

ENVIRONMENTAL ASSESSMENT

1. **Date:** March 30, 1998
2. **Name of Applicant/Petitioner:** Mitsui Chemicals, Inc.
3. **Address:** All communications on this matter are to be sent in care of Counsel for Petitioner, 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 in this Petition is the amendment of an existing Food Additive Regulation to expand the permitted use conditions for currently cleared olefin copolymers. Its specific purpose is to amend 21 C.F.R. § 177.1520(c), item 3.2b, to provide for the use of propylene/butene-1 copolymers containing more than 15 but not more than 35 weight-percent of polymer units derived from butene-1 in blends at levels not to exceed 30% by weight of total polymer with polypropylene homopolymer and high-propylene olefin copolymers subject to no limitation on the maximum thickness of the food-contact article.

We note that, while FDA promulgated regulations, effective August 29, 1997, amending its requirements for environmental assessments, the Agency has not yet made available guidance documents for preparing EA's under the new 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 new regulations. Since the

requirements set forth under new 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.

By way of background, the subject propylene/butene-1 copolymers, described at Section 177.1520(a)(3)(i)(c)(2), are now permitted under item 3.2b of 177.1520(c) for use in all food-contact applications subject to the limitation that the polymer be used in a thickness not to exceed 0.001 inch (1 mil). The purpose of this petition is to remove the restriction on the maximum thickness of the food-contact article manufactured from the copolymers when they are used as a component of certain olefin polymer blends. Specifically, it is requested that the subject propylene/butene-1 copolymers be permitted for use in blends with polypropylene complying with Section 177.1520(c) item 1.1 and high-propylene olefin copolymers complying with 21 C.F.R. § 177.1520(c) items 3.1 and 3.2, with no limit on the maximum thickness of the food-contact article.

In addition to the current clearance for the subject copolymers under Section 177.1520(a)(3)(i)(c)(2), propylene/butene-1 copolymers containing a maximum of 15 weight-percent of polymer units derived from butene-1, identified in Section 177.1520(a)(3)(i)(c)(1), are permitted under Section 177.1520(c) item 3.2a for use in contact with food with no limitations on the thickness or conditions of use of the finished food-contact article. The propylene/butene-1 copolymers dealt with here differ from those cleared under Section 177.1520(a)(3)(i)(c)(1) only in that they contain a higher proportion of polymer units derived from butene-1.

Due to the similarity of Tafmer XR to the propylene/butene-1 copolymers containing up to 15% of butene-1 units, the subject copolymers are expected to be used in applications similar to those in which these cleared copolymers are currently employed. Specifically, as discussed in the text of this petition, the subject copolymers are expected to be used in a fairly limited range of food-contact applications. These primarily include multilaminate retort pouches, where the heat-seal properties of _____ provide significant advantages, particularly in reducing the risk of seal failure in high-speed food-packing processes. A potential market also exists for use of _____ in polypropylene heat-shrink films. The use of _____ in these applications will not alter the use or disposal of the finished food-contact article. Rather, use of the copolymers will result in improvements in various characteristics of the finished food-contact material, allowing these materials to perform better in the intended applications.

The Petitioner manufactures the subject propylene/butene-1 copolymers at its production facilities located in _____. These copolymers are currently produced at this site for use in a wide range of applications, including use in the food-contact materials for which the polymers are currently cleared.

The finished propylene/butene-1 copolymers will be sold to manufacturers who will blend them with other cleared olefin polymers used in the manufacture of food-contact materials. Food-contact articles produced with the use of _____ propylene/butene-1 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

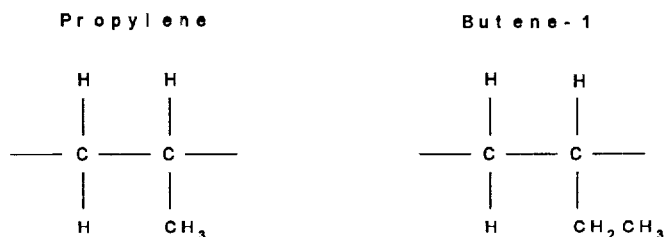
occur nationwide, with about 80% of the materials being deposited in land disposal sites, and about 20% incinerated.

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 propylene/butene-1 copolymers.

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

The additives that are the subject of this Petition are certain olefin copolymers, *i.e.*, those prepared with greater than 15, but not more than 35, weight-percent of polymer units derived from butene-1 with the remainder consisting of propylene. As dealt with by the Petitioner, the copolymers are marketed under the trade name [redacted]

The Chemical Abstracts Service (CAS) Registry Number for [redacted] is 29160-13-2; the CAS nomenclature is Butene-1, polymer with propylene. The molecular formula is $(C_3H_6)_x(C_4H_8)_y$. 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. The polymer is typically produced with a propylene:butene-1 weight ratio of about 65:35.

The copolymers dealt with here have a density of 0.880 to 0.895 and a maximum melt flow index of 10 g/10 min at 230°C. The polymer typically has an average molecular weight of approximately 450,000.

