



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Review of the Sinanen Co., Limited Zeomic® Type AJ10D Silver
Zeolite A Study Migration Study For Dietary Risk Assessment from
Drinking Water In Contact With Water Contact Articles

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Introduction:

Laird's Regulatory Consultants, Inc. on behalf of the Sinanen Company, Ltd. has submitted a request for the registration of Zeomic Type AJ10D Silver Zeolite A product for the use of the active ingredient, silver, for use in various water contact articles. The registrant has provided a list of water contact materials into which the product is to be incorporated, such as plastics, rubber, paper, fibers, etc. as well as the types of water contact articles into which the materials will be fabricated.

The submission includes labelling for non-food or non-water contact use entitled, Zeomic® Type AJ10D Silver Zeolite A, a list of water contact articles and water contact materials from which the articles are to be fabricated and a study entitled, "Migration Studies and Extraction Data From LDPE Films Containing Zeomic® Silver Zeolite A". The migration study has been reviewed by an EPA contractor, Sciences International. That review is attached to this memo.

Background:

There are no established tolerances or tolerance exemptions established under 40 CFR 180 for silver.

There are many silver-containing products registered by the EPA for uses in or on bedding, clothing, water filters, swimming pools, adhesives, paints, coatings, plastics, and fibers.

The materials which the registrant proposes to impregnate with the silver zeolite product all have various FDA clearances for food contact use.

Note: The "bean sheet" for this action lists the active ingredient as silver nitrate. The EPA REFS site shows no active products exist for silver nitrate. The silver zeolite products presently registered by the EPA are included in REFS under "silver" with a PC code of 72501.

Conclusions:

1. The contractor review of the migration study was "secondary reviewed" by an AD review chemist. The EPA reviewer concurs with the contractor review. The review of the migration study noted several minor deficiencies with the migration study. Providing the registrant can answer the questions raised, the migration study is acceptable. The contractor also notes that the study deviated from FDA protocol in that an 8% ethanol food-simulating solvent was used instead of the recommended 10% ethanol solvent recommended by the FDA. RASSB finds no problem with this deviation. The contractor had several comments regarding sample preparation, calibration curves, how the limit of detection (LOD) was established and absence of absorbance spectra for several of the analytes.

RASSB requests that the registrant submit information on the sample preparation procedure for silver, the calibration curve for silver and information on how the LOD for silver was determined. Information for the other analytes is not required unless the AD toxicologist needs

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residue data for sodium, aluminum and silicon.

2. RASSB anticipates that the Food & Drug Administration(FDA) will clear the inert ingredients in the pesticide formulation because the intended use of this antimicrobial is to protect the treated articles and the FDA will regulate use of the active ingredients under FFDCFA § 409.

3. The materials into which the active ingredient is to be incorporated all have food contact clearances under 21 CFR.

4. Assuming that the questions raised during the review of the method in Conclusion 1 above, the analytical method was adequate for the determination of silver in the silver migration study.

5. The migration study to determine the migration of silver, sodium, silicon and aluminum was conducted with a low density polyethylene(LDPE) plastic impregnated with the Silver Zeolite product and the impregnated material was exposed to food simulating solvents. Assuming the method questions raised can be satisfactorily answered, the study is adequate to determine the migration of silver from the impregnated plastic under the proposed conditions of use. This conclusion should be revisited if the registrant in the future proposes a food use in which the impregnated plastic could be used under situations which involve oven-baking or micro-wave cooking of foods.

6. This review assumes that the residue of concern is silver. The migration study involved use of an LDPE impregnated with Zeomic® at concentrations of 2% and 5%. The maximum concentration of silver which leached from Zeomic® into the food-simulating solvents was 30 parts per billion(ppb).

The migration study reflects the use of Zeomic® at the rates of 2% and 5% in the LDPE. The silver concentration in the Zeomic® Type AJ10D Silver Zeolite A product is 2.5%. This is equivalent to 0.125% silver actually incorporated into the LDPE film containing 5% of the Zeomic® product. This study is adequate for the products which contain 2.5% silver. If the registrant should in the future propose to register a product containing a higher concentration of silver as the active ingredient, for example 5% silver, and incorporate the Zeolite product into materials at the 5% rate, then the existing migration study may not be adequate. In the above cited example, the rate of silver incorporation would be 0.5% in the treated product and the existing study is not conducted at this high of a level. The registrant should be so informed.

7. For a 70 kg. adult, the chronic exposure is 0.49 mcg. Ag/bodyweight/day. For a 60 kg. adult, the chronic exposure is 0.57 mcg. Ag/kg. bodyweight/day. For a 10 kg. child, the chronic exposure is 3 mcg. Ag/kg. bodyweight/day.

Recommendations:

The registrant should supply RASSB with the following additional information:

1. Information on the sample preparation procedure used for silver.

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2. Calibration curve for silver analysis.
3. A discussion on how the registrant determined the LOD for silver.

Detailed Considerations

OPPTS GLN 860.1100 Chemical Identity

The name of the chemical that is to be incorporated into various materials that will have water contact is silver nitrate.

