

1. **Date:** February 22, 2017
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4. **Description of the Proposed Action**

The action requested in this Food Contact Notification (FCN) is clearance for the food contact substance (FCS), 2-methylene-1,3-propanediol (MPDiol)-modified ethylene-vinyl alcohol (EVOH) copolymer. The MPDiol-modified EVOH copolymers are intended for use as a basic polymer component of films, bottles, and molded articles that may contact all types of food under FDA's Conditions of Use A through H as defined in Tables 1 and 2 at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm>, except for use in contact with infant formula and breast milk.

2-Methylene-1,3-propanediol will be used at a maximum level of 3 percent in the manufacture of MPDiol-modified EVOH copolymers. The finished food-contact article containing the FCS may contact all food types under conditions of use A through H, as described in Tables 1 and 2. The FCS is not for use in contact with infant formula and breast milk. Such uses were not included as part of the intended use of the substance in the FCN.

The FCS is used to manufacture modified EVOH copolymers that have the same superior gas barrier properties as unmodified EVOH, thereby preventing oxygen from entering the packaging and spoiling its contents. Copolymers modified with the FCS also prevent undesirable odors from entering the packaging, and effectively maintains the fragrance and aroma of foods by preventing them from escaping the package. The FCS also has superior processability in that it is more easily processed on package manufacturing equipment.

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS will be sold to formulators engaged in the production of finished food-contact articles. Food-contact articles produced with 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 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 2014 update regarding municipal solid waste in the United States, of the total of 258 million tons of municipal solid waste (MSW) generated in 2014, approximately 52.6% was land disposed, 12.8% was combusted, and 34.6% was recovered for recycling or composting.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 FCS.

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

The FCS that is the subject of this notification is MPDiol-modified EVOH. The modified EVOH copolymers are manufactured into food-contact articles. The finished modified EVOH copolymers shall contain a total of not more than 3.0 mol-percent of the MPDiol monomer units.

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, the Notifier is not aware of data that suggests that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the modified copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided.

No significant environmental release is expected upon the use of the subject copolymers to fabricate food-contact materials. In these applications, the modified EVOH copolymers are expected to be used as the basic polymer to fabricate all forms of food-contact articles, and will be entirely incorporated into the finished articles. 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.

Finished food packaging materials and films produced from the MPDiol-modified EVOH copolymers will be used nationwide. Therefore, food-contact articles and films produced from these copolymers are expected to be disposed of in patterns similar to the current disposal of any other food-contact articles and films, *i.e.*, by conventional rubbish disposal and, hence, primarily

¹ *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

by sanitary landfill or incineration. Because the FCS is expected to be disposed primarily by landfill or combustion (*i.e.*, not recovered for recycling or composting), we adjust the disposal pattern based on the quantities of MSW that are land disposed or combusted. Therefore, about 80.4% of articles containing the FCS are expected to be land disposed with the remaining 19.6% incinerated.²

When food packaging containers and films made from the subject FCS are added to sanitary landfills, no significant amount of leaching of any substance from these materials into the environment is anticipated. Only extremely small amounts, if any, of the polymer 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 a threat of any leaching of the subject FCS is supported by the fact that the FCS is a high molecular weight polymer.

We have compared the market volume information for the FCS, contained in a confidential attachment to the Environmental Assessment (Annex 1- Confidential Environmental Information), to annual municipal solid waste (MSW) production (258 million tons total MSW in 2014),³ and conclude that the FCS will make up a very small portion of the total MSW. Therefore, we do not expect there are any extraordinary circumstances, which otherwise would indicate a significant environmental impact, resulting from post-consumer disposal of articles containing the FCS in sanitary landfills.

With respect to disposal by combustion, the subject copolymer consists of carbon, hydrogen, and oxygen, elements that are commonly found in municipal solid waste. The

² *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf. According to this report, of the total of 258 million tons of municipal solid waste (MSW) generated in 2014, 52.6% generally was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting). As the food-contact substance is expected to be disposed of primarily by land-filling or combustion (*i.e.*, not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19.6% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: $12.8\% \text{ combusted} \div (12.8\% \text{ combusted} + 52.6\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

³ *Ibid.*

proposed use of the FCS and the market volume data (available in a confidential attachment to the Environmental Assessment) show that (1) the FCS will make up a small portion of the total municipal solid waste currently combusted; (2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors; 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).

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance⁴ to agencies regarding addressing GHG emissions and climate change impacts in NEPA documents. This guidance is “intended to help Federal agencies ensure their analysis of potential GHG emissions and effects of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action” (CEQ, 2016 p. 3). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 CFR Part 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG”. Section 2 of this Part (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO₂-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 the 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.” GHG emissions from MSW combustion facilities are regulated under 40 CFR 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, 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 well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

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 copolymers produced from the FCS. The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the copolymers.

⁴ *Advancing Sustainable Materials Management: Facts and Figures 2014*, EPA-530-R-17-001, U.S. Environmental Protection Agency, (5306P), November 2016, at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

(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. No significant quantities of the FCS will enter water systems upon the proper disposal in landfills as the FCS is a high molecular weight polymer and because of the regulations in place to control leaching from landfills (*i.e.*, as discussed under Item 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 copolymers. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

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

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject copolymers in landfills and by combustion, because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject copolymers in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency'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 MPDiol-modified EVOH copolymers involves the use of natural resources such as petroleum products, coal, and the like. Because the copolymers are intended to be used in place of similar materials now on the market for use in food-contact articles, however, the use of the FCS is not expected to result in a net increase in the use of energy and resources. Polymers currently used in such applications include, but are not limited to, polymers having good barrier properties such as nylons and unmodified EVOH copolymers.

The partial replacement of these types of materials by the subject modified EVOH copolymers is not expected to have any adverse impact on the use of energy and resources. Manufacture of the modified EVOH copolymers, and their conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers that it is intended to replace. Moreover, because with the FCS copolymers provide excellent barrier properties in very thin layers, 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 overall intended effect will be reduced.

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 copolymers. Thus, the use of the copolymers as proposed does not require mitigation measures.

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 copolymers would otherwise replace; such action would have no environmental impact. In view of the fact that the 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 establishment of an effective Food Contact Notification to permit the use of the subject copolymers as described herein is environmentally safe in every respect.

12. List of Preparers

Mark A. Hepp, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. As a former FDA staff member, primary and secondary reviews of environmental submissions accompanying indirect food additive petitions assigned to the Office of Food Additive Safety's Special Projects Team were among Dr. Hepp's routine duties.

Joan Sylvain Baughan, Partner, Keller and Heckman LLP, 1001 G Street, NW, 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 her knowledge.

Date: February 22, 2017


Joan Sylvain Baughan
Counsel for Kuraray Company, Ltd.

14. List of References

The following footnotes are found within the Environmental Assessment document:

1. *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.
2. *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf. According to this report, of the total of 258 million tons of municipal solid waste (MSW) generated in 2014, 52.6% generally was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting). As the food-contact substance is expected to be disposed of primarily by land-filling or combustion (*i.e.*, not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19.6% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: 12.8% combusted ÷ (12.8% combusted + 52.6% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.
3. *Ibid.*
4. *Advancing Sustainable Materials Management: Facts and Figures 2014*, EPA-530-R-17-001, U.S. Environmental Protection Agency, (5306P), November 2016, at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

15. List of Attachments

1. Annex 1- Confidential Environmental Information