Australian Government

Australian Pesticides and Veterinary Medicines Authority

PUBLIC RELEASE SUMMARY

on the evaluation of the new active bistrifluron in the product

Xterm™ Defence Against Termites

APVMA Product Number 64601

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This publication is available from the APVMA website: www.apvma.gov.au.

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing, Office of Chemical Safety (OCS), Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), and State Departments of Primary Industries.

The APVMA 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 products containing new active constituents.

The information and technical data required by the APVMA to assess the safety of new chemical products, and the methods of assessment, must be consistent with accepted scientific principles and processes. Details are outlined in the APVMA's publications Ag MORAG: Manual of Requirements and Guidelines and Vet MORAG: Manual of Requirements and Guidelines.

This Public Release Summary is intended as a brief overview of the assessment that has been conducted by the APVMA and of the specialist advice received from 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.

About this document

This is a Public Release Summary.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's assessment, which may include details of:

- the toxicology of both the active constituent and product
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety.

Comment is sought from interested stakeholders on the information contained within this document.

Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of **Xterm™ Defence Against**

Termites should be granted. Submissions should relate only to matters that the APVMA is required, by legislation, to take into account in deciding whether to grant the application. These matters include aspects of public health, occupational health and safety, chemistry and manufacture, environmental safety, and efficacy. Submissions should state the grounds on which they are based. Comments received that address issues outside the relevant matters cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 9 May 2013 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address (if available)
- the date you made the submission.

All personal information, and confidential information judged by the APVMA to be confidential commercial information (CCI)1 contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Contact Officer
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[1] A full definition of "confidential commercial information" is contained in the Agvet Code.

Further information

Further information can be obtained via the contact details provided above.

Copies of full technical evaluation reports covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request.

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

1 INTRODUCTION

Applicant

Sumitomo Chemical Australia Pty Limited

Details of product

It is proposed to register Xterm™ Defence Against Termites containing 10.0 g/kg bistrifluron as a bait intended for use in the control of termites. The product will generally be used by professional pest control operators in and around households and other situations, e.g. farm and commercial sites, around bridges, wharfs, poles, fences, tree stumps, logs etc. using in-ground or above-ground bait stations. The product consists of a matrix of bistrifluron and cellulose, which is compressed into tablet form. The tablets are fabricated into bait cartridges that are inserted into the bait stations. In-ground stations are to be installed at 3 metre intervals around the structure to be protected, and above-ground stations can be affixed directly to infested timber. The Xterm™ baiting system involves monitoring to identify active termites, delivery of the bait, and on-going monitoring to detect new termite infestations. Termites are detected by inserting monitoring stations (containing untreated wood or cellulose) in and/or around a building or at other appropriate sites. Once termites have been detected in the monitoring stations, Xterm™ bait cartridges are substituted. Xterm™ Defence Against Termites is intended to be used at the rate of two 60 g bait canisters per above ground bait stations and one 120 g bait canister per in-ground bait station.Termites are found throughout Australia. They often infest buildings and damage wood formations, wallpaper, plastics, paper products and fabric made of plant fibres. The most serious damage results from the loss of structural strength. Other costly losses include attacks on flooring, carpeting, art work, books, clothing, furniture and other valuable items. Aside from the giant termite (Mastotermes darwiniensis), the most destructive termites in Australia belong to the Rhinotermitidae (lower termites), principally species of Coptotermes, in particular Coptotermes acinaciformis. This termite species is widely distributed across Australia, and is responsible for greater economic losses to timber-in-service than all other Australian termite species combined (including M. darwiniensis). North of the Tropic of Capricorn, C. acinaciformis forms discrete mounds, whereas in the south nests are located within cavities in trees and in roof spaces. The discrete mounds of C. acinaciformis in northern Australian woodlands generally provide the best opportunity to study the effects of termiticide products on this species. Xterm™ Defence Against Termites claims general effectiveness for the control of subterranean termites (excluding Mastotermes darwiniensis). Bistrifluron is a new active constituent to the Australian market and is an insecticide that belongs to the benzoylphenylurea chemical class. A number of other chemicals in this class, including hexaflumuron, diflubenzuron and chlorfluazuron, have been registered for use in pesticide preparations in Australia for some time. The mode of action of this class of chemicals is the inhibition of chitin synthesis, which causes the disruption of the termite moulting process. Both the active, bistrifluron, and the product Xterm™ Defence Against Termites are registered in Indonesia, Thailand, Singapore, Vietnam, Malaysia and the Philippines.

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of Xterm™ Defence Against Termites, and approval of the new active constituent, bistrifluron.

2 CHEMISTRY AND MANUFACTURE

2.1 Active constituent

The active constituent bistrifluron is an insecticide which inhibits chitin synthesis. Bistrifluron belongs to the urea family of compounds.

Manufacturing site

The active constituent bistrifluron is manufactured by Dongbu Fine Chemicals Co Ltd, 32 Lot, 7 Block, 433, Mongnae-dong, Danwon-gu, Ansan-si, Gyeonggi-do, 425-100, Republic of Korea.

Chemical characteristics of the active constituent

COMMON NAME (ISO):	Bistrifluron
IUPAC NAME:	1-[2-chloro-3,5-bis(trifluoromethyl)phenyl]-3-(2,6-difluorobenzoyl)urea
CAS NAME:	N-[[[2-chloro-3,5-bis(trifluoromethyl)phenyl]amino]carbonyl]-2,6-difluorobenzamide
CAS REGISTRY NUMBER:	201593-84-2
MOLECULAR FORMULA:	$C_{16}H_7ClF_8N_2O_2$
MOLECULAR WEIGHT:	446.6
STRUCTURAL:	

