

Attachment 16

Environmental Assessment

- 1. Date:** May 6, 2021
- 2. Name of Notifier:** BASF Corporation
- 3. Address:** All communications should be sent to:
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4. Description of Proposed Action

a. Requested Action

The action requested in this notification is the establishment of a clearance to permit the use of styrene, methyl methacrylate, and glycidyl methacrylate copolymer as a polymeric chain extender at a maximum level of 0.4% by weight in polyester polymers.

b. Need for Action

Polymers employing the subject food contact substance (FCS) are intended for use as food contact articles in contact with all types of food under Conditions of Use B through H as defined at 21 CFR 176.170(c), Table 2.

Use of the subject FCS in polyester polymers increases the molecular weight of the polymers, offering several technical properties that make them useful in a variety of food contact applications. In particular, the FCS is used to address the molecular weight degradation that occurs under prolonged storage conditions and/or high temperature exposure of typical polyesters.

The notifier does not intend to produce finished food packaging materials from polyester polymers employing the subject FCS. Primarily, polyester polymers employing the FCS will be sold to manufacturers engaged in the production of food contact materials.

c. Location of Use/Disposal

Food contact materials produced with the use of such modified polyester polymers 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.

According to the U.S. Environmental Protection Agency's (US EPA) report December 2020 update regarding municipal solid waste (MSW) in 2018 in the United States, 50.0% of MSW generally was land disposed, 11.8% was combusted, 8.5% was composted, 6.1% was disposed of in other food management pathways, and 23.6% was recovered for recycling.¹

We do not view composting as a viable disposal mechanism at this point in time for food-contact articles manufactured with the FCS. This assertion is supported by the above noted EPA MSW report. In 2018, no composting of plastic containers or packaging were recorded. Assuming that all food-contact articles manufactured with the FCS are land disposed or combusted, it is estimated that approximately 80.9% of the materials will be deposited in land disposal sites and about 19.1% will be incinerated.²

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

The FCS that is the subject of this notification is a copolymer of styrene (CAS No. 100-42-5), methyl methacrylate (CAS No. 80-62-6), and glycidyl methacrylate (CAS No. 106-91-2).

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, information available to the notifier does not 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 styrene/methyl methacrylate/glycidyl methacrylate copolymer. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of the substance into the environment as a result of use/disposal:

No significant environmental release is expected upon the use of the subject FCS to fabricate packaging materials. In these applications, the FCS will be entirely incorporated into the finished food contact articles. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials employing the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill and incineration.

¹ US EPA Report: *Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States* (December 2020), available at: [Advancing Sustainable Materials Management: 2018 Fact Sheet \(epa.gov\)](https://www.epa.gov/sustainable-materials-management/advancing-sustainable-materials-management-2018-fact-sheet)

² The distribution of disposal is adjusted as follows: %Combusted = 11.8% combusted / (11.8% combusted + 50.0% land disposed) = 19.1%. The remaining 80.9% will be land-disposed.

The subject FCS consists of carbon, oxygen and hydrogen – elements that are commonly found in municipal solid waste. The products of complete combustion would be carbon dioxide and water. No toxic combustion products are expected as a result of the proper incineration of the polymers.

Since carbon dioxide is a greenhouse gas (GHG), a GHG analysis has been provided in a confidential attachment to the EA to determine whether the GHG emitted from incineration of the FCS at MSW combustion facilities will significantly impact the environment. Background information and a summary follow.

MSW combustion facilities are regulated by the EPA under 40 CFR 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG”. Part 2 of this regulation (40 CFR 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO₂-e emission threshold for required reporting. To evaluate the significance of the environmental impact of these GHG emissions, we refer to the Council on Environmental Quality (CEQ) regulations under 40 CFR 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (NEPA) documents. 40 CFR 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 CFR 98.2. Based on projected market volume information provided in the confidential attachment to the EA and on information about the operation of MSW combustion facilities in the US, the expected carbon dioxide equivalent emissions resulting from the disposal FCS by combustion will not result in significant environmental impacts.

