



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: MICRONISED COPPER AZOLE WOOD PRESERVATIVE
Applicant: KOPPERS PERFORMANCE CHEMICALS AUSTRALIA PTY LTD
Product number: 67259
Application number: 55636

Purpose of Application and Description of Use: Registration of a 582 g/L copper (Cu) present as copper carbonate plus 23.8 g/L tebuconazole suspension concentrate product for the protection of timber against fungal decay, wood borers and termites.

Active Constituent(s): COPPER AS COPPER CARBONATE
TEBUCONAZOLE

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 and Batch Number

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

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Australian Government Department of Health and Ageing, Office of Chemical Safety

A toxicology dossier comprised of acute toxicology and dislodgeable residue studies were submitted in support of the application. The acute toxicology studies were conducted in accordance with contemporary test guidelines. The data provided in the acute studies were relied on by the OCS in considering whether the proposed use of the product would not be an undue health hazard to humans.

Based on the findings of the toxicological studies evaluated, the product has low acute oral, acute dermal and acute inhalation toxicity. It is a slight eye irritant, but not a skin irritant or a skin sensitiser.

An ADI (acceptable Daily Intake) or ARfD (Acute Reference Dose) for copper carbonate have not been established. It is considered to be exempt from inclusion in the SUSMP under an entry for copper compounds in paints in Appendix A, which lists general exemptions from the SUSMP. The SUSMP interprets paint as including any substance used for application as a protective coating to any surface. The proposed use of the product falls within the scope of this interpretation and therefore copper carbonate when present in Osmose Micronised Copper Azole Wood Preservative is exempt from SUSMP listing.

An ADI of 0.03 mg/kg bw/d for tebuconazole was established in 2010 based on a NOEL (No Observed Effect Limit) of 2.96 mg/kg bw/d (100 ppm) in a one year dog dietary study and applying a 100 fold safety factor. No ARfD has been established for tebuconazole. Tebuconazole is currently in Schedule 5 of the SUSMP at all concentrations regardless of preparation.

As the product Osmose Micronised Copper Azole Wood Preservative contains tebuconazole it is included in Schedule 5 of the SUSMP. Based on the toxicology profile of the product, this classification is considered appropriate.

Based on the occupational risk assessment of exposure during use the OCS considers that the risks to the health of workers involved in the treatment of timber with Osmose Micronised Copper Azole Wood Preservative can be mitigated through engineering constraints and the use of PPE.

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.
71816	S	P. Cooper	Wipe Study to Define Dislodgeable residues on Southern Pine Lumber Treated with MicroPro 200C V1 + MTZ	12 January 2012	OH and S	Other information	Prev Sub, Not Protected	

71815	S	C. Barber	AWPA E11 Leachability Testing	8 November 2007	OH and S	Other information	Prev Sub, Not Protected	
76807	S	P. Cooper	ADDENDUM TO REPORT To include Efficiency and Reproducibility of Copper Data Wipe Study to Define Dislodgeable Residues on Southern pine Lumber Treated with MicroPro 200C V1+ MTZ	2 July 2013	OH and S	Other information	Applicant	
61443	S	J. Durando	Acute Dermal Toxicity In Rats	11 December 2008	Toxicology	Acute dermal studies, product	Applicant	
61445	S	J. Durando	Primary Eye Irritation In Rabbits	11 December 2008	Toxicology	Acute eye irritation studies, product	Applicant	
61444	S	J. Durando	Acute Inhalation Toxicity In Rats	8 December 2008	Toxicology	Acute inhalation studies, product	Applicant	
61441	S	J. Durando	Acute Oral Toxicity Up And Down Procedure In Rats	11 December 2008	Toxicology	Acute oral studies, product	Applicant	
61446	S	J. Durando	Primary Skin Irritation In Rabbits	8 December 2008	Toxicology	Acute skin irritation studies, product	Applicant	
61450	S	J. Durando	Dermal Sensitization Study In Guinea Pigs (Beuhler Method)	11 December 2008	Toxicology	Acute skin sensitisation studies, product	Applicant	

State/External Efficacy Reviewer

Data were supplied from a laboratory decay test, a laboratory termite test and an extensive review of sundry overseas laboratory and field tests against decay and termites. This review document also provided leaching data and results of metal coupon corrosion tests.

The laboratory tests were conducted according to AWPC Protocols and employed both softwood and hardwood substrates, three retention rates of the candidate as well a registered industry azole standard and a reference preservative CCA (Chromated Copper Arsenate).

Results of the laboratory tests and results from the reviewed overseas testing all demonstrate that Osmose Micronised Copper Azole Wood Preservative performed as well or better than the registered industry standard and the CCA reference preservative. The data and other information provided supports the label claims that the candidate will provide timber protection against decay and termites when used at the proposed active retention levels which are equivalent active retentions to those specified in the national treatment standards, AS 1604.1 and AS/NZ 1604 Parts 2 to 5.

Based on the data provided, the APVMA is satisfied that use of Osmose Micronised Copper Azole Wood Preservative according to the label instructions would be as effective as claimed and would not be likely to have an unintended effect other than to control the target organisms.

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.
61448	S	M.H. Freeman & C.R. McIntyre	A Comprehensive review of Copper-based Wood Preservatives with a focus on a new micronized or dispersed copper systems.	November 2008	Efficacy and safety	Efficacy	Public	
61447	S	K.J. McCarthy & J. Carr	Laboratory determination of the fungal effectiveness of a novel copper-based/Tebuconazole preservative system plus Aqualite additive	May 2008	Efficacy and safety	Efficacy	Applicant	
61449	S	D.K. Scown, J.M. Carr, J.B.R. Hague & J.W. Creffield	Laboratory assessment of the efficacy of a micronised copper azole preservative formulation to prevent attack in softwood and hardwood by <i>Mastoterme darwiniensis</i> .	July 2011	Efficacy and safety	Efficacy	Applicant	
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* S = Data submitted with the application

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