

Attachment 66

Environmental Assessment

1. **Date:** January 15, 2016
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4. **Description of the Proposed Action:**

The action requested in this notification is to permit the use of a copolymer of acrylonitrile-methyl methacrylate-trimethylolpropane trimethacrylate, CAS Reg. No. 57192-88-6, at levels of up to 10% in closures for bottles used to hold alcoholic beverages having up to 50 percent alcohol by volume, e.g., wine and distilled spirits, under pasteurization and less severe conditions, i.e., under FDA's Conditions of Use D through G, as defined in Table 2 at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm>.

The food contact substance (FCS) provides improved compressibility in stoppers composed of cork granules, as well as reduced weight, improved elasticity, and density control in stoppers made from synthetic materials (plastics).

Closures 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.¹

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 acrylonitrile-methyl methacrylate-trimethylolpropane trimethacrylate, CAS Reg. No. 57192-88-6. Due to the use of trimethylolpropane trimethacrylate in its production, the polymer is highly cross-linked and has a very high molecular weight. The FCS is produced using a blowing agent so as to form small spheres encapsulating the blowing agent. These are referred to as “microspheres.” The blowing agent currently used is identified in Attachment 1 of this notification. As noted there, the blowing agent is generally recognized as safe (GRAS) for use in food.

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 food-contact substance. 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 food-contact substance to fabricate bottle closures. In these applications, the FCS (*i.e.*, a polymer) is expected to be entirely incorporated into and remain with the finished food-contact article/closure. Any waste materials generated in this process, *e.g.*, plant 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 closures containing the subject food-contact substance will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

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. See 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. 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 stoppers 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 closures containing the FCS will be combusted annually. This amount is calculated as follows: $12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

The FCS is composed of carbon, oxygen, nitrogen, and hydrogen, elements that are commonly found in municipal solid waste. 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 which would otherwise suggest a significant environmental impact resulting from post-consumer disposal of closures 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 2013.² 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 closures 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).

Pursuant to the Council on Environmental Quality (CEQ) “Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts,”³ a quantitative analysis is required if greenhouse gas (GHG) emissions from the action are expected to exceed 25,000 metric tons CO₂ equivalent on an annual basis. Based on market volume information provided in the Confidential Attachment, the expected carbon dioxide and nitrous oxide emissions from combustion of discarded closures containing the FCS will amount to less than 25,000 metric tons of total CO₂ equivalents on an annual basis; therefore, no quantitative analysis is required for this action.

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.

² See Footnote 1.

³ Council on Environmental Quality (CEQ). *Revised Draft Guidance on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change*. December 18, 2014. https://www.whitehouse.gov/sites/default/files/docs/nepa_revised_draft_ghg_guidance.pdf.

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 food-contact substance, as the FCS is a polymer and thus non-volatile.

As indicated above in item 6, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted. Therefore, the food-contact substance will not significantly alter the emissions from 40 C.F.R. 60-compliant operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste 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 polymer. The fate of the food-contact substance 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 food-contact substance. In particular, the polymeric nature of the food-contact substance is expected to result in virtually no leaching of FCS components under normal environmental conditions when finished stoppers are disposed of. Furthermore, the very low production of the polymer for use in food-contact applications precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the food-contact substance.

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 stoppers intended for use 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 stoppers containing the food-contact substance. 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 closures 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 food-contact substance involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject food-contact substance in the fabrication of bottle closures is not expected to result in a net increase in the use of energy and resources, since the food-contact substance is intended to be used in closures which will be used in place of similar articles already on the market for use in food-contact applications, such as 100% synthetic, *i.e.*, plastic, bottle closures.

Manufacture of the food-contact substance, and its conversion to use in a finished closure, will consume energy and resources in amounts comparable to the manufacture and use of other, similar food-contact substances. Furthermore, the finished stopper in which the FCS is used is not currently recovered for recycling. Food-contact materials produced using the subject food-contact substance 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 closures fabricated using the subject food-contact substance. This is primarily due to the minute levels, if any, of leaching of components of the food-contact substance from finished closures employing the food-contact substance, and the insignificant impact on environmental concentrations of combustion products of the food-contact substance. Thus, the use of the food-contact substance 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 food-contact substance would otherwise replace; such action would have no environmental impact. In view of the fact that the food-contact substance constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished closures,

and the absence of any significant environmental impact which would result from its use, the establishment of an effective Food Contact Notification to permit the use of the subject food-contact substance as described herein is environmentally safe in every respect.

12. List of Preparers

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13. Certification

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

Date: January 15, 2016



George G. Misko
Counsel for Akzo Nobel Pulp and Performance
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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.

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.

15. List of Attachments

1. Confidential Attachment