Again, as the subject FCS consists of carbon, oxygen, and hydrogen - elements that are commonly found in municipal solid waste - the action requested in this FCN is also not expected to significantly alter the emission from properly operating MSW combustors. Furthermore, based on the proposed use of the FCS and the expected market volume³, the FCS will make up a very small portion of the total municipal waste currently combusted (estimated to be 34.55 million tons or 11.8% of 292.36 million tons in 2018⁴). In sum, 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. 98.2, 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 food contact articles comprised of the FCS. 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, to have ground water monitoring systems and

³ The expected market volume is provided in a confidential attachment to the Environmental Assessment

⁴ US EPA Report: *Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States* (December 2020), available at: [Advancing Sustainable Materials Management: 2018 Fact Sheet \(epa.gov\)](https://www.epa.gov/osmre/advancing-sustainable-materials-management-2018-fact-sheet). The percent noted above are based on municipal solid waste, excluding waste recovered from composting.

to take corrective action as appropriate (40 CFR Part 258).

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 in polyester polymers. The FCS is of relatively high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food contact articles manufactured with polyester polymers employing the FCS.

As indicated above in item 6 the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

Additionally, because the use of the FCS proposed in this FCN is the same as the use of the similar FCS's already authorized by FDA (e.g. FCNs 545, 853 & 1109), the FCN is intended to compete with and replace other polyester polymers already used as proposed. Consequently, no new emissions are expected when this notification becomes effective.

b. Water

No significant effects on the concentrations of and exposure 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 proper incineration of polyester polymers employing the FCS, nor upon its disposal in landfills with composite lines and leachate monitoring protocols.

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 low production of the subject FCS for use in polyester polymers used in food contact applications is not expected to result in significant introductions of landfill leachate.

Thus, there is little expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of subject FCS.

Considering the foregoing, there is no reasonable expectation of a significant impact on the environment due to the proposed use the subject FCS in the manufacture of articles intended for use in contact with food.

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 finished food contact articles fabricated with the use of polyester polymers

employing the subject FCS consist of extremely small quantities of combustion products and leachates. As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food-contact articles fabricated with the use of polyester polymers employing the subject FCS consist of extremely small quantities of combustion products, landfill leachates and the products of commercial composting. Several migration studies were conducted to assess the potential migrating species from polyethylene terephthalate (PET) and polylactic acid (PLA) polymers manufactured with the FCS and exposed to a range of food simulants. These analyses are described with the Confidential Attachment to this EA. No significant levels of migrants were determined. Based on these considerations, no significant adverse effects on organisms in the environment are expected as a result of the disposal of food contact articles made of polyester polymers employing the subject FCS. In addition, the use and disposal of food contact articles made of polyester polymers employing the subject FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.* EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors and 40 C.F.R. Part 258 that pertain to landfills.

9. Use of resources and energy

As is the case with other food contact materials, the production, use, and disposal of polyester polymers employing the subject FCS involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS in polyester polymers used in the fabrication of food contact materials is not expected to result in a net increase in the use of energy and resources, since polyester polymers employing the subject FCS are intended to be used in place of similar products now on the market for use in packaging applications.

Manufacture of the FCS, its use in polyester polymers, and subsequent conversion to finished food contact materials will consume energy and resources in amounts comparable to the manufacture and use of polyester employing other chain extenders.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food contact articles made from polyester polymers employing the subject FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished article, and secondly, to the insignificant impact on environmental concentrations of combustion products of the copolymer. Thus, the use of the subject FCS in polyester polymers as proposed is not reasonably expected to result in any significant environmental impact requiring mitigation measures of any kind.

11. Alternatives to the proposed action

No significant adverse environmental effects are identified herein, which would necessitate alternative actions to that proposed in this notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials currently used in the manufacture of food contact articles made of polyester polymers. Such action would have no significant environmental impact.

12. List of preparers

Dr. Li Zhang, Ph.D. in Insecticide Toxicology, 13 years of experience related to food contact

compliance review and registrations. Senior Product Regulatory Specialist, BASF Corporation, Florham Park, NJ 07932

13. Certification

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

Date: May 6, 2021



Li Zhang, Ph.D.
Senior Product Regulatory Specialist

14. Attachments

Attachment 17 – Confidential Attachment to the Environmental Assessment