

Environmental Assessment

1. **Date:** September 27, 2022
2. **Name of Applicant/Petitioner:** Amano Enzyme U.S.A. Co., Ltd.
3. **Address:** All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. Description of Proposed Action

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), identified as 2-propenoic acid, 2-methyl-, 1,1'-(1,2-ethanediyl) ester, polymer with phenylmethyl 2-methyl-2-propenoate (CAS Reg. No. 126969-53-7), when used in food-contact materials.

B. Need for Action

The FCS is intended for use as a solid support for immobilizing lipase enzymes that allow for the production of food oils, except for infant formula ingredients.

C. Location of Use/Disposal

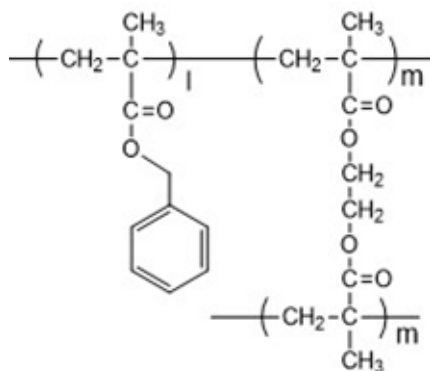
The FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solids waste is currently deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting), and 6.1% was directed to other food management pathways.¹ The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the articles in which they are used.

¹ United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency

(continued ...)

5. Identification of the Subject of the Proposed Action

The subject of this notification is 2-propenoic acid, 2-methyl-, 1,1'-(1,2-ethanediyl) ester, polymer with phenylmethyl 2-methyl-2-propenoate (CAS Reg. No. 126969-53-7). The FCS is a high molecular weight polymer, which cannot be represented by a discrete chemical structure due to the presence of multiple monomeric repeating units. A generalized chemical structure of this substance may be represented as follows:



6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) (“Environmental assessments”), 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 materials. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances² in this case indicative of any significant adverse environmental impact as a result of the manufacture of the subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected when the subject FCS is used as a solid support for immobilizing lipase enzymes that allow for the production of food oils. The

Management, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

² Such extraordinary circumstances would include: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

FCS will be used entirely at industrial sites. Any waste material generated during the manufacture of the finished articles, *e.g.*, plant scraps, is expected to be disposed as part of the finished article manufacturer's overall nonhazardous solid waste in accordance with established procedures. The FCS is intended for single use as a solid support for immobilizing lipase enzymes and, therefore, will not be reused or regenerated. Disposal of the FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

According to the U.S. Environmental Protection Agency's update regarding municipal solid waste in the United States, it is estimated that, of the of 292.4 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% generally was land disposed and 11.8% was combusted, with the remainder variously managed via recycling, composting, or other food management pathways.³ 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 the percentage of food-contact materials containing the FCS combusted annually as follows:

$$11.8\% \text{ combusted} \div (11.8\% \text{ combusted} + 50.0\% \text{ land disposed}) = 19.1\% \text{ combusted.}$$

The remainder: $100\% - 19.1\% = 80.9\%$, will be land-disposed.

For purposes of evaluating the potential greenhouse gas (GHG) emissions from combustion of food-contact materials containing the FCS, we assume that 19.1% of the materials containing the FCS will be disposed of by combustion. Based on the confidential market volume and formular carbon composition of the FCS, the expected carbon dioxide equivalent emissions can be calculated, as shown in the confidential attachment to the EA, and are below 25,000 metric tons on an annual basis.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment. Such facilities are regulated by the 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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting. The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Further, when materials containing the FCS are combusted, there is nothing to suggest they would threaten a violation of 40 CFR 60 and 62.

As the estimated GHG emissions are below the threshold for mandatory reporting, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 CFR Part 60, 40 CFR Part 98.2, and/or relevant state and local laws). Therefore, no significant environmental adverse impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

³ See FN 1.

With respect to land disposal of the FCS, EPA regulations require all 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 ground-water monitoring systems (40 CFR Part 258 and Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, when materials containing the FCS are combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60 and 62. As such, no significant environmental impacts are anticipated resulting from combustion of articles containing the FCS in MSW combustion facilities.

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 below the threshold for mandatory reporting, no significant environmental adverse impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60, 40 C.F.R. Part 98.2, and/or relevant state and local laws).

EPA regulations require all 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 ground-water monitoring systems (40 C.F.R. Part 258 and Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfills.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS. The FCS will make up a very small portion of the municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60 compliant operating municipal solid waste combustors to threaten a violation of applicable emission laws and regulations.

B. Water

No significant effects on the concentrations of and exposures to any substances in freshwater, 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. Similarly, no significant effects on the concentrations of and exposures to any substances are anticipated as a result of the proposed use of the subject FCS. The fate of the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

C. Land

Considering the factors discussed above, no significant effects on the concentration of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS.

Considering the foregoing, the environmental fate does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS was identified under Item 6.

8. Environmental Effects of Released Substances

As discussed above, we do not expect the FCS to be released to the environment. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulation in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal waste combustors and Part 258 that pertain to landfills. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS.

9. Use of Resources and Energy

As is the case with other food contact materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS as solid support for immobilizing lipase enzymes is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used as a component of food-contact materials in which similar products that are already on the market (*e.g.*, solid supports for immobilizing enzymes) are used. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated with the subject FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No significant adverse effects are identified herein which would necessitate alternative actions to those proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed enzyme support materials that the subject FCS would replace. Such action would have no environmental impact.

12. List of Preparers

1. Mitzi Ng Clark, J.D., Partner, Keller and Heckman LLP, Three Embarcadero Center, Suite 1420, San Francisco, CA 94111. Ms. Clark has over 19 years of experience counseling and representing corporate entities on Food Contact Notifications, including Environmental Assessments.
2. Michael A. Hubbard, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Dr. Hubbard has over 3 years of preparing Food Contact Notifications, including Environmental Assessments. Dr. Hubbard has 30 years of total experience in FDA regulated industries.

13. Certification

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

Date: September 27, 2022



Mitzi Ng Clark
Counsel for Amano Enzyme U.S.A. Co., Ltd.

14. List of References

The following footnotes are found within the Environmental Assessment document:

1. FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.
2. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

15. Appendices

1. Confidential Attachment to Environmental Assessment.