

Environmental Assessment

1. **Date:** November 25, 2019
2. **Name of Applicant/Notifier:** Kuraray Co., Ltd.,
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All communications on this matter are to be sent in care of Counsel for Notifier:

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4. **Description of the Proposed Action**

The action requested in this notification is to permit the use of acetic acid ethenyl ester, polymer with ethene and ethenol (CAS Reg. No. 26221-27-2) in contact with food. This FCN seeks to clear the use of the FCS polymer alone, or in blends with otherwise cleared polymers, in single-use coffee capsules. The single-use coffee capsules contain ground coffee that is stored under room temperature until brewing, at which the capsules are exposed to water at a temperature of up to 100°C for up to 2 minutes.

The subject FCS offers technical properties that make it useful in coffee capsule applications. In particular, the FCS exhibits high water resistance and low moisture absorption. The FCS is a type of polymer that does not contain chloride atoms and, thus, may be burned without releasing dioxins.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the food-contact substance that is the subject of this Notification will be sold to formulators engaged in the production of food-contact articles. Food-contact articles produced with the food-contact substance 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 80.4% of the materials being

deposited in land disposal sites, and about 19.6% combusted.¹ Recycling of articles manufactured with the FCS is not anticipated.

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

The FCS that is the subject of this Notification is: acetic acid ethenyl ester, polymer with ethene and ethenol (CAS Reg. No. 26221-27-2).

The molecular weight range for the FCS polymer is approximately 50,800 to 120,000.

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 FCS. 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 FCS to fabricate packaging materials. In these applications, the FCS (*i.e.*, a polymer) is expected to be entirely incorporated into and remain with the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as a part of the food-

¹ See EPA's 2015 internet summary of "Advancing Sustainable Materials Management: Facts and Figures", July 2018, available at:

https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf

See also "Advancing Sustainable Materials Management: 2015 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", July 2018 at:

https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf

According to this report, of the total 262 million tons of municipal solid waste (MSW) generated in 2015, 52.5% was land disposed, 12.8% was combusted, and 34.7% was recovered (a combination of waste recovered for recycling and for composting). As the FCS is expected to be disposed 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: $12.8\% \text{ combusted} \div (12.8\% \text{ combusted} + 52.5\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced by the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The subject FCS consists of carbon, oxygen, and hydrogen. Thus, carbon dioxide (which is a greenhouse gas (GHG)) and water are expected to form upon combustion of the FCS. The carbon content of the FCS has been calculated based on the elemental composition of the FCS.

In accordance with 40 C.F.R. § 1508.27 the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context the greenhouse gas (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 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report to GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting. Based on the proposed use of the FCS, the anticipated market volume, and calculations regarding the maximum introduced level of carbon dioxide equivalent as a combustion product, we have quantified the potential carbon dioxide and CO₂ equivalent emissions resulting from combustion of the FCS.

The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis. Furthermore, we have concluded that the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal 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).

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, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills (40 C.F.R. Part 258). 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.² 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 collection 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 resin that contains only low levels of low molecular weight oligomers, which is the portion of the resin that can potentially be leachable.

² 40 C.F.R. Part 258.

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 FCS. The FCS 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 FCS.

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills.

c) Land

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

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. Accordingly, the environmental fate of the FCS does not need to be addressed because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS.

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 FCS consist of extremely small quantities of combustion products and leachate, 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 Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy or resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace materials already on the market for this use. The manufacture of the FCS and use of the FCS in the food-contact applications will consume comparable amounts of energy and resources as similar currently marketed products. The raw materials used in the production of the FCS are commercially manufactured chemicals that are produced for use in various chemical reactions and production purposes. Therefore, the partial replacement of these materials by, and their use in food-contact applications with, the subject FCS is not expected to have any adverse impact on the use of energy and resources.

Food-contact materials produced using the subject 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 discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles made containing the FCS; therefore, the FCS is not expected to result in environmental issues that 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 food-contact substance would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Patricia Kinne, Environmental Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue N.W., Washington, D.C. 20036-1795. Over 20 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Avenue N.W., Washington, D.C. 20036-1795. J.D. with 28 years of experience with Food Additive Petitions, FCN submissions, and environmental assessments.

13. Certification

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

Date: November 25, 2019



Joan Sylvain Baughan
Counsel for Kuraray Co., Ltd., Kuraray America, Inc.,
Kuraray Europe GmbH, and Kuraray Asia Pacific Pte. Ltd.

14. References

1. See EPA's 2015 internet summary of "Advancing Sustainable Materials Management: 2015 Tables and Figures," July 2018, available at: https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf. See also "Advancing Sustainable Materials Management: 2015 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", July 2018 at: https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf.

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2. 40 C.F.R. Part 258.