

**ENVIRONMENTAL ASSESSMENT
MITSUI CHEMICALS, INC. FOOD CONTACT NOTIFICATION**

1. **Date:** April 21, 2006
2. **Name of Applicant/Notifier:** Mitsui Chemicals, Inc.
3. **Address:** Shiodome City Center 1-5-2 Higashi-Shimbashi
Minato-ku, Tokyo 105-7117 Japan

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
Facsimile: (202) 434-4646
E-mail: misko@khlaw.com

4. **Description of the Proposed Action**

The action requested in this notification is to establish the clearance of the food-contact substance (FCS) that is maleated polypropylene for use as a component of polypropylene used in the fabrication of food-contact articles. With the clearance of this food-contact notification (FCN), the FCS will be used in contact with all food types under Conditions of Use A through H, as set forth in Tables 1 and 2, respectively, of 21 C.F.R. § 176.170(c).

The subject resin offers several technical properties that make it useful in a variety of food-contact applications. In particular, it acts as an adhesion promoter when blended into polypropylene to improve the adhesion between polypropylene and adjoining layers when polypropylene is used in multilayer articles.

000450

~~000450~~

The Notifier does not intend to produce finished food packaging from the subject resin. Rather, the resin will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the resin 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 of the subject resin will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's 2001 update regarding municipal solid waste in the United States, 55.7% of municipal solid waste generally was land disposed, 14.7% was combusted, and 29.7% was recovered for recycling.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 the resin.

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

The FCS that is the subject of this Notification is "2,5-Furandione, polymer with 1-propene," with Chemical Abstracts Service Registry Number (CASRN) 25722-45-6.

¹ *Characterization of Municipal Solid Waste in the United States: 2001 Update*, EPA 530-R-03-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2003.

000451



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 resin. 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 resin to fabricate food-contact articles. In these applications, the resin is expected to be used as a component of food-contact articles, and 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 packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles produced by the subject resin will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The resin consists primarily of carbon, hydrogen, and oxygen. Thus, no toxic combustion products are expected as a result of the proper incineration of the resin.

000452

~~000101~~

Only extremely small amounts, if any, of the resin 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 especially true considering 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.²

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 the resin. 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 resin.

² This expectation is confirmed by the results of calculations of the maximum migration to food described in the FCN. As shown there, worst-case migration calculations, based on an assumption of 100% migration to the food, demonstrate very low levels. Thus, the quantity of leachate from the resin in solid waste deposited in landfills will be extremely small.

000453

The products of complete combustion of the resin 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 polymer in the amounts utilized for food-contact 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 resin. 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 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 resin. In particular, the extremely low levels of maximum migration of components of the resin, demonstrated by the worst-case migration calculations, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Furthermore, the low production of the resin 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 resin.


000454

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 resin 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-contact articles fabricated with the use of the resin consist of extremely small quantities of combustion products and extractables. As discussed in the FCN, the monomers from which the resin is manufactured are not considered to present a substantive genotoxicity or carcinogenicity risk at the minute levels at which they may enter the diet. Furthermore, it is generally recognized that oligomeric substances are of lower potential toxicity than the monomers from which they are produced. Consequently, based on the absence of any concern vis-à-vis the monomers, the oligomers also are not expected to present any toxicological concern. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the resin. In addition, the use and disposal of the resin is not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors, and Part 258 that pertain to landfills.

000455




9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use and disposal of the resin involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject resin 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 resin is intended to be used in food-contact articles which will be used in place of similar materials now on the market for use in food-contact applications. Polymers currently used in the applications in which the subject FCS is anticipated to be used include other adhesion promoters for polypropylene.

The replacement of these types of materials by the resin is not expected to have any adverse impact on the use of energy and resources. Manufacture of the resin, and its conversion to finished food-contact articles, will consume energy and resources in amounts comparable to the manufacture and use of the other adhesion promoters. The clearance requested in this FCN involves use of the resin in polypropylene, a resin that currently is not generally recycled to any significant extent. As PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as polypropylene containing the subject FCS will not be used in such applications, articles fabricated from the subject resin will be disposed by means of sanitary landfill and incineration. Packaging materials produced from the resin are expected to be disposed according to the same patterns as polypropylene currently. Thus, there will be no impact on current or future recycling programs.

000456




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 resin. This is primarily due to the minute levels of leaching of potential migrants from finished food-contact articles, the insignificant impact on environmental concentrations of combustion products of the resin, and the insignificant impact on the use of resources and energy when compared with the materials they are intended to replace. Thus, the use of the resin 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 that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject resin would otherwise replace; such action would have no environmental impact. In view of the fact that the resin components 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 establishment of an effective FCN to permit the use of the subject resin as described herein is environmentally safe in every respect.

000457



12. List of Preparers

Dr. Koji Kitajima, Deputy General Manager, Mitsui Chemicals, Inc., Shiodome City
Center 1-5-2 Higashi-Shimbashi, Minato-ku, Tokyo 105-7117 Japan

Lester Borodinsky, Ph.D., 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: 04-20-06



George G. Misko
Counsel for Mitsui Chemicals, Inc.

000458

