Environmental Assessment

1. **Date:** February 24, 2022

2. **Name of Applicant/Petitioner:** DuPont Nutrition & Biosciences ApS

3. **Address:** All communications on this matter are to be sent in care of Counsel for Notifier:

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4. Description of Proposed Action

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), hydrogenated castor oil monoglycerides, acetylated (CAS Registry name: octadecanoic acid, 1-(12-acetyloxy)-2,3-bis(acetyloxy)propyl ester; 1-(12-acetoxystearoyl)-2,3-diacetylglycerol); (CAS Reg. No. 736150-63-3), when used in the manufacture of food-contact materials. The polymer is intended for use as a carrier for additives to polypropylene homopolymers and copolymers that contact all types of food, including infant formula and human milk. The FCS is for use at a maximum level of 350 parts per million (ppm) in polypropylene (PP) homopolymers and copolymers.

B. Need for Action

The FCS is intended to be used as a carrier and/or dispersant for additives of polypropylene (PP) homopolymers and copolymers that are used to produce food-contact plastics. The carrier is used to assist in the delivery and blending of additives with the polyolefin base resin in the reaction vessel.

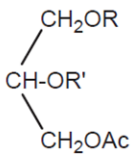
C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solids waste is currently deposited in land disposal sites, 11.8% is combusted with energy recovery, 32.1% is recovered (a combination of waste recovered for recycling and for composting), and 6.1% was processed

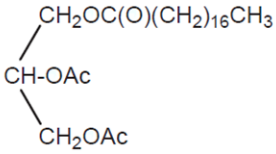
through other food management pathways.[1] The low use level of the FCS in polyolefins will not significantly impact the disposal patterns of the polymeric resins in which they are used.

5. Identification of the Subject of the Proposed Action

The subject of this notification is octadecanoic acid, 1-(12-acetyloxy)-, 2,3-bis(acetyloxy)propyl ester; 1-(12-acetoxystearoyl)-2,3-diacetylglycerol (CAS Reg. No. 736150-63-3). The FCS is not a discrete chemical substance and cannot be represented by a single chemical structure and/or formula. Nevertheless, representative structures of the major and minor components of the FCS: 1- and 2- monoglycerides ($C_{27}H_{48}O_8$) and glycerol 1,2-diacetate 3-octadecanoate ($C_{25}H_{46}O_6$), respectively, are shown below:



Acetylated 1- and 2-monoglycerides



Glycerol 1,2-diacetate 3-octadecanoate
(aka 1-(12-acetoxystearoyl)-2,3-diacetylglycerol)

1-Monoglyceride [aka octadecanoic acid, 1-(12-acetoxy)-, 2,3-bis(acetoxy)propyl ester]
R= $-C(O)(CH_2)_{10}C(H)(OAc)(CH_2)_5CH_3$
R'= $-C(O)CH_3$ (aka -Ac)

2-Monoglyceride [aka octadecanoic acid, 1-(12-acetoxy)-, 1,3-bis(acetoxy)propyl ester]
R= $-C(O)CH_3$(aka -Ac)
R'= $-C(O)(CH_2)_{10}C(H)(OAc)(CH_2)_5CH_3$

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), 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 in this case indicative of any significant adverse environmental impact as a result of the manufacture of the subject FCS.

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[1] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Material Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf. According to this report, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% generally was land disposed, 11.8% was combusted, 32.1% was recovered (a combination of waste recovered for recycling and for composting), and 6.1% was processed through other food management pathways.

Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used in the manufacture of packaging materials. The FCS will be entirely incorporated into the finished article and is expected to remain with these materials throughout the use of the plastics in the packaging applications and use/disposal by the consumer. Any waste material generated in this process, *e.g.*, plant scraps, is expected to be disposed as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal of the finished food-contact materials manufactured with the FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, incineration, or recovery for recycling.

The FCS is composed of carbon, oxygen, and hydrogen. Thus, the combustion products of the FCS include carbon dioxide. The carbon content of the FCS has been calculated based on the elemental composition of the FCS (available in a confidential attachment to the EA).

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. 98.30(a). 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 U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 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 equivalent (CO_2-e) emission threshold for required reporting.

GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulation (*i.e.*, 40 C.F.R. 60 and/or relevant state and local laws).

Based on the estimated market volume of the FCS (available in a confidential attachment to the EA) used in the requested applications, 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 below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, oxygen, and hydrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

We compared the confidential market volume information for the FCS (contained in a confidential attachment to the EA), to the annual MSW production (292 million tons), and to the portion of that total that is landfilled (146 million tons) and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled. 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 articles, in light of the EPA regulations governing MSW landfills. (40 C.F.R. Part 258).

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with these products.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

B. Water

No significant effects on exposures to any substances from the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to its proposed use. The fate of the FCS is the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

C. Land

Considering the factors discussed above, no significant effects on the concentration of and exposure to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the chemical characteristics of the FCS are expected to result in virtually no leaching of FCS components under normal environmental conditions when the food packaging articles in which they are contained are disposed of. Furthermore, the very low production of the FCS for use in food-contact applications precludes any substantial release to the environment of its 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.

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 FCS in the manufacture of food-contact polyolefins. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food packaging materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the polymer is not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The manufacturer of the FCS will consume comparable amounts of energy and resources as similar products already being marketed (such as those described in numerous sections of Part 178 of Title 21 of the Code of Federal Regulations), as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles. Because the FCS is used at an exceedingly low level in the manufacture of polyolefins, there will be no significant impact on current or future recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated within the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished food-contact materials, and the insignificant impact on environment concentrations of combustion products of the FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would replace. Such action would have no significant environmental impact.

12. List of Preparers

1. George G. Misko, J.D., Over 30 years of experience evaluating and preparing all aspects of Food Additive Petitions and Food Contact Notifications, Partner, Keller

and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

2. Peter N. Coneski, Ph.D. in Chemistry, 8 years of experience evaluating and preparing all aspects of Food Additive Petitions and Food Contact Notifications, Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

3. Rachel D. Deese, Ph.D. in Chemistry, 9 months of experience evaluating and preparing all aspects of Food Contact Notifications, Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

13. Certification

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

Date: February 24, 2022 George G. Misko

Counsel for DuPont Nutrition & Biosciences ApS

14. Reference

The following footnote is found within the Environmental Assessment document:

1. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

15. Attachment

1. Confidential Attachment to Environmental Assessment.