear. If the return emits cloudy water after addition, this does not indicate pool or product malfunction.
- After addition of this product allow the pump and filter to run for at least 12 hours to ensure proper mixing of the product throughout the pool water.

SITUATION	RATE		CRITICAL COMMENTS
	Initial Dose	Maintenance Dose	
Swimming Pools	125 - 250 mL / 10,000 L water	32 mL / 10,000 L water every 5 to 7 days	Use high rate for heavy algae contamination.

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

CAUTION

ENSURE any treatment of pool water with SwimCare T ceases at least two weeks before disposing of water during large scale cleaning or emptying of pools.

DO NOT allow treated pool water to enter waterways or storm water drains during disposal, nor allow contact with desirable vegetation/crops or onto soil to be planted with susceptible plants.

STORAGE AND DISPOSAL

Store in the closed, original container in a cool, dry place out of the reach of children. Do not store in direct sunlight.

Triple or (preferably) pressure rinse containers before disposal. Add rinsings to pool. Do not dispose of undiluted chemicals on-site. If recycling, replace cap and return clean containers to recycler or designated collection point.

If not recycling, break, crush or puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

SAFETY DIRECTIONS

May irritate the eyes. Avoid contact with eyes. When opening the container and using the product, wear rubber gloves.

FIRST AID

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

MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet which can be obtained from the supplier.

CONDITIONS OF SALE AND WARRANTY

The directions for use for this product reflect the opinion of experts, based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness, or other unintended consequences, may result because of such factors as the presence of other materials or the manner of use, all of which are beyond the control of FMC (Australia) Limited ("FMC") or the seller. All such risks shall be assumed by the buyer. FMC makes no warranty whether expressed or implied, including warranties of merchantability or of fitness for a particular purpose for this product. Under no circumstances shall FMC be liable for incidental, consequential or other damages from alleged negligence, breach of warranty, strict liability or any other theory, arising out of the use or handling of this product. The sole liability of FMC for any claims arising out of the manufacture, use or sale of its products shall be for the buyer's purchase price.

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GLOSSARY

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

Suggested Further Reading

Felton, J.C., Oomen, P.A. & Stevenson, J.H. 1986, 'Toxicity and hazard of pesticides to honeybees: harmonisation of test methods', *Bee World*, vol. 67, no. 3, pp. 114-24.

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Hassall, K.A. 1990 *The Biochemistry and Uses of Pesticides –structure, metabolism, mode of action and uses in crop protection*, 2nd ed., MacMillan, London.

Goring, C.A.I. et al. 1975, 'Principles of pesticide degradation in soil', in *Environmental Dynamics of Pesticides*, edited by R. Haque and V.H. Freed, Plenum Press, New York, pp 135-72.

Matthews, G.A. 1992, *Pesticide Application Methods*, 2nd ed., Longman, London.

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 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 terbuthylazine in the product SwimCare ® T Swimming Pool Algaecide, please fill in this form and send it, along with payment of $30 to:

David Hutchison
Agricultural & Veterinary 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.

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Card number _____/_____/_____/_____ Expiry date ...../...../.....

Signature_____ Date _____