

**ATTACHMENT 5 - ENVIRONMENTAL ASSESSMENT  
TICONA FOOD CONTACT NOTIFICATION**

1. **Date:** May 30, 2007
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:  
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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 Nos. 103 and 423, the FCS is currently permitted to manufacture films, sheets, and articles (including bottles) made therefrom for food-contact applications. 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 two aspects of the current clearance. Specifically, the minimum percentage of the polymer units derived from 6-hydroxy-2-naphthoic acid alone or in combination with 4-hydroxybenzoic acid in would be modified from the current levels in FCN Nos. 103 and 423 of **55%** to a proposed minimum of **50%**. The second modification would be to broaden the use conditions from (a) the current Conditions of Use A-H to (b) Conditions of Use A-H, and J.<sup>1</sup> 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 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 (EPA) 2005 update regarding municipal solid waste in the

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<sup>1</sup> Condition of Use J does not appear in Table 2 of 21 C.F.R. §176.170(c). Rather, this new Condition of Use, which permits use of food contact substances for "Cooking (e.g., baking or browning) at temperatures exceeding 250° F (121°C)," appears only as a page attached (linked) to FDA's *Inventory of Effective Food Contact Notifications* on the agency's Web site. This category includes dual-ovenable containers and microwave heat susceptors under the conditions and temperatures as specified in the notification language, and it is an expansion of the Conditions of Use from those included Table 2 of 21 C.F.R. §176.170(c).

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.<sup>2</sup>

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.

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

The FCS that is the subject of this Notification includes “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 50 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 Vectra®.

**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

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<sup>2</sup> *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.



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 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 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 million tons or 14% of 236 million tons in 2003),<sup>3</sup> 2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors,<sup>4</sup> 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 EPA's regulations governing municipal solid waste landfills. EPA's regulations require new municipal

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<sup>3</sup> U S EPA *Municipal Solid Waste Generation, Recycling and Disposal in the United States - Facts and Figures for 2003*, EPA530-F-05-004, 2005

<sup>4</sup> Paul M Sullivan, Hallenbeck, W H , Brenniman, G R. *Municipal Solid Waste Combustion*, University of Illinois at Chicago - Chicago, IL, 1993

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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 substances are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.<sup>5</sup>

**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 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 resin.

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.

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<sup>5</sup> This expectation is confirmed by the results of extraction studies referenced in the FCN. As described there, when representative lots of the resins were extracted with either 10% ethanol, 50% ethanol, or corn oil at 121°C for 2 hours followed by 40°C for 30 days, minute levels of components of the subject resins were found in the extracts at levels ranging from non-detected at approximately 50 parts per billion (ppb) to a maximum of approximately 345 ppb. Thus, the quantity of leachate from the resin in solid waste deposited in landfills will be extremely small.

**(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, primarily no significant introductions of substances into the environment were identified under Format Item 6 above.

**(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. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Format Item 6.

**8. Environmental Effects of Released Substances**

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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. In conclusion, no information need be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS 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. Therefore, the use and disposal of the food additive are 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 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 Vetra® 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 proposed use includes 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 of PET bottles that is deemed critical by beverage suppliers. In fact, bottles manufactured from the copolymers are even “cloudier” than 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, Vectra® is not expected to be used as a replacement for PET in soda bottles or HDPE in milk bottles. As PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as Vectra® 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**

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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 to 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 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**

Lester Borodinsky, Ph.D., 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 her knowledge.

Date: 5/30/07



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