Physical and chemical properties of active constituent

COLOUR	White
ODOUR	Odourless
PHYSICAL STATE	Powder
MELTING POINT	171.5 °C (range 171.4 - 174.0 °C)
PARTITION COEFFICIENT: (LOG K_{OW}) OCTANOL / WATER	5.70 ± 0.1 at 20°C 5.74 ± 0.6 at 25°C
SOLUBILITY IN WATER	30 ± 4 ppb
SOLUBILITY IN ORGANIC SOLVENTS	Methanol: 25.6 g/L at 15 °C; 33.5 g/L at 25 °C Methylene chloride: 33.1 g/L at 15 °C; 63.5 g/L at 25 °C Hexane: 2.3 g/L at 15 °C; 3.6 g/L at 25 °C
FLAMMABILITY	Not classified as highly flammable
EXPLOSIVE PROPERTIES	Not explosive
OXIDISING PROPERTIES	Not an oxidizing agent
SELF-IGNITION	Not self-ignition below 220 °C

The Chemistry Section of the APVMA has evaluated the chemistry aspects of bistrifluron active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for bistrifluron active constituent:

CONSTITUENT	SPECIFICATION	LEVEL
bistrifluron	bistrifluron	970 g/kg minimum

Based on a review of the data provided by the applicant, the APVMA is satisfied that the chemistry and manufacturing details of bistrifluron are acceptable.

2.2 Product

The Chemistry Section has evaluated the chemistry aspects of the product, Xterm™ Defence Against Termites (physico-chemical properties, formulation process, quality control procedures, batch analysis results, stability, analytical methods and packaging).

Xterm™ Defence Against Termites

DISTINGUISHING NAME:	Xterm™ Defence Against Termites
FORMULATION TYPE:	Bait
APPEARANCE:	White and odourless tablet
ACTIVE CONSTITUENT CONCENTRATION:	bistrifluron 10 g/kg
SPECIFIC GRAVITY (1% W/V IN DISTILLED WATER)	1.004
PH (1% W/V IN DISTILLED WATER)	6.8
SAFETY PROPERTIES:	Not corrosive, flammable or explosive

The product Xterm™ Defence Against Termites will be formulated in South Korea using bistrifluron manufactured in South Korea. The manufacturing and quality control procedures, including compliance with the release specifications, are acceptable.

The applicant provided the results of accelerated stability testing conducted using samples stored in plastic cartridges (the proposed commercial container type). Testing of all of the important parameters for bait formulations was conducted. The results indicate that the formulated product is expected to be stable for at least two years when stored under normal conditions in the proposed commercial packaging.

2.3 Recommendation

Based on a review of the data provided by the applicant, the APVMA is satisfied that the chemistry and manufacturing details of Xterm™ Defence Against Termites are acceptable.

3 TOXICOLOGICAL ASSESSMENT

3.1 Summary of public health aspects and toxicology

The product Xterm™ Defence Against Termites is a formulation bait tablet (60 and 120 g wrapped in plastic) containing 10 g/kg bistrifluron that is placed in designed above-ground and in-ground bait stations for the control of subterranean termite species (except Mastotermes darwiniensis).

In rats, following oral administration, bistrifluron is rapidly and extensively absorbed, and widely distributed to organs and tissues, with the highest level detected in the liver. It is extensively metabolised and eliminated from the body was relatively slow and predominantly via the faeces with the urine a minor route of elimination. There was no evidence of bioaccumulation following repeated dosing.

Based on the submitted data, bistrifluron is of low acute oral, dermal and inhalational toxicity in rats, is not a skin or eye irritant in rabbits, and is considered unlikely to be a skin sensitiser in guinea pigs.

Following repeat oral dosing in rats, mice and dogs, the key toxicology findings were reduced food consumption and body weight gain, and changes in liver function, liver weight and liver histopathology. Bistrifluron was not mutagenic in vitro, and the observed weak genotoxic potential observed in vitro was not expressed in vivo. Thus, bistrifluron is not an in vivo genotoxicant. Bistrifluron was not carcinogenic in rats and mice, a reproductive toxicant in rats or a developmental toxicant in rats and rabbits. Furthermore, although no neurotoxicity studies were submitted there was no evidence of a neurotoxicity potential in the oral repeat dose studies in rats, mice and dogs.

Xterm™ Defence Against Termites is of low acute oral and dermal toxicity in rats, is not a skin or eye irritant in rabbits, and is considered unlikely to be a skin sensitiser in guinea pigs. No acute inhalational study is available for Xterm™ Defence Against Termites, though its acute inhalation toxicity potential is considered likely to be low given the product constituents.

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of Xterm™ Defence Against Termites when used in accordance with the label directions.

3.2 Evaluation of toxicology

The toxicological database for bistrifluron, which consists primarily of toxicity tests conducted using animals, is extensive though the quality of the studies was variable. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects might be generated in humans. From a conservative risk assessment perspective however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available. Where possible, considerations of the species specific mechanisms of adverse reactions weigh heavily in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels compared with those, usually many times higher,

which produce effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No Observable Effect Level (NOEL) are generally used to develop acceptable limits for dietary or other intakes (ADI and ARfD) at which no adverse health effects in humans would be expected.

Chemical class

Bistrifluron belongs to the benzoylphenylurea chemical class. It is an insect growth regulator that inhibits chitin synthesis. Ingestion of the chemical by termites causes improper moult and consequent death. Bistrifluron does not kill termites immediately, so giving ample time for the termite to return to the nest and spread the chemical toxicant amongst its nest mates through tropholaxis and cannibalism.

Toxicokinetics and metabolism

Bistrifluron was investigated for its absorption, distribution, metabolism and excretion following an oral dose of 1 or 10 mg/kg bw, an i.v. dose of 1 mg/kg bw, or repeated oral doses of 1 mg/kg bw (14x) in rats. Following an oral low or high dose, bistrifluron was rapidly absorbed, with the highest plasma levels achieved at 1 to 2 hours post dosing, with a slightly higher level seen in females compared to males. The bioavailability was 63–64%, with negligible binding of the test substance to red blood cells. Elimination half-life ranged from 12.7 to 19.7 hours.

Of a total excretion of over 88% of the dose, the vast majority of the radioactivity administered was eliminated via the faeces (85–93%), with minor excretion via the urine (3% or less), and negligible excretion as volatiles in expired air. Excretion mainly occurred during the first 48 hours, and was almost complete by 72 hours. The pattern of excretion was similar between oral and i.v. dosing, between the single low and high oral dose as well as repeated oral doses, and between males and females.

