Part IV – Environmental Information (21 C.F.R. Part 25)

Environmental Assessment

1. **Date**: October 1, 2021

2. **Name of Applicant/Notifier**: Daikin America, Inc.

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

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4. **Description of the Proposed Action**

A. Requested Action

The action requested in this Notification is to provide for the use of the food-contact substance (FCS) 2-propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with 2-(C_{16-18} acylamino)ethyl acrylate and 4-hydroxybutyl acrylate, acetates (salts) as a grease-proofing agent in the manufacture of paper and paperboard. More specifically, the FCS will be added at the size press to impart grease and oil resistance to paper and paperboard, except food for infants, under Conditions of Use A ("High temperature heat-sterilized (*e.g.*, over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use").[1]

B. Need for Action

This FCS is intended to impart grease and oil resistance to food-contact paper and paperboard. The FCS is intended to serve as an alternative for the short-chain fluorotelomer chemistries that have been used as grease-proofing agents for paper in food-contact applications.

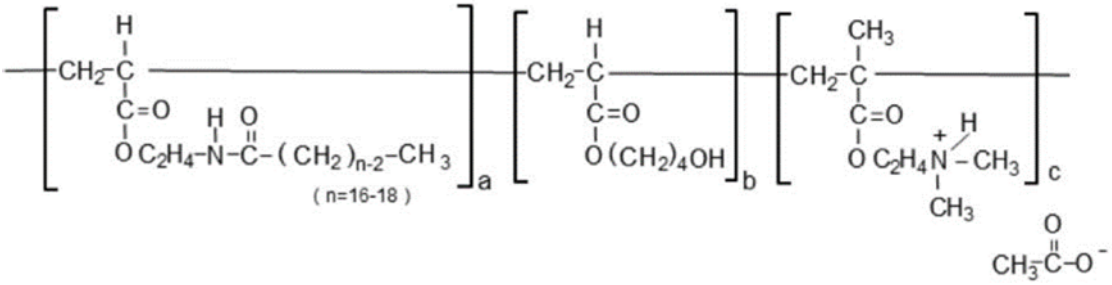
[1] FDA's food types and Conditions of Use are defined in Tables 1 and 2, *available at*: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

C. Locations of Use/Disposal

Paper and paperboard containing the FCS will be used in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of food-contact materials containing the FCS will occur nationwide. It is estimated that, of the 67,390,000 tons of paper and paperboard present in municipal solid waste (MSW) generated in 2018, approximately 25.6% was land disposed, 6.2% was combusted, and 68.2% was recovered for recycling.[2] The low use level of the FCS in paper and paperboard will not impact the disposal patterns of the products in which the FCS is used.

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

The FCS that is subject of this Notification is 2-propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymers with 2-(C_{16-18} acylamino)ethyl acrylate and 4-hydroxybutyl acrylate, acetates (salts) (CAS Reg. No. 2374117-56-1).



6. Introduction of Substances into the Environment

A. As a Result of Manufacture

An environmental assessment should focus on relevant environmental issues relating to the use and disposal from use rather than the production of FDA-regulated articles (21 C.F.R. § 25.40(a)). Information available to the Notifier suggests no extraordinary circumstances, in this case, indicating any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided.

B. As a Result of Use and Disposal

No significant adverse environmental release is expected upon use of the subject FCS. The FCS (*i.e.*, a polymer) is expected to remain with the finished food-contact article in this application. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be

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[2] *Advancing Sustainable Materials Management: 2018 Tables and Figures*, U.S. Environmental Protection Agency, November 2020, Table 8 (Plastics in Products in MSW, 2018), page 10, accessed January 2021, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures. Disposal by the ultimate consumer of food-contact articles containing the subject FCS will occur by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The FCS is composed of carbon, hydrogen, nitrogen, and oxygen. These are elements that are commonly found in municipal solid waste (carbon, hydrogen, and oxygen) or mitigated via Clean Air Act regulations. Specifically, Section 129 of the Clean Air Act (CAA) directs the Administrator to develop regulations under Section 111 of the Act limiting emissions of nine air pollutants (*i.e.*, particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from four categories of solid waste incineration units: municipal solid waste; hospital, medical and infectious solid waste; commercial and industrial solid waste; and other solid waste.[3] The disposal of the FCS, therefore, does not threaten a violation of 40 C.F.R. Part 60, which establishes emissions requirements for certain stationary sources, because the FCS is composed of elements commonly found in municipal solid waste (MSW).

