



**Part IV — ENVIRONMENTAL IMPACT OF
FOOD-CONTACT SUBSTANCE**

1. **Date:** August 17, 2000

2. **Notifying Party:**
Michelle Burnett
Agway, Inc., D/B/A
Agway CPG Technologies International
Post Office Box 4933
Syracuse, NY 13221-4933
Telephone: (315) 449-6966
Facsimile: (315) 449-6289
E-mail: mburnett@agway.com

3. **Authorized Agent:**
Melvin S. Drozen
Keller and Heckman LLP
1001 G Street, NW, Suite 500W
Washington, DC 20001
Telephone: (202) 434-4222
Facsimile: (202) 434-4646
E-mail: drozen@khlaw.com

4. **Description of the Proposed Action** Polyvinyl alcohol is proposed for use in coatings for fruits and vegetables with inedible peels.

5. **Environmental consequences of the proposed action**
 - a. **Production of the food-contact substance**

FDA has advised that environmental assessments no longer routinely must provide information on the introduction of substances to the environment resulting from the manufacture of food-contact substances unless extraordinary circumstances exist. As the manufacture of PVOH does not involve any extraordinary circumstances that are not addressed by general emission requirements, no data are submitted.

000018

b. Use and disposal of the food-contact substance

PVOH is intended for use as a component of coatings for fruits and vegetables, and use is limited to fruits and vegetables that have inedible peels. This use involves a food-contact substance that is added directly to the exterior of fruits and vegetables with inedible peels, with the intended technical effect of extending the shelf-life of fruits and vegetables by maintaining the fruits or vegetables in marketable condition for an extended period of time. This is accomplished by retardation of ripening and prevention of moisture loss. The PVOH coating is intended to remain with food up to the point of ingestion, where the substance, PVOH, used as a component of coatings for fruits and vegetables with inedible peels, is discarded. There is no ingestion of the peels of bananas, plantains, avocados, melons, pineapples, mangos, or papaya.

The use of PVOH as a component of coatings for fruits and vegetables such as those above, with inedible peels, meets the criteria of paragraph (5)(b)(3)(a) of "Preparing an Environmental Assessment for Premarket Notifications: Interim Guidance," where the substance is added directly to food. The proposed use of PVOH as a component of coatings for fruits and vegetables with inedible peels will result in very low levels of PVOH in either the effluents and/or sewage sludge from publicly owned wastewater treatment plants or in municipal landfills. The expected levels of PVOH are not expected to be toxic to organisms in the environment.

Because PVOH is composed only of carbon, hydrogen, and oxygen, the combustion products of PVOH in a properly operated incinerator are carbon dioxide and water. Therefore, the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymer in the amounts utilized.

As noted in the FCN, the highest consumption of fruits and vegetables with inedible peels consumed by the average eater is 26 g/day in a 3 kilogram diet, and the maximum amount of PVOH per kilogram of fruit or vegetable is 0.18 gram. Thus, the contribution to landfill sites or waste treatment facilities is not expected to be environmentally significant.

6. Alternatives to the proposed action

No potential adverse environmental effects are identified that would necessitate alternative actions to those proposed in this FCN. The alternative of not approving the action proposed in this FCN will result in continued use of competing products, and therefore has no environmental impact.

7. Market Penetration Data

See confidential Appendix IV.

000019

8. List of Preparers

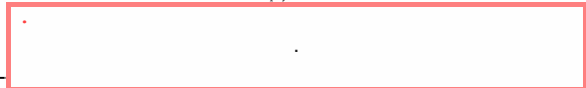
Melvin S. Drozen, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

Thomas C. Brown, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Qualifications: B.S., Chemistry, with 22 years of experience in evaluation of food additive petitions with FDA and 4 years involved in preparation and submission of food additive petitions and food-contact notifications.

9. Certification

The undersigned certifies that the information provided in this Environmental Assessment is true, accurate, and complete to the best of his knowledge.

Date: August 17, 2000



Melvin S. Drozen
Counsel for Agway CPG Technologies
International

000020

Part V — CERTIFICATION

The undersigned counsel for the Notifier hereby certifies that the information provided herein is accurate and complete to the best of his knowledge.

Respectfully submitted,

Date: August 17, 2000

By:

Melvin S. Drozen
Keller and Heckman LLP

Counsel for the Notifier,
Agway CPG Technologies International

000021