Bistrifluron was widely distributed to organs and tissues. Residual radioactivity in organs / tissues was low (total < 1.8%) at 96 hours post dosing, with the highest level seen in the liver, followed by kidneys, lungs, fat, skin and intestine. Tissue accumulation was not evident following repeated dosing.

The parent compound was extensively metabolized. The main metabolites, including OH-parent (and its isomer), OH-parent-sulfatide and other break down compounds, were detected in the faeces, urine, plasma and organs (liver, kidneys, muscle and fat). Unchanged parent compound was also detected in faeces, organs and tissues, but not in the urine.

Acute studies

Bistrifluron has low oral (LD50 > 5000 mg/kg bw with no deaths in rats and mice), dermal (LD50 > 2000 mg/kg bw with no deaths) and inhalational toxicity (4hr LC50 > 4022 mg/m3 with no deaths) in rats. It was not a skin or eye irritant in rabbits. No evidence of a skin sensitisation potential was seen in guinea pigs, though noting reporting limitations it is considered unlikely to be a skin sensitiser.

Xterm™ Defence Against Termites (containing 10 g/kg bistrifluron, bait) was of low oral and dermal toxicity in rats (both LD50‘s > 10,000 mg/kg bw with no deaths), and was non-irritant to rabbit skin and eyes.

No evidence of a skin sensitisation potential was seen in guinea pigs, though as this was a non-standard study it is considered unlikely to be a skin sensitiser.

No acute inhalational study is available for the product Xterm™ Defence Against Termites. However, its acute inhalational toxicity potential is considered likely to be low given the format of the product and its constituents.

Systemic effects

In repeat dose oral studies in mice, rats and dogs, the key toxicology findings were reduced food consumption and body weight gain, and changes in liver function, liver weight and liver histopathology. The available data did not robustly demonstrate a difference in sensitivity to bistrifluron toxicity between rats, mice and dogs. The lowest observed NOEL and LOEL were established in a 2-year dietary rat study for liver toxicity. The NOEL was 7.38/9.57 mg/kg bw/d in males/females, based on increased liver weight in males and bile duct hyperplasia in both sexes at 15.05/19.66 mg/kg bw/d in males/females.

Additionally in 13-week oral studies in rats, mice and dogs which included a 4-week recovery group, liver findings were reversible in female rats, while the liver findings were partially reversible in female rats, and male and female mice and dogs within the 4-week non-treatment period. Thus, the data shows gradual reversibility of the observed liver toxicity in all 3 species.

A 4-week dermal toxicity study in rats showed no toxicologically significant effects were seen up to and including the limit dose of 1000 mg/kg bw/d.

Carcinogenicity and genotoxicity

Bistrifluron did not show a carcinogenic potential in an 18-month dietary mouse study and a 2-year dietary rat study, however no LOEL was identified in the study. Bistrifluron was not mutagenic in bacteria with and without metabolic activation. In an in vitro chromosome aberration study in mammalian cells an increase in chromosome aberrations was only seen at concentrations that were cytotoxic or very close to cytotoxic concentrations in the presence of metabolic activation. While in a further in vitro chromosome aberration study in mammalian cells in the absence of metabolic activation, an increase in chromosome aberrations was only seen at concentrations in the presence of precipitation of the test material, with an increase in polyploidy seen in a single experiment in the absence of precipitation. However, bistrifluron was not genotoxic in an in vivo mouse micronucleus study up to and including the limit dose. Therefore, the observed weak genotoxic potential observed in vitro was not expressed in vivo. Thus, bistrifluron is not an in vivo genotoxicant.

Reproductive toxicity

In a dietary rat 2-generation reproduction study that produced parental toxicity, the NOEL for reproductive toxicity was established at the top dose (187.3/234.5 mg/kg bw/d in males/females) based on the absence of treatment related toxicologically significant effects. Thus, bistrifluron was not a developmental toxicant in rats. In the same study, decreased body weight was seen in F2 male and female pups from birth to weaning and changes were seen in absolute and relative brain, spleen and thymus weights particularly in F2 male and female pups which were attributed to the lower body weight seen in these animals at

37.0/44.4 mg/kg bw/d, a dose level that also produced parental toxicity (decreased food consumption throughout the pre-mating, gestation and lactation period in F0 females, increased liver weight and histopathological changes to the liver [hepatocellular hypertrophy and hepatocellular vacuolization] in F1 males).

Developmental toxicity

In an oral developmental study in rats, although no historical control data was provided the only increased incidence seen in treated animals compared to controls was an increased incidence of visceral malformations, due to an increase in the number of foetuses with thymic remnant in the neck and dilated ureter. However, these findings were not statistically significant and were seen in the absence of a dose response relationship. Consequently, they were considered unlikely to be treatment related. The maternal and developmental NOEL in this study were both established at the limit dose of 1000 mg/kg bw/d, the highest dose tested. Thus, bistrifluron was not a developmental toxicant in rats.

In an oral developmental study in rabbits, an increased incidences were seen in a limited number of external, visceral and skeletal findings at the top dose that were absent in control animals. While historical control data was provided for the laboratory the reporting was somewhat limited, making it necessary in some instances to cautiously use ‘general’ historical control data on the NZW rabbit that was not from the testing laboratory. Additionally, the incidence of dead fetuses and fetuses with visceral variations in both the control and treated groups was greater than the laboratory historical control range. While this made the interpretation of the observed findings difficult and their biological significance unknown, noting the increases were not statistically significant they were considered unlikely to be of toxicological significance. While the observed finding of a single foetus with a malrotated forelimb in the treated groups was also occasionally seen in the general historical control database. Similarly, the observed incidence of a convoluted ureter and a dilated ureter were also within the general historical control range, and the singular incidence of fused sternebrae was within the laboratory control range. While no historical control data was available for fused lumbar centrum, the observance of this finding in a single foetus at the limit dose of 1000 mg/kg bw/d was not considered to provide robust evidence of a developmental toxicity potential for bistrifluron.

