AMENDED ENVIRONMENTAL ASSESSMENT

1. **Date:** March 9, 1999

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, Jerome H. Heckman, 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. Its purpose is to amend 21 C.F.R. § 177.1520 to expand the compositional range of cleared olefin copolymers based on 4-methylpentene-1. If the requested action is taken, an improved polyolefin food-contact material will be available as an alternative to similar polymers currently permitted for use in contact with food.

Section 177.1520 currently clears 4-methylpentene-1 (4-MP) copolymers with l-alkenes having from 6 to 10 carbon atoms provided the polymer contains a minimum of 95 mole-percent of polymer units derived from 4-MP. This petition requests that the compositional range for these copolymers be expanded to

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permit the use of 4-methylpentene-1 copolymers manufactured with 1-alkenes having 12 to 18 carbon atoms such that the resulting polymer contains not less than 97 molar percent of polymer units derived from 4-MP. It is proposed that these copolymers, marketed by the Petitioner under the tradename TPX, be cleared for use in the same food-contact applications for which 4-MP copolymers with 1-alkenes having 6 to 10 carbon atoms are currently permitted; thus, the polymers are proposed for use in contact with all food types under all conditions of use.

Due to the similarity of TPX to the currently cleared copolymers of 4-MP, the subject copolymers are expected to be used in applications similar to those in which the cleared copolymers are currently employed. The use of TPX in these applications will not alter the use or disposal of the finished food-contact article. Rather, the use of TPX will simply result in an improvement in certain characteristics of the article.

The Petitioner manufactures the subject 4-methylpentene-1 copolymers at its production facilities located in Yamaguchi Prefecture, Japan. The manufacturing process for TPX is comparable to that of the cleared 4-MP copolymers except for

the use of higher molecular weight alkenes as the comonomers. No new manufacturing technologies are involved that might pose new or unique environmental concerns.

The finished 4-MP copolymers will be sold to customers who will use them in the manufacture of food-contact materials. Food-contact articles produced with the use of TPX 4-MP 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 4-MP copolymer food-contact materials.

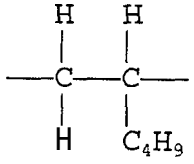
5. Identification of Substance that Is the Subject of the Proposed Action

The additives that are the subject of this Petition are certain olefin copolymers based on 4-methylpentene-1.

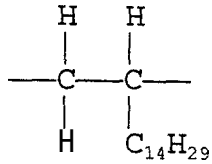
Specifically, the copolymers of interest are those copolymers prepared with at least 97 mole-percent of polymer units derived from 4-methylpentene-1 with the remainder consisting of one or more of the l-alkenes having from 12 to 18 carbon atoms (i.e., C_{12}-C_{18} l-alkenes) . As dealt with by the Petitioner, the copolymers are marketed under the trade name TPX.

Because this Petition deals with a variety of copolymer compositions depending upon which comonomer(s) are used in their manufacture, it is not practical to describe **a** discrete polymer that represents the entire range of products. However, for purposes of illustration, information is provided here for a specific, representative product manufactured by the Petitioner, i.e., a copolymer of 4-MP with C_{16} **and** C_{18} 1-alkenes; The molecular formula for the copolymer is $(C_6H_{12})_x$ $(C_{16}H_{32})_y$ $(C_{18}H_{36})_z$. The structural formulae for the polymer repeating units are as follows:

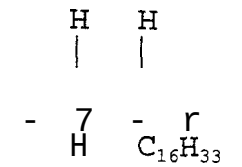
4-Methylpentene-1



1-Hexadecene



1-Octadecene



The Chemical Abstracts Service (CAS) Registry Number for the copolymer is 81229-87-O; the corresponding CAS nomenclature

is l-Octadecene, copolymer with 1-hexadecene and 4-methyl-1-pentene. The molecular structure of the polymer consists of varied lengths of sequences of the units shown above randomly incorporated along the polymer chain. The polymer is typically produced with a 4-MP:1-hexadecene plus 1-octadecene molar ratio of 97:3.

The average molecular weight of the copolymers varies for different applications. Commonly used products have weight-average molecular weights of *520,000 ± 250,000,* and not less than 100,000.

TPX 4-MP copolymers have a density of 0.82 to 0.85 g/cc, a melt temperature of 220 to 250°C, and a minimum intrinsic viscosity of 1.0 dl/g, as determined by the methods described at 21 C.F.R. § 177.1520(d) (1), (d) (8), and (d) (9), respectively.

