

Environmental Assessment

- 1. Date** February 4, 2008
- 2. Name of Applicant/Notifier** Mitsui Chemicals, Inc.
- 3. Address** All communications on this matter are to be sent in care of Counsel for Notifier, George G. Misko, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4170.
- 4. Description of the Proposed Action**

The action requested herein is to allow this Notification to become effective, so that the Notifier's ethylene/butene-1 copolymers containing up to 34 weight-percent of polymer units derived from butene-1 may be used in the manufacture of articles that will contact food. The articles manufactured from the subject copolymers will be used in contact with all types of food in applications as severe as FDA's Conditions of Use B through H, as set forth in Table 2 of 21 C.F.R. Section 176.170(c).

The subject copolymers offer several technical properties that make them useful in certain food-contact applications. Specifically, such properties of the polymers as their tensile strength, tensile elongation, and torsional rigidity make them well suited for use as elastomers. The polymers will be used in both single and repeated-use food-contact applications such as sealing gaskets, packing, plugs, and so forth.

The Notifier does not intend to produce finished food packaging materials from the subject copolymers. Rather, the polymers will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the polymers 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 80% of the materials being deposited in land disposal sites, and about 20% combusted.¹

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. According to this report, of the total of 245.7 million tons of municipal solid waste (MSW) generated in 2005, 54.3% generally was land disposed, 13.6% was combusted, and 32.1% was recovered (a combination of waste recovered for recycling and for composting). As the food-contact substance (FCS) is expected to be disposed of primarily by land-filling or combustion (i.e., not recovered for recycling), we will recalculate the disposal pattern based on only the
(footnote continued)

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 subject copolymers.

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 butene-1. Specifically, the subject of the FCN is copolymers produced by the polymerization of ethylene and butene-1 such that the finished copolymers will contain up to 34 percent by weight of polymer units derived from butene. The polymers have a minimum density of 0.860 g/cm³ and maximum melt flow rate of 50 g/10 min at 190°C.

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.

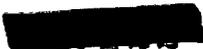
No environmental release is expected upon the use of the subject polymers to fabricate packaging materials. In these applications, the polymers will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the manufacturer's overall non-hazardous 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 copolymers consist of carbon and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers.

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

quantities of MSW that are land disposed or combusted. On this basis, we estimate that 20% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: 13.6% combusted ÷ (13.6% combusted + 54.3% land disposed) = 20.0% combusted. The remaining 80% will be land-disposed.

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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 supported by the fact 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

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject 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 polymers.

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.

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 their disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

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 migration of components of the polymer, even at 100°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 low production of the copolymers for use in food-contact applications, as shown in Attachment 15 of this Notification, indicates low potential introduction of extractables from the subject polymer into terrestrial ecosystems. Thus, there is no expectation of any

² This expectation is confirmed by the results of extraction studies described in Section II-F of the Notification. As shown there, when 20 mil thick test plaques were extracted with 10% ethanol at 100°C for 2 hours followed by 40°C for 10 days (conditions that greatly exaggerate conditions in land disposal sites), total nonvolatile extractives were less than 0.05 milligram per square inch. Thus, the quantity of copolymer constituents in solid waste deposited in landfills will be extremely small.

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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 the subject ethylene/butene-1 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 Part III of the Notification, the potential migrating components of the polymers do not present any toxicological concern at the minute levels at which they could be extracted upon use and disposal. 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 subject 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 place of similar polymers now on the market for use in food packaging applications. Polymers currently used in the applications in which the subject copolymer is anticipated to be used include other polyolefin elastomers. These include, e.g., olefin copolymers complying with 21 C.F.R. Section 177.1520(c) 3.4 and 3.5.

The replacement of these types of materials by the subject copolymers 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 the currently cleared polymers. Moreover, the properties of the subject copolymers, like those of the polymers with which they may compete, are such that the subject copolymers are not anticipated for use in the manufacture of bottles used for packaging milk or carbonated soft drinks. Packaging for types of food other than milk or soft drinks are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from the subject 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.

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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 polymers. 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 Notification. 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 subject ethylene/butene-1 copolymers for use in food-contact applications, the fact that the polymer 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 clearance of the use of the subject copolymers as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

- 1) George G. Misko, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.
- 2) Holly H. Foley, 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: February 4, 2008

George G. Misko
Counsel for Mitsui Chemicals, Inc.

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