

Appendix 5

Revised Environmental Assessment

1. **Date:** July 12, 2017
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4. **Description of the Proposed Action:**

The action requested in this notification is to permit the use of acrylonitrile-methacrylonitrile-methyl acrylate-trimethylolpropane trimethacrylate copolymer at levels of up to 10% in the production of closures for bottles containing alcoholic beverages 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>.

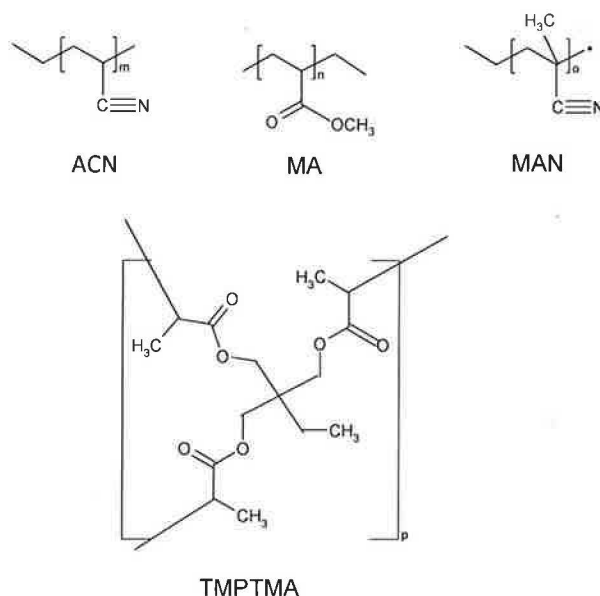
The food contact substance (FCS) provides improved compressibility in stoppers composed of cork granules, as well as reduced weight, improved elasticity, and density control in stoppers made from synthetic materials (plastics).

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, methacrylonitrile, methyl acrylate, and trimethylolpropane trimethacrylate. 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.

The polymer has a complex molecular structure that cannot be accurately depicted by a single structural formula. However, representative structures of the repeating units present in the FCS polymer may be depicted as follows:



6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) (“Environmental assessments”), 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 used in the manufacture of bottle closures and will 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. 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

The FCS is composed of carbon, oxygen, nitrogen, and hydrogen. Thus, the combustion products of the FCS may include carbon dioxide and nitrous oxide. The carbon and nitrogen contents of the FCS have been calculated based on the elemental composition of the FCS (available in a confidential attachment to the FCN).

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 threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO₂ equivalents (CO₂-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 CFR 98.30(a). 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 facilities that directly emit GHG.” Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-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

¹ *Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, *available at*: https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf. According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, approximately 52.6% generally was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting). If we assume that food-contact articles containing the FCS are expected to be disposed of by land-filling or combustion (i.e., not recovered for recycling), we 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 food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows: $12.8\% \text{ combusted} \div (12.8\% \text{ combusted} + 52.6\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

imposed for the protection of the environment.” 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 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 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 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, no significant adverse environmental 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 food-contact substance would otherwise replace; such action would have no environmental impact.

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: July 12, 2017



George G. Misko
Counsel for Akzo Nobel Pulp and Performance
Chemicals AB, Expancel

14. List of References

1. Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, *available at:* https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.
2. 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.energy.gov/sites/prod/files/2016/08/f33/nepa_final_ghg_guidance.pdf.
3. EPA, *Energy and the Environment: Greenhouse Gas Equivalence Calculator* (last updated September 15, 2016), *available at:* <https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator>.

15. List of Attachments

1. Confidential Attachment