6. Introduction of Substances into the Environment

No extraordinary circumstances apply to the manufacture of the subject 4-MP copolymers that will result in emissions significantly affecting the quality of the human environment. Consequently, in accordance with 21 C.F.R. Part 25, 'revised as of July 29, 1997 (62 *Fed. Reg.* 40570), information about

environmental introductions resulting from the production of the polymers is not included 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 4-MP 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 4-MP 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

[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 of 4-MP copolymer were exposed to 10% aqueous ethanol at 104°F for 10 days, the average concentration of total nonvolatile (TNV) extractives was 0.2 part per million (ppm), calculated based on 10 grams of food simulant per square inch of surface area. Thus, **0.002** mg of TNV was extracted per square inch of film [i.e., (0.2 μg/g) x (10 g/in^2) ÷ (1000 μg/mg) 1 ; this represents less than 0.004% of the total plaque weight *[i.e.,* (0.002 mg/in^2) ÷ [(0.01 cm) x (2.54 cm/in)^2 **x (0.835** g/cm^3) x (1000 mg/g)] = 3.7 x 10-5, or

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.

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 4-MP copolymers with 1-alkenes having from 12 to 18 carbon atoms. As indicated under Item 15, Appendices, no significant quantities of volatile substances used in the production of the copolymers are released to the atmosphere at the site of manufacture. Moreover, the polymer per se is of high molecular weight and does not volatilize. Data presented in Section B of this Petition demonstrate only

<0.004%].

minute levels of residual l-alkene monomers in the finished polymer." Thus, no significant quantities of these substances will be released upon the use and disposal of food-contact articles manufactured with the use of 4-MP 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. Information provided in Item 6 above demonstrates that no substance will be emitted to aqueous compartments of the environment at levels that could cause any adverse environmental impact. More specifically, there is no significant aqueous release of substances at the site of production or use of the polymer. No significant quantities of

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2/ Specifically, l-hexadecene and 1-octadecene were extracted from the polymer at maximum levels equivalent to approximately 1 microgram per square inch when 0.6 mm plaques were exposed to 95% ethanol at 250°F for two hours plus storage at 120°F for ten days.

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 4-MP 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, either when small quantities of plant scrap or larger amounts of 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 4-MP copolymers with C_{12}-C_{18} 1-alkenes in the manufacture of articles intended for use in contact with food.

a. 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 4-MP copolymers consist of extremely small quantities of the combustion products discussed in Item 6 and of 4-MP/1-alkene copolymer residual monomers and oligomers. The copolymers are expected to be employed in place of other polymeric materials that **are** expected to yield similar combustion products and migrants; these consist primarily of the currently cleared 4-MP copolymers with l-alkenes having from 6 to 10 carbon atoms. The subject copolymers differ from the cleared materials only in the chain length of the permitted 1-alkene comonomers, which are limited to a maximum of 3 mole-% of the polymer. Thus, the use and disposal of the subject 4-MP copolymers in place of 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. Consequently, no effect on organisms in the environment is

expected as a result of the disposal of articles containing 4-MP copolymers with C_{12}-C_{18} 1-alkenes.

9. Use of Resources and Energy

As is the case with other food-packaging materials, the production, use and disposal of 4-MP 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. The polymers primarily expected to be replaced by the subject copolymers are 4-MP copolymers with lower alkenes, *i.e.,* those having from 6 to 10 carbon atoms. The subject copolymers, which consist of a minimum of 97 mole-% of polymer units derived from 4-MP, differ from the cleared 4-MP olefin copolymers only in the chain lengths of the 1-alkene comonomers, which represent a maximum of 3 mole-% of the polymer. The use of the subject 4-MP copolymers in place of the currently cleared polymers is not intended 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 low density (in the range of 0.82 to 0.85 g/cm^3), to the extent they are used in place of polymers of relatively 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 discussed in Section C of this Petition, 4-methylpentene-1 copolymers offer several technological advantages over the currently cleared 4-MP copolymers with C_6-C_{10} 1-alkenes, including improved impact strength. Other important characteristics of the polymers are their transparency and their resistance to heat, boiling water, and oil. In light of these properties, the copolymers are expected largely to be used in housewares applications, such as parts for household appliances, microwave oven cookware, and food service trays, all of which are intended for repeated use. Single-service applications may include articles such as transparent containers and lids for carry-out foods, as well as films and coatings on food packaging materials. The polymers are not expected to be used in the fabrication of bottles.