The maternal and developmental NOEL in this study were both established at the limit dose of 1000 mg/kg bw/d, the highest dose tested. Thus, bistrifluron was not a developmental toxicant in rabbits.

Neurotoxicity

No neurotoxicity studies were submitted. However, there was no evidence of a neurotoxicity potential in oral repeat dose studies in rats, mice and dogs.

3.3 Public Health Standards

Poisons scheduling

On 30 May 2012, the delegate to the Secretary to the Department of Health and Ageing made a delegate only decision on bistrifluron. The Secretary's delegate recommended that an Appendix B entry for bistrifluron

be created in the Standard Uniform Scheduling of Medicines and Poisons, along with an implementation date of 1 September 2012.

NOEL/ADI

The Acceptable Daily Intake (ADI) is that quantity of an agricultural or veterinary chemical which can safely be consumed on a daily basis for a lifetime and is based on the lowest NOEL obtained in the most sensitive species. This NOEL is then divided by a safety factor which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

Since the current application for registration is not associated with food producing use, no ADI for bistrifluron is required at this stage.

Acute reference dose

The acute reference dose (ARfD) is the maximum quantity of an agricultural or veterinary chemical that can safely be consumed as a single, isolated event. The ARfD is derived from the lowest NOAEL as a single or short-term dose which causes no adverse effect in the most sensitive species of experimental animal tested, together with a safety factor which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

Since the current application for registration is not associated with food producing use, no ARfD for bistrifluron is required at this stage.

4 OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

4.1 Summary

The product XtermTM Defence Against Termites will generally be used by professional pest control operators. Workers will be exposed to the product predominately by skin contact, with limited potential for inhalation and eye contact when opening the plastic wrapper for the bait canister, placing the canister into a bait station, and replacing canisters at treatment intervals.

Information on worker exposure to bistrifluron or the product XtermTM Defence Against Termites was not available, and no exposure model is available to estimate worker exposure for the proposed product use pattern. However, both the product and bistrifluron have a low acute toxicity profile, and no toxicologically significant effects were seen at the limit dose of 1000 mg/kg bw/d (the NOEL) in a 28-day dermal study in the rat, which was chosen for the occupational health and safety risk assessment.

In view of the nature of product formulation (i.e. tablets in plastic cartridges, a bait canister) and its specific use pattern, the user's hands are likely to be exposed to only a very small amount of the chemical which has become dislodged from the tablet. Furthermore, this exposure will be significantly reduced further (up to 90%) when the worker wears latex gloves as required on the product label to prevent contamination of the tablets. Hence, based on the low toxicity profile, the specific formulation and use pattern of the product, and also noting that wearing latex gloves is recommended by the applicant to prevent contamination of the bait which might deter termites from feeding, the use of personal protective equipment is not considered necessary. Based on the risk assessment, a First Aid Instruction has been recommended for the product label.

Based on an assessment of occupational health and safety, it was considered that there should be no adverse effects on human health from the use of XtermTM Defence Against Termites when used in accordance with the label directions.

4.2 Health hazards

Bistrifluron (CAS: 201593-84-2) is not listed on Safe Work Australia's (SWA) Hazardous Substances Information System (HSIS) Database (SWA, 2012). With the available information, OCS classified bistrifluron as a non-hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004). No human health risk phrases will be required for this new active constituent.

Based on the product toxicology information and concentrations of bistrifluron in the product (1%), XtermTM Defence Against Termites is not classified as a hazardous substance in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004). Thus, no human health risk phrases have been assigned.

4.3 Formulation, packaging, transport, storage and retailing

The active constituent bistrifluron will be manufactured overseas. The product XtermTM Defence Against Termites will be manufactured overseas and imported into Australia as a ready-to-use package containing the product (i.e. bait) tablets wrapped in plastic.

4.4 Use pattern

XtermTM Defence Against Termites is a bait tablet (60 and 120 g) containing 10 g/kg bistrifluron and is intended for use as a termiticide for the control of subterranean termite species (except Mastotermes darwiniensis). The product will be used by pest control operators for the control of termite infestation in and around residential, farm and commercial buildings. The bait tablet(s) are placed in bait stations that have been designed for both above- and in-ground use. The specifically designed rectangular boxes used as above-ground stations are to be tightly closed after the bait is put in, and placed in a suitable position where it can avoid any unnecessary disturbance to the bait station in order to attract termites and achieve the best result of treatment.

4.5 Exposure during use

The product will generally be used by professional pest control operators. Workers will be exposed to the product predominately by skin contact, with limited potential for inhalation and eye contact when opening the plastic wrapper for the tablets, placing the tablet baits into a bait station, and replacing used baits with new baits at treatment intervals. Information on worker exposure to bistrifluron or the product XtermTM Defence Against Termites was not submitted, and no exposure model is available to estimate worker exposure for the proposed product use pattern.

It is anticipated that a pest control operator will visit and conduct above-ground or in-ground monitoring/installations of up to four sites per day, and the maximum daily use rate for a pest control operator will be 960 g of the product XtermTM Defence Against Termites, or 9.6 g (9600 mg) of bistrifluron, which for a worker of 70 kg bw70 kg is equivalent to 137 mg/kg bw/d assuming a default 100 % dermal absorption of bistrifluron in the absence of dermal absorption data.

A NOEL of 1000 mg/kg bw/d derived from a rat 28-day dermal study is chosen for the occupational health and safety risk assessment. Since the NOEL (1000 mg/kg bw/d) is derived from an animal toxicity study, a margin of exposure (MOE) of 100 or above, which takes into account both interspecies extrapolation and intraspecies variability, is considered to be acceptable in this instance. Hence, assuming a default dermal absorption of 100% for bistrifluron in the absence of dermal exposure data, the acceptable maximal daily dermal exposure is calculated to be 10 mg bistrifluron/kg bw/d. Thus, the estimated maximum daily exposure of 137 mg bistrifluron/kg bw/d exceeds this value.

