Environmental Assessment

1. Date: July 22, 2022

2. Name of Applicant/Notifier: Palsgaard A/S

3. Address: 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), oleic acid, mono ester with oxybis(propanediol) (also known as diglyceryl monooleate (DGMO)) (CAS Reg. No. 49553-76-6 or 9007-48-1), as an antistatic/antifouling agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers. The finished materials made with the FCS are intended for use in contact with all food types, including infant formula and human milk, under FDA's Conditions of Use A ("High temperature heat-sterilized (e.g., over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use") and J ("Cooking at temperatures exceeding 250°F").[1] The Notifier's FCS would be a competitive replacement for the same FCS with essentially identical uses authorized by effective FCN 2037 (albeit at slightly higher use levels in the manufacture of polypropylene).

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of polypropylene and polyethylene that will, in turn, be used to fabricate food-contact films and articles. Food-contact materials produced with the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. According to the U.S. Environmental Protection Agency's (EPA) update regarding municipal solid waste (MSW) in the U.S., it is estimated that, of the 292,360,000 tons of MSW generated in 2018, 50.0% of MSW was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management

[1] FDA's food types and Conditions of Use are defined in Tables 1 and 2, *available at*: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

pathways.[2] As the FCS, an additive in polyolefins, is expected to be primarily disposed of through recycling, combustion, or land-filling (*i.e.*, not composted or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed, recycled, or combusted. On this basis, we estimate that 13.8% of food-contact materials containing the FCS will be combusted annually.[3]

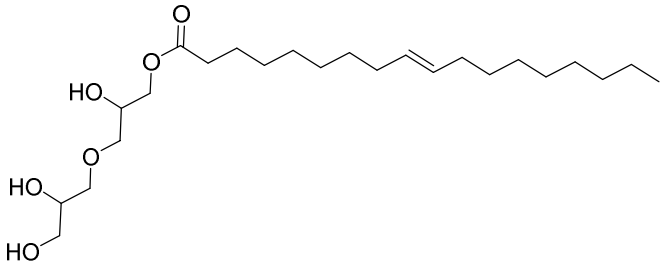
5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is oleic acid, mono ester with oxybis(propanediol) or diglyceryl monooleate, CAS Reg. No. 49553-76-6.

Chemical Abstracts Service (CAS) Name: Oleic acid, mono ester with oxybis(propanediol)

CAS Registry Number: 49553-76-6 or 9007-48-1[4]

Structural Formula:



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. The Notifier is not aware of any information to suggest that there are any 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 (40 C.F.R. § 1508.27(b)(10)); or (3)

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[2] 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 3, Figure 3). Available at the following website: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[3] 11.8% Combusted ÷ (11.8 % combusted + 23.6 % recycled + 50% land disposed) = 13.8% combusted.

[4] CAS Reg. No. 49553-76-6 is specific to diglyceryl monooleate. CAS Reg. No. 9007-48-1 more broadly encompasses polyglycerol oleates, including diglyceryl monooleate.

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 the manufacture of food-contact materials. The FCS will be used as an additive in polypropylene and polyethylene which, in turn, are used to fabricate all forms of food-contact articles. The FCS will be entirely incorporated into the finished food-contact article and is expected to remain with these materials throughout the use of the FCS in the food-contact applications and use/disposal by the consumer. 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.

Disposal by the ultimate consumer of 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 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 this worst-case release 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 MSW combustion facilities. Such facilities are regulated by the 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 (CO2-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 the 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's 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 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 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 articles manufactured with this 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 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 articles 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 FCS 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 FCS in landfills or by combustion are 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. However, the use of the subject FCS in the fabrication of food-contact polymers is not expected to result in a net increase in the use of energy and resources because it is intended to be used as a replacement for other antistatic/antifouling agents, particularly DGMO cleared by FCN 2037, currently on the market for use in food-contact applications.

Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of DGMO that are currently permitted. Packaging materials containing the FCS are expected to be disposed of according to the same patterns when used in place of current materials. As a low-level additive in polypropylene and polyethylene, no significant impact on current recycling programs is anticipated.

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 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 anticipated environmental impact.

12. List of Preparers

Kristin P. Wiglesworth, Ph.D. in Chemistry, 5 years of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 16 years of total experience in FDA regulated industries. Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C. 20001.

Rachel A. Bond, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Bond has a J.D., with many years of experience drafting 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: July 22, 2022

Rachel A. Bond
Counsel for Palsgaard A/S

14. References

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2, *available at*: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. 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.
Available at the following website:

https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

3. 40 C.F.R. Part 258.

15. Appendices

1. Confidential Environmental Information (**CONFIDENTIAL**) (Attachment 11).