

**ATTACHMENT 4 - ENVIRONMENTAL ASSESSMENT
TICONA FOOD CONTACT NOTIFICATION**


1. **Date:** January 15, 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:
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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), ethylene-2-norbornene copolymer for use in food-contact articles. In accordance with effective FCN No. 75, the FCS is currently permitted to manufacture films, sheets, and articles made therefrom for food-contact applications, but not for use in making bottles. Furthermore, the FCS, having a density of $1.02 \pm 0.04 \text{ g/cm}^3$, may contain not less than 30 but no more than 70 mole percent of polymer units derived from norbornene in contact with all food types under all conditions of use. The purpose of the current Notification is to modify some of the limitations noted above, such that (1) the current compositional restriction would be broadened so that the FCS may contain not less than 20 but no more than 70 mole percent of

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polymer units derived from norbornene, and (2) the FCS will be cleared for use in making bottles. All other provisions will remain the same.

The subject ethylene-2-norbornene copolymer offers several technical properties that make it useful in a variety of food, pharmaceutical, and medical device applications. In particular, it provides (1) a moisture barrier, of importance in food and pharmaceutical flexible packaging, and in certain rigid packaging applications; (2) clarity, of importance in applications requiring a transparent package; and (3) high heat deflection temperature (HDT), of importance in applications involving steam autoclave treatment of the product.

The Notifier does not intend to produce finished food packaging from the subject ethylene-2-norbornene copolymer. Rather, the copolymer will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the copolymer 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 ethylene-2-norbornene copolymer.

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.

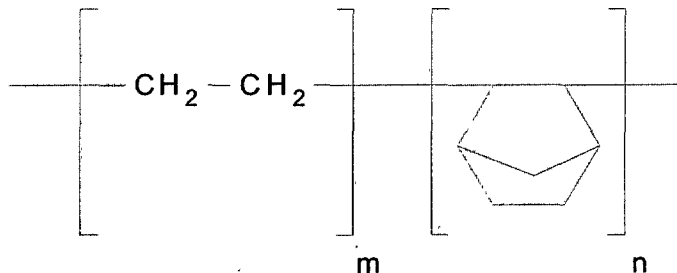
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5. **Identification of Substance that is the Subject of the Proposed Action**

The FCS that is the subject of this Notification is ethylene-2-norbornene copolymer containing not less than 20 but no more than 70 mole percent of polymer units derived from 2-norbornene.

The CAS Reg. No. for ethylene-2-norbornene copolymer is 26007-43-2. The CAS nomenclature is bicyclo[2.2.1]hept-2-ene, polymer with ethene. The structure of ethylene-2-norbornene copolymer is depicted below:



The copolymer is marketed under the trade name _____ and referred to as

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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

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environmental impact as a result of the manufacture of ethylene-2-norbornene copolymer. 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 copolymer to fabricate packaging materials. In these applications, the polymer 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 by the subject copolymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject ethylene-2-norbornene copolymer consists of carbon, hydrogen, and oxygen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

Only extremely small amounts, if any, of ethylene-2-norbornene 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.

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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.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 ethylene-2-norbornene. 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 copolymer.

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

² This expectation is confirmed by the results of extraction studies described in FCN No. 75. As shown there, when 125 mil (0.125 inch) thick samples of the copolymer were extracted with either 10% ethanol or 95% ethanol at 121°C for 2 hours followed by 40°C for 10 days and with 95% ethanol at 40°C for 10 days, minute levels of components of the subject copolymer were found in the extracts at levels ranging from non-detected at 0.1 parts per billion (ppb) to a maximum of 446 ppb. Thus, the quantity of ethylene-2-norbornene copolymer in solid waste deposited in landfills will be extremely small.

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(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 copolymer and optional adjuvant. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymer, 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 ethylene-2-norbornene copolymer. In particular, the extremely low levels of maximum migration of components of ethylene-2-norbornene copolymer, 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 ethylene-2-norbornene copolymer 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 ethylene-2-norbornene copolymer.

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

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proposed use of ethylene-2-norbornene copolymer 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 subject copolymer consist of extremely small quantities of combustion products and extractables. As discussed in FCN No. 75, two grades of the copolymer, having different percentages of polymer units derived from 2-norbornene, were subjected to acute oral toxicity studies in male and female rats demonstrating that the acute oral lethal dose (LD₅₀) for each test material is greater than 2000 mg/kg b.w. In addition, the monomer 2-norbornene is of a very low order of acute toxicity, as demonstrated by an LD₅₀ in excess of 11,000 mg/kg b.w., and the monomer also has been shown to be non-genotoxic in genetic toxicity screening assays, specifically, the Reverse Mutation Assay (Ames Test) using *Salmonella Typhimurium*, an *in vitro* gene mutation assay in Chinese hamster ovary cells, and an *in vitro* chromosome aberration assay in Chinese hamster ovary cells. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the copolymer. In addition, the use and disposal of the copolymer 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.

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9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of ethylene-2-norbornene copolymer involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymer 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 copolymer is 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 copolymer 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 ethylene-2-norbornene copolymer 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 one of the changes requested in this FCN involves use of the copolymer in the fabrication of bottles, the properties of the copolymer are such that they will not replace PET bottles in applications that require sufficient gas barrier properties, e.g., soft drink bottles. See for example the chart provided in Attachment 2 of this Notification, which includes a comparison of the barrier properties of film to carbon dioxide with the barrier properties of PET. On average, PET is an order of magnitude better as a carbon dioxide barrier than (nominal data $90 \text{ cm}^3/(\text{m}^2 \text{ d bar})$ for PET versus an average of nearly 900 for). Also, as indicated

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in the product bulletin included in Attachment 2 of this Notification, the oxygen permeability of _____ is ten times worse than that of PET. Thus, the subject copolymer is not suitable for use in the food-contact applications in which the gas barrier properties of PET now are necessary. In addition, _____ is much more expensive than either PET or HDPE. Thus, _____ is not expected to be used as replacements for PET soda bottles or HDPE milk bottles. As PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as _____ will not be used in such applications, articles fabricated from the subject copolymer will be disposed of by means of sanitary landfill and incineration. Packaging materials produced from ethylene-2-norbornene copolymer 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 copolymer. 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 polymers, and the close similarity of the subject copolymer to the materials they are intended to replace. Thus, the use of the copolymer as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

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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 copolymer 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 its use, the establishment of an effective Food Contact Notification to permit the use of ethylene-2-norbornene copolymer as described herein is environmentally safe in every respect.

12. List of Preparers

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13. Certification

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

Date: 1/15/04



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Counsel for Ticona

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