However, in view of the nature of product formulation (i.e. tablets in plastic cartridges, a bait canister) and its specific use pattern, the user's hands are likely to be exposed to only a very small amount of the chemical which has become dislodged from the tablet. Furthermore, this exposure will be significantly reduced further (up to 90%) when the worker wears latex gloves as required on the product label to prevent contamination of the tablets. Hence, the amount of direct dermal exposure to a trained pest control operator will be

substantially lower than 10 mg bistrifluron/kg bw/d. That is, the MOE is likely to be significantly greater than 100. Hence, no personal protective equipment is considered necessary, noting that wearing latex gloves is recommended by the applicant purely to prevent contamination of the bait which might deter termites from feeding.

In a rare case of dermal contact with the product tablets by residents, and in particular in the worst case of accidental intake by a toddler, the risk to human health and safety is likely to be low based on the low concentration of bistrifluron in the product (10 g/kg) and the low acute toxicity of the active constituent (oral and dermal LD50 >5000 and >2000 mg/kg bw respectively for bistrifluron) and the product (oral and dermal LD50's are both >10,000 mg/kg bw for XtermTM Defence Against Termites).

4.6 Exposure during re-entry/re-handling

There is no concern of worker exposure during re-entry to the treated area where the above-ground or in-ground stations containing XtermTM Defence Against Termites bait have been placed. Re-handling exposure is limited to replacing used baits with new baits or removal of used bait station. However since pest control operators are trained in the handling of pesticides the potential for occupational exposure will be limited. Thus, no re-entry or re-handling statement is required.

However, it is noted that the product label will state 'when removing the plastic wrapping and handling the bait canisters, (the users should) wear disposable latex gloves to ensure no contamination of the bait pellets which might deter termites from feeding'. This requirement of wearing gloves when handling the bait will also effectively minimise dermal exposure to the user from re-handling the product.

4.7 Recommendations for safe use

Users should follow the First Aid Instruction and Safety Directions on the product label.

4.8 Conclusion

The registration of XtermTM Defence Against Termites containing bistrifluron at 10 g/kg for the control of subterranean termite species (except Mastotermes darwiniensis) is supported.

XtermTM Defence Against Termites can be used safely if handled in accordance with the instructions on the product label and any other control measures described above. Additional information is available on the product Material Safety Data Sheet.

5 ENVIRONMENTAL ASSESSMENT

5.1 Introduction

Sumitomo Chemical Australia Pty Ltd. has applied for registration of a bait formulation XtermTM Defence Against Termites containing 1% bistrifluron. This is the first time registration for bistrifluron has been sought in Australia. The registration is being conducted based on the submitted data package for bistrifluron.
The product will be used in household and professional pest control arenas, e.g. farm and commercial sites, around bridges, wharfs, poles, fences, tree stumps, logs etc. using in-ground or above-ground bait stations. The proposed maximum application rate of the product is 240 g/bait station that is equivalent to 2.4 g ac/(in-ground) bait station.

5.2 Environmental fate for bistrifluron

Hydrolysis

Bistrifluron is stable at pH 4 and 7 with an estimated t½ >1 year at room temperature, but readily hydrolyses at pH 9 with a half-life of 6.0 days at 25°C.

Photolysis

For aqueous photolysis, the DT50 was estimated to be in the range of 1.7 to 22.4 days in aqueous systems at latitudes between 30°N and 50°N. Three major photoproducts were identified.

Soil metabolism

Bistrifluron dissipated fairly to slightly in aerobic soils with DT50 values in the range of 33—128 days. Bistrifluron is immobile in soil based on the determined KOC value of 37480. Bistrifluron is expected to be persistent in air with an estimated half-life of 3.5 days.

The applicant did not provide a study for aquatic metabolism for clarification of the persistence property.

Bioaccumulation

Bistrifluron is considered to be highly concentrating based on the determined BCF value of 2414 in killifish.

5.3 Environmental effects

Birds

Birds were not sensitive to bistrifluron with LD50 values being > 2250 mg/kg bw for acute oral tests for northern bobwhite quail and mallard ducks, and with LC50 > 5000 mg/kg feed for dietary tests for Japanese quail.

Aquatic organisms

Bistrifluron's acute endpoints for fish, daphnids and algae are all greater than its water solubility limit. However, bistrifluron is considered to be very toxic to daphnids on a chronic basis with a 21 d NOEC of 1.2 µg ac/L.

Terrestrial invertebrates

Earthworms and bees were not found to be sensitive to bistrifluron to the level tested. In the case of bees the LD50 is > 100 µg/bee, and the NOEC is 100 µg/bee, for acute contact and oral exposure. For earthworms, the 14 d acute LC50 was > 1000 mg/kg dry weight soil.

5.4 Risk assessment

The product XtermTM Defence Against Termites containing 1% bistrifluron is intended for use in household and professional pest control arenas, e.g. farm and commercial sites, around bridges, wharfs, poles, fences, tree stumps, logs etc using in-ground or above ground bait stations. The proposed maximum application rate of the product is 240 g/bait station that is equivalent to 2.4 g ac/(in-ground) bait station.

Given the use pattern of the product and the low market volume, environmental release of bistrifluron is expected to be very limited. The risks for the exposure to bistrifluron were assessed for both terrestrial organisms and aquatic life. No unacceptable potential risk to the aquatic life was predicted from the application and use pattern.

The risk for the exposure of the product to terrestrial organisms, including birds, bees, predators from secondary poisoning, non-target plants, and particularly terrestrial invertebrates that may get into the bait stations was assessed based on the available endpoints, the use pattern and proposed application rate of the product. The assessment shows that the risk from the proposed use and application rate of the product will be acceptable to terrestrial organisms.

6 EFFICACY AND SAFETY ASSESSMENT

The applicant, Sumitomo Chemical Australia Pty Ltd, seeks registration of the proposed new product Xterm™ Defence Against Termites, a bait product containing 10 g/kg bistrifluron, for use in the management of subterranean termites in Xterm™ above-ground and in-ground monitoring stations.

