Ms. Oleta Melnicoe  
Copper Development Association  
c/o Technology Sciences Group, Inc.  
712 Fifth Street, Suite A  
Davis, California 95616

Dear Ms. Melnicoe:

RE: Registration of a Major Change in Labeling for the Active Ingredient Copper Alloy (Chemical Code 022501)

The New York State Department of Environmental Conservation (Department) has reviewed your application to register the following pesticide products which contain the active ingredient **copper alloy (chemical code 022501):** Antimicrobial Copper Alloys Group I (EPA Reg. No. 82012-1), Antimicrobial Copper Alloys Group II (EPA Reg. No. 82012-2), Antimicrobial Copper Alloys Group III (EPA Reg. No. 82012-3), Antimicrobial Copper Alloys Group IV (EPA Reg. No. 82012-4), and Antimicrobial Copper Alloys Group V (EPA Reg. No. 82012-5).

The application was deemed complete for purposes of technical review on September 19, 2008, and a registration decision was due by **February 19, 2009.** The registration of these products is based on the technical review received from the New York State Department of Health for impacts to human health.

These pesticide products are comprised of different copper alloys which are labeled for manufacturing into end-use products such as nonfood use touch items (e.g., door knobs and hand rails). The end-use products manufactured with these alloys are intended to provide a reduction in viable bacteria on their surfaces. Metallic copper is currently registered in the State for use as an algaecide in various products. The proposed new uses for copper in touch surface items represents a major change in labeling for this active ingredient.

The United States Environmental Protection Agency (USEPA) waived the requirement for all toxicity data to support federal registration of the copper alloy active ingredients, and no such data were submitted in the registration package. Because the alloys themselves and the end-use products manufactured from these alloys are solid metals to which humans will have only limited dermal contact, the potential for a significant absorbed dose from these products is minimal.
Moreover, copper is an essential element for which the human body has homeostatic control mechanisms, so any such absorption is unlikely to cause health effects. Copper has also been used for many years in a number of applications that can result in human exposure (e.g., water supply pipes, jewelry, furniture hardware and other touch surfaces), without being associated with causing adverse health effects under normal circumstances. A search of the scientific literature did not yield any information on adverse effects in humans from dermal contact with copper.

The USEPA required the registrant to develop a stewardship plan to promote a clear understanding of the proper use and expectations for end-use copper alloy products in regard to their antibacterial claims. This plan includes outreach to State health agencies and infection control professionals. The key messages in this outreach are: (1) copper alloys are a supplement, not a substitute, for standard infection control practices such as cleaning and disinfection of environmental surfaces; (2) copper alloys have been shown to reduce bacterial contamination, but not necessarily prevent cross contamination; (3) antibacterial efficacy depends on proper cleaning of the copper alloy surfaces; and (4) the copper alloy surfaces must not be coated in any way in order to retain the antibacterial properties. These elements are included on the product labels.

The label of the copper alloy products indicates that end-use products manufactured with these materials will result in only limited contact of the public with the metals. This use is not likely to result in adverse effects in humans. As a requirement of federal registration, the registrant is informing State health departments and infection control specialists that these products do not serve as stand alone measures to control bacteria. As such, users/installers of these alloys should be adequately informed about the limitations of these products in intended settings. In view of the minimal risks posed by the copper alloy products, and the potential for some benefit in bacterial control, we do not object to registration of these products in New York State. Similarly, we do not object to the registration of end-use products manufactured with these alloys provided that they have labeled use on touch surfaces only in healthcare, public, commercial and residential buildings as defined in the materials submitted in the registration package.

Based on the above-mentioned information, the Department accepts for general use registration in New York State Antimicrobial Copper Alloys Group I (EPA Reg. No. 82012-1), Antimicrobial Copper Alloys Group II (EPA Reg. No. 82012-2), Antimicrobial Copper Alloys Group III (EPA Reg. No. 82012-3), Antimicrobial Copper Alloys Group IV (EPA Reg. No. 82012-4), and Antimicrobial Copper Alloys Group V (EPA Reg. No. 82012-5) containing the active ingredient copper alloy.

Enclosed are your Certificate of Registration and New York State stamped “ACCEPTED” labels. The Copper Development Association is reminded that if New York State registration is requested for this active ingredient which contains an expansion of use patterns, the product will be considered a Major Change in Labeling and the Department will require an extensive review.
If you have any questions, please contact Luanne Whitbeck, of our Pesticide Product Registration Section, at (518) 402-8768.

Sincerely,

Maureen P. Serafini

Maureen P. Serafini
Director
Bureau of Pesticides Management

Enclosures

ecc: A. Grey/E. Horn, NYSDOH
     R. Mungari, NYSA&M
     W. Smith, Cornell University, PSUR