

Environmental Assessment

1. **Date:** June 1, 2021
2. **Name of Applicant/Petitioner:** Cytec Industries Inc.
3. **Address:** All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. Description of Proposed Action

A. Requested Action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), alcohols, C16-18, ethoxylated (CAS Reg. No. 68439-49-6), as a dispersant for additives to polyolefin resins. The maximum use level of the FCS will not exceed 0.2% by weight of the polymer. The finished polymers containing the FCS will contact food under Conditions of Use C ("Hot filled or pasteurized above 150°F") through G ("Frozen storage (no thermal treatment in the container)").¹ The finished polymers containing the FCS are not for use in contact with infant formula and human milk, as these uses are not addressed in the FCN.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the FCS that is the subject of this Notification will be sold to food-contact article manufacturers.

B. Need for Action

The FCS is intended to be used as a dispersant for additives to polyolefins that contact food. The FCS functions to disperse other additives in the target polyolefin resins. The food-contact articles may include food packaging and repeat-use articles, as well as disposable food-contact materials such as utensils and serving