6.1 Proposed product use pattern

It is proposed that Xterm™ Defence Against Termites (10 g/kg bistrifluron bait canisters) be used for the monitoring and management of subterranean termites in conjunction with in-ground and above-ground bait stations. Xterm™ Defence Against Termites may be used in an integrated termite management system incorporating bait stations around the perimeter of a structure. The bait stations should be installed in areas of known or suspected termite activity where they can be inspected with ease, in accordance with the agreed site termite management plan or at least every 2–4 weeks, for above-ground stations, or 2 months, for in-ground stations. Regular inspections are necessary to ensure continuous feeding by termites via bait replenishment and, once activity ceases, to detect possible re-infestation.

6.2 Summary of evaluation of efficacy

Data provided in support of the palatability, attractiveness and efficacy of Xterm™ Defence Against Termites included the results of laboratory and field trials conducted between 2002 and 2012 in Australia and overseas, together with published studies on the efficacy of the active constituent. Published studies on termite management, ecology and phylogenetics were also submitted to support the application.

Overseas data comprised laboratory and field trials of different concentrations of bistrifluron in Southeast Asia. In most laboratory trials, the Formosan termite Coptotermes formosanus was used. Six published studies were submitted in support of the speed of efficacy of bistrifluron in Japanese laboratory bioassays against the termite C. formosanus. Two of these studies also included the termite Reticulotermes speratus for comparison. Termites were exposed to paper impregnated with three concentrations of bistrifluron in choice and no-choice environments (bistrifluron alone, or with other chitin synthesis inhibitors, hexaflumoron and diflubenzuron). The laboratory trials demonstrated a dose response in termiticidal efficacy, with more rapid mortality being achieved with the higher concentrations of bistrifluron. The trails also showed that rate of bait consumption tended to decrease with an increase in the concentration of bistrifluron. These laboratory trials demonstrated that bistrifluron was as efficacious as, and in some cases superior to, the other chitin synthesis inhibitors tested in achieving termite mortality.

In most overseas field trials, Coptotermes gestroi was the targeted pest species. Six individual overseas studies (conducted in Malaysia, Indonesia and Maldives) investigated the efficacy of bistrifluron baits on the control of C. gestroi infestations. Colony elimination was achieved in a range of four to twelve weeks. Five replicated overseas field trials and one published study (Malaysia, Indonesia and Singapore) investigated the efficacy of bistrifluron baits for the control of C. gestroi, Microcerotermes sp., Globitermes sulphureus and Coptotermes curvignathus. Bistrifluron baits were shown to be efficacious for treating infestations under an assortment of commercial situations including houses, high-rise buildings and plantations. On average, termite populations were eliminated in four to six weeks after treatment with Xterm™ Defence Against Termites.

Three commercial trials were conducted in Australia against C. acinaciformis; one in southern NSW, and two trials near Sydney. In these trials, Xterm™ Defence Against Termites bait was placed where termites were found to be feeding. The deployment of Xterm™ Defence Against Termites bait was associated with the departure of C. acinaciformis three months after treatment from an aggregation station on a residential property (Wagga Wagga, NSW), and two months after treatment from bait boxes and infested timber on an industrial site (Kurnell, NSW). Product efficacy was also demonstrated in field trials against C. lacteus (southern NSW), C. acinaciformis (Northern Territory), and Nasutitermes exitiosus (Sydney).

In the field trials conducted in southern NSW (three trials) and near Sydney (one trial), Xterm™ Defence Against Termites baits were placed in or around termite mounds (C. lacteus). Whilst baiting was in progress, colony health was monitored by observing the ability of termites to repair damage inflicted to mounds and by monitoring mound internal temperature. After a defined period, baits were removed and inspected and the amount of bait consumed was assessed. At the end of the trials mounds were broken up to confirm the death of the colony. All treated C. lacteus colonies were eliminated within approximately four months. From observations made of mound repair and internal temperature, signs of colony decline were evident from as early as four weeks from the start of baiting.

The field trials conducted in northern Australia examined the efficacy of different concentrations of bistrifluron bait on sixteen mound-colonies of C. acinaciformis. These field trials demonstrated the efficacy and palatability of Xterm™ Defence Against Termites under conditions of ample alternative food in the dry season. Colonies were monitored for their ability to maintain the constant internal temperature environment and repair mound damage, which are indicators of colony health. At four weeks after treatment, two of the treated mounds were dissected and found to be moribund; 83% of colonies were either eliminated or moribund by eight weeks after treatment.

The efficacy of Xterm™ Defence Against Termites N. exitiosus was tested against 52 mound-colonies (and five control mounds) at various locations around southern Sydney. Different methods of delivery were investigated; in-ground bait stations were placed adjacent to mounds or delivered directly to mounds by various methods. Most colonies succumbed 30–40 weeks after initial bait feeding. Xterm™ baits were effective for controlling colonies of N. exitiosus, but over a more protracted period than for C. acinaciformis or C. lacteus. Slow colony elimination of N. exitiosus was also shown by other published studies; this is consistent with the explanation that the final instar (non-moulting) Nasutitermes continue to forage long after the central nest has been negatively affected by the bait.

6.3 Conclusion

The claim on the proposed label that the product Xterm™ Defence Against Termites provides a method for the management of subterranean termites in above-ground and in-ground monitoring stations, when used as directed, is supported by the results from overseas and Australian trials. The supporting data from efficacy trials demonstrate that the new active constituent, bistrifluron, in the product Xterm™ Defence Against Termites offers effective management of termites, and its performance was equal to or slightly superior to the comparator termiticides against which it was tested. Efficacy was demonstrated against members of the economically important termite families Rhinotermitidae and Termitidae listed in Australian Standard 3660.3. For the Rhinotermitidae, the product was efficacious against the economic pest species C. acinaciformis, as well as other Coptotermes species including C.lacteus,C. formosanus, C. gestroi and C. curvignathus.

Efficacy was also demonstrated against the rhitotermitid taxa R. speratus, Microceratermes sp. and G. sulphureus. Efficacy against higher termites (Termitidae) was demonstrated against the economic pest species N. exitiosus. The efficacy of the product against other economic pest species within the Rhitotermitidae and Termitidae families is expected to be comparable by extrapolation from the data submitted. The directions for use are appropriate and consistent with termiticide use in Australia. The application by Sumitomo Chemical Australia Pty Ltd for the registration of Xterm™ Defence Against Termites is supported on efficacy grounds when used in accordance with label instructions.

