United States Environmental Protection Agency (letterhead)
Washington, D.C. 20460

Office of Prevention, Pesticides and Toxics Substances

January 9, 2004

Michael V. Coffey
Regulatory Manager
Arch Wood Protection, Inc.
1995 Lake Park Drive, Suite 250
Smyrna, GA 30080

Subject: Wolmanac? ACC 50% Concentrate
EPA File Symbol No. 62190-EG
Application Dated March 31, 2003

Dear Mr. Coffey:

On March 31, 2003, you submitted an application for registration of a pesticide product containing acid copper chromate (ACC). In your application, you stated that you were seeking a "me-too" registration pursuant to the authority of sections 3(c)(7)(A) of FIFRA which states, in pertinent part:

> The Administration may conditionally register… a pesticide if the Administration determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration on amendment in the manner proposed by the applicant would not significantly increase the risk of unreasonable adverse effects on the environment.

You based your application for registration on the sole registered ACC product, specifically EPA Reg. No. 3008-60, ACC 50% Wood Preservative.

In response to that application, the Agency has reviewed the data which have been submitted to support t he registration of the currently registered product, surrogate data that are appropriate, data provided by you and others since the time the application was submitted, and data available in the open literature. At this time, particularly in the light of the available information supporting the registration of 3008-60 and the limited use of that product, the EPA does not believe that the data and information before it for hexavalent chromium are adequate to allow it to determine whether you meet the requirements under section 3(c)(7). Accordingly, the Agency is soliciting further information, outlined in this letter, to assist it in making a final decision in this matter.

There are a number of areas where either the Agency needs additional information or the Agency could perform a more refined assessment if additional data were developed. Specifically, to assess your application adequately, the Agency needs five additional studies in order to better understand the nature and magnitude of exposures to Cr6. Additionally, you may elect to conduct another study (a toxicity study) to allow the Agency to perform a more refined assessment. The five studies include data on the amount of exposure to individuals who come in contact with treated wood from dermal contact as well as to individual exposed in the treatment plant from dermal and inhalation routes, data on the length of time of the fixation/reduction process under various conditions, and data which determine the amount and rate at which leaching occurs into the environment (soil and water) from ACC-treated wood. You may also wish to provide additional data on hexavalent chromium regarding the dermal effects of

sensitization and irritation in order that a more refined assessment be conducted. More detailed description of these data are outlined below.

The Agency has relied upon the study of Nethercott et al (1994) to develop an interim working value for the dermal level of concern for sensitization potential of hexavalent chromium and feels that this value is adequately protective. A list of references mentioned in this letter is enclosed. However, a more refined assessment could be performed from submission of a study designed to adequately characterize the dermal hazard of hexavalent chromium, specifically, the dose-response relationship from exposure to treated wood containing hexavalent chromium. This relationship has not been adequately studies to date, and the protocol would need to be approved prior to conducting the study. In the absence of this study, the Agency would rely on the value for dermal that it is currently using.

A dermal endpoint for sensitization/irritation has been selected for Cr6 to assess the potential for worker and residential contact with ACC-treated wood. The dermal endpoint selected is based on a surface concentration of Cr6 on a patch applied to human test subjects (Nethercott, et al, 1994). To compare the dermal toxicological endpoint, in units of ?g/em2, to potential worker and/or residential exposures, surface concentrations of Cr6 available on ACC-treated wood surfaces are required. It is also essential to have information which demonstrates the length of time necessary, under various conditions, to reduce Cr6 to Cr3, which is less toxic and does not pose a risk of concern. Because this reduction is dependent upon temperature and time (also humidity and pH), a well designed study is necessary to characterize the surface residue concentrations on various types of wood and differing temperatures. In addition, ACC-treated wood surface concentrations need to be correlated to the industry standard wood core boring tests in concentrations of parts per million (ppm). The correlation of Cr6 surface residues to core sample residues is required to determine if the industry standard colorimetric test for fixation to 15 ppm is adequate to protect against dermal sensitization/irritation. Furthermore, the accuracy of the colorimetric test must be established using an analytical method such as ICP-MS or AAS. Finally, if the surface residue levels of concern are correlated to below 15 ppm in core samples, then other test methods must be presented that accurately teset to those levels of concern (e.g. diphenylcarbazide (DPC) is more sensitive than chromotropic acid).

Other considerations in developing a protocol to assess wood surface residues include:

* Partial testing is required to establish a wipe method that achieves equilibrium of surface residues from contact with ACC-treated wood to the selected wipe matrix. Similar methods were recently (2003) developed by the CPSC and RTI that established wipe methods to achieve equilibrium between CCA-treated wood surface residues and sampling media. The protocols for these studies can be made available to you, if needed.
* The media selected for wipe testing must be comparable in transfer efficiency to the media used in Nethercott et al (1994) to determine dermal sensitization/irritation of Cr6 in humans.
* Sufficient wipe samples need to be collected over time to establish a relationship between Cr6 reduction of wood surface residues and time (days) at various temperatures.
* A submitted protocol is required for approval prior to conducting the study.

The available data in the CCA worker exposure study (ACC, 2001) is insufficient to characterize the inhalation risks for Cr6 from the use of ACC because the method used to analyze the samples was not sensitive enough for the toxicological endpoint of concern (i.e. carcinogenicity). An exposure study monitoring workers at ACC pressure treatment facilities is required to characterize the dermal and inhalation exposures of Cr6. The

Agency will work with the study sponsor to accommodate the use of ACC at a pressure treatment facility. Current registration efforts for CCA have not been completed. If inhalation sampling of ACC pressure treatment plants indicate risks of concern, mitigation measures may be required. The applicant(s) sponsoring an ACC exposure study should consider potential mitigation options when designing the study (e.g., venting pressure treatment cylinder prior to opening vessel).

Finally, the Agency is in need of information on the leaching potential for ACC in soil and water. Depending on the results of these studies, additional data may be needed to assess any potential adverse effects on fish and wildlife.

In light of the limited database on ACC, EPA will also accept other information you may possess, including the economic, social and environmental costs and benefits of ACC.

My staff is available to answer any questions that you may have regarding the need and conduct of the above studies. If you are interested in providing these data to the Agency, please contact me in order to discuss the timing and development of these studies.

Sincerely,

Frank T. Sanders, Director
Antimicrobial Division

References

ACC, 2001. American Chemistry Council Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure-Treated Wood with Arsenical Products. MRID 455021-01. September 24, 2001.

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