

## Environmental Assessment for FCN 1685

1. **Date:** August 9, 2016
2. **Name of Applicant:** Purolite Corporation
3. **Address:** 150 Monument Road  
Bala Cynwyd, Pennsylvania 19004

All communications on this matter are to be sent  
in care of Counsel for the Notifier:

Jeffrey A. Keithline  
Keller and Heckman LLP  
1001 G Street, NW, Suite 500 West  
Washington, DC 20001  
Telephone: (202) 434-4136  
Facsimile: (202) 434-4646  
E-mail: Keithline@khlaw.com

### 4. Description of the Proposed Action

#### a. Requested Action

The action identified in this Notification is clearance for the food-contact substance (FCS) copolymer of glycidyl methacrylate and ethylene glycol dimethacrylate with 1,6-diaminohexane or ethylenediamine for use in applications where the resin will be used as a solid support for the immobilization of enzyme preparations, which are in turn used to process foods (e.g., wheat and corn based sweeteners, sugar solutions, and artificial sweeteners). The enzyme preparations used with the FCS have an appropriate FDA status for the intended use.

#### b. Need for Action

The notifier produces a product line of copolymers of glycidyl methacrylate and ethylene glycol dimethacrylate with 1,6-diaminohexane or ethylenediamine. The clearance will provide a product that is suitable for use as a support agent to immobilize enzyme preparations, which are in turn used to process foods, to the marketplace. Examples of food and food ingredients are noted directly above.

#### c. Locations of Use/Disposal

The FCS is intended for use in food processing plants throughout the United States. Disposal of the FCS is expected to occur nationwide with the FCS ultimately being deposited in municipal solid waste landfills or combusted.

According to the U.S. Environmental Protection Agency's (EPA) Advancing Sustainable Materials Management: Facts and Figures 2013, 52.8% of municipal solid waste generally was land disposed, 12.9% was combusted, and 34.3% was recovered for recycling.<sup>1</sup> The materials in which the FCS will be

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<sup>1</sup> *Advancing Sustainable Materials Management: Facts and Figures 2013*, EPA-530-R-15-002, U.S. Environmental Protection Agency, (5306P), June 2015, at [http://www3.epa.gov/epawaste/nonhaz/municipal/pubs/2013\\_advncng\\_smm\\_rpt.pdf](http://www3.epa.gov/epawaste/nonhaz/municipal/pubs/2013_advncng_smm_rpt.pdf).

used are not expected to be collected for recycling to a significant extent, except as part of a mixed plastics recycling stream. Excluding this means of disposal and assuming that all food contact articles made from 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 incinerated.<sup>2</sup>

The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food contact material in current use. Consequently, there are no special circumstances regarding the environment surround either the use or disposal of the FCS.

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

The FCS is fully described elsewhere in the Notification. (*See* Form 3480, Part II, Section A.) The identity of the FCS is summarized below.

### **a. Chemical Name**

Copolymer of glycidyl methacrylate and ethylene glycol diemthacrylate with 1,6-diaminohexane or ethylenediamine

### **b. Trade or Common Name**

ECR8315 or ECR8415

### **c. Other Chemical Names**

Crosslinked copolymer of methacrylate containing amino groups

### **d. Molecular Formula**

The FCS cannot be represented by a discrete chemical structure.

### **e. Molecular Weight**

Given that the FCS polymer is highly cross-linked, determination of the number average and weight average molecular weight of the polymer is not feasible.

## **6. Introduction of Substances into the Environment**

### **a. Introduction of the substance into the environment as a result of manufacture**

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, the Notifier is not aware of information to suggest that there are any extraordinary circumstances indicative of adverse environmental impacts that may result from the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided herein.

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<sup>2</sup> The distribution of disposal is adjusted as follows: % Combusted =  $12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 19.6\% \text{ combusted}$ . % Land disposed =  $52.8\% \text{ land disposed} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 80.4\% \text{ land disposed}$ .

**b. Introduction of substances into the environment as a result of use/disposal**

No introduction of the FCS into the environment is expected to occur as a result of its intended use. Any waste materials generated in this process are expected to be disposed of as part of the food or food ingredient manufacturer's overall nonhazardous solid waste in accordance with established procedures, primarily by sanitary landfill or incineration.

The FCS is composed of carbon, hydrogen, nitrogen, and oxygen – elements that are commonly found in municipal solid waste. The products of complete combustion would be carbon dioxide, nitrogen oxides, and water. Based on the proposed use of the FCS and the expected market volume,<sup>3</sup> the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 32.66 million tons or 12.9% of 254.11 million tons in 2013).<sup>4</sup> With respect to carbon dioxide and nitrogen oxide emissions, we have considered that the combustion of solid waste is the only potential source of such emissions arising from the disposal of the FCS; greenhouse gas emissions from the recycling or landfilling of the immobilized enzyme support are expected to be *de minimis*.