7 LABELLING REQUIREMENTS

Xterm™
Defence against Termites

Termite Bait

ACTIVE CONSTITUENT: 10.0 g/kg Bistrifluron

An insect growth regulator
For use in the management of subterranean termites in Xterm™ in ground (IG) monitoring stations as specified in the Directions for Use

Contents: 1.44kg NET

Contains 12 x 120 g bait canisters
(which is illegal to be sold separately)

SUMITOMO CHEMICAL

SUMITOMO CHEMICAL AUSTRALIA PTY LTD
51 Rawson Street
EPPING NSW 2121
Tel: 02 8752 9000
A B N: 21 081 096 255

Directions for Use:

Situation	Pest	Rate	Critical Comments
For use in integrated termite management programs in and around residential, farm and commercial buildings including food handling establishments, and any other timber structures such as bridges, wharfs, utility poles, fences, landscape structures, and logs, tree stumps or known termite mounds or subterranean colonies.	Subterranean termites* (except *Mastotermes darwiniensis)*	Place one 120g bait canister into the in-ground bait station once feeding is evident in the timber feeding blocks. Replace as required. Bait canisters may be lightly sprayed with water during installation, if required.	**IMPORTANT**: Read GENERAL INSTRUCTIONS before use When removing the plastic wrapping and handling the bait canisters, wear disposable latex gloves to ensure no contamination of the bait pellets which might deter termites from feeding.

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

GENERAL INSTRUCTIONS

To use this bait effectively, the user should have a thorough understanding of termite biology and behavior particularly in regard to feeding, attractancy and disturbance. Termite baiting relies heavily on the transfer of bait back to the colony and the subsequent transfer between individuals through tropholaxis (mutual feeding) and grooming. The active ingredient in Xterm™ Defense Against Termites termite bait interferes with the normal moulting process in termites leading to a gradual decline in numbers and collapse of the colony.

* In some termites eg. *Nasutitermes* spp., the soldiers are particularly long lived and may survive long after the queen, brood and workers have been eliminated but further structural damage is unlikely. Early signs that bait is impacting the colony include discoloration of the workers (the result of a build-up in uric acid) and an increase in the ratio of soldiers to workers.

Xterm™ Defense Against Termites termite bait is used in conjunction with an in-ground bait station. Bait stations should be installed in areas of known or likely termite activity where they can be easily inspected. Suitable sized holes should be dug at 3 metre intervals around the structure to be protected, where stations with timber feeding blocks are placed. These should be inspected on a regular basis and once termite activity is confirmed then one Xterm™ IG canisters should be placed on top of the timber feeding blocks. In-ground stations should be inspected on a regular basis in accordance with the agreed site termite management plan or at least every 2 months.

Once activity is confirmed within the bait station then more frequent inspections are required to ensure continuous feeding by termites is not interrupted. Avoid any unnecessary disturbance of the bait station as termites may abandon feeding within the bait station.

Once termite activity ceases then bait stations can be removed or maintained with fresh timber feeding blocks to detect any possible re-infestation.

Xterm™ Defense Against Termites termite bait may be used in an integrated termite management system incorporating both above-ground (AG) stations where termite activity in the structure is evident (refer to the separate label instructions provided with the above-ground canisters) and IG termite monitoring stations around the perimeter of the structure.

Integrated Termite Management

The risk of termite infestation should be minimized by removing all available food sources (other than the structure itself). Subfloor areas and areas surrounding the structure should be kept free of timber and any cellulose-based materials which might attract termites. Action should be taken to eliminate any sources of unnecessary dampness such as leaking water or sewer pipes, or inadequate drainage under or around the structure.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT
Very toxic to aquatic life with long lasting effects. **DO NOT** contaminate wetlands or watercourses with this product or used bait stations.

STORAGE AND DISPOSAL

Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Dispose of unused bait or used bait stations by wrapping with paper and putting in garbage.

SPILLS

Sweep up material and wrap in paper. Dispose of as above. Prevent entry of spilled material into drains or waterways.

SMALL SPILL MANAGEMENT
Sweep up material and contain in a refuse vessel for disposal in the same manner as for containers (see Storage and Disposal).

FIRST AID
If poisoning occurs, contact a doctor or Poisons Information Centre (Tel. 131126).

MATERIAL SAFETY DATA SHEET
Additional information is listed in the Material Safety Data Sheet (MSDS).

IMPORTANT NOTICE
These goods are to be used only for the purpose and as specified on the label, and are not suitable for any other purpose. To the fullest extent permitted by law, we do not accept or bear any liability on any basis for any loss, damage, cost or expense, arising in any way, directly or indirectly, in connection with the goods.

APVMA Approval No: 64601/52411
Batch No:
Date of Manufacture:

In a Transport Emergency Dial **000** Police or Fire Brigade	SPECIALIST ADVICE IN EMERGENCY ONLY **1800 024 973** ALL HOURS - AUSTRALIA WIDE

Xterm In Ground (IG)
Termite Bait Canister

ACTIVE CONSTITUENT:
10g/kg Bistrifluron

Contents: 120g NET

Remove the plastic wrap before placing the canister in the monitoring station

IMPORTANT: Not to be sold separately.
Before use read all directions on the outer pack.

APVMA No.: 64601/52411

Termite Bait

ACTIVE CONSTITUENT: 10.0 g/kg Bistrifluron

An insect growth regulator
For use in the management of subterranean termites in Xterm™ above ground (AG) monitoring stations as specified in the Directions for Use

Contents: 720g NET

Contains: 12 x 60 g bait canisters
(which is illegal to be sold separately)

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SUMITOMO CHEMICAL AUSTRALIA PTY LTD
51 Rawson Street
Epping NSW 2121
Tel: 02 8752 9000
A B N: 21 081 096 255

Directions for Use:

Situation	Pest	Rate	Critical Comments
For use in integrated termite management programs in and around residential, farm and commercial buildings including food handling establishments, and any other timber structures such as bridges, wharfs, utility poles, fences,	Subterranean termites* (except *Mastotermes darwiniensis)*	Place up to two 60g bait canisters into the above ground bait station. Replace as required. Bait canisters may be lightly sprayed with	**IMPORTANT**: Read GENERAL INSTRUCTIONS before use When removing the plastic wrapping and handling the bait

landscape structures, and logs, tree stumps or known termite mounds or subterranean colonies.		water during installation, if required.	canisters, wear disposable latex gloves to ensure no contamination of the bait pellets which might deter termites from feeding.