Further, only extremely small amounts, if any, of the FCS constituents are expected to enter the environment from landfill disposal of food-contact articles containing the FCS in light of the U.S. Environmental Protection Agency's (EPA's) regulations at 40 C.F.R. Part 258 governing municipal solid waste landfills. These EPA 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 ground-water 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.

The greenhouse gas (GHG) emissions may result from the combustion of paper and paperboard containing the FCS in municipal solid waste facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 98, which "established 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 (CO_2)-emission threshold for required reporting. Title 40 C.F.R. § 1508.27 defines 'significantly' as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (NEPA) documents. Title 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. The expected carbon dioxide equivalent emissions have been estimated based on the 5-year market volume projection of the FCS. This assessment is fully described in the confidential attachment to this Environmental Assessment and is far below

[3] *See*, for example, https://www.epa.gov/stationary-sources-air-pollution/small-municipal-waste-combustors-smwc-new-source-performance and https://www.epa.gov/stationary-sources-air-pollution/large-municipal-waste-combustors-lmwc-new-source-performance.

25,000 metric tons on an annual basis. No significant environmental impacts are anticipated resulting from combustion of food-contact articles containing the FCS in MSW combustion facilities because the estimated GHG emissions are far below the threshold for reporting. Further, food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustors, as the FCS contains carbon, oxygen, hydrogen, and nitrogen, 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).

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 is a high molecular weight polymer and does not volatilize. No significant adverse environmental impacts are anticipated to result from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released into the atmosphere upon the use and disposal of food-contact materials manufactured with this FCS.

The FCS will make up a very small portion of the total MSW currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating MSW combustors, and incineration of 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. The fate of the FCS in 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

Similarly, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated to result from the proposed use of the subject FCS. EPA's regulations at 40 C.F.R. Part 258 require MSW owners to operate their facilities to prevent leaching from sanitary landfills. Furthermore, the polymeric nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when food-contact articles containing the FCS are disposed in sanitary landfills. Thus, there is no expectation of any meaningful exposure of these substances to terrestrial organisms resulting from the proposed use(s) of the FCS.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, 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 the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the EPA'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

The notified use of the FCS will require no additional energy resources for the treatment and disposal of wastes as the FCS is expected to replace short-chain fluorotelomer chemistries currently on the market. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the polymer are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. The use of this FCS as an alternative to other grease-proofing products now on the market for use in this application will have no significant impact on the use of resources and energy.

Paper and paperboard products containing the FCS will be disposed of according to the same patterns used currently for paper products generally. No impact on current recycling programs is expected because the FCS is used at a very low level in the manufacture of paper products.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of the FCS when present in food-contact paper and paperboard. Therefore, the FCS is not reasonably expected to result in any new environmental issues that require mitigation measures.

11. Alternatives to the Proposed Action

No adverse effects are identified herein that 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 currently marketed grease-proofing agents now on the market for use in paper and paperboard. Such action would have no significant environmental impact.

12. List of Preparers

Devon Wm. Hill, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Mr. Hill has a J.D., with many years of experience drafting FCN submissions and environmental assessments.

Mark Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Dr. Hepp has a Ph.D. in Chemistry with many years of experience with FCN submissions and environmental assessments.

13. Certification

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

Date: October 1, 2021

[redacted]

Devon Wm. Hill
Counsel for Notifier

14. List of 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. Advancing Sustainable Materials Management: 2018 Tables and Figures, U.S. Environmental Protection Agency, November 2020, Table 8 (Plastics in Products in MSW, 2018), page 10, accessed January 2021, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.