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WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Zeomic® Type AJ10 Silver Zeolite A: request for use of the active ingredient for treated articles used in heating and cooling systems.

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TO: Dennis Edwards / Marshall Swindell / Tony Kish
Regulatory Management Branch I / PM Team 33
Antimicrobials Division (7510C)

FROM: Timothy F. McMahon, Ph.D. 2/1/01
Senior Toxicologist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

THRU: A. Najm Shamim, Ph.D. 2/2/2001
Acting Team Leader, Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

and

02/06/2001

Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

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Action Requested: request for addition of new use of Zeomic Type AJ10 Silver Zeolite A in treated articles used in heating and cooling systems.

Background

The registrant (AgION Technologies LLC), has an acccepted label for Zeomic® Type AJ10D Silver Zeolite A containing silver as the active ingredient at 2.5% (acceptance dated October 12, 2000). The product is intended for use as an antimicrobial additive to be used by compounding into many polymeric materials during the manufacturing process to impart antimicrobial activity to the manufactured products. It is for commerical and industrial use only. Included in the manufactured products are non-food contact fibers [interior furnishings, apparal, fabrics in automobiles, and industrial and other household items]; non-food contact coatings, films, and laminates; adhesives and sealants; and miscellaneous non-food contact uses such as toilets, sinks, tile, flooring, stucco, plaster, cat litter, and drainage and sewerage pipe; human drinking water contact articles such as water filter components, ice machine trays, water bottles, cups, and water storage vessels; and food-contact uses including packaging, gaskets, sponges, tiles, dishes, conveyor belts, food trays, general purpose containers, food processing equipment, and beverage processing equipment.

RASSB has previously addressed the data requirements for food- and water-contact uses as well as non-food uses of Silver Zeolite A (D270581; D270664). Since the writing of that memorandum, new information has been obtained on studies conducted with related silver zeolite compounds. Specifically, the registrant cited several studies conducted with silver copper zeolite and/or silver zinc zeolite in support of the Toxicology data requirements for uses of Silver Zeolite A. RASSB has learned that much of the data cited has been reviewed. A memorandum dated February 23, 1993 (D169923) cited reviews of data for Silver Zinc Zeolite, while a memorandum dated September 27, 1991 cited reviews for Silver Copper Zeolite.

For Silver Zinc Zeolite, an acute toxicity testing battery of studies was reviewed as well as an Ames Salmonella assay and an in vivo cytogenetics assay. The acute studies were all found to be unacceptable but upgradable upon submission of the stability of the test material. The Ames assay was found to be acceptable, and the in vivo cytogenetics assay was found unacceptable but upgradable upon submission of an explanation as to why slides from male animals could not be read.

For Silver Copper Zeolite, an acute toxicity testing battery was also reviewed, as well as a developmental toxicity study, a subchronic dermal toxicity study, and a mutagenicity testing battery. All of these studies were found to be acceptable with the exception of the developmental toxicity study, which was found unacceptable but upgradable.

Conclusions/Recomendations

The addition of HVAC uses for Silver Zeolite A is not supported at this time for the following reasons:

1) Although data exists for Silver Copper Zeolite and Silver Zinc Zeolite, it is not known whether these data will be adequate to support uses involving Silver Zeolite itself. A determination as to the equivalency of these compounds in terms of hazard potential has not been formally made. In addition, there are outstanding data gaps for Silver Zeolite A (subchronic non-rodent study, subchronic inhalation study, reproduction study) for the proposed use in HVAC systems.

2) A formal risk assessment has not been conducted for Silver Zeolite A and cannot be conducted in the absence of an adequate Toxicology database.

3) The Agency has not finalized its policy with regard to data requirements for HVAC uses. This issue is still under active development.