Environmental Assessment

1. Date: March 21, 2019

2. Name of Notifier: Perstorp AB

3. Address: All communications on this matter are to be sent in care of Counsel for Notifier,
Mitchell Cheeseman, Ph.D.
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

4. Description of the Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of 2,2-bis((pentanoyloxy)methyl) propane-1,3-diyl dipentanoate (CAS Reg. No. 15834-04-5), as a plasticizer at up to 31% in polyvinyl chloride polymers that may be used in the following applications: 1) repeat-use articles, 2) adhesives and pressure-sensitive adhesives that comply with 21 CFR § 175.105 and 175.125, respectively; and 3) as a coating or component of paper or paperboard intended for use in contact with dry foods with no free surface fat or oil in contact with food as a component of food-contact articles in contact with all types of food under Condition of Use B through H.
In applications 1 and 2, the plasticized PVC polymers may be used in contact with all food types. For applications 1 and 3, the plasticized PVC polymers may be used under Conditions of Use A through H, as described in Tables 1 and 2. The FCS is not for use in contact with infant formula and human milk.

The subject FCS is a soft, durable, non-phthalate plasticizer for PVC.

The Notifier does not intend to produce finished food packaging materials containing this FCS; rather it will sell the FCS to manufacturers that are engaged in the production of food contact articles. Food contact articles 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 will occur nationwide with material being land disposed, combusted, composted, or recycled. According to the U. S. Environmental Agency's (US EPA) 2015 update regarding municipal solid waste in the United States, 52.5% of municipal solid waste (MSW) generally was land disposed, 12.8% was combusted with energy recovery at permitted MSW combustion facilities, 8.9% was composted, and 25.8% was recovered for recycling.[1] Assuming that all food-contact articles manufactured with the FCS are land disposed or combusted, it is estimated that approximately 80.4% of the materials will be deposited in land disposal sites and about 19.6% will be combusted.[2]

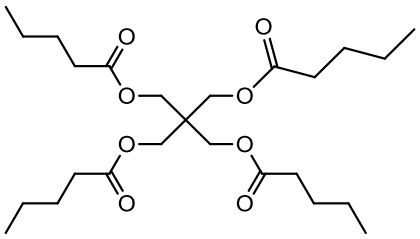
5. Identification of the Subject of the Proposed Action

The subject of this notification is 2,2-bis((pentanoyloxy)methyl) propane-1,3-diyl dipentanoate (CAS Reg. No. 15834-04-5).

[1] US EPA Report: *Advancing Sustainable Materials Management: Tables and Figures 2015, Assessing Trends in Material Generation, Recycling Composting, Combustion with Energy Recovery and Landfilling in the United States. July* 2018. https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf

[2] 12.8% combusted ÷ (12.8% combusted + 52.5% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

The structure may be represented as follows:



Molecular Weight: 472 g/mol
Chemical Formula: $C_{25}H_{44}O_8$

Property	**Value**
Appearance	Slightly yellow liquid
Melting point	< 223 K
Boiling point	408 C
Decomposition Temperature	none
Log P_{OW}	6.1
Water solubility (at 20 C)	<0.01 g/l

6. Introduction of Substances into the Environment

Resulting from manufacture of the FCS:

Under 21 C.F.R. Section 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. Current information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Hence, information on the manufacturing site and compliance with relevant emission requirements is not provided in this Notification.

Resulting from use of the FCS:

No environmental release is expected based on the use of the subject FCS as a component of food-contact materials. In these applications, the FCS will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process are expected to be disposed as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Resulting from disposal of the FCS:

As noted previously, disposal by the ultimate consumer of food-contact materials produced containing the FCS will be by conventional trash disposal and primarily by sanitary landfill or incineration. The FCS is composed of carbon, hydrogen and oxygen. Thus the combustion products of the FCS may include carbon dioxide. The carbon content of the FCS has been calculated, based on the chemical composition (available in the confidential attachment to the EA).

The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of materials 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 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

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."

Based on the confidential market volume, the expected annual carbon dioxide equivalent emission, as shown in the confidential attachment to the EA, is below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting regulated under 40 C.F.R. Part 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 C.F.R. Part 60, 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 (40 C.F.R. Part 258), only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food contact articles manufactured with 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. Landfills also are required to have ground-water monitoring systems. Although owners and operators of existing municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections 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. Articles manufactured containing the FCS do not readily volatilize. As indicated above in Item 6, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured containing 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. As indicated above in Item 6, no significant quantities of any substances will be added to these water systems, so the fate of the FCS in the aqueous environment does not need to be addressed.

C. Land: Considering the factors discussed above, no significant introductions of the FCS to terrestrial ecosystems are anticipated as a result of the proposed use and disposal 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 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.

Herein, we respectfully state that there is no reasonable expectation of a significant impact on any substance in the environment due to the proposed use of the FCS in articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the substances that may be released to the environment upon the use and disposal of food-contact articles containing the FCS are extremely small quantities of combustion products and leachates, if any. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of FCS-containing food-contact articles. The use and disposal of the FCS food-contact articles are not expected to violate applicable laws and regulations, e.g., the EPA regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resource and Energy

The notified use of the FCS will not require additional energy or resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar plasticizers already on the market. In particular, the FCS is expected to compete with the products that are the subject of effective Food Contact Notifications (FCN) 224, 597, 663, 744, 750, 1056, 1126, 1417, 1587 and 1771. The manufacture of the FCS and the use of the FCS in the food-contact applications will consume comparable amounts of energy and resources as similar currently marketed products. The raw materials used in the production of the FCS are commercially manufactured chemicals that are produced for use in various chemical reactions and production purposes. Therefore, the partial replacement of these materials by and for use in food-contact applications with the subject FCS is not expected to have any adverse impact on the use of energy and resources.

The use of the FCS is also not expected to have any impact on current or future recycling programs. As plasticizers are typically added to PVC, to the extent that plasticized PVC containing currently cleared plasticizers is recycled after consumer use, PVC containing the FCS is equally recyclable with these materials.

The FCS is intended for use in certain applications for which no recycling is anticipated (e.g., adhesives used in multilayered laminate structures are not typically recycled, nor are fruit and vegetable labels applied using pressure sensitive adhesives). For food-contact packaging applications, e.g., in paper and paperboard applications, data from the EPA on municipal solid waste (MSW) indicate that recycling of PVC plastic containers and packaging is negligible.[3]

Consequently, the proposed use of the FCS is expected to have no adverse impact on current or future recycling programs.

[3] See Table 8, page 9 of US EPA, *Advancing Sustainable Materials Management: Tables and Figures 2015,* https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf).

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles made containing the FCS, therefore the FCS is not expected to result in environmental issues that require mitigation measures.

11. Alternatives to the Proposed Action

As no potential adverse environmental effects are identified, it is therefore unnecessary to propose alternative actions to that proposed in the Notification. If the proposed action is not approved, food packaging manufacturers would simply continue the use of those materials which this FCS would otherwise replace, resulting in no significant environmental impact.

12. List of Preparers

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Ave., 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 nine 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 21, 2019

Mitchell Cheeseman, PhD

14. References

U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management:* 2015 Tables and Figures, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recover and Landfilling in the United States. July 2018.

15. Attachments

Confidential Attachment to the Environmental Assessment.