Environmental Assessment

1. Date: August 28, 2020

2. Name of Applicant/Notifier: Avery Dennison Corporation

3. Address:

Avery Dennison Corporation
8080 Norton Parkway
Mentor, Ohio 44060

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4. Description of the Proposed Action:

The action requested in this notification is to permit the use of a food-contact substance (FCS), a polymer of butyl acrylate and 4-hydroxybutyl acrylate, with a methylene diphenyl diisocyanate-based crosslinker, for use as an adhesive at a coat weight of 23 g/m^2 in contact with all types of food, except infant formula and breast milk, 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]

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 2017, approximately 52.1% of municipal solid waste is currently deposited in land disposal sites, 12.7% is combusted, and 35.2% is recovered (a combination of waste recovered for recycling and for composting).[2]

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

[2] *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation

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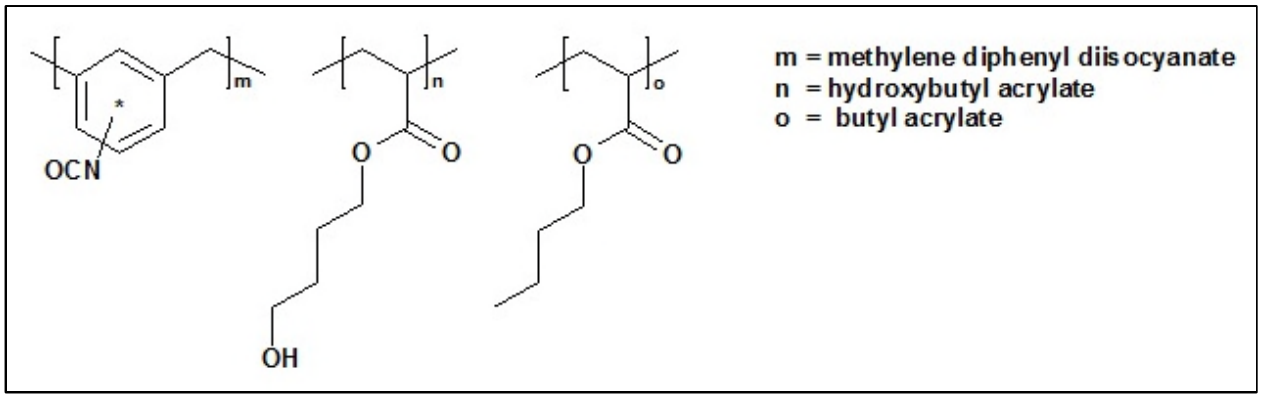
5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is a polymer of butyl acrylate and 4-hydroxybutyl acrylate, with a methylene diphenyl diisocyanate-based crosslinker, which is intended for use as a food-contact adhesive, including on labels intended to reclose packaged food. The FCS is composed of the elements carbon, hydrogen, oxygen, and nitrogen. The chemical structures for the FCS monomers are provided below:



The FCS is a relatively high molecular weight polymer and, therefore, it is inherently non-volatile. In addition, the molecular weight of the FCS is set out in the confidential attachment to the Environmental Assessment.

6. Introduction of Substances into the Environment

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

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

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and Recovery, November 2019, *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf. According to this report, of the total 268 million tons of municipal solid waste (MSW) generated in 2017, approximately 52.1% generally was land disposed, 12.7% was combusted, and 35.2% was recovered (a combination of waste recovered for recycling and for composting).

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 the subject FCS will occur by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

As noted above, the FCS is composed of carbon, oxygen, nitrogen, and hydrogen, elements that are commonly found in municipal solid waste. Because of EPA's regulations governing landfills (40 C.F.R. Part 258), and the marginal amount of the FCS that would be landfilled only very small amounts of the FCS is expected to be introduced to land, and to an even lesser extent water. Similarly, because of the composition of the FCS and the low market volume of the FCS, it is not anticipated that combustion of the FCS would threaten a violation of EPA regulations governing MSW combustion facilities (40 C.F.R. Part 60). As secondary support that disposal of the FCS will not significantly impact the environment, we compared the market volume information for the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual municipal solid waste (MSW) production (268 million tons MSW in 2017), and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there is a significant environmental impact resulting from post-consumer disposal of the FCS. Further, the proposed use of the FCS and corresponding market volume (available in the Confidential Attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which EPA has indicated to be 34.0 million tons, as of 2017.[3] 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 (40 C.F.R. Part 60 and/or relevant state and local laws).

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (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 to GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-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." In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action

[3] *See* Footnote 1.

threatens a violation of federal, state, or local laws imposed for the protection of the environment. MSW combustion 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.

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 Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. 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 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 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. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

The composition of the FCS is similar to other MSW incinerated at MSW combustion facilities, and the analysis in the confidential attachment to the EA supports the use of the FCS as described in the Notification will not exceed the EPA GHGRP threshold of 25,000 metric tons.

(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 polymer. 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

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. In particular, the polymeric nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when articles containing the FCS are disposed in sanitary landfills. Further, the low production volume of food-contact articles containing the FCS precludes any substantial release of its

components to the environment. The regulations at 40 C.F.R. 258 prevents MSW components from leaching from landfills. 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 polymer in contact with food. 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 previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer consist of extremely small quantities of combustion products and leachables, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS.

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. However, the use of the subject FCS is not expected to result in a net increase in the use of energy and resources, because the FCS will be used in place of other adhesives on the market.

Manufacture of the FCS and its conversion to use in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of other, similar FCSs. Food-contact materials produced using the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no significant impact on current recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of the subject FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the

action proposed herein would simply result in the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

Jeffery A. Keithline, B.A. Physics, J.D., Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001; 22 years of experience counseling and representing corporate entities on Food Additive Petitions and Food Contact Notifications, and assisting in the preparation of same, including Environmental Assessments.

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001; 4 years of experience evaluating and preparing Food Contact Notifications, including Environmental Assessments.

13. Certification

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

Date: August 28, 2020

[redacted]

Jeffrey A. Keithline
Counsel for Avery Dennison Corporation

14. List of References

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

2. *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf.

15. List of Attachments

1. Confidential Attachment