This expectation is based on the properties of the polymer, which are not suitable to meet the technological requirements for bottles. In particular, TPX has a significantly lower melt viscosity than required to fabricate bottles. (See Attachment 1 showing melt viscosity of TPX to LDPE, which has only limited bottle applications.) The expectation that TPX will not be used to make bottles is further supported by the Petitioner's many years of experience with the use of the closely related 4-MP copolymers with 1-alkenes having from 6 to 10 carbon atoms, which are expected to be replaced by the subject 4-MP copolymers with higher alkenes. Since markets have not been identified for the cleared 4-MP copolymers in bottle applications, the new copolymers likewise are not expected to be used in this way.

Additional illustration of the intended food-contact markets for the polymers is shown in the TPX product brochure provided as Appendix VI. It will be noted that the brochure depicts laboratory containers produced from TPX. These are made from the currently cleared copolymer of 4-methylpentene-1 with 1-decene. While the new copolymers dealt with here offer some desirable properties, the use of the higher comonomers results in properties that make the polymer unsuitable for use in bottles for packaging liquid food such as beverages. In

particular, the new copolymers have insufficient gas barrier properties, and thus allow high oxygen permeation. (See Attachment 2 comparing oxygen permeability of TPX with polyethylene terephthalate (PET).) Moreover, the polymers have low rigidity and thus would not retain their shape if used to fabricate food bottles. Comparison of the melt viscosity, tensile strength, and flexural modulus of TPX with LDPE, which only has limited use in bottle applications, demonstrates that TPX would not be desirable for use in bottle applications. (See melt viscosity data in Attachment 1. See tensile strength and flexural modulus data for TPX and LDPE in Attachment 2.)

The properties of the modified TPX polymers described here clearly make them unsuitable for use in such conventional, mass-market areas 'as bottles for packaging carbonated soft drinks and milk, or in smaller markets such as bottles for juice and other beverages and foods. Thus, the use of the bottles clearly will not have any impact on the types of materials currently used in these applications and thus will not adversely affect recycling programs for such containers. Moreover, were there to be some limited use of TPX in minor, niche container applications, this would have only a negligible impact since the market would be extremely small.

It should also be noted that the current clearance for copolymers of 4-MP with l-alkenes having from 6 to 10 carbon atoms is not limited as to the end-use application for the polymers. Thus, these polymers are now (and have been for many years) permitted for use in any type of container for which they may be technologically suited. Due to the close similarity of the polymers, disposal of finished food packaging materials would be expected to be the same whether produced from the cleared or new 4-MP copolymers. Thus, the replacement of one 4-MP copolymer with another will have no environmental impact.

Food-contact materials produced from'the cleared 4-MP copolymers 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 articles manufactured with the use of the 4-MP copolymers with C_{12} to C_{18} l-alkenes. Consequently, the proposed use of TPX is expected to have no adverse impact on current or future recycling programs for food packaging materials.

10. Mitigation Measures

Measures taken in the plant to recover or safely dispose of excess raw materials and by-products from the manufacture of 4-MP copolymers are described under Item **15,** Appendices.

The only other potential adverse environmental impacts would be those resulting from the use and disposal of articles fabricated from the subject copolymers. **As** shown above, no significant effects on the environment are anticipated; 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 currently cleared 4-MP copolymers which 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 currently cleared 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 4-MP 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 safe use of 4-MP copolymers with 1-alkenes having from 12 to 18 carbon atoms in contact with food is environmentally safe in every respect.

12. List of Preparers

a. Mr. M. Tokuwame, Associate Director, Safety & Quality Assurance Department, Mitsui Chemicals, Inc., 3-2-5, Kasumigaseki, Chiyoda-ku, Tokyo 100, JAPAN.

b. Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Washington, D.C. 20001.

