

An EA Revision Sheet has been prepared for this Environmental Assessment – See the FONSI for this Food Contact Notification

Environmental Assessment

1. **Date** March 7, 2017
2. **Name of Applicant** Perstorp Holding AB
3. **Address** Communications to be sent care of:
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4. Description of Proposed Action

a. Requested Action

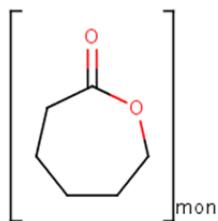
The action requested in this food contact notification (FCN) is to permit the use of the substance polycaprolactone (CAS Reg. No. 24980-41-4) (hereinafter PCL, the food contact substance, or FCS) as a polymer in blends with polylactide (PLA) polymers and thermoplastic starch (TPS) polymers intended for use in food contact applications, except for use in contact with infant formula and breast milk. The FCS is intended for use in these blends at levels up to 35%. Polymer blends produced with the FCS may be used in contact with all types of food and under Conditions of Use B through H as described in FDA's Tables 1 and 2.¹

b. Need for Action

Use of the FCS in PLA and TPS blends provides several technical advantages. When used in PLA blends, PCL provides added thermal stability, toughness, and transparency to the polymer. When used in TPS blends, PCL improves strength and elongation.

5. Identification of Substances that are Subject of the Proposed Action

The FCS is polycaprolactone (CAS Reg. No. 24980-41-4), with a chemical formula of $(C_6H_{10}O_2)_n$, where n represents the repeating unit. One unit of the polymer has a molecular weight of 114.143 and the following structure:



The FCS is intended for use as a polymer in the production of polymeric blends with PLA and TPS for use in food contact applications.

1

<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm>.

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

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 FCS is primarily intended to be manufactured in plants outside of the United States. When manufactured in the US, the plants meet all applicable federal, state and local environmental regulations. 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 (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action 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 environmental release is expected upon the use of the FCS in the manufacturing of finished packaging materials. The FCS 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 part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Finished articles containing the FCS are expected to be utilized in patterns corresponding to the national population density and widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide. According to the US Environmental Protection Agency's (EPA) 2014 update regarding municipal solid waste in the United States, which is the most recent data available, 65.4% of MSW was not recycled, of which 52.6% of MSW was disposed in landfills or elsewhere and 12.8% was combusted.² Thus, based on the above numbers, 80.4% of the material not recycled is land disposed and 19.6% is combusted.³ Articles produced with the FCS are intended as alternatives to similar polymer materials currently permitted under FDA regulations and effective food contact notifications. Packaging materials produced with PLA or TPS polymers are not currently recovered for recycling to a significant extent, but rather are disposed by landfill or incineration.⁴ Packaging materials produced from the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the

² U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Fact Sheet*, November 2016, pg. 5, Figure 4. Available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

³ $12.8\% \text{ combusted} \div (12.8\% \text{ combusted} + 52.6\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

⁴ See EPA, *Advancing Sustainable Materials Management: 2014 Tables and Figures*, December 2016, Table 8, pg. 10, which identifies the level of PLA recycled as negligible, https://www.epa.gov/sites/production/files/2016-11/documents/2014_smm_tablesfigures_508.pdf.

current materials. Although finished materials containing the FCS, when used in blends with PLA and TPS per the specifications of this FCN, may be marketed as compostable, such products are compostable only in industrial or commercial composting facilities. As industrial/commercial composting is not a typical disposal pathway in the U.S. at this time, the pathway and impact are not considered in this EA. In addition, it is not anticipated that materials containing the FCS will be marketed as recyclable and these materials are not expected to contaminate current recycling streams. Moreover, any items that inadvertently end up in the process stream should be easily removed as part of every company's source control practices.