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

With respect to the introduction of substances into the environment upon the use and disposal of food-contact articles manufactured with the use of the subject polymers, disposal by the ultimate consumer of such articles 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 olefin copolymer constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles. This expectation is based on (1) the minute amount of the polymers that is expected to migrate from food-contact materials under landfill conditions,^{1/} and (2) 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 collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

Moreover, it should be noted that the subject polymers are expected to be used in place of other regulated olefin polymers; that is, is expected to be used primarily in place of propylene/butene-1 copolymers with a lower butene-1 content, which are currently cleared for the proposed use. This will not result in any meaningful change in the nature or

^{1/} This expectation is confirmed by the results of extraction studies described in Section B of this Petition. As shown there, when 4-mil (0.01 cm) films prepared from blends of with polypropylene random copolymer were exposed to 10% aqueous ethanol at 40°C for 10 days, the average concentration of total nonvolatile (TNV) extractives was indistinguishable from that of the solvent blank. Maximum migration of under these conditions was estimated at 0.003 mg/in², equivalent to 0.005% of the total sample weight [*i.e.*, (0.003 mg/in²) ÷ [(0.01 cm) x (2.54 cm/in)² x (0.896 g/cm³) x (1000 mg/g)] = 5.2 x 10⁻⁵, or 0.005%].

quantity of substances released to the environment upon the manufacture, use, or disposal of food-contact materials containing such polymers.

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 propylene/butene-1 copolymers in blends with other cleared olefin polymers. 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 use of blends containing the 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 polymer, nor upon its disposal in landfills due to the extremely low levels of migration of resin components, as demonstrated in Section B of this Petition and as discussed in 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 propylene/butene-1 copolymers. In particular, the extremely low levels of migration of polymer constituents, even at elevated temperature, 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. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the polymer.

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 propylene/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 propylene/butene-1 copolymers consist of extremely small quantities of the combustion products and oligomeric extractables discussed in Item 6. The copolymers are expected to be employed in place of other olefin polymers, especially other propylene/butene-1 copolymers, that would yield essentially the same combustion products and migrants.

Moreover, data presented in Section B demonstrate that [redacted] does not contain a higher level of extractable material than do these cleared copolymers. Thus, the use of [redacted] in place of other currently cleared materials is not expected to lead to a substantial change in the nature of, or any net increase in the amounts of, substances being released to the environment. Finally, as discussed in Section E of the Petition, the extractable fraction of [redacted] has been subjected to an acute oral toxicity study in mice demonstrating that the LD₅₀ for the test material is greater than 5000 mg/kg b.w. 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.

9. Use of Resources and Energy

As is the case with other food-packaging materials, the production, use and disposal of [redacted] propylene/butene-1 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 olefin polymers currently on the market for use in food packaging applications. These include propylene/butene-1 copolymers that are essentially identical in composition to the subject copolymers but contain lower levels of polymer units derived from butene-1 and correspondingly higher levels of propylene. The use of [redacted] in place of these polymers

is not expected to result in any change in the types of applications in which the polymers may be employed.

The manufacture and use of the subject copolymers involves the consumption of raw materials in quantities comparable to the production of the polymers which they are expected to replace. Moreover, since the polymers are of relatively low density (in the range of 0.880 to 0.895 g/cm³), to the extent they are used in place of polymers of comparatively higher density, their use may actually be seen as having a beneficial effect in terms of resource conservation in that the weight of the product needed to produce an article of a given thickness will be reduced.

As shown in Section C of this Petition, the use of propylene/butene-1 copolymers in blends with other olefin polymers offers several technological advantages over the base polymers alone, including improved heat-seal properties. Like the similar copolymers intended to be replaced by which provide similar technical advantages, the copolymers are expected largely to be used in polyolefin film food packaging applications, including polypropylene retort packaging and shrink-wrap film. The food-contact applications in which these materials are employed will be the same as those in which polymer blends or multilaminate layers made with the cleared propylene/butene-1 copolymers are now used. This is because, rather than providing significant new properties which make new types of applications possible, the use of the higher-butene copolymers merely results in improvements in the desirable properties of the base polymer. However, it is noteworthy that

the technical advantages offered by _____ particularly the improved heat-sealability, will allow food packing operations to be run at higher speeds and, thus, more efficiently.

The use of the subject copolymers in blends with other olefin polymers will not result in any change in post-consumer disposal patterns for finished food-contact articles due to the close similarity of such materials to the polymer blends that will be replaced. Food-contact materials produced from the cleared polymers are currently disposed of by means of landfill or incineration; if there is any collection of such post-consumer food-contact articles for purposes of recycling, it is believed to be limited to mixed-polymer recycling streams. The same is expected to be true of materials manufactured from blends of _____ with other polymers. Consequently, the proposed use of the copolymers is expected to have no adverse impact on current or future recycling programs for food packaging materials.

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 olefin polymers 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 olefin polymers 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 articles, the fact that 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 promulgation of a Food Additive Regulation to permit the use of _____ in blends with other olefin polymers as described herein is environmentally safe in every respect.

12. List of Preparers

- a. Mr. M. Tokuwame, Associate Director, Quality Management Division, Mitsui Chemicals, Inc., 3-1-5, Kasumigaseki, Chiyoda-ku, Tokyo 100, JAPAN.
- b. 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: March 30, 1998

A rectangular box with a red border, used to redact the signature of George G. Misko.

George G. Misko
Counsel for Mitsui Chemicals, Inc.