Environmental Assessment

1. Date: March 28, 2018

2. Name of Notifier: Peter Greven GmbH & Co. KG

3. Address: All communications on this matter are to be sent to:

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4. Description of the Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of Fatty acids, C14-C20, esters with pentaerythritol, (CAS Reg. No. 68440-28-8), for use in polyethylene terephthalate (PET) and polybutylene terephthalate (PBT) polymers. The FCS may be used as a processing agent, at a level of up to 2% in the finished PET or PBT polymer, in contact with all foods, under Conditions of Use B through H, as described in Table 2[1].

The subject FCS is used as an additive in the plastics industry. Due to its excellent thermal stability, it is used as a lubricant for the processing of thermoplastics, such as PET and PBT.

The Notifier does not intend to produce finished food contact 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 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.[2] 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.[3]

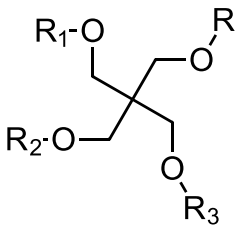
5. Identification of the Subject of the Proposed Action

The subject of this notification is Fatty acids, C14-C20, esters with pentaerythritol, (CAS Reg. No. 68440-28-8), for use in polyethylene terephthalate (PET) and polybutylene terephthalate (PBT) polymers.

[1]https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm

[2] US EPA Report: *Advancing Sustainable Materials Management: Tables and Figures2015, 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

[3] 12.8% combusted ÷ (12.8% combusted + 52.5% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.



R, R_1,R_2 and R_3 = H or $C(=O)(CH_2)_nCH_3$, where n = 12-18

Fatty acids, C14-C20, esters with pentaerythritol
CAS Reg. No. 68440-28-8

The FCS is a structure of variable composition that cannot be represented by a unique structure or molecular formula. Consequently, the molecular weight is also variable.

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 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, which is a greenhouse gas (GHG). 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. The FCS s not expected to volatilize from food-contact articles.

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 the FCS as a result of the proposed use of the FCS.

Herein, we respectfully state that there is no expectation of the FCS being introduced into 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 made 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 the 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 processing aids already on the market. In particular, FCNs 618. The manufacture of the FCS and 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 their 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 not expected to have any impact on current or future recycling programs because processing agents, similar in function to the FCS, are added to PET and PBT that may be recycled. For these reasons, no adverse impacts on the use of natural resources and energy are expected as a result of this Notification becoming effective.

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 significant 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

Naeem Mady, M.Sc.

VP of Regulatory Market Access, *Food Contact and Regulatory Services,* Intertek Health, Environmental and Regulatory Services. With an educational background in Chemistry, Naeem has over 30 years of experience in chemical, health and regulatory consulting.

13. Certification

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

Date: March 26, 2018

[redacted]

Naeem Mady
VP, Regulatory Market Access
Health, Environmental & Regulatory Services
Intertek

14. References

U.S. Environmental Protection Agency, *Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recover and Landfilling in the United States - 2015 Tables and Figures. July 2018*.

15. Attachments

Attachment 4 - Confidential Attachment to the Environmental Assessment.