

<https://www.fda.gov/Food>, see [Environmental Decisions under Ingredients and Packaging \(Search FCN 2378\)](#)

1. **Date** May 24, 2024 \*
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:  
  
Rachel Bond, Partner  
Keller and Heckman LLP  
1001 G Street, N.W., Suite 500 West  
Washington, D.C. 20001  
Telephone: (202) 434-4131  
Facsimile: (202) 434-4646  
E-mail: [bond@khlaw.com](mailto:bond@khlaw.com)

#### 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), lauric acid, monoester with oxybis(propanediol) (diglyceryl monolaurate (DGML), CAS Reg. No. 96499-68-2). The FCS is intended for use at levels not to exceed 80 parts per million (ppm) as an antistatic/antifouling agent in the manufacture of polypropylene and polyethylene homopolymers and copolymers under Conditions of Use A through H and J.<sup>1</sup> The Notifier's FCS is a competitive replacement for the same FCS permitted for use by TORs 1998-021, 1998-005, and 1996-007<sup>2</sup> and an alternative to diglyceryl monooleate (a related compound), which is permitted under FCNs 2213 and 2244 for use as an antistatic/antifouling agent in the manufacture of PP and PE homopolymers and copolymers.

---

<sup>1</sup> 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>.

<sup>2</sup> TOR 1998-021 permits the use of polyglycerol esters of fatty acids regulated in 21 C.F.R. § 172.854 at a maximum level of 0.15 mg/in<sup>2</sup> as antifogging agents in polyolefin films complying with 21 C.F.R. § 177.1520 ("Olefin polymers"). TOR 1998-005 permits the use of polyglycerol esters of fatty acids regulated in 21 C.F.R. § 172.854 at a maximum level of 0.14 mg/in<sup>2</sup> as antifogging agents in all types of films. TOR 1996-007 permits the use of polyglycerol esters of fatty acids regulated in 21 C.F.R. § 172.854 as an adjuvant (*e.g.*, antifogging agent or antistatic agent) in polypropylene films regulated under Section 177.1520 and having a maximum thickness of 100 microns.

\* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several corrections to harmonize the EA to the final FCN regulatory language.

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 plastics 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. Therefore, it is anticipated that disposal of the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste (MSW) generally.<sup>3</sup> According to the U.S. Environmental Protection Agency's (EPA) update regarding 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 pathways.<sup>4</sup> As the FCS, an additive in plastics, 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.<sup>5</sup>

---

<sup>3</sup> *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, 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).

<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 3, Figure 3). 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).

<sup>5</sup>  $11.8\% \text{ MSW combusted} \div (11.8\% \text{ MSW combusted} + 23.6\% \text{ MSW recycled} + 50\% \text{ MSW land disposed}) = 13.8\% \text{ combusted}$ .

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

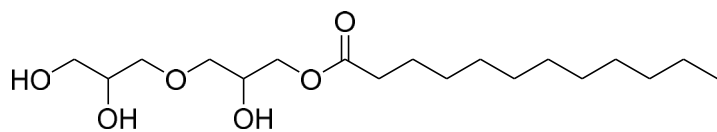
**Food Contact Substance:** Lauric acid, monoester with oxybis(propanediol)

**Chemical Abstracts Service (CAS) Registry Number:** 96499-68-2

**Molecular Weight ( $M_w$ ):** 348.5 g/mol

**Molecular Formula:**  $C_{18}H_{36}O_6$

**Representative Chemical Structure:**



## 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 aware of no information suggesting the existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS. 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. 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 as well as in polymer films more generally. The FCS will be entirely incorporated into the finished food-contact articles or films 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.

As noted above, the FCS consists of carbon, hydrogen, and oxygen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. The carbon content of the FCS has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (available in the confidential attachment to the EA) and is below 25,000 metric tons carbon dioxide equivalent (CO<sub>2</sub>-e) emission per MSW combustor (MSWC) on an annual basis.<sup>6</sup> Thus, the concentration of carbon dioxide in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications.

Furthermore, 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 (*i.e.*, 40 CFR Part 60, 40 CFR Part 98.2, and/or relevant state and local laws). In this context, the U.S EPA, under 40 CFR 98, “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG.” This regulation describes that facilities must report GHG emissions and sets an annual 25,000 metric ton CO<sub>2</sub>-e threshold for required reporting (40 CFR 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 CFR 98.30(a). 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.

Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact materials, in light of the EPA regulations governing MSW landfills. EPA’s regulations require new MSW 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, “to have ground water monitoring systems and to take corrective action as appropriate (40 CFR Part 258).” 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 FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

## **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 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

---

<sup>6</sup> The U.S. has an estimated 75 MSWCs. See US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), available at: <https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-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.

As discussed above in Section 6, combustion of the FCS will not significantly alter the emissions from properly operating MSW combustors, and the incineration of food-contact materials containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (*see* Confidential Attachment for additional details).

## **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**

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 food-contact articles and films containing 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 polyglycerol fatty acid esters (PGEs), including diglyceryl monooleate, which are already authorized for use as (1) an antistatic/antifogging additive as permitted in TORs 1998-021, 1998-005, and 1996-007 or as (2)

an antifouling agent used in the manufacture of polypropylene and polyethylene homopolymers and copolymers, consistent with FCNs 2244 and 2213.

Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of other PGEs currently authorized for use. 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, 7 years of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 18 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: May 24, 2024

  
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](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**)