1.	**Date:**	May 2, 2023
2.	**Name of Applicant/Petitioner:**	Perstorp AB
3.	**Address:**	All communications on this matter are to be sent in care of Counsel for the Notifier: Mark Thompson, Partner Keller and Heckman LLP 1001 G Street, NW, Suite 500 West Washington, DC 20001 Telephone: (202) 434–4252 E-mail: thompson@khlaw.com

4. Description of Proposed Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), identified as 1,4-benzenedicarboxylic acid, polymer with 1,2-ethanediol and β,β,β',β',-tetramethyl-2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol (CAS Reg. No. 102070-64-4), when used in food-contact materials. The FCS is intended for use in contact with all food types, not including infant formula and human milk, under (1) Conditions of Use C through G as set forth in Tables 1 and 2, where the spiro glycol content constitutes approximately 25 mol% total glycol units in the polyester; and (2) Conditions of Use B through H as set forth in Tables 1 and 2, where the spiro glycol content constitutes approximately 35 mol% total glycol units in the polyester.[1]

The subject polymer offers several technical properties that make it useful in certain food-contact applications. Specifically, the subject polymer has a higher glass transition temperature (Tg), and therefore has a higher resistance to heat than typical polyethylene terephthalate (PET). Further, because the FCS is an amorphous polymer, it has a high transparency and therefore can be easily molded.

The Notifier does not intend to produce finished food packaging materials from the subject polymer. Rather, the polymer will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the polymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the country.

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[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.

Therefore, it is anticipated that disposal of the FCS will occur nationwide. According to the U.S. Environmental Protection Agency's 2020 update regarding municipal solid waste in the United States, it is estimated that, of the 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% of municipal solid waste generally was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.[2]

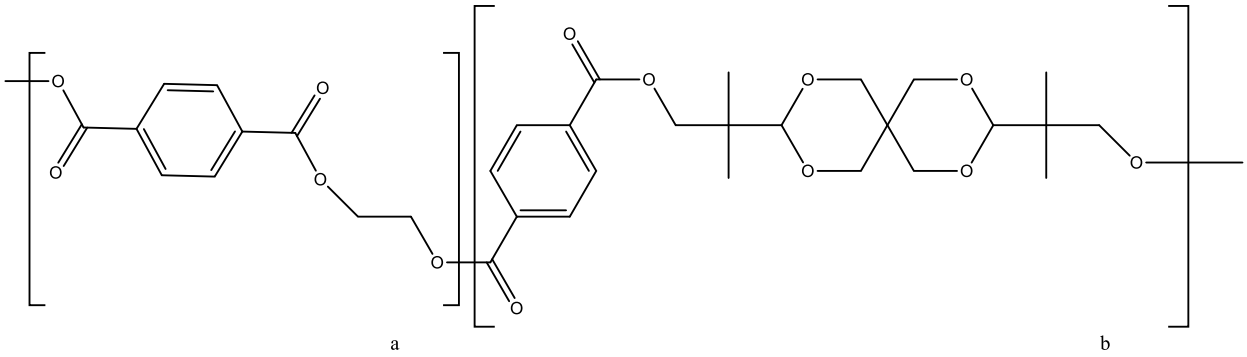
The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the subject FCS.

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

The FCS that is the subject of this notification is 1,4-benzenedicarboxylic acid, polymer with 1,2-ethanediol and β,β,β',β',-tetramethyl-2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol (CAS Reg. No. 102070-64-4). Chemical information on this substance is presented below:

CAS Registry Number: 102070-64-4

Structural Formula:



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 circumstances that would indicate the potential for significant 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

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[2] *Advancing Sustainable Materials Management: Facts and Figures 2018,* U.S. Environmental Protection Agency, accessed June 2022, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

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 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 polymer will 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 as part of the food-contact material manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal of the finished food-contact materials containing the FCS will be by recycling or conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. The subject polymer 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 release of carbon dioxide from the FCS has 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.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles comprised of the FCS in 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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalents (CO2-e) emission threshold for required reporting.

GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW combustion facilities to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or

relevant state and local laws). Based on the estimate market volume of the FCS (identified in a confidential attachment to the EA) used in the requested applications, the expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting, no significantly environmental impacts are anticipated as a result of the combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, oxygen, and hydrogen, elements that are commonly found in MSW. 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 and/or relevant state and local laws).

We compared the confidential market volume information for the FCS (contained in a confidential attachment to the EA), to the annual MSW generation (292 million tons), and to the portion of that total that is landfilled (146 million tons) and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled. Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of landfill disposal of food-contact articles comprised of the FCS, in light of EPA's regulations governing municipal solid waste landfills. (40 C.F.R. Part 258).

7. Fate of Emitted Substances in the Environment

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. The FCS polymer is of high molecular weight and does not volatize. 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 the FCS.

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 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 substance 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 FCS in the manufacture of food-contact materials and articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a

result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the polymer is not expected to threaten a violation of applicable laws and regulation, *e.g.*, the U.S. EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to MSW 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 or resources since the FCS will replace the use of other food-contact materials. Polymers currently used in the applications in which the subject FCS is anticipated to be used include traditional polyethylene terephthalate (PET) and other polyester polymers that are currently permitted under FCN 1135.

The partial replacement of these types of materials by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the polymer and the final conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of the currently cleared alternative polymers noted above.

For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this Notification becoming effective.

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 significant environmental impacts that require mitigation procedures.

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 FCS would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Mark Thompson, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Over twelve years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

Rachel D. Deese, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Two years of experience preparing FCN submissions and Environmental Assessments in support of the same.

13. Certification

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

Date: May 2, 2023

Signature:  _____

14. References

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: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed June 2022, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

15. Appendices

1. Confidential Addendum to Environmental Assessment