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

GENERAL INSTRUCTIONS

To use this bait effectively, the user should have a thorough understanding of termite biology and behavior particularly in regard to feeding, attractancy and disturbance. Termite baiting relies heavily on the transfer of bait back to the colony and the subsequent transfer between individuals through tropholaxis (mutual feeding) and grooming. The active ingredient in Xterm™ Defense Against Termites termite bait interferes with the normal moulting process in termites leading to a gradual decline in numbers and collapse of the colony.

* In some termites eg. *Nasutitermes* spp., the soldiers are particularly long lived and may survive long after the queen, brood and workers have been eliminated. Early signs that bait is impacting the colony include discoloration of the workers (the result of a build-up in uric acid) and an increase in the ratio of soldiers to workers.

Xterm™ Defense Against Termites is used in conjunction with an above-ground bait station. Above ground bait stations should be placed on areas of active termite feeding. Above ground bait stations can be affixed directly to infested timber using either screws provided or other appropriate method. Either one or two 60g canisters may be placed in the AG station. The lid of the AG station should be securely closed to maintain a dark environment inside. AG stations may also be covered with black plastic or otherwise taped over to ensure a dark environment is maintained.

Above ground stations should be inspected regularly to ensure continuous feeding by termites is not interrupted. It is important to minimise disturbance when inspecting AG stations to ensure termite activity is maintained.

Regularity of inspection should be in accordance with the agreed site termite management plan or at least every 2-4 weeks.

Once termite activity ceases then bait stations can be removed.

Xterm™ Defense Against Termites termite bait may be used in an integrated termite management system incorporating both AG stations where termite activity in the structure is evident and IG termite monitoring stations (refer to separate label instructions provided with the in-ground canisters) around the perimeter of the structure.

Integrated Termite Management

The risk of termite infestation should be minimized by removing all available food sources (other than the structure itself). Subfloor areas and areas surrounding the structure should be kept free of timber and any cellulose-based materials which might attract termites. Action should be taken to eliminate any sources of unnecessary dampness such as leaking water or sewer pipes, or inadequate drainage under or around the structure.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Very toxic to aquatic life with long lasting effects. **DO NOT** contaminate wetlands or watercourses with this product or used bait stations.

STORAGE AND DISPOSAL

Store in the closed original container in a dry, cool, well ventilated area out of direct sunlight.

Dispose of unused bait or used bait stations by wrapping with paper and putting in garbage.

SPILLS

Sweep up material and wrap in paper. Dispose of as above. Prevent entry of spilled material into drains or waterways.

SMALL SPILL MANAGEMENT
Sweep up material and contain in a refuse vessel for disposal in the same manner as for containers (see Storage and Disposal).
FIRST AID
If poisoning occurs, contact a doctor or Poisons Information Centre (Tel. 131126).
MATERIAL SAFETY DATA SHEET
Additional information is listed in the Material Safety Data Sheet (MSDS).
IMPORTANT NOTICE
These goods are to be used only for the purpose and as specified on the label, and are not suitable for any other purpose. To the fullest extent permitted by law, we do not accept or bear any liability on any basis for any loss, damage, cost or expense, arising in any way, directly or indirectly, in connection with the goods.

APVMA Approval No: 64601/52411
Batch No:
Date of Manufacture:

In a Transport Emergency Dial **000** Police or Fire Brigade	SPECIALIST ADVICE IN EMERGENCY ONLY **1800 024 973** ALL HOURS - AUSTRALIA WIDE

Xterm Above Ground (AG)
Termite Bait Canister

ACTIVE CONSTITUENT:
10g/kg Bistrifluron
Contents: 60g NET

Remove the plastic wrap before placing the canister in the above ground station

IMPORTANT: Not to be sold separately.
Before use read all directions on the outer pack.
APVMA No.: 64601/52411

ABBREVIATIONS

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
ARfD	Acute Reference Dose
BBA	Biologische Bundesanalstalt fur Land – und forstwirschaft
BCF	Bioaccumulation factor
bw	bodyweight
d	day
DAT	Days After Treatment
DSEWPaC	Department of Sustainability, Environment, Water, Populations and Communities
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
EI	Export Interval
EGI	Export Grazing Interval
ESI	Export Slaughter Interval
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
HSIS	Hazardous Substance Information System
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 quantified
mg	milligram
mL	millilitre
MOE	Margin of exposure
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee

NEDI	National Estimated Daily Intake
NESTI	National Estimated Short Term Intake
ng	nanogram
NHMRC	National Health and Medical Research Council
NOAEL	No observed adverse effect level
NOEC/NOEL	No Observable Effect Concentration Level
NOHSC	National Occupational Health and Safety Commission
OC	Organic Carbon
OCS	Office of Chemical Safety
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
SWA	Safe Work Australia
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

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 a material from or through 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	Repels water
Leaching	Removal of a compound by use of a solvent
Log Pow	Log to base 10 of octanol water partitioning co-efficient, synonym KOW
Metabolism	The chemical processes that maintain living organisms
Photodegradation	Breakdown of chemicals due to the action of light
Photolysis	Breakdown of chemicals due to the action of light
Subcutaneous	Under the skin
Toxicokinetics	The study of the movement of toxins through the body
Toxicology	The study of the nature and effects of poisons

REFERENCES

Australian Pesticides and Veterinary Medicines Authority 2008, *Ag MORAG: Manual of Requirements and Guidelines*, APVMA, Canberra.

Standards Australia 2000, AS 3660.3 – 2000 *Termite management - Part 3: Assessment criteria for termite management systems*, Australian Standard, distributed by SAI Global Limited. www.saiglobal.com.