

Re-evaluation Decision Document

Re-evaluation of Antisapstain Use for 2-(thiocyanomethylthio) Benzothiazole (TCMTB), Copper-8-quinolinolate, Borax and Disodium Octaborate Tetrahydrate

Occupational Risk Assessment

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed an interim occupational risk assessment for the antisapstain uses of 2-(thiocyanomethylthio) benzothiazole (TCMTB), copper-8-quinolinolate, borax and disodium octaborate tetrahydrate, as part of the re-evaluation of these chemicals pursuant to Section 19 of the *Pest Control Products Regulations*.

Based on a review of the available information, the PMRA has determined that the registrations of antisapstain products containing TCMTB, copper-8-quinolinolate, borax and disodium octaborate tetrahydrate continue to be acceptable with provisions.

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Publications Coordinator Pest Management Regulatory Agency Health Canada 2720 Riverside Drive A.L. 6605C Ottawa, Ontario K1A 0K9 Internet: <u>pmra_publications@hc-sc.gc.ca</u> <u>www.hc-sc.gc.ca/pmra-arla/</u>

Information Service: 1-800-267-6315 or (613) 736-3799 Facsimile: (613) 736-3798





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Foreword

This document addresses only the occupational risks to workers having contact with antisapstain chemicals at lumber processing facilities such as sawmills. An assessment of the environmental risks of using antisapstain products containing TCMTB, copper-8-quinolinolate, borax and disodium octaborate tetrahydrate is underway, but has not yet been completed. The outcome of those assessments will be communicated in a future document.

Based on a review of the available information, the PMRA has determined that the registrations of antisapstain products containing TCMTB, copper-8-quinolinolate, borax and disodium octaborate tetrahydrate continue to be acceptable provided that:

- additional chemical-specific data are submitted to refine the occupational risk assessment and
- a product stewardship program (with follow-up monitoring) is implemented to reduce exposure to workers. The product stewardship program is to be developed in 2004 and implemented in 2005, with follow-up monitoring and any additional chemical-specific data to be completed by 1 September 2006.

This interim decision will be revisited in light of the assessment of the additional data that are required.

1.0 Purpose

The purpose of this document is to communicate the following:

- the results of the occupational exposure and risk assessments conducted for workers having contact with antisapstain chemicals at lumber processing facilities such as sawmills and
- the interim re-evaluation decision for TCMTB, copper-8-quinolinolate, borax and disodium octaborate tetrahydrate.

2.0 Background

A re-evaluation of the antisapstain use of products containing TCMTB, copper-8-quinolinolate and borax¹ was announced by Agriculture Canada² in July 1992 under the authority of Section 19 of the *Pest Control Product Regulations* (Announcement A92-01, *Re-evaluation Announcement TCMTB, Copper-8 and Borax Antisapstain Applications*). The decision to initiate the re-evaluation was in part based on the outcome of multi-stakeholder consultations for antisapstain chemicals in 1989 (Note to CAPCO C90-10, *Wood Treatment Materials*, 1 August 1990). As stated in Announcement A92-01, operator exposure information was identified as a requirement for the re-evaluation of TCMTB, copper-8-quinolinolate and borax. The requirement for data to better characterize occupational exposures to workers has also been a condition of registration for all other antisapstain products registered in Canada (i.e., didecyl dimethyl ammonium chloride (DDAC), 3-iodo-2-propynyl butyl carbamate (IPBC), azaconazole³ and propiconazole). Registrants have been encouraged to explore opportunities for sharing in development of these necessary data.

Under the auspices of the Sapstain Industry Group (SIG), the registrants of end-use products containing TCMTB, copper-8-quinolinolate, borax, disodium octaborate tetrahydrate and other antisapstain chemicals (DDAC, IPBC, azaconazole and propiconazole) funded a generic occupational exposure study. This study will address the requirement for occupational exposure data regarding workers handling sapstain control chemicals or handling lumber that has been treated with sapstain control chemicals. The PMRA was consulted during the protocol development and agreed to the use of one active ingredient, DDAC, as a surrogate for the other active ingredients. The use of a surrogate compound was considered appropriate as it is generally accepted that

¹ The re-evaluation of borax was expanded to include the antisapstain use of disodium octaborate tetrahydrate.

² Agriculture Canada was the federal department responsible for administering the *Pest Control Products Act* prior to the formation of the PMRA in April 1995.

³ The registration for azaconazole has since been discontinued by the registrant.

occupational exposure (i.e., dermal deposition, inhalation) is predominantly a function of formulation type (e.g., liquid), application equipment and task rather than the physicalchemical properties of the active ingredient.

3.0 Occupational exposure assessment

The occupational exposure and risk assessments were conducted for workers having contact with antisapstain chemicals at lumber processing facilities such as sawmills. During the assessment, it was considered that exposure to workers through contact with dried lumber after sale (e.g., construction workers) would be minimal as antisapstain chemicals are intended to provide short-term protection only (e.g., during shipment to overseas markets.) Similarly, exposure to consumers from contact with treated lumber was also considered to be minimal.

