

US EPA ARCHIVE DOCUMENT



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

FEB 25 2002
FEB 25 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Review of the Sinanen Co., Limited Zeomic® Type AJ Silver Zeolite A for Risk Assessment for Dermal Exposure From the Treated Bathtubs Use

TO: Marshall Swindell, Product Manager Team 33
Regulatory Management Branch I
Antimicrobials Division(7510C)

and

Timothy McMahon, PhD., Toxicologist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

FROM: Robert Quick, Chemist *Robert Quick*
Risk Assessment and Science Support Branch
Antimicrobials Division(7510C)

THRU: Norm Cook, Chief *Norm Cook 02/25/02*
Risk Assessment and Science Support Branch
Antimicrobials Division(7510C)

ID#: 071227-00001

DP BARCODES: D280270

SUBMISSION: S590546

CASE NO.: 064467

PC CODE: 07250¹~~3~~ Silver Nitrate

MRID#S: 452917-00, 452917-01, 454468-00, 454468-01

Background:

RASSB has reviewed the residue chemistry considerations for non-dietary oral exposure for this product in the RASSB/AD memo dated December 11, 2001, by Robert Quick.

This follow-up memo is intended to review the dermal exposure that will result from the use of this product, Zeomic® Type AJ Silver Zeolite A. The label also permits use on garbage bags and garbage cans; office equipment; spas, bathtubs, showers, and filters and components thereof; cosmetic brushes; and HVAC and HVAC related materials. These uses are in addition to the uses on the label which would result in non-dietary oral exposure and which have previously been reviewed in our RASSB memo of 12/11/2001.

The registrant's submission dated 1/28/2002, deletes a diaper use that was included on an earlier submission.

RASSB has reviewed these new uses noted above to determine which will result in dermal exposure and concluded that the worst case dermal exposure that will result from the additional proposed uses remaining on the revised 1/28/2002 label(after the diaper use removal) is the use of the product impregnated into or coated on bathtubs during manufacture. The Zeomic® treatment will be done at the time of manufacture, not as an add-on treatment. RASSB will address in this memo the dermal exposure and absorption that will occur from the bathtub use.

The Detailed Considerations for the chemical identity, nature of the residue, etc., can be found in the RASSB 12/11/2001 memo.

Conclusions and Recommendations:

Based on the migration study that is available for the Zeomic®-treated product, RASSB concludes that dermal absorption resulting from the proposed bathtub use will be:

1. The dermal exposure/absorption for a 60 kg adult will be 0.0011 µg Ag/day/kg bwt
2. The dermal absorption for a 22 kg 6 year child will be 0.0030 µg Ag/day/kg bwt
3. The dermal absorption for a 15 kg small child will be 0.0045 µg Ag/day/kg bwt

Dermal Absorption of Silver Resulting from Dermal Exposure to Zeomic® Impregnated Into Bathtubs

RASSB has concluded that the worst case dermal exposure from the newly proposed uses will occur as a result of the the bathtub use; this is based on the surface area of the bathtub that would be exposed to water during a sit-down bath and on the time interval that a person would likely spend seated or lying in a bathtub. RASSB will assume that the entire surface area of the body is wetted by the bath water.

RASSB will use the migration study that was generated to support the dietary risk assessment from drinking water in contact with water contact articles. That study was also used by RASSB to support the non-dietary oral exposure to the Zeomic®- treated articles. Obviously, the dermal exposure resulting from the bathtub use is much different from the oral ingestion uses. However, the Zeomic®-treated bathtub will be filled with bath water and the water will extract/leach silver residues from the treated bathtub. The skin of the person bathing will have contact with the silver in the water which has migrated/leached from the Zeomic®-treated bathtub during bathing or soaking in the tub. The skin will absorb silver which has leached /migrated from the Zeomic®-treated bathtub. The flux rate calculated by RASSB for the drinking water study was $1.3 \times 10^{-3} \mu\text{gAg}/\text{cm}^2/\text{hour}$; this value is slightly higher than the 1.1×10^{-3} figure used by the registrant. See discussion below for the % dermal absorption for silver.

Bathtub:

RASSB has made the following assumptions.

Assume that:

Standard tub measures 5 feet long, 14 inches high and 3 feet wide (Information from ImproveNet Inc.: Project Tools); Surface area of the tub = 33.7 ft^2 or $31,307 \text{ cm}^2$ [$(5' \times 3') + 2(1.17' \times 3') + 2(1.17' \times 5') = 33.7 \text{ ft}^2$ or $31,307 \text{ cm}^2$ ($929 \text{ cm}^2/\text{ft}^2 \times 33.7 \text{ ft}^2$)

Average bath time is 20 minutes (Exposure Factors handbook, Volume III, August 1997, pages 15 and 16). One event/day.

Assume average tub is filled $\frac{1}{2}$ full [$0.5 \times 15654 \text{ cm}^2$ surface area of the tub exposed to water in a half filled tub]

Ag flux rate is $1.3 \times 10^{-3} \mu\text{g}/\text{cm}^2/\text{hour}$

Then:

$1.3 \times 10^{-3} \mu\text{gAg}/\text{cm}^2/\text{hour} \times 15654 \text{ cm}^2 \times 0.33 \text{ hours/bath} \times 1 \text{ bath/day} = 6.7 \mu\text{gAg/day}$

Assume 1% dermal absorption of the silver from the bath water (Information from EPA toxicologist, Timothy McMahon, % dermal absorption for silver),

Then:

$6.7 \mu\text{g/day} \times 0.01 = 0.067 \mu\text{g Ag absorbed per day}$

Assume:

Adult weight of 60 kg

6 year old weight of 22 kg

3

Small child weight of 15 kg

Then:

For an adult: $(0.067 \mu\text{g Ag/day})/60 \text{ kg bwt} = 0.0011 \mu\text{g Ag/kg bwt/day}$
and

For a 6 year old child: $(0.067 \mu\text{g Ag/day})/22 \text{ kg bwt} = 0.003 \mu\text{g Ag/kg bwt/day}$
and

For a small child: $(0.067 \mu\text{g Ag/day})/15 \text{ kg bwt} = 0.0045 \mu\text{g Ag/kg bwt/day}$