



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

JAN 17 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Zeomic® Type AJ10D Silver Zeolite A: risk assessment for addition of uses to an existing label.

EPA Identification Numbers:

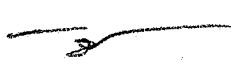
P.C. Code:072503

MRID's: 45291700

DP Barcodes:D272375; D272376

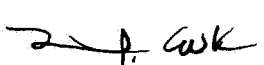
Submissions: S590546; S590670.

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Action Requested: request for hazard/dose response assessment to support additional uses requested for the Zeomic® Type AJ10D Silver Zeolite A label.

Background

Zeomic® Type AJ10D Silver Zeolite A contains silver as the active ingredient at 2.5%. The current label includes use in the manufacture of polymer, plastic, and latex products, specifically, water contact treated articles. Two previous memoranda (D263210 and D272375) discussed the use of Zeomic® Type AJ10D Silver Zeolite A in water contact articles as well as for use in treated articles used in heating and cooling systems.

The registrant (Sinanen Company, Ltd., now represented by Technology Sciences Group) has submitted a request for use of the existing Zeomic® Type AJ10D Silver Zeolite A product in garbage bags and garbage cans; office equipment; toys; spas, bathtubs, showers, and filters and components thereof; personal care items including toothbrushes, mouthguards, cosmetic brushes, and grooming items; and materials related to use in heating and cooling systems. It is noted that a name change is also requested, from Zeomic® Type AJ10D Silver Zeolite A to Zeomic® Type AJ Silver Zeolite A.

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. Already included in the existing label are non-food contact fibers [interior furnishings, apparel, 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.

RASSB is asked to determine the additional risks associated with the proposed added uses for Zeomic® Type AJ Silver Zeolite A.

To re-iterate from a previous memorandum (D270581; D270664), following is the current status of toxicology data for the Zeomic® Type AJ Silver Zeolite A chemical.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

SILVER [REDACTED] (Zeomic Type AJ Silver Zeolite A; silver at 2.5%; [REDACTED])

Guideline Number	Data Requirement	Data Submitted?	Data Reviewed?	MRID Number
870.1100	Acute Oral Toxicity	Y	Y	42032802
870.1200	Acute Dermal Toxicity	Y	Y	41615803
870.1300	Acute Inhalation Toxicity	Y	Y	42032802
870.2400	Primary Eye Irritation	Y	Y	42032802
870.2500	Primary Dermal Irritation	Y	Y	42032802
870.2600	Dermal Sensitization	Y	Y	42032802
870.3100	Subchronic Oral Toxicity-Rodent	Y	N	to be reviewed
870.3700	Developmental Toxicity in Rats	N	N	
870.3800	Reproductive Toxicity in Rats	N	N	in progress
870.5100	Ames Salmonella reverse mutation assay	Y	Y	42032803
870.5380	In vivo chromosome aberration assay	Y	N	42820101; 42032804
870.5300	In vitro Cytogenetics	Y	N	41615809

In addition to the non-food uses listed on the Zeomic® Type AJ Silver Zeolite A label, there are food contact and water contact uses for this product. Food contact uses for the active ingredient will require, in addition to what is listed for non-food use, a subchronic toxicity study in the non-rodent.

Assessment of New Label Uses and Exposure

RASSB has previously considered uses for the silver zeolite A product for non-food uses as well as for water contact articles. Using conservative assumptions and limited reviewed toxicology data, RASSB considered the non-food uses and water contact uses acceptable for the silver zeolite A product. However, the new proposed uses require separate consideration, and the exposures associated with these uses must also be aggregated with existing exposures to determine if total exposure is still acceptable. An accurate risk assessment requires submission and review of the additional requested data (subchronic toxicity study in the non-rodent) and review of existing submitted data before an accurate risk assessment can be performed.