The name of the product that is to be incorporated into the materials that will have water contact use is Zeomic® Type AJ10D Silver Zeolite A. The label onto which the water contact use is to be added has a label claim of 2.5% silver. RASSB anticipates that the FDA will regulate the inert ingredients of the formulation under FFDC A § 409 because the intended use of the antimicrobial is to protect the treated article.

The product is presently registered with the EPA for inclusion into plastics including films, sheets, slabs and molded plastic parts and also into fibers. NOTE: The existing label states that "this product may not be used for any applications involving food contact, food packaging and human drinking water". However, the label allows use in countertops, sinks, conveyer belts, dishes, tableclothes, napkins and brush bristles. These are food contact surfaces.

<u>Component (CAS NO.)</u>	<u>Empirical Formula</u>	<u>Formula Weight</u>
Silver nitrate (CAS NO. 7761-88-8)	AgNO ₃	169.9

OPPTS GLN 860.1200 Proposed Use

The product, Zeomic® Type AJ10D Silver Zeolite A, is to be used as an additive incorporated into or as a coating on a large variety of plastics, rubber products, fibers, papers, ceramics and metals that will be fabricated into water contact articles that are listed on a use sheet as ice machine trays, water filter components or housing units, water bottles, water bottle dispensers, ice machine bins, ice machine water hoses and cups. There are undoubtedly other items that can be water contact articles. The label permits the additive to be incorporated into the finished product at up to 5.0% by weight. This is equivalent to 0.125% silver in the treated material.

The materials into which the silver product is to be incorporated all have food contact clearances under 21 CFR.

OPPTS GLN 860.1300 Nature of the Residue

No information is provided as to the nature of the residue that will leach into or migrate into water from the treated water-contact article. The likely residue of concern in water contacting the

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treated article is silver. Sodium, aluminum and silicon as well as the inert ingredients in the product may also leach into water contacting the treated article.

OPPTS GLN 860.1340 Analytical Method

OPPTS GLN 860.1500 Residue Chemistry

The results of a migration study and the accompanying analytical method used in the study were reviewed by an EPA contractor. The study is entitled, "Migration Studies and Extraction Data From LDPE Films Containing Zeomic® Silver Zeolite A". The contractor review is attached to this review. The contractor concludes, and RASSB concurs, that the study adequately describes the migration of silver, sodium, aluminum and silicon from the LDPE articles containing Zeomic® at a maximum concentration of 5% to food-simulating solvents. The study closely follows FDA guidelines. The registrant should submit the following additional information to the migration study:

1. The method of sample preparation for silver.
2. Calibration curves for silver.
3. Information on how the LOD for silver was determined.

The maximum amount of silver that was extracted/leached from the LDPE articles containing Zeomic® with a label claim of 2.5% silver and at the highest proposed incorporation rate of 5% in the treated article is 30 ppb(parts per billion). Data are also reported in the migration study for sodium, aluminum and silicon. RASSB assumes that the residue of concern from the proposed use is silver.

If the registrant should in the future propose registration of a Zeolite product with a label claim of 5% silver and continue to propose incorporation of the Zeolite product into the treated material at a level of 5%, then the existing migration study may not be adequate to support such a registration change. This is because the silver content in the treated article would be 0.25% whereas the present migration study only supports silver incorporation into the treated product at a level of 0.125%.

RASSB also concludes that the existing migration study reflecting incorporation of the Zeolite product into LDPE is adequate to cover the range of treated materials that are included in the registrant's list of treated materials for water contact.

The chronic daily exposure for silver was calculated as follows:

$$ADD = DD \times (F/365) \times (ED/LT)$$

Where:

ADD = DD amortized over an individual's lifetime

F = Frequency of exposure events or number of days exposed to the pesticide. For water, this is

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365 days because water is consumed daily.

ED = Exposure during a lifetime. For an adult is 40 years. For infants and children, this is 70 years. These are Agency values.

LT = Anticipated lifetime of an individual in the exposed population.

DD = Daily dose.

RASSB assumes water consumption of 2L/day for adults(60 and 70 kg. body weight and 1L/day for children(10 kg. body weight).

Then:

ADD for a 70 kg. adult male = $60 \text{ mcg. Ag} \times 365/365 \times 40 \text{ years}/70 \text{ years}$
= 34 mcg. Ag/day

or

34 mcg. Ag per day/70 kg. bodywt.
= 0.49 mcg. Ag/kg. bodywt./day

ADD for a 60 kg. adult = $60 \text{ mcg. Ag} \times 365/365 \times 40 \text{ years}/70 \text{ years}$
= 34 mcg. Ag/day

or

34 mcg. Ag per day/60 kg. bodywt.
= 0.57 mcg. Ag/kg. bodywt./day

ADD for an infant or child = $30 \text{ mcg. Ag} \times 365/365 \times 70 \text{ years}/70 \text{ years}$
= 30 mcg. Ag/day

or

30 mcg. Ag per day/10 kg. bodywt.
= 3 mcg. Ag/kg. bodywt./day

Other Considerations

If the registrant should in the future plan to incorporate this Zeomic® product into materials that could be exposed to high temperature food contact conditions, such as oven baking or microwave cooking, then additional migration data may be needed which reflect this type of use.