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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

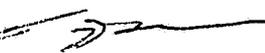
**SUBJECT:** Zeomic® Silver Zeolite A: request for dietary risk assessment from drinking water use of the active ingredient in water contact articles.

**EPA Identification Numbers:**

P.C. Code:072503  
DP Barcodes:D263210

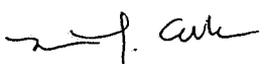
MRID's: N/A (correspondence)  
Submissions: S574982

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

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**THRU:** Timothy F. McMahon, Ph.D.  4/24/00  
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and

 05-09-2000  
Norm Cook, Chief  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510C)

**Action Requested:** Review of the registrant's request for use of the active ingredient (silver) as formulated into Zeomic Silver Zeolite A for use in water contact articles.

### **Background**

Laird's Regulatory Consultants, Inc. As agent for Sinanen Company Ltd., Tokyo, Japan, has submitted a request for use of the product Zeomic Silver Zeolite A containing silver (2.5%) for use in the manufacture of polymer, plastic, and latex products, specifically, water contact treated articles including ice machine trays, water filter components or housing units, water bottles, water bottle dispensers, ice machine bins, ice machine water hoses, and cups. Toxicology data on the active ingredient were not submitted.

### **Conclusions**

RASSB has conducted a limited assessment of the risk from exposure to treated articles which may come into contact with drinking water. This assessment is based in part upon submitted data (MRID # 45008001) which indicates that no greater than 30 ppb silver migrates from low density polyethylene. RASSB has used this assumption as well as the assumptions of 2L/day water intake for adults (70 and 60 kg body weights), and 1 L/day for children (10 kg body weight).

Estimated average daily exposure to silver was determined to be 3.0  $\mu\text{g}/\text{kg}/\text{day}$  for a 10kg child, 0.57  $\mu\text{g}/\text{kg}/\text{day}$  for a 60 kg adult, and 0.48  $\mu\text{g}/\text{kg}/\text{day}$  for a 70 kg adult. These exposure values are below the published Reference Dose for Silver (5  $\mu\text{g}/\text{kg}/\text{day}$ ) and occupy 60%, 11%, and 10% of the published RfD value respectively. Cumulative exposure to silver cannot be addressed from exposure to various sources that may occur together (i.e. ice trays and water filters), based on the information provided and is a limitation of the current assessment. However, the assumptions used in this limited assessment are conservative and are felt to be protective of human health. It is noted that the RfD is based upon a cosmetic effect (argyria) of silver and not a toxic effect.

Based upon the limited assessment conducted, RASSB has no objection to the proposed water contact uses of silver for Zeomic Silver Zeolite A. However, any additional uses including food uses and/or uses in textiles will require submission of Toxicology data, which would encompass food use data requirements as published in 40 CFR 158.340.

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