Certain new proposed uses, such as toys, toothbrushes, and mouthguards, involve oral exposure and these exposures have been assessed in a memorandum from Robert Quick, Chemist, to Marshall Swindell, Product Manager (D272418, D276170, D271685). In addition, dermal exposures are expected from the proposed use in spas, bathtubs, showers, and cosmetic brushes. These exposures, using diapers as a worst-case example, have also been addressed in a follow-up memorandum from Robert Quick, Chemist.

Of all of the proposed new uses that are requested, RASSB considers mouthguards, toothbrushes, and toys as the sources of the greatest potential exposure in relation to the other proposed uses.

From use of the silver product in water contact articles, RASSB calculated exposures of 3.0 $\mu\text{g}/\text{kg}/\text{day}$, 0.57 $\mu\text{g}/\text{kg}/\text{day}$, and 0.48 $\mu\text{g}/\text{kg}/\text{day}$ for a 10 kg child, a 60 kg adult, and a 70 kg adult, respectively.

For mouthguards, RASSB calculated an exposure of 0.009 $\mu\text{g}/\text{kg}/\text{day}$ for a 60 kg adult. For toothbrushes, exposures of 0.000028 $\mu\text{g}/\text{kg}/\text{day}$ and 0.00011 $\mu\text{g}/\text{kg}/\text{day}$ were calculated for a 60 kg adult and 10 kg child respectively. For toys, an exposure of 0.29 $\mu\text{g}/\text{kg}/\text{day}$ was calculated for a 10 kg child.

Assessment of Risk from Proposed New Uses

The toxicology database for the silver zeolite A chemical is still under active development. The only endpoint available to date is the published Reference Dose value for silver of 5 $\mu\text{g}/\text{kg}/\text{day}$, which is based upon the appearance of argyria, a cosmetic effect of silver which is not thought to be of actual toxicological significance. Specific endpoints for dermal and incidental oral exposure to silver zeolite A cannot be determined at this time until the database for the silver zeolite A chemical is submitted and reviewed. The Reference Dose value for silver represents a very conservative endpoint to use in the current assessment. Aggregate risk assessment cannot be accurately performed at this time until the remainder of the hazard database is reviewed and the additional requested study is also submitted and reviewed.

The existing and proposed uses of silver zeolite A as an antimicrobial result in exposures which can and do occur together. Contact with drinking water, toothbrushes, mouthguards, showers, spas, and bathtubs are events that can occur together on a daily basis for both adults and children. Exposure to treated toys is usually just to children. Therefore, it is appropriate to aggregate the estimated exposures and compare these to the Reference Dose value to determine potential risk.

Using conservative assumptions regarding exposure, as outlined in the memoranda from Robert Quick, as well as the conservative Reference Dose value for silver, total exposure is estimated as follows:

Exposure to Silver Zeolite A from Water Contact, Oral Contact, and Dermal Contact Uses

Use	60 kg Adult ($\mu\text{g}/\text{kg}/\text{day}$)	10 kg Child ($\mu\text{g}/\text{kg}/\text{day}$)
Toothbrushes	0.000028	0.00011
Water contact articles	0.57	3.0
Mouthguards	0.009	0.054
Toys	N/A	0.29
Total ($\mu\text{g}/\text{kg}/\text{day}$)	0.59	3.35

Conclusions

The total exposures calculated above were performed using very conservative assumptions regarding the magnitude of the exposure. In addition, the Reference Dose value for silver is a conservative value as well, based upon preliminary review of toxicology data submitted for silver zeolite A that shows effects at much higher doses than the Reference Dose value and which would be typically used instead of the Reference Dose value for assessment of oral and dermal risks. As noted, the total exposures to adults and children are below the 5 $\mu\text{g}/\text{kg}/\text{day}$ reference dose value. Therefore, RASSB concludes that there is a reasonable certainty of no harm from aggregate exposure to the silver zeolite A product for proposed uses to date. Aggregate assessment must be deferred pending submission and/or review of the additional data.