

Attachment No. 16

ENVIRONMENTAL ASSESSMENT

1. **Date:** 01.21.2016
2. **Name of Applicant/Notifier :** Idemitsu Kosan Co.,Ltd.
3. **Address:** 28 Fl. JP Tower, 2-7-2, Marunouchi, Chiyoda-ku, Tokyo, 100-7028, Japan
(All communications on this matter are to be sent to the US Technical Contact for the notifier, William A. Olson, Center for Regulatory Services, Inc., 5200 Wolf Run Shoals Road, Woodbridge, VA 22192-5755 (Telephone No. 703 590 7337))
4. **Description of the Proposed Action**
 - a. **Requested Action:**

The action requested in this Notification is the establishment of a clearance for the food contact substance (FCS), polypropylene which has lower melting point than currently approved polypropylene under 21CFR177.1520(c), in the manufacture of films for contact with food types I , II, IV-B, VI-A, VI-B, VII-B and VIII under FDA Conditions of Use A through H with other authorized polyolefins at levels up to 50 weight percent of the FCS.
 - b. **Need for Action:**

The Notifier does not intend to produce finished food packaging materials or films from the FCS. Rather, the polymers will be sold to manufacturers engaged in the production of food contact applications. The subject polymer improves transparency and gloss of polyolefin films.
 - c. **Location of Use/Disposal:**

Finished food contact articles made from the FCS will be used 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 material being land disposed, combusted, or recycled.

According to the U.S. Environmental Protection Agency's 2013 update regarding municipal solid waste in the United States, 52.8% of municipal solid waste generally was land disposed, 12.9% was combusted, and 34.3% was recovered for recycling.¹

The materials in which the FCS will be used are not expected to be collected for recycling stream. Excluding this means of disposal and assuming that all food contact articles made from the FCS are land disposed or combusted, it is estimated that approximately 80.4% of

¹ *Advancing Sustainable Materials Management: 2013 Fact Sheet*, EPA-530-R-15-003, U.S. Environmental Protection Agency (5306P), Washington DC, 20460, June 2015.

the materials will be land disposed and 19.6% will be combusted.²

The types of environments present at and adjacent to the 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 articles prepared using the FCS.

5. Identification of substance that is the subject of the proposed action

The substance that is the subject of this notification, i.e., the chemical name is polypropylene (CAS Registry No. 9003-07-0), with a lower melting point than the currently authorized polypropylene under 21CFR177.1520(c).

6. Introduction of substance into the environment

a. Result of Manufacture:

The FCS is manufactured in Japan, thus the manufacturing residues will not be introduced into the United States environment. The production facilities for this food contact substance are operated in compliance with the environmental regulations of Japan. No extraordinary circumstances are reasonably known to exist for the manufacture of the FCS that would cause or threaten to cause non-compliance with such regulations.

b. Result of Use:

No environmental release is expected upon the use of the FCS to fabricate food contact materials. The FCS is used as a polymer additive for the improvement of transparency and gloss of polyolefins film and it will be entirely incorporated into finished food contact articles. Any waste materials generated in the process (e.g. plant scraps) are expected to be disposed of as part of the food contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

c. Result of Disposal from Use:

Disposal by the ultimate consumer of food contact articles produced with the FCS will primarily be by conventional rubbish disposal and, thus, will primarily occur by landfill or incineration. The FCS is composed of carbon and hydrogen which are elements commonly found in municipal solid waste. The products of complete combustion would be carbon dioxide and water. Based on the proposed use of the FCS and the expected market volume³, the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 32.8 million tons or 12.9% of 254.1 million tons in 2013).⁴

² The distribution of disposal is calculated as follows:

$\% \text{Land disposed} = 52.8\% \text{Land disposed} / (12.9\% \text{Combusted} + 52.8\% \text{Land disposed}) = 80.4\% \text{Land disposed.}$

$\% \text{Combusted} = 12.9\% \text{combusted} / (12.9\% \text{Combusted} + 52.8\% \text{Land disposed}) = 19.6\% \text{Combusted.}$

³ The expected market volume is provided in a confidential attachment to the Environmental Assessment (Attachment 17 to the FCN).

⁴ See Footnote 1.