Indeed, in its *Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations*, FDA recommends that recyclers implement "controls on the source of the post-consumer polymer, adequate sorting procedures for the incoming post-consumer material, use limitations on the finished recycled packaging (such as use at room temperature or below), or food-type restrictions (such as dry or aqueous foods only)."⁵ When companies are submitting requests to FDA for No Objection Letters (NOL) on their recycling processes, they are supposed to submit "a description of the source of the recyclable plastic and a description of any source controls in place intended to ensure that only plastic that initially complied with the applicable regulations is recycled."⁶ Moreover, the emergence of next generation near-infrared recycling equipment is enabling the sorting of plastics using each material's unique spectral signature. This technology facilitates the effective separation of petroleum-based plastics as well as biopolymers such as PLA and TPS. For these reasons, the FCS is not expected to have any effect on current commercial recycling processes.

The subject resin consists of carbon, hydrogen, and oxygen, elements commonly found in municipal solid waste. To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide and assumed that 19.6% of the market volume will be combusted.

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance⁷ to agencies regarding addressing GHG emissions and climate change impacts in NEPA documents. This guidance is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effects of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action."⁸ 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. Such facilities are regulated by the 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 CO₂-e emission threshold for required reporting.

⁵ See FDA's *Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations* (August 2006), available at

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120762.htm>.

⁶ <https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RecycledPlastics/ucm093435.htm>.

⁷ Council on Environmental Quality (CEQ), *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews*, August 1, 2016, available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf.

⁸ *Id.*, p. 3.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states that when evaluating intensity of an impact, one should consider “whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.” GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. 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 well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

In light of EPA’s regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of finished articles containing the FCS. EPA’s regulations require new municipal 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 groundwater monitoring systems. (40 C.F.R. Part 258.) Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

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 FCS. As described above, the emission of carbon dioxide due to the combustion of finished articles containing the FCS is not expected to be significantly increased. Thus, no significant quantities of any substances will be released upon the use and disposal of finished articles manufactured with the FCS.

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of food packaging employing the FCS, or upon its disposal in landfills.

c. Land

Considering the factors discussed above, 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. As discussed above, EPA’s regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate. Furthermore, the low production of the FCS for use in food-contact applications, as evidenced by the market volume described in the confidential attachment, precludes any substantial release to the environment of the components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

On these bases, 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 food contact applications.

8. Environmental Effects of Released Substances

No significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified above. Therefore, an evaluation of the environmental effects of the proposed use of the FCS is not required. In addition, the use and disposal of finished articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors as the FCS is composed of elements typical of MSW and will comprise a negligible amount of combusted MSW (based information provided in the confidential attachment) and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food contact substances, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The use of the 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 the FCS is intended to be used in packaging which will be used in place of similar polymer materials now on the market for use in food packaging applications. 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 FCS, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of the other polymers with similar physical properties. As discussed in Item 6, packaging materials produced using blends with the subject FCS are not currently recovered for recycling to a significant extent, but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the current materials. Although finished materials containing the FCS may be marketed as compostable, industrial/commercial composting is not a typical disposal pathway in the U.S. at this time and is not expected to significantly increase the use of energy and resources. In addition, it is not anticipated that materials containing the FCS will be marketed as recyclable and these materials are not expected to contaminate current recycling streams.

10. Mitigation Measures

As shown above, there are no significant adverse environmental effects associated with the use of the FCS. Thus, the use of the FCS as described in this notification does not require any specific mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this FCN. If the proposed action is not approved, the result would be the continued use of the currently marketed materials that the subject FCS would replace. Such action would have no environmental impact. The addition of the FCS as a polymer for use in food contact materials to the options available to food packaging manufacturers is not expected to increase the use of the food packaging materials.

12. List of Preparers

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011.

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Attwood has seven years of experience preparing environmental submissions to FDA for the use of food contact substances.

13. Certification

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

Date: March 7, 2016



Mitchell Cheeseman, PhD

14. References

Council on Environmental Quality's *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews*, August 1, 2016.

U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Fact Sheet*, November 2016.

U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Tables and Figures*, December 2016.

U.S. Food and Drug Administration, *Food Types & Conditions of Use for Food Contact Substances*.

U.S. Food and Drug Administration, *Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations* (August 2006).

15. Attachments

Confidential Attachment to the Environmental Assessment.