The occupational exposure study comprises four phases.

- **Phase I** of the project involved selecting an antisapstain chemical in current use which that best represent the other products. DDAC was selected and used in this study as the surrogate compound.
- **Phase II** involved video imaging workers at workplaces where sapstain treatment typically occurs. The results of the video imaging defined four strata (work scenarios) in which significant exposure occurs:
 - 1) handling wet treated lumber (wet lumber);
 - 2) handling dry treated lumber (dry lumber);
 - 3) maintenance; and
 - 4) operating diptanks.
- Phase III of the project involved quantifying worker exposure to the surrogate compound under typical working conditions. These results are documented in the SIG report entitled *Measurement and Assessment of Dermal and Inhalation Exposure to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber*.
- **Phase IV** (to be conducted) will address additional data/information requirements necessary to generate sufficiently refined chemical-specific exposure and risk assessments (e.g., dermal absorption, follow-up monitoring).

Phase III of the study was performed at 11 Canadian sawmills during typical treatment of lumber with the antisapstain active ingredient DDAC. The study design was acceptable. The study involved 78 workers and was considered to be representative of the Canadian antisapstain industry. Workers were monitored while performing tasks in the four above-noted strata for a full workday. Monitoring consisted of whole body dosimeters, cotton

glove liners and personal inhalation monitors. As expected, significant variability was observed in the exposure data, with the highest mean exposures to the clean-up crew in the maintenance stratum and the pilers in the wet lumber stratum, and the lowest mean exposures to the bander in the wet lumber stratum and the painter in the dry lumber stratum. For all workers, the majority of total exposure was to the hands, even when gloves were worn. Those with the highest exposure also had significant deposition on the arms.

The results provide acceptable exposure data to generate high confidence exposure estimates for the majority of sawmill workers (i.e., workers handling treated lumber and workers operating the diptank). The results for workers piling freshly treated lumber and for maintenance workers are less rigorous due to small sample size. Consistent with the multi-phase approach to this exposure study, these estimates can be used for interim risk assessments for these workers, pending generation of additional monitoring data.

Chemical-specific occupational exposure and risk assessments based on the Phase III results of the generic occupational exposure study were conducted for all end-use products containing TCMTB, copper-8-quinolinolate, borax, disodium octaborate tetrahydrate and other antisapstain chemicals (DDAC, IPBC and propiconazole) for workers handling wet and dry treated lumber, for pilers, for the clean-up crew and for workers maintaining the diptank.

Risk assessments were conducted for each antisapstain chemical by deriving margins of exposure based on product-specific exposure estimates (based on results from Phase III of the generic occupational exposure study) and chemical-specific no observed adverse effect levels (NOAELs). For each NOAEL selected, a target margin of exposure was established by incorporating two safety factors: a 10-fold factor to account for extrapolation from animals to humans (i.e., interspecies) and a 10-fold factor to account for variation within the human population (i.e., intraspecies). In addition to these two 10-fold safety factors, where applicable, additional safety factors were incorporated into the target margin of exposure to address severity of toxicology endpoint, sensitive sub-populations or any uncertainties regarding the toxicology database. Therefore, for the antisapstain chemicals, target margins of exposure ranged from 100 to 1000 depending on the toxicology database.

Workers handling wet and dry treated lumber

These strata are considered to be representative of the majority of workers in antisapstain facilities.

The initial division of workers into handling wet and dry treated lumber was not considered meaningful from an occupational exposure perspective as the degree of wetness on the lumber is more of a function of the mill facilities (speed of conveyor belt, treatment time, etc.) rather than the task performed. Therefore, for risk assessment purposes, the workers handling wet treated lumber and dry treated lumber were pooled into one group of 48 workers (pilers excluded).

In order to relate the exposure from the surrogate compound to other antisapstain active ingredients, the mean exposures to the surrogate compound were normalized to the target deposition of active ingredient on the wood. Since the workers handling treated lumber are exposed to antisapstain chemicals from the treated lumber, it was considered appropriate to relate exposures to other antisapstain chemicals as a function of their target deposition on the lumber.

For the majority of active ingredients and end-use products, target margins of exposure were achieved for workers handling wet and dry treated lumber. Upon submission of additional chemical-specific data, target margins of exposure are expected to be achieved for all active ingredients and end-use products. These specific data requirements will be communicated to the registrants directly.

Workers operating the diptank

In the occupational exposure study, nine diptank workers were monitored; seven of these workers were monitored twice. In order to relate the exposure from the surrogate compound to other antisapstain chemicals, the mean exposures were normalized to the concentration of surrogate compound in the diptank. On the labels for antisapstain end-use products, the recommended concentration for both sprayboxes and diptanks is presented as a range. In the absence of supplemental information from the registrant indicating the diptank concentration typically used in sawmills, the highest concentration on the label was used for risk assessment purposes. This is considered conservative as the higher end of the range on the label is often associated with spraybox systems and the lower end of the range on the label is often associated with diptank systems. Where available, typical diptank concentrations were used.

