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Attachment IX
Environmental Assessment

000436

ENVIRONMENTAL ASSESSMENT

1. **Date** April 24, 2000
2. **Name of Applicant/Notifier** Ticona
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, Jerome H. Heckman, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4110.
4. **Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of ethylene-2-norbornene copolymers containing not less than 30 but no more than 70 mole percent of polymer units derived from norbornene in contact with food. Such copolymers would be used in the manufacture of films and sheets, and containers formed from them, in contact with all types of food under all conditions of use.

We note that, while FDA promulgated regulations, effective August 29, 1997, amending its requirements for environmental assessments (EA's), the Agency has not yet made available guidance documents for preparing EA's under the revised regulations. Consequently, the EA presented here has been prepared in accordance with the format requirements that previously appeared at 21 C.F.R. § 25.31a, modified as appropriate to focus on the impact of use and disposal of the subject polymers, in keeping with the revised regulations. Since the requirements set forth under the revised Section 25.40 are less extensive than the former requirements, we understand that an EA prepared in accordance with the previous formats will be accepted.

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The subject ethylene-norbornene copolymers offer several technical properties that make them useful in a variety of food, pharmaceutical, and medical device applications. In particular, the moisture barrier properties of the polymers make them useful in food and pharmaceutical flexible packaging, and in certain rigid packaging applications (e.g., containers formed from thermoforming of sheets). The polymers also offer good clarity, and a high heat deflection temperature. The latter is of importance in applications involving steam autoclave treatment of the product.

The Notifier does not intend to produce finished food packaging materials from the subject ethylene-norbornene copolymers. Rather, the copolymers will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of 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/}

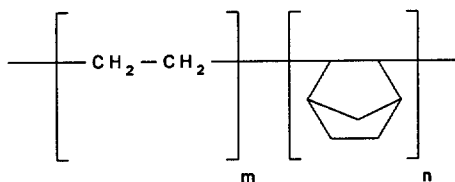
The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials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

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

The additives that are the subject of this Notification are copolymers of ethylene and 2-norbornene prepared with not less than 30 but no more than 70 mole percent of polymer units derived from 2-norbornene. As dealt with by the Notifier, the copolymers are marketed under the trade name _____ and referred to as ‘_____’.

The Chemical Abstracts Service (CAS) Registry Number for _____ is 26007-43-2; the CAS name is Bicyclo[2.2.1]hept-2-ene, polymer with ethene. The CAS molecular formula is $(C_7H_{10} \cdot C_2H_4)_x$. The structural formulae for the polymer repeating units are as follows:



The molecular structure of the polymer consists of varied sequences of the units shown above randomly incorporated along the polymer chain.

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 copolymers. 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 copolymers to fabricate packaging materials. In these applications, the polymers will be entirely incorporated into the finished food package. 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 materials produced by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject olefin copolymers consist of carbon and hydrogen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymers.

Only extremely small amounts, if any, of 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 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/}

^{2/} This expectation is confirmed by the results of extraction studies described in Section II-D of the Notification. As shown there, when 125 mil thick test placques were extracted with either 10% ethanol or 95% ethanol at 121 °C for 2 hours followed by 40 °C for 10 days, minute levels of components of the subject substances were found in the extracts at levels ranging from non-detected at 0.1 parts per billion (ppb) to 299 ppm. Thus, the quantity of copolymer constituents in solid waste deposited in landfills will be extremely small.

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 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 these copolymers.

The products of complete combustion of the polymer 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 polymers in the amounts utilized for food packaging applications.

(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 ethylene-norbornene copolymers. In particular, the extremely low levels of migration of components of the polymer, even at 121 °C, 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 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 proposed use of 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 subject copolymers consist of extremely small quantities of combustion products and extractables. As discussed in Section III of the Notification, two copolymers, having different percentages of polymer units derived from 2-norbornene, were subjected to acute oral toxicity study in rats demonstrating that the LD₅₀ for each test material is greater than 2000 mg/kg bw. In addition, the monomer 2-norbornene is of very low acute toxicity, as demonstrated by an LD₅₀ in excess of 11,000 mg/kg bw; and the monomer also has been shown to be non-genotoxic. 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 copolymers involves 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 place of similar polymers 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 replacement of these types of materials by _____ is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymers and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of HDPE, LDPE, LLDPE, polypropylene, and PET (film). Moreover, _____ copolymers will be used to manufacture films and sheets, and containers formed from them. Consequently _____ copolymers are not anticipated for use in the manufacture of bottles used for packaging milk or soda; packaging for other types of food are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from ethylene-norbornene 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 polymers; and the close similarity of the subject copolymers 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 which would necessitate alternative actions to that proposed in this Petition. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject copolymers would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the polymers for use in food-contact applications, 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 the clearance of the use of polymers as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers


- a. 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 24, 2000

A red rectangular box, likely a placeholder for a signature or stamp.

 Jerome H. Heckman

Counsel for Ticona