13. Certification

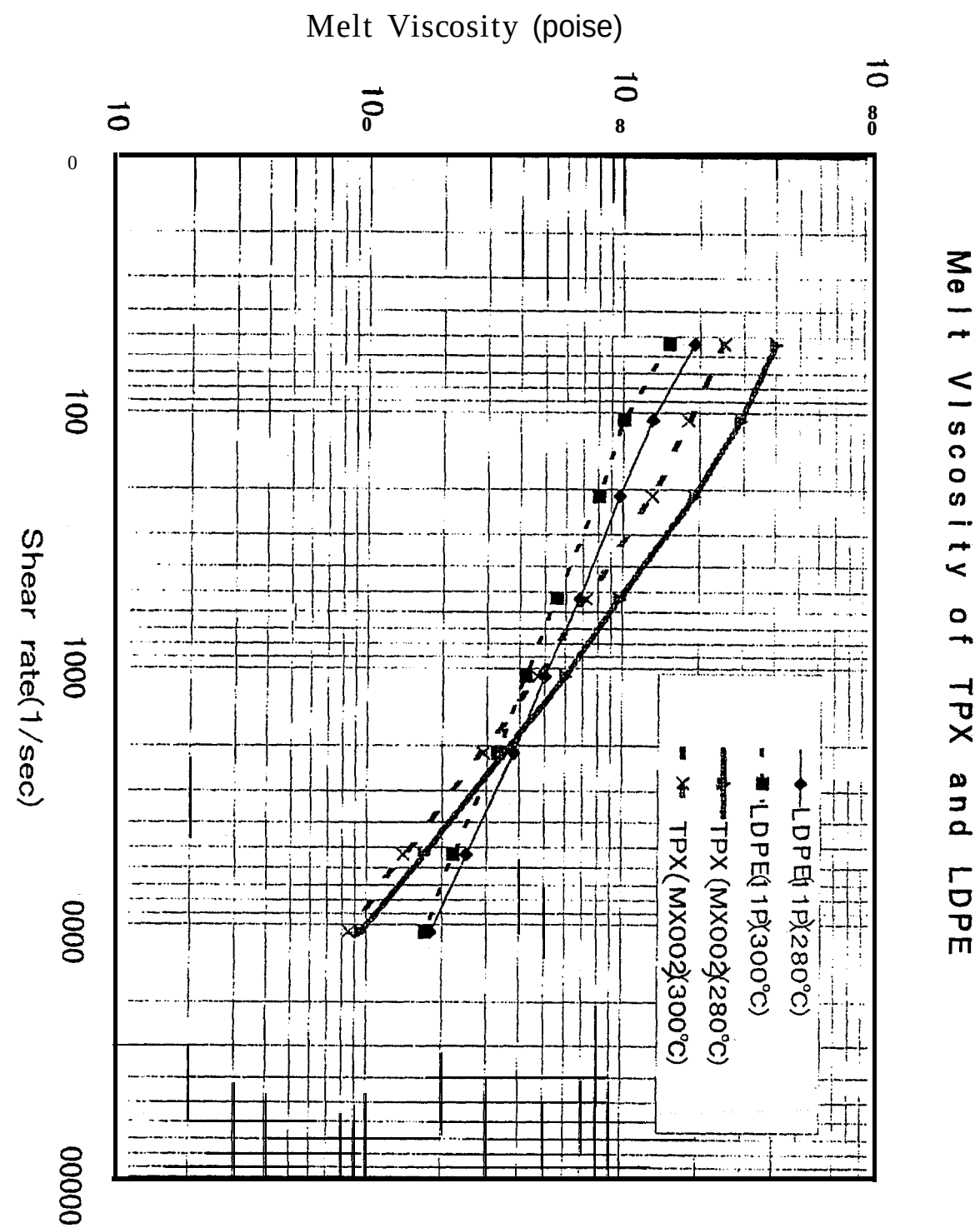
The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: March 9, 1999

Jerome H. Heckman
George G. Misko

Counsel for Mitsui Chemicals, Inc.

Attachment 1



Melt Viscosity of TPX and LDPE

Attachment 2

Phisical properties of TPX, LDPE and PET

Property Test Method		TPX	LDPE	PET
Tensile Strength at break point $kg \cdot cm^2$	ASTM D638	245—280	90-300	
Flexual Modulus $10^3 \cdot kg \cdot cm\text{-}2$	ASTM D790	7.9-18.0	2.5-3.5	
Oxygen permeability $cc/m^2 \cdot d \cdot Mpa$ at 25℃, 90%RH	ASTM D3985	470,000 at 25 m thickness		1,200 at 12 m thickness