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**Environmental Assessment for FCN 000351**

1. **Date:** July 28, 2003
2. **Name of Notifier:** AgION Technologies, Inc.
3. **Address:** 60 Audubon Road
Wakefield MA
01880

4. Description of Proposed Action:

- a. Use of the Food Contact Substance in or on a variety of repeat use food contact articles and in food packaging.
- b. The Food Contact Substance will control micro-organism growth on the food contact articles and on the food packaging thereby preserving the articles and packaging, thus providing a public health benefit.
- c. The use sites will be those businesses that prepare products listed on the attached Type AJ (2.5% silver) pesticide. Upon FDA approval AgION Technologies will submit a request to EPA to allow the similar list of end use sites to be added to the Type AK (5% silver) registration.

5. Identification of substances that are the subject of the proposed action:

The substance is an inorganic matrix of zeolite, silver, zinc and ammonium.

6. Introduction of substances into the environment:

- a. The Food Contact Substance is manufactured in Japan. No extraordinary circumstances apply to the manufacture of the Food Contact Substance.
- b. Little or no introduction of zeolite or its exchangeable ions (silver, zinc and ammonium) into the environment will result from the use of the FCS because it is almost completely incorporated into food contact articles and food packaging materials, and essentially all is expected to remain with those articles throughout their use.
- c. We believe that the primary route of introduction of the substances into the environment for the proposed use of this type of zeolite is as a result of disposal by landfilling and combustion of municipal solid waste.

Landfilling: Based on migration studies of food packaging containing the FCS that were performed to demonstrate its safety
Only very low levels of substances are expected to leach from food-packaging and food contact articles in landfills. In addition, the introduction of these substances into the environment will not threaten a violation of the

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Environmental Protection Agency's regulations in 40 CFR Part 258 that pertain to landfills.

Combustion: The incremental increase in emissions of byproducts from food-packaging material will be very small. The market volumes of this FCS are reported in a confidential attachment (see Attachment 1).

7. Fate of substances released into the environment:

Little or no introduction of zeolite or its exchangeable ions (silver, zinc and ammonium) into the environment will result from its use and disposal because it is almost completely incorporated into food-packaging materials and food contact articles, and essentially all of it is expected to remain with the packaging throughout use and disposal of the product.

8. Environmental fate of released substances:

No information need be provided on the environmental effects of substances released into the environment as a result of use and disposal of zeolite or its exchangeable ions, because, as discussed under Format Item 6, only very small quantities of the FCS components, breakdown products or combustion by-products, if any, will be introduced into the environment as a result of its use and disposal.

9. Use of resources and energy: The Food Contact Substance will preserve food contact articles and the use of resources and energy need to manufacture these articles will be reduced. The AgION antimicrobial is intended to replace and/or compete with several other products used in the manufacture of food packaging and repeat-use food contact articles. These products include:

FCN 0001	Silver sodium hydrogen zirconium phosphate
FCN 0047	Silver-zinc-zeolite
FCN 0193	Silver-zinc-zeolite
FCN 0248	Silver-zinc glass
FCN 0270	Silver-zinc sodium aluminosilicate zeolite
FCN 0275	Silver-magnesium-sodium-boron phosphate glass
FCN 0296	Silver nitrate

It is not envisioned that this product will have any effects on recycling as the silver zeolite additive is an aluminosilicate based material which at the requested loading level of 10% does not effect the physical properties of numerous tested polymers. As silver zeolite treated products are designed for the end application, the higher loading of 10% silver zeolite is not used for disposable products. Food processing plastics, such as cutting boards and fixtures are not typically recycled by the end use processing plant.

In regards to aseptic packaging, this product is not marketed as a replacement for good hygiene and therefore it would not be sold as a replacement for standard HDPE milk jugs.

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That is, single use packaging which incorporates the silver zeolite would not become repeat use packaging merely due to the incorporation of the antimicrobial therein.

10. Mitigation measures:

Mitigation measures to the proposed action need not be considered because no potential adverse effects have been identified.

11. Alternatives to the proposed action:

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

12. List of preparers:

Gary J. Burin, Ph.D., DABT, Director, Toxicology, Ecotoxicology and Risk Assessment at Technology Sciences Group Inc., Washington DC. Dr. Burin has worked in the areas of toxicology and risk assessment for 25 years. This has included 13 years at the US Environmental Protection Agency.

Paul Ford, P.E., JD, Director of Regulatory Affairs, AgION Technologies, Inc.

13. Certification:

The undersigned official certifies that the information is true, accurate, and complete to the best of the knowledge of AgION Technologies Inc.

7/28/03
Date

Signature of Responsible Official

PAUL C. FORD
Name and Title
Director of Regulatory Affairs

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