

An EA Revision Sheet has been prepared for this Environmental Assessment – See the FONSI for this Food Contact Notification

## ENVIRONMENTAL ASSESSMENT

1. **Date:** July 2, 2018
2. **Name of Applicant/Notifier :** Idemitsu Kosan Co.,Ltd.
3. **Address:** 1-1, Marunouchi 3-Chome, Chiyoda-ku, Tokyo, 100-8321, 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, in the manufacture of films for contact with all food types 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 2014 update regarding municipal solid waste in the United States, 52.6% of municipal solid waste generally was land disposed, 12.8% was combusted, and 34.6% was recovered for recycling.<sup>1</sup>

FCS is used by blending with other polymers to produce not only recycled food contact substances but also non-recycled food contact substances. Accordingly, even if used to

---

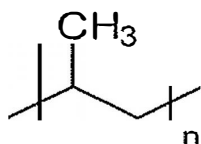
<sup>1</sup> *United States Environmental Protection Agency, Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, November 2016 at: <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report>.

recycleable food contact materials, it is difficult to classify into specific 'recycleable' Resin Identification Code.

If it is used only for applications not covered by recycling, we estimated that 80.4% will be disposed of in the landfill and 19.6% will be combusted.<sup>2</sup>

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

- a. Chemical Name  
polypropylene
- b. CAS Registry Number  
9003-07-0
- c. Trade or Common Name  
L-MODU
- d. Other Chemical Names  
Polypropene, 1-Propene polymers
- e. Molecular Formula



- f. Molecular weight  
Typical weight average molecular weight (Mw) and number average molecular weight (Mn) are ;  
Mw :  $6.2 \times 10^4 \sim 1.0 \times 10^5$   
Mn :  $3.1 \times 10^4 \sim 5.2 \times 10^4$
- g. Physical Property  
Density : 0.90~0.91  
Melting Point : 70 ~ 80°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

---

<sup>2</sup> The distribution of disposal is calculated as follows:  
 $\% \text{Land disposed} = 52.6\% \text{Land disposed} / (12.8\% \text{Combusted} + 52.6\% \text{Land disposed})$   
 $= 80.4\% \text{Land disposed.}$

operated in compliance with the environmental regulations of Japan. No extra-ordinary 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.ee Result of Use:ee

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.ee Result of Disposal from Use:ee

Disposal by the ultimate consumer of food contact articles produced with the FCS will primarily be by conventional rubbish disposal and, thus, will primarily be 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 volume<sup>3</sup>, the FCS will make up a very small portion of the total municipal solid waste currently combusted (indicated to be 33.1 million tons or 12.8 % of million tons in 2014)<sup>4</sup>.

Even though the FCS will make up a very small portion of MSW combusted, since carbon dioxide is a greenhouse gas (GHG) we have analyzed the potential contribution to GHG emissions.

The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of materials containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 CFR Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG". Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO<sub>2</sub>-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 CFR 1508.27(b)(10) states, that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

---

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

<sup>4</sup> See Footnote 1.

” Based on the confidential market volume, the expected carbon dioxide equivalent emission, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting regulated under 40 CFR 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 CFR 60, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

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 Part258).

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 collections systems, they are required to monitor ground water and to take corrective action as appropriate.

## 7. Fate of emitted substances in the environment

The main disposal method of the packaging material which is assumed is a landfill, and partially the combustion is also performed.

### 7-1. 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 FCS. The FCS is a polymer having a mean molecular weight greater than 31,000 Daltons by Number Average Molecular Weight and does not readily volatilize. Further, because the FCS contains only carbon and hydrogen, the products of complete combustion are carbon dioxide and water. As described above, incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations and GHG emissions are below the EPA level for mandatory reporting. Therefore, no significant quantities of any substances will be released upon the use and disposal of finished materials manufactured with the FCS.

### 7-2. Water

No significant effect on the concentrations of, and exposures to FCS in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of FCS or the disposal of food contact articles made from the FCS.

FCS is a high molecular weight polymer, and the exposure of any substance which will be released into the aqueous environment water (river, lake and sea) will be expected to be very small amounts if any as the results of proposed use and disposal (landfill).

### 7-3. Land

No significant effects on the concentrations of, and exposures to, any substances in terrestrial ecosystems are anticipated as a result of the propose use of the FCS and its proper disposal.

Only very small amounts of leaching of the FCS may be expected to occur under normal environmental conditions when finished food contact materials are disposed of. Furthermore, if the FCS were to migrate from the discarded food contact articles, the leachate will be prohibited from entering adjacent ecosystems by proper environmental controls in place at landfill sites.

Thus, there is little expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use.

#### **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 manufactured with the FCS consist of extremely small quantities of combustion products and leachables. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of finished materials containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 CFR Parts 60 and 98 that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

#### **9. Use of resources and energy**

The use of the FCS is not expected to result in an increase in the use of energy and resources, since the FCS is intended to replace other packaging materials, such as polyolefin, sourced from similar materials.

#### **10. Mitigation measures**

The use of Food contact substance is not expected to generate any new environmental impact that requires the mitigation measures of any kind based on the following reasons.

(1) The amount of leaching components of the FCS from finished articles employing the FCS is the minute levels.

(2) The impact on environmental concentrations of incineration products of the FCS is insignificant.

(3) The FCS is intended to replace the similar existing packaging materials.

Thus, there would be no environmental impact from the use of disposal of food contact substance.

#### **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.

12. **List of preparers**

Hiroshi Ishiwata, more than 5 years' experience conducting Food Contact Notifications,  
Technical Director, DJK Corporation, Tokyo, Japan

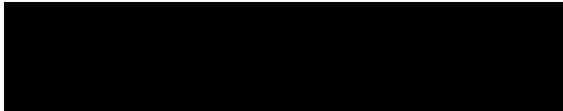
William A. Olson, Ph.D., more than 40 years' experience conducting Food Additive  
Petitions and Food Contact Notifications, Center for Regulatory Services, Inc., VA,  
U.S.A

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.

July 2, 2018

(date)



Global Business Manager  
Adhesive Material Section No.2 (L-MODU)  
Advanced Materials & Performance Chemicals Department  
Idemitsu Kosan Co., Ltd.  
Tokyo, Japan

Idemitsu Kosan  
EA-L-MODU-07-02-2018