



## ADVICE SUMMARY

### APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

**Product name:** WOLSIT T-35  
**Applicant:** DR WOLMAN GMBH  
**Product number:** 63004  
**Application number:** 44510

**Purpose of Application and Description of Use:** Registration of a 43.66 g/L fipronil, liquid formulation for the protection of wood composite against wood destroying insects including termites.

**Active Constituent(s):** FIPRONIL  
FIPRONIL MANUFACTURING CONCENTRATE

#### **Regulatory Decision:**

To grant the application subject to the following conditions:

#### **Standard Conditions of Registration/Approval**

1. Containers must meet AgVet Code Regulation 18
2. Agricultural products must meet Active Constituents Quality Assurance Requirements
3. Label must contain a Date of Manufacture, Batch Number and Expiry Date no greater than 1 year after the DOM

For full conditions, refer to [http://www.apvma.gov.au/advice\\_summaries/adv\\_summaries.shtml](http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml).

#### **Non-Standard Conditions of Registration/Approval**

Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 59 of the NRA / APVMA Gazette dated October 2003 (Fipronil).\*

\*Explanatory Note: you should be aware that the APVMA will take steps to apply the outcomes of that reconsideration to this registration/approval as it thinks fit.

## **ADVICE**

### **Australian Government Department Of Health And Ageing, Office Of Chemical Safety**

Dr. Wolman GmbH, BASF Group, submitted an application for registration of Wolsit<sup>®</sup>T-35, a wood preservative in a liquid formulation, containing 44 g/L fipronil. Wolsit<sup>®</sup>T-35 is intended for control of wood-destroying insects, including termites, in wood-based panels. It will be used in processing in the chipboard and plywood industry.

Fipronil belongs to the phenylpyrazole family and acts by blocking the gamma-aminobutyric acid (GABA) regulated chloride channels. It is a broad-spectrum insecticide and is used to control insect pests in a wide range of agricultural crops. Fipronil products are also used as insecticidal seed dressings and for the control of termites, cockroaches and ants in residential and commercial buildings. In veterinary situations, fipronil products are used as spray-on or concentrated spot-on formulations to control fleas and ticks on cats and dogs.

Fipronil has an ADI of 0.0002 mg/kg bw/day established in 1994, based on a NOEL of 0.02 mg/kg bw/day in a 89-91 week rat chronic/carcinogenicity dietary study using a safety factor of 100. The ARfD for fipronil is 0.02 mg/kg bw/d based on a combined NOEL of 2.5 mg/kg bw/d from two acute oral neurotoxicity studies in rats using a safety factor of 100.

Fipronil is currently in Schedule 6 of the SUSDP, except in preparations containing 10% or less of fipronil, which are in Schedule 5. Preparations containing 0.05% or less of fipronil are unscheduled. Based on the toxicity of the formulated product, Schedule 5 is considered appropriate for Wolsit<sup>®</sup>T-35. The applicant did not submit acute toxicity studies for the product. The OCS therefore estimated the product toxicity. Based on the toxicological profiles of the individual ingredients, Wolsit<sup>®</sup>T-35 is expected to have low acute oral, dermal and inhalation toxicity, and to be a slight skin and eye irritant and a mild skin sensitiser.

Exposure will be to workers and people exposed to treated timber. Workers can be exposed to the product via dermal and inhalation routes when mixing with bonding agents, manufacturing chipboard and plywood, working with treated chipboard and plywood (eg. sawing, sanding) and as occupants of rooms stored with treated chipboard and plywood. The acute and repeat dose health risks for workers may be reduced with appropriate personal protective equipment.

The public can be exposed to the product via inhalation as occupants of rooms with furniture made of treated chipboard and plywood, or when working with treated chipboard and plywood in home workshops, but will not be exposed to an unacceptable risk.

The toxicology data on the product considered in this assessment justify the Safety Directions established. Furthermore, the proposed use of “Wolsit®T-35” will not be an undue health hazard to humans according to the criteria stipulated in Section 14 of the Ag/Vet Code Act of 1994.

### Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
21544	S	Scholle, A.	Assessment of the health risk during use of Wolsit T-35 and Wolsit T-35 treated chipboard and plywood	4th March 2008	OH and S	Worker Exposure	Applicant	
21542	S	Dr. Wolman GmbH	Summary of the toxicology of the formulation ingredients of Wolsit T-35	4th March 2008	Toxicology	Other Information	Applicant	

### Australian Government Department Of Environment And Heritage

Data used in the assessment were sourced from literature data or summaries from previous assessments.

Fipronil is a very potent insecticide and has very high toxicity to a range of non-target fauna including birds and in particular to non-target insects and other invertebrates. However, the release of fipronil to the environment from its use in Hazard Class 1 and 2 wood products for the control of wood destroying insects including termites as proposed is expected to be only to licensed drum recyclers and authorised landfill or from spills and accidents. Fipronil from degraded products is expected to remain associated with the soil in a dispersed manner and degrade at a moderate rate. Accordingly the exposure to the environment is likely to be minimal.

To mitigate the risk to the environment from these routes of exposure DEWHA recommends additional label statements relating to the storage and disposal of containers and for the protection of wildlife, fish crustaceans and environment.

### State/External Efficacy Reviewer

Fipronil, the active ingredient in Wolsit T-35 has been assessed in both laboratory and field tests against termites. The test substrates were *Pinus radiata* (radiata pine) wood blocks, and *Araucaria cunninghamii* (hoop pine) plywood – veneer thicknesses 1.5 mm, 2.4 mm and 3.0 mm. The test termite species were *Coptotermes acinaciformis*, and *Mastotermes darwiniensis*. In addition, Wolsit T-35 has been assessed in waferboard (of unknown wood species but probably

aspen or southern yellow pine) against *Coptotermes formosanus*. All test substrates were appropriately weathered and placed into test using approved protocols, and both fipronil and Wolsit T-35 were compared against known or yardstick treatments. In the cases of the composite substrates the candidate chemical was incorporated into the glue mix and therefore tested as a glue-line additive.

All tests confirmed the efficacy of either the active or the formulation in preventing termite attack, and in all cases they out-performed or performed as well as the known yardstick biocides.

### Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
38201	S	J. W. Creffield and R. J. Owen	Laboratory bioassay on the termiticidal effectiveness of Araucaria cunninghamii (hoop pine) plywood treated by glueline addition of fipronil, CSIRO, Division of Forestry and Forest Products	2003	Efficacy and Safety	Efficacy	Applicant	
38202	S	D. K. Scown, J. W. Creffield	Field assessment of the efficacy of Fipronil as a glueline treatment for the protection of hoop pine plywood from attack by Mastotermes darwiniensis	25th September 2008	Efficacy and Safety	Efficacy	Applicant	
38200	S	B. Ahmed & J. R. J. French	Laboratory evaluation of fipronil as a timber preservative candidate against the subterranean termite, Coptotermes acinaciformis Froggatt (Isoptera: Rhinotermitidae) in Australia, CSIRO, Division of Forestry and Forest Products	1996	Efficacy and Safety	Efficacy	Applicant	
38203	S	J. Norton	Susceptibility of plywood treated by the glueline addition of Fipronil to subterranean termite damage	11th June 2003	Efficacy and Safety	Efficacy	Applicant	
38204	S	John N. R. Ruddick	Durability of preservative treated waferboards	27th October 2008	Efficacy and Safety	Efficacy	Applicant	

\* S = Data submitted with the application

I = Data inherited (that is, referenced) from another application