Based on confidential market volume information for the FCS, we have calculated the carbon dioxide equivalent emissions associated with combustion of the FCS, as discussed in the confidential attachment to this document. Pursuant to the Council on Environmental Quality's (CEQ) August 1, 2016 "Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews," projected greenhouse gas emissions should be quantified and used "as a proxy for assessing potential climate change."<sup>5</sup> Based on the calculations set forth in the attached document, we are not aware of any reason why a quantitative analysis of carbon dioxide is needed for this FCS.<sup>6</sup>

The FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and, therefore incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emission laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of the immobilized enzyme support. 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 are also required to have groundwater monitoring systems. (40 C.F.R. Part 258). 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 collection systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of concern regarding leachate is especially relevant in this case, because the subject FCS is a

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<sup>3</sup> The expected market volume is provided in a confidential attachment to the Environmental Assessment.

<sup>4</sup> See Footnote 1.

<sup>5</sup> See [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).

<sup>6</sup> We note that the earlier CEQ draft guidance provided a reference point of 25,000 metric tons of CO<sub>2</sub> emissions below which a GHG analysis is not needed; however, the final guidance no longer includes this threshold. We are not aware that FDA has issued any guidance on the August 1, 2016 guidance. In the absence of specific guidance from the Agency, we refer to the 25,000 metric tons per year benchmark in assessing the environmental impact of this action. In that regard, we have calculated that carbon dioxide equivalent emissions associated with combustion of the FCS is far below the 25,000 metric tons per year benchmark.

high molecular weight polymer that contains only minute levels of extractable material, even under conditions that greatly exaggerate environmental exposure conditions.

## **7. Fate of Substances Released into the Environment**

As described in further detail below, 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.

### **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 is a high molecular weight polymer and does not readily volatilize. Thus, no significant quantities of any substances will be released during the use and disposal of the immobilized enzyme support.

As indicated above, the FCS will make up a very small portion of the total municipal solid waste currently combusted, and the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

### **b. Water**

No significant effect on the concentrations of and exposures to the FCS or its constituents in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS or the disposal of the immobilized enzyme support. No significant quantities of the FCS will be added to these systems upon the proper incineration of the article, nor upon its disposal in landfills equipped with composite liners and leachate monitoring protocols.

As noted under Section 6 above, even if small amounts of the FCS or its constituents were to transfer from a disposed immobilized enzyme support into landfill leachate, EPA's regulations governing landfills (40 C.F.R. Part 258) will minimize migration of the leachate into the natural environment. MSW landfills must comply with the federal regulations in 40 CFR Part 258 or equivalent state regulations. The federal standards include composite liner requirements, leachate collection and removal systems, groundwater monitoring requirements, and closure and post closure care requirements.

The environmental fate of substances does not need to be addressed because no significant introduction of substances into the environment as a result of the proposed use of the FCS is identified.

### **c. Land**

Considering the factors discussed above, no significant effects on the concentrations of, or exposures to, any substances in terrestrial ecosystems are anticipated as a result of the proposed uses of the FCS and its proper disposal. Only very small amounts of leaching of the FCS may be expected to occur under normal environmental conditions when finished food contact materials are disposed of. Furthermore, as noted above, if the FCS were to migrate from the discarded immobilized enzyme support, the leachate will be prohibited from entering adjacent ecosystems by proper environmental controls in place at landfill sites. Thus, there is little expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

## **8. Environmental Effects of Released Substances**

No adverse environmental effects are expected as a result of the anticipated release of substances into the environment. No significant quantities of any substance are expected to be released to the environment as a result of the proposed use of the subject FCS. As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of the immobilized enzyme support consist of extremely small quantities of combustion products and leachables, if any.

Accordingly, no adverse effects on organisms in the environment are expected as a result of the immobilized enzyme support. 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 (or immobilized enzyme support) because, as discussed under Item 6, only extremely small quantities of substances, if any, will be introduced into the environment as a result of use and/or disposal of the FCS (or the immobilized enzyme support). 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**

The use of the FCS in the manufacture of food is not expected to result in a net increase in the use of energy and resources since the FCS is intended to be used in place of other enzyme support materials currently on the market for use in the production of food and/or food additives.

The partial replacement of these materials by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture of other similar materials. Furthermore, the use of the subject FCS proposed in this Notification is as a replacement for similar polymers.

The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is not significant.

## **10. Mitigation Measures**

As discussed above no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. This is primarily due to (1) the minute levels, if any, of leaching of components of the FCS from the immobilized enzyme support, (2) the insignificant impact on environmental concentrations of combustion products of the FCS, and (3) the similarity of the subject FCS to the materials it is intended to replace. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

## **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. In view of the fact that the FCS constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of the FCS and immobilized enzyme support, and the absence of any significant environmental impact which would result from its use, the establishment of an effective FCN to permit the use of the subject FCS as described herein is environmentally safe in every respect.

## 12. List of Preparers

- 1) 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.
- 2) Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001; 3 years of experience evaluating and preparing Food Contact Notifications, including Environmental Assessments.

## 13. Certification

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

**Date:** August 9, 2016



*JA*  
Jeffery A. Keithline, Counsel for Notifier,  
Purolite Corporation