

**ENVIRONMENTAL ASSESSMENT
NIPPON GOHSEI FOOD CONTACT NOTIFICATION**

1. **Date:** June 14, 2007
2. **Name of Applicant/Notifier:** The Nippon Synthetic Chemical Industry Co., Ltd.
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4. **Description of the Proposed Action**

The action requested in this notification is to establish the clearance of the food-contact substance (FCS) that is referred to as "acetic acid ethenyl ester, polymer with ethene and 1,1'-(1-ethenyl-1,2-ethanediyl) diacetate, hydrolyzed," for use in the fabrication of food-contact articles. With the clearance of this Food-Contact Notification (FCN), the FCS will be used in contact with fatty food under Conditions of Use C through G, as set forth in Tables 1 and 2, respectively, of 21 C.F.R. §176.170(c).

The subject resin offers several technical properties that make it useful in a variety of food-contact applications. In particular, the FCS shows a lower melting temperature than conventional EVOH products. In order to lower the melting temperature of EVOH resins, plasticizing agents are typically added; however, this process requires extrusion or kneading with electric energy. The FCS can be manufactured with conventional production plants without being extruded or kneaded by a plasticizing agent, thus saving electric power. In addition, the processing temperature of the resin may be lowered due to the lower melting temperature of the

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FCS, thereby also conserving electric power. As a result, the Notifier estimates that a decreased of 10°C in processing temperatures conserves roughly 10% of electric power.

The Notifier does not intend to produce finished food packaging from the subject resin. Rather, the resin will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the resin will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of the subject resin will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's 2005 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 13.6% was combusted, and 32.1% was recovered for recycling and composting.¹

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the resin.

5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this notification is "acetic acid ethenyl ester, polymer with ethene and 1,1'-(1-ethenyl-1,2-ethanediy) diacetate, hydrolyzed" (CASRN 917249-65-1).

The resin is marketed under the name, "Modified Soarnol."

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the resin. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject resin to fabricate food-contact articles. In these applications, the resin is expected to be used as a basic polymer to fabricate all forms of food-contact articles, and will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, e.g., plant scraps, are

¹ *Municipal Solid Waste in the United States. 2005 Facts and Figures*, EPA530-R-06-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2006.

expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles produced from the subject resin will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The FCS is composed of carbon, hydrogen, and oxygen, elements that are commonly found in municipal solid waste. The proposed use of the FCS and the market volume (available in a confidential attachment to the FCN) show that 1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 33.4 million tons or 13.6% of 245.7 million tons in 2005),² 2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors,³ and, therefore, 3) incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

Only extremely small amounts, if any, of the resin constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of any leaching is especially true considering that the subject substance is a high molecular weight polymer that contains only minute levels of extractable material.

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the resin. The polymer is of high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the resin.

² *Municipal Solid Waste in the United States. 2005 Facts and Figures*, EPA530-R-06-011, U.S. Environmental Protection Agency, *ibid*.

³ Paul M. Sullivan; Hallenbeck, W.H.; Brenniman, G.R. *Municipal Solid Waste Combustion*, University of Illinois at Chicago: Chicago, IL, 1993.

As indicated above in item 6, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

(b) Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject resin. The fate of the food contact substance in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Format Item 6.

(c) Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject resin. In particular, the extremely low levels of maximum migration of components of the resin, demonstrated by the extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the low production of the resin for use in food-contact applications precludes any substantial release to the environment of their components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the resin.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the resin in the manufacture of articles intended for use in contact with food. Likewise, the environmental fate of substances does not need to be addressed given that no significant introduction of substances into the environment results from the proposed use of the FCS, as discussed under Item 6 herein.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food-contact articles fabricated with the use of the resin consist of extremely small quantities of combustion products and extractables. As discussed in the FCN, the resin, as well as the monomers from which the resin is manufactured, are not considered to present a substantive genotoxicity or carcinogenicity risk at the minute levels at which they may enter the diet. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the resin. Information on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS is not necessary here because, as discussed under Item 6,

only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS. As a consequence, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR Parts 60 and 258.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use and disposal of the resin involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject resin in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the resin is intended to be used in food-contact articles which will be used in place of similar materials now on the market for use in food-contact applications. Polymers currently used in the applications in which the acetic acid ethenyl ester, polymer with ethene and 1,1'-(1-ethenyl-1,2-ethanediyl) diacetate, hydrolyzed polymer is anticipated for use include certain currently cleared polymers, such as ethylene-vinyl alcohol (EVOH) polymers.

The replacement of the other resins by the subject resin is not expected to have any adverse impact on the use of energy and resources. Manufacture of the resin, and its conversion to finished food-contact articles, will consume energy and resources in amounts comparable to the manufacture and use of the other polymers. While the clearance requested in this FCN involves use of the resin in any food-contact article used in contact with fatty food, the food-contact applications in which the resin is most likely to be used are film applications, particularly shrink wrap films; it is unlikely that the subject resin will be used to fabricate bottles. Furthermore, the clearance sought in this Notification is for use of the subject polymer in articles in contact with fatty food only. For this reason, the FCN, once effective, will not permit the subject resin to be used in articles that would be replacements for polyethylene terephthalate (PET) in soda bottles or high density polyethylene (HDPE) in milk bottles. As these PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as the subject polymer will not be used in such applications, articles fabricated from the subject resin will be disposed of by means of sanitary landfill and incineration. Packaging materials produced from the resin are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject resin. This is primarily due to the minute levels of leaching of potential migrants from finished food-contact articles, the insignificant impact of the FCS on environmental concentrations of combustion products of the resin, and the insignificant impact on the use of resources and energy when compared with the materials they are intended to replace. Thus, the use of the resin as proposed

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is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject resin would otherwise replace; such action would have no environmental impact. In view of the fact that the resin components are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from their use, the establishment of an effective Food Contact Notification to permit the use of the subject resin as described herein is environmentally safe in every respect.

12. List of Preparers

Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: June 14, 2007



Jerome H. Heckman
Counsel for The Nippon Synthetic Chemical
Industry Co., Ltd.