

## Environmental Assessment

1. **Date:** September 20, 2022
2. **Name of Applicant/Notifier:** Kaneka North America
3. **Address:** Kaneka North America  
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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 the Notifier's food-contact substance (FCS), pentaerythritol (CAS Reg. No. 115-77-5), which has the molecular formula  $C_5H_{12}O_4$  and the chemical formula  $C(CH_2OH)_4$ , for use at levels not to exceed: 1) 1.5% in poly((R)-3-hydroxybutyric acid-co-(R)-3-hydroxyhexanoic acid) (PHBH; CAS Reg. No. 198007-37-3) in contact with aqueous, acidic, and fatty foods (Food Types I-V, VIB, and VII-IX) under Conditions of Use C through G 2) 1.0 weight percent in PHBH, in contact with alcoholic beverages containing up to 8 percent of alcohol (Food type VIA) under Conditions of Use E through G. PHBH is cleared by way of Kaneka North America LLC's Food Contact Notification (FCN) 1835.<sup>1</sup> The FCS is for use as a nucleating agent in the manufacture of PHBH authorized under FCN 1835 for use in the manufacture of food materials, except for use in contact with infant formula and human milk.

Pentaerythritol, the FCS, is currently permitted, under FCN No. 2069, for use at up to 1% in the manufacture of PHBH authorized under FCN 1835, in contact with all foods except foods containing more than 8% alcohol, infant formula, and human milk, under Conditions of Use E ("Room temperature filled and stored (no thermal treatment in the container)") through G

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<sup>1</sup> FCN 1835 is listed on FDA's online inventory of effective FCNs at the following link: <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=FCN&id=1835>. FCN 1835 permits the use of PHBH in the manufacture of food-contact materials that contact all food, except food having more than 8% alcohol, under Conditions of Use B ("Boiling water sterilized") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"). PHBH is not intended for use in contact with infant formula and human milk.

("Frozen storage (no thermal treatment in the container)"). The FCS is also authorized for use, under FCN No. 2116,<sup>2</sup> at up to 1.5% in the manufacture of polymers of 3-hydroxybutyric acid with up to 25% 3-hydroxyvaleric acid, 3-hydroxyhexanoic acid, 3-hydroxyoctanoic acid, and/or 3-hydroxydecanoic acid authorized under FCN 1398,<sup>3</sup> under Conditions of Use C ("Hot filled or pasteurized above 150 °F") through G.

The objective of this FCN is to expand upon FCN No. 2069 to increase the use level of pentaerythritol to 1.5% in PHBH, authorized under FCN 1835, and to expand the Conditions of Use to encompass Condition of Use C through G. The material used by the notifier would be a competitive replacement for pentaerythritol currently marketed in the US.

Food-contact materials containing the FCS 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 of food-contact materials containing the FCS will occur nationwide. It is estimated that of the 35.68 million tons of plastics present in municipal solid waste (MSW) generated in 2018, approximately 75.5% generally was land disposed, 15.8% was combusted, and 8.7% was recovered for recycling.<sup>4</sup> As the FCS is used in a resin that 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 17.3% of food-contact materials containing the FCS will be combusted annually.<sup>5</sup>

Food-contact materials containing the FCS may ultimately be subject to composting because polyhydroxyalkanoate (PHA) polymers, like PHBH, are compostable. Based on the scarcity of composting facilities nationally, and source controls at the limited existing facilities, the Notifier expects the FCS to be disposed of almost entirely by landfill.<sup>6</sup> Thus, the majority of

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<sup>2</sup> FCN 2116 is listed on FDA's online inventory of effective FCNs at the following link: [https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN&id=2116&sort=FCN\\_No&order=DESC&startrow=1&type=basic&search=1398](https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN&id=2116&sort=FCN_No&order=DESC&startrow=1&type=basic&search=1398).

<sup>3</sup> FCN 1398 is listed on FDA's online inventory of effective FCNs at the following link: [https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN&id=1398&sort=FCN\\_No&order=DESC&startrow=1&type=basic&search=1398](https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN&id=1398&sort=FCN_No&order=DESC&startrow=1&type=basic&search=1398).

<sup>4</sup> United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States*, November 2020 (Page 4, Table 1). Available at the following website: [https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_ff\\_fact\\_sheet.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf) (accessed May 2022).

<sup>5</sup>  $15.8\% \text{ combusted} \div (15.8\% \text{ combusted} + 75.5\% \text{ land disposed}) = 17.3\% \text{ combusted}$ . The remaining 82.7% will be land-disposed.

