

An EA Revision Sheet has been prepared for this Environmental Assessment – See the FONSI for this Food Contact Notification

## Environmental Assessment

1. **Date:** October 26, 2016
2. **Name of Applicant/Notifier:** Avery Dennison Corporation
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#### 4. **Description of the Proposed Action:**

The action requested in this notification is to permit the use of 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 21 g/m<sup>2</sup> in reclosure labels for packaged food under Conditions of Use C (“Hot filled or pasteurized above 150°F”) through H (“Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use”), as defined in Table 2 at

<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm>.

The food contact substance (FCS) is the adhesive component of a reclosure label that provides the ability to “reseal” packaged food after it has initially been opened by the consumer.

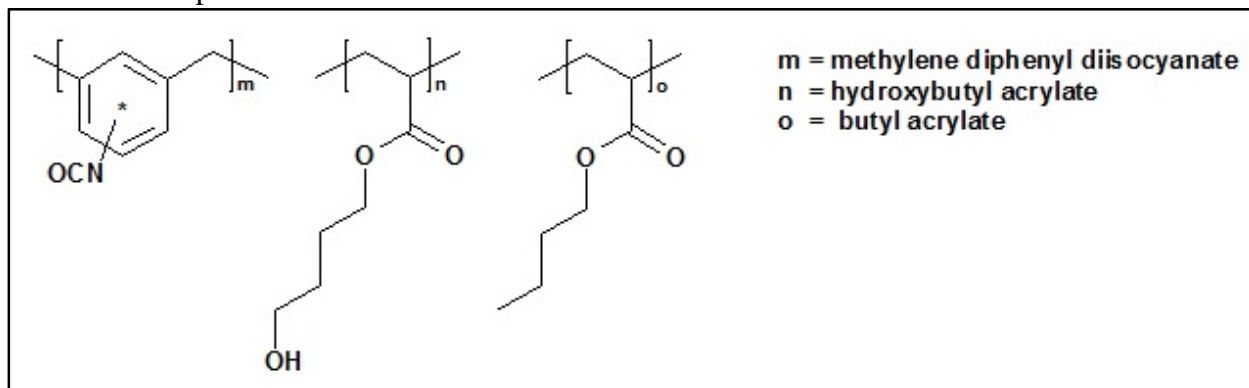
Reclosure labels containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.<sup>1</sup>

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<sup>1</sup> *Advancing Sustainable Materials Management: 2013 Fact Sheet, Assessing Trends in Material Generation, Recycling and Disposal in the United States*, EPA530-R-15-003, U.S. Environmental Protection Agency, Solid Waste and Emergency Response (5306P), June 2015. See [http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013\\_advncng\\_smm\\_fs.pdf](http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_fs.pdf). See also [http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013\\_advncng\\_smm\\_rpt.pdf](http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_rpt.pdf).

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

The FCS that is the subject of this Notification is a component of a pressure sensitive adhesive consisting of a polymer of butyl acrylate and 4-hydroxybutyl acrylate, with a methylene diphenyl diisocyanate-based crosslinker, which is intended to be applied as a viscous liquid to various substrates intended for labels used 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. 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 environmental release is expected upon the use of the subject FCS to fabricate reclosure labels. In these applications, the FCS (*i.e.*, a polymer) is expected to remain with the finished food-contact article/closure. Any waste materials generated in this process, *e.g.*, plant

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According to this report, of the total 254.1 million tons of municipal solid waste (MSW) generated in 2013, approximately 52.8% generally was land disposed, 12.9% was combusted, and 34.3% was recovered (a combination of waste recovered for recycling and for composting). As reclosure labels containing the FCS are expected to be disposed of by land-filling or combustion (*i.e.*, not recovered for recycling), we will recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19.6% of reclosure labels containing the FCS will be combusted annually. This amount is calculated as follows: 12.9% combusted ÷ (12.9% combusted + 52.8% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

scraps, are expected to be 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 reclosure labels containing 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. Accordingly, the disposal of the FCS does not threaten a violation of 40 C.F.R. Part 60 because the regulations at 40 C.F.R. Part 258 prevent leaching of the FCS from sanitary landfills. 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.

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 (254.1 million tons MSW in 2013), and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there are any extraordinary circumstances that would otherwise suggest a significant environmental impact resulting from post-consumer disposal of reclosure labels that contain 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, estimated to be 12.9% of 254.1 million tons, or 32.8 million tons, as of 2013.<sup>2</sup>

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance<sup>3</sup> to agencies regarding addressing greenhouse gas (GHG) emissions and climate change impacts in NEPA documents. As stated in the guidance, the document is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effect of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action." The 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

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<sup>2</sup> See Footnote 1.

<sup>3</sup> Council on Environmental Quality (CEQ) Final Guidance for Federal Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Review, dated August 1, 2016, *available at*: [https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa\\_final\\_ghg\\_guidance.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf).

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<sub>2</sub>-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.” 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.

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 reclosure labels containing 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).

## **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, as the FCS is a high molecular weight polymer and thus non-volatile.

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. EPA's regulations at 40 C.F.R. 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 the reclosure labels are disposed in sanitary 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 the manufacture of reclosure labels intended to contact 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 reclosure labels containing 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 reclosure labels containing the FCS. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

## **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 in the fabrication of reclosure labels is not expected to result in a net increase in the use of energy and resources, since the FCS will be used in place of non-reclosable adhesives on the market.

Manufacture of the FCS, and its conversion to use in reclosure labels, 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 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 reclosure labels fabricated using the subject FCS. Thus, the use of

the FCS as proposed is not reasonably expected to result in environmental problems requiring 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 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; 18 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.


Jason P. Schmidt, Ph.D. in Chemistry, Senior Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001; 7 years of experience evaluating and preparing Food Contact Notifications, 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; less than 1 year 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: October 26, 2016

  
Jeffrey A. Keithline  
Counsel for Avery Dennison Corporation

**14. List of References**

1. Advancing Sustainable Materials Management: 2013 Fact Sheet, Assessing Trends in Material Generation, Recycling and Disposal in the United States, EPA530-R-15-003, U.S. Environmental Protection Agency, Solid Waste and Emergency Response (5306P), June 2015, available at: [http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013\\_advncng\\_smm\\_fs.pdf](http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_fs.pdf).

2. Advancing Sustainable Materials Management: Facts and Figures 2013, Assessing Trends in Material Generation, Recycling and Disposal in the United States, EPA530-R-15-002, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), June 2015, available at: [http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013\\_advncng\\_smm\\_rpt.pdf](http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_rpt.pdf).

3. Council on Environmental Quality (CEQ), *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews*, August 1, 2016, available at [https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa\\_final\\_ghg\\_guidance.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf)

**15. List of Attachments**

1. Confidential Attachment