

**ATTACHMENT 2 - ENVIRONMENTAL ASSESSMENT
TICONA FOOD CONTACT NOTIFICATION**

1. **Date:** April 9, 2004
2. **Name of Applicant/Notifier:** Ticona
3. **Address:** 86 Morris Avenue
Summit, New Jersey

All communications on this matter are to be sent in care of Counsel for Notifier:
Ralph A. Simmons, Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4120
Facsimile: (202) 434-4646
E-mail: Simmons@khlaw.com

4. **Description of the Proposed Action**

The action requested in this notification is to modify the existing clearance of the food-contact substance (FCS), "copolymers produced by the polymerization of 6-hydroxy-2-naphthoic acid with one or more of the following monomers: 4-hydroxybenzoic acid; 4,4'-biphenol; N-(4-hydroxyphenyl)acetamide; terephthalic acid; resorcinol; and isophthalic acid such that a minimum of 55 percent of the polymer units are derived from 6-hydroxy-2-naphthoic acid alone or in combination with 4-hydroxybenzoic acid, not more than 25 percent of the polymer units are derived individually from 4,4'-biphenol, N-(4-hydroxyphenyl)acetamide and terephthalic acid, and not more than 15 percent of the polymer units are derived individually from resorcinol and isophthalic acid" for use in food-contact articles. In accordance with effective FCN No. 103, the FCS is currently permitted to manufacture films, sheets, and articles made therefrom for food-

000033

0060

contact applications, but not for use in making bottles. Furthermore, the FCS may be used in contact with all food types under Conditions of Use A through H, as set forth in Tables 1 and 2, respectively, of 21 C.F.R. §176.170(c). The purpose of the current Notification is to modify one of the limitations noted above, namely that the FCS will be cleared for use in making bottles. All other provisions will remain the same.

The subject copolymers offer several technical properties that make them useful in a variety of food, pharmaceutical, and medical device applications. In particular, they provide good moisture and oxygen barrier properties, good thermal stability, good mechanical properties, and excellent chemical resistance.

The Notifier does not intend to produce finished food packaging from the subject copolymers. Rather, the copolymers will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the copolymers 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 will occur nationwide, with about 76% of the materials being deposited in land disposal sites, and about 24% combusted.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 copolymers.

¹ *Characterization of Municipal Solid Waste in the United States 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, May 1998.

000034



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

The FCS that is the subject of this Notification is "copolymers produced by the polymerization of 6-hydroxy-2-naphthoic acid with one or more of the following monomers: 4-hydroxybenzoic acid; 4,4'-biphenol; N-(4-hydroxyphenyl)acetamide; terephthalic acid; resorcinol; and isophthalic acid such that a minimum of 55 percent of the polymer units are derived from 6-hydroxy-2-naphthoic acid alone or in combination with 4-hydroxybenzoic acid, not more than 25 percent of the polymer units are derived individually from 4,4'-biphenol, N-(4-hydroxyphenyl)acetamide and terephthalic acid, and not more than 15 percent of the polymer units are derived individually from resorcinol and isophthalic acid."

The copolymers are marketed under the trade name

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 copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

000035



No environmental release is expected upon the use of the subject copolymers to fabricate packaging materials. In these applications, the copolymers are expected to be used as the 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 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 by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The copolymers consist primarily of carbon, hydrogen, and oxygen, with some of them containing small mounts of nitrogen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

Only extremely small amounts, if any, of the copolymer 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

000036



appropriate. The lack of any leaching is especially true considering that the subject substances are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.²

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 copolymers. The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the copolymers.

The products of complete combustion of the copolymer would be carbon dioxide and water, along with small amounts of nitrogen oxides; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications.

² This expectation is confirmed by the results of extraction studies described in FCN No. 103. As shown there, when several different grades of the copolymers were extracted with either 10% ethanol, 50% ethanol, or corn oil at 121°C for 2 hours followed by 40°C for 10 days and with 95% ethanol at 40°C for 30 days, minute levels of components of the subject copolymer were found in the extracts at levels ranging from non-detected at 50 parts per billion (ppb) to a maximum of 308 ppb. Thus, the quantity of leachate from the copolymers in solid waste deposited in landfills will be extremely small.

000037



(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 copolymers. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

(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 copolymers. In particular, the extremely low levels of maximum migration of components of the copolymers, 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 very low production of the copolymers 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 copolymers.

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

000038



proposed use of the copolymers in the manufacture of articles intended for use in contact with food.

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 packaging materials fabricated with the use of the copolymers consist of extremely small quantities of combustion products and extractables. As discussed in FCN No. 103, the monomers from which the copolymers are manufactured are not considered to present a substantive genotoxicity or carcinogenicity risk at the minute levels at which they may enter the diet. Furthermore, it is generally recognized that oligomeric substances are of lower potential toxicity than the monomers from which they are produced. Consequently, based on the absence of any concern vis-à-vis the monomers, the oligomers also are not expected to present any toxicological concern. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the copolymers. In addition, the use and disposal of the copolymers are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors, and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the copolymers involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymers 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 copolymers are intended to be used in packaging which will be used in place of similar materials now on the market for use in food packaging applications. Polymers currently used in the applications in which is anticipated to be used include high density polyethylene (HDPE), low density polyethylene (LDPE), linear low density polyethylene (LLDPE), polypropylene, and possibly polyethylene terephthalate (PET; films only).

The partial replacement of these types of materials by the copolymers is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymer, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of the other polymers. While the change requested in this FCN involves use of the copolymers in the fabrication of bottles, bottles fabricated from the copolymers are not transparent and, thus, do not possess one of the important technical properties that is deemed critical by beverage suppliers. In fact, bottles manufactured from the copolymers are "cloudier" than is HDPE, a resin that is nearly white in appearance. For this reason, the subject copolymers will not replace PET bottles in applications that require transparent bottles, e.g., soft drink bottles. In addition, Vectra® is much more expensive than either PET or HDPE. Thus is not expected to be used as a replacement for PET in soda

000040



bottles or HDPE in milk bottles. As PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as [redacted] will not be used in such applications, articles fabricated from the subject copolymers will be disposed of by means of sanitary landfill and incineration. Packaging materials produced from the copolymers 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 copolymers. This is primarily due to the minute levels of leaching of potential migrants from the finished article, the insignificant impact on environmental concentrations of combustion products of the copolymers, 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 copolymers as proposed 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

000041
[redacted]

copolymers would otherwise replace; such action would have no environmental impact. In view of the fact that the copolymer constituents 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 copolymers as described herein is environmentally safe in every respect.

12. List of Preparers

Ralph A. Simmons, Attorney, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

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: April 9, 2004



Ralph A. Simmons
Counsel for Ticona

000042