For the majority of active ingredients and end-use products, target margins of exposure were achieved for workers operating the diptank. Upon submission of additional chemical-specific data and/or supplemental information on typical diptank concentrations, target margins of exposure are expected to be achieved for all active ingredients and end-use products. These specific data requirements will be communicated to the registrants directly.

Pilers

Pilers represent a unique group of workers that are only present in mills that have a greenchain (i.e., non-automated system for sorting and piling wood) situated after treatment of the lumber with antisapstain chemicals. The majority of the sawmills monitored (10 out of 11) use automated systems. Because of this, the group of pilers monitored consisted of only two workers. Exposure results for these two individuals varied widely, and it was not possible to accurately characterize exposure based on this small sample size.

Similar to the workers handling treated lumber, the exposures to the surrogate compound were normalized to the target deposition of active ingredient on the wood. Since the group of pilers only consisted of two workers, the maximum exposure value normalized to target deposition of the surrogate compound was used to estimate exposure to pilers. Target margins of exposure, in the interim risk assessment, were not achieved for pilers handling wood treated with any of the end-use products. These assessments are considered to be conservative due to the use of the maximum exposure value.

As a next step, the PMRA and the registrants have agreed that a product stewardship program will help to reduce exposure to mill employees and should be implemented. Since the end-use products are used in an industrial setting, they are considered to be good candidates for a product stewardship program (details on the product stewardship program provided below). To verify effectiveness of the product stewardship program in reducing exposure to these workers, confirmatory follow-up monitoring is required. With the implementation of a product stewardship program and more rigorous exposure data, target margins of exposure are expected to be achieved.

Clean-up and maintenance

The clean-up crew is a subset of workers within the maintenance stratum responsible for the general clean-up of the mill. These workers had among the highest exposures in the study and were selected to quantify exposure for the maintenance stratum. Due to the small sample size, the 90th percentile of dermal and inhalation exposures for the clean-up crew were used for risk assessment purposes.

Target margins of exposure, in the interim risk assessment, were not achieved for the clean-up crew for any of the antisapstain chemicals. This assessment is considered to be conservative due to the use of the 90th percentile instead of a measure of central tendency and the intermittent nature of the exposure scenario.

Since it is considered that exposure can be significantly reduced through implementation of a product stewardship program, the PMRA will revisit the interim risk assessment after completion of the program described above. Given that these chemicals are used in an industrial setting, they are considered to be good candidates for a product stewardship program (details on required product stewardship program provided below). To verify effectiveness of the product stewardship program in reducing exposure to these workers, confirmatory follow-up monitoring is required. With the implementation of a product stewardship program and more rigorous exposure data, target margins of exposure are expected to be achieved.

Product stewardship program

In order to reduce occupational exposure to antisapstain chemicals to acceptable levels, a product stewardship program will be required as Phase IV of the SIG generic occupational exposure study, in all sawmill operations that use sapstain end-use products containing TCMTB, copper-8-quinolinolate, borax and disodium octaborate tetrahydrate. This requirement will extend to the other registered antisapstain chemicals (DDAC, IPBC and propiconazole)⁴. The purpose of the product stewardship program would be to reduce occupational exposure to antisapstain chemicals.

The product stewardship program could include the following elements.

- Education: Worker training in the proper use of personal protective equipment, handling of end-use products and adherence to health and safety requirements on the label, such as personal protective equipment.
- **Personal hygiene:** On-site laundry and shower facilities and decontamination of personal protective equipment.
- **Improved work practices:** Analysis of work practices by an industrial hygienist and adoption of resulting exposure reduction measures.
- **Follow-up monitoring:** Verification that the product stewardship program is effective in reducing occupational exposure to antisapstain chemical from working as a maintenance worker or as a piler.

The PMRA is prepared to work with the SIG to ensure development and implementation of an effective product stewardship program.

4.0 Regulatory decision

Based on a review of the available information, the PMRA has determined that the registrations of antisapstain products containing TCMTB, copper-8-quinolinolate, borax and disodium octaborate tetrahydrate continue to be acceptable provided that:

- additional chemical-specific data are submitted to refine the occupational risk assessment and
- a product stewardship program (with follow-up monitoring) is implemented to reduce exposure to workers. The product stewardship program is to be developed in 2004 and implemented in 2005, with follow-up monitoring and any additional chemical-specific data to be completed by 1 September 2006.

⁴ The registration for azaconazole has been discontinued by the registrant.

This interim decision will be revisited in light of the assessment of the additional data that are required.

In addition, further measures may be proposed at a future date pending completion of the environmental risk assessments for TCMTB, copper-8-quinolinolate, borax and disodium octaborate tetrahydrate.