<sup>6</sup> This is further supported by the EPA's *Advancing Sustainable Materials Management: 2018 Tables and Figures*, U.S. Environmental Protection Agency, December 2020, Table 24. Products Recycled and Composted in MSW, 2018, page 38, accessed May 2022, at:

(continued ...)

articles containing the FCS will ultimately be land-disposed or combusted. No significant adverse environmental impact is anticipated due to the landfilling or incinerating of compostable PHBH. We did not account for composting in our quantitative CO<sub>2</sub> assessment because the value determined based on incineration provides a worst-case scenario with respect to greenhouse gas emissions. In any event, should some composting of food-contact materials containing the FCS occur, the Notifier does not expect this to adversely impact the environment.<sup>7</sup>

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

The FCS that is the subject of this Notification is pentaerythritol (CAS Reg. No. 115-77-5), which has the molecular formula C<sub>5</sub>H<sub>12</sub>O<sub>4</sub> and the chemical formula C(CH<sub>2</sub>OH)<sub>4</sub>.

*Chemical Abstracts Service (CAS) name:* 2,2-Bis(hydroxymethyl)-1,3-propanediol

*CAS Registry Number:* 115-77-5

*Structural Formula:*



*Physical Description of FCS:*

Physical Form: white solid

Melting Point: 260°C

## 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 food-contact materials. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 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

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[https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_tables\\_and\\_figures\\_fnl\\_508.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf), which confirms that food, yard trimmings, and other municipal solid waste (MSW) organic materials are the categories of waste that are composted in the U.S.; plastics are not included among the materials reported to be composted.

<sup>7</sup> See EPA's *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Material Generation and Management in the United States*, December 2020, accessed May 2022, available at:

[https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_ff\\_fact\\_sheet.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf).

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 and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. In these applications, the FCS (*i.e.*, an additive for PHBH) is expected to be entirely incorporated into 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-contact material manufacturer's overall nonhazardous solid waste in accordance with established procedures.

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

The subject FCS consists of the elements carbon, hydrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS have been calculated in a confidential appendix to the Environmental Assessment, and an assessment of these worst-case releases is also included in the same confidential appendix.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of packaging 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. 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 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalents (CO<sub>2</sub>-e) emission threshold for required reporting.

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. The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis (provided in a Confidential Attachment to Environmental Assessment). As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

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 landfill.

## **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 subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with this 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.

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. Similarly, 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 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 subject FCS in the manufacture of food-contact articles and packaging intended for use in contact with food.

## **8. Environmental Effects of Released Substances**

As discussed under Item 6 above, significant environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion are not anticipated as 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 substance 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. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

## **9. Use of Resources and Energy**

As is the case with other food-contact 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 subject FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because it will replace use of other additives.

Manufacture of the FCS, its use in PHBH, and the final conversion to finished food-contact articles and packaging will consume energy and resources in amounts comparable to the manufacture and use of other additives. Articles and packaging materials produced from PHBH containing the FCS are expected to be disposed of according to the same patterns when used in

place of current materials. Thus, there will be no impact on current recycling programs. Importantly, PHBH containing the FCS is not recycled and would instead be removed from the recycling stream based on source control procedures.<sup>8</sup>

#### **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 FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

#### **11. Alternatives to the Proposed Action**

No significant 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 FCS would otherwise replace; such action would have no significant impact.

#### **12. List of Preparers**

Mitzi Ng Clark, Partner, Keller and Heckman LLP, Three Embarcadero Center, Suite 1420, San Francisco, CA 94111. Over 19 years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

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. Over 3 years of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 31 years of total experience in FDA regulated industries.

#### **13. Certification**

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



Mitzi Ng Clark  
Counsel for the Notifier  
Date: September 20, 2022

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<sup>8</sup> See NatureWorks LLC, “Using Near-Infrared Sorting to Recycle PLA Bottles,” at: [https://www.natureworkslc.com/~media/The\\_Ingeo\\_Journey/EndofLife\\_Options/mech\\_recycli ng/20090708\\_NatureWorks\\_UsingNIRSortingtoRecyclePLABottles\\_pdf](https://www.natureworkslc.com/~media/The_Ingeo_Journey/EndofLife_Options/mech_recycli ng/20090708_NatureWorks_UsingNIRSortingtoRecyclePLABottles_pdf), detailing a method for sorting biopolymers from traditional plastic resins.

**14. References**

1. *Advancing Sustainable Materials Management: 2018 Tables and Figures, Assessing Trends in Material Generation and Management in the United States*, December 2020. Available at the following website:  
[https://www.epa.gov/sites/default/files/2020-11/documents/2018\\_tables\\_and\\_figures\\_fnl\\_508.pdf](https://www.epa.gov/sites/default/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf).

**15. Appendices**

1. Confidential Environmental Information