With respect to carbon dioxide emissions, we have considered that the combustion of solid waste is the only potential source of carbon dioxide emissions arising from disposal of the FCS; carbon dioxide emissions from the recycling or landfilling of the FCS are expected to be *de minimus*. Based on the confidential market volume, the expected carbon dioxide emissions are below 25,000 metric tons on an annual basis.⁵ In accordance with the Council on Environmental Quality's (CEQ) revised draft guidance on greenhouse gas emissions and climate change impacts⁶, for annual emissions falling below 25,000 metric tons, a quantitative analysis of carbon dioxide emissions is not warranted (unless quantification below that reference point is easily accomplished, which is not case in here). Because the carbon dioxide emissions associated with the FCS will not exceed 25,000 metric tons per year, a quantitative analysis of carbon dioxide is not needed. The FCS will not significantly alter the emissions from properly operating municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 CFR, Part 60, under/or relevant state and local laws).

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food contact articles comprised of the FCS. 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. Landfills also are required to have groundwater monitoring systems (40 CFR Part 258). Although owners and operators of existing 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 ground water and to take corrective action as appropriate. The lack of concern regarding leachate is especially relevant in this case, because the FCS is a hydrocarbon polymer that contains only minute levels of extractable material, even under conditions that greatly exaggerate environmental exposure conditions.⁷

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 FCS. The FCS is high molecular weight polymer 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 FCS.

⁵ The expected market volume and the expected carbon dioxide emissions are provided in a confidential attachment to the Environmental Assessment (Attachment 17 to the FCN).

⁶ *Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts*, Council on Environmental Quality, Dec. 2014.

⁷ This expectation is confirmed by the results of extraction studies described in Attachment 10 to the FCN. As shown there, when 0.5 mm thick test sheets contained 50% of the FCS were extracted with 10% ethanol at 100°C for 2 hours followed by 40°C for 10 days, minute levels of components of the subject substances were found in the extracts at levels less than 10 parts per million (ppm). Thus the quantity of the FCS in leachate of solid waste deposited in landfills will be extremely small.

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Format Item 6. Consequently, evaluation of the environmental fate of the FCS or its combustion products is not required.

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 FCS. No significant introductions of substances into the aqueous environment are anticipated as the result of the proposed use of the FCS as discussed in Format Item 6.

Considering the factors discussed above, no significant effects on the concentrations of and exposure to any substances in terrestrial ecosystems are anticipated as the result of the proposed use of the FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of proposed use of the FCS.

Considering the foregoing, we 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

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6. Consequently, evaluation of the environmental effects of the proposed use of the FCS is not required.

9. Use of resources and energy

As in the case with other food packaging materials, the production, use and disposal of the FCS involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the FCS 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 FCS is intended to be used in partially place of similar polyolefins now on the market for use in food contact applications.

The partial replacement of the polyolefins by the FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS and conversion to finished food contact articles will consume energy and resources in amounts comparable to the manufacture or conversion to similar articles of similar polyolefins. Moreover, the use of the FCS is as a partially replacement for polyolefins which are not currently recovered for recycling.

Food contact materials produced using the FCS 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.

10. Mitigation measures

As shown in above, no significant adverse environmental impacts are expected to result from the use and disposal of food contact materials fabricated from the FCS. This is primarily due to the minutes levels of leaching of potential migrants from the finished articles; the insignificant impact on environmental concentrations of combustion products of the FCS; and

the similarity of the FCS to the materials they are intended to replace. Thus, the use of the FCS as proposed is not reasonable expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternative 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 FCS would otherwise replace; such action would have no environmental impact. In view of the fact that the FCS 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 establishment of an effective FCN to permit the use of the FCS as described herein is environmentally safe in every respect.

12. List of preparers

Naoaki Morotomi, Manager of QC Department, Idemitsu Kosan Co., Ltd., Tokyo, Japan,

Hiroshi Ishiwata, Technical Director, DJK Corporation, Tokyo, Japan

William A. Olson, Ph.D., more than 40 years' experience conducting Food Additive Petitions and Food Contact Notifications, Center for Regulatory Services, Inc., VA, U.S.A

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Idemitsu Kosan Co.,Ltd.

01.21.2016
(date)



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