

Environmental Assessment

1. **Date** **March 5, 2010**
2. **Name of Applicant/Notifier** Mitsubishi Chemical Corporation
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, NW, Suite 500 West, Washington, DC 20001. Telephone: (202) 434-4170.
4. **Description of the Proposed Action**

The action requested herein is to allow this Food-Contact Notification to become effective so that the Notifier's 1,4-butanediol-polytetramethylene glycol-terephthalic acid block copolymer, reaction products with maleic anhydride may be used as an adhesive layer and as a heat-seal layer in multilayer packages for contact with food. The subject copolymer will be used in contact with all food types in applications under FDA's Conditions of Use A through H, as set forth on FDA's website at www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm109358.htm.

The subject copolymer offers several technical properties that make it useful in certain food-contact applications. Specifically, the food-contact substance (FCS) bonds polyester and polar polymeric materials such as polyamide and ethylene vinyl alcohol (EVOH), and can also be used on metal substrates. These multilayer products are suitable for use in films, bottles, and bags.

The Notifier does not intend to produce finished food packaging materials from the subject copolymer. Rather, the polymer will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the polymer 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 81% of the materials being deposited in land disposal sites, and about 19% combusted.¹

¹ *Municipal Solid Waste in the United States: 2007 Facts and Figures*, EPA530-R-08-010, U.S. Environmental Protection Agency (5305W), Washington, DC, 20460, November 2008. According to this report, of the total of 254.1 million tons of municipal solid waste (MSW) generated in 2007, approximately 54.0% generally was land disposed, 12.6% was combusted, and 33.5% 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
(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 copolymer.

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

The subject of the FCN is 1,4-butanediol-polytetramethylene glycol-terephthalic acid block copolymer, reaction products with maleic anhydride.

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 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 polymer to fabricate packaging materials. In these applications, the polymer 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 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 using the subject copolymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject copolymer consists of carbon, hydrogen, and oxygen, elements that are commonly found in municipal solid waste. The proposed use of the FCS and the market volume (available in a confidential attachment to the FCN) show that (1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 31.9 million tons or 12.6% of 254.1 million tons in 2007, as noted in Footnote 1), (2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors,² and, therefore, (3) incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: 12.6% combusted ÷ (12.6% combusted + 54.0% land disposed) = 19% combusted. The remaining 81% will be land-disposed.

² Paul M. Sullivan; Hallenbeck, W.H.; Brenniman, G.R. *Municipal Solid Waste Combustion*; University of Illinois at Chicago: Chicago, IL, 1993.

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 prevent leachate from entering ground and surface water, and to have groundwater 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 substance is a high molecular weight polymer that contains only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

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 is anticipated due to the proposed use of the subject copolymer. 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 this polymer.

As indicated above in Section 6, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, will not significantly alter the emissions from properly operating municipal solid waste combustors, and will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations when it is incinerated.

(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. The fate of the food-contact substance in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Section 6.

(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 copolymer. In particular, the polymeric nature of the food-contact substance is expected to result in virtually no leaching of the components of the food-contact substance under normal environmental conditions when finished food-contact materials are disposed. Furthermore, the very low production of the food-contact substance for use in food-contact applications precludes any substantial release to the environment of its

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 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 the FCS 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, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the food-contact substance. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Section 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of the use and/or disposal of the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of the subject copolymer involve 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 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 maleic anhydride adducts to polypropylene and polyethylene.

The partial replacement of these types of materials by the subject copolymer is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymer and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of the currently cleared alternative polymers noted above. Moreover, because the FCS provides relatively higher adhesive strength, its use may be seen as having a beneficial effect in terms of resource conservation in that the thickness of the product needed to achieve the intended effect will be reduced. 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. In that case, the FCS is compatible with polyesters, polyamides, and ethylene vinyl alcohol (EVOH). Food-contact materials produced using the subject food-contact substance are expected to be disposed of according to the same patterns when they are used in place of the current materials. Consequently, the proposed use of the polymer is expected to have no adverse impact on current or future recycling programs for 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 polymer. 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 polymer; and the similarity of the subject copolymer to the materials it is 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.

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 copolymer would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the FCS 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 its use, the clearance of the use of the subject copolymer 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, NW, Suite 500 West, Washington, DC 20001.
- 2) Lester Borodinsky, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

13. Certification

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

George G. Misko
Counsel for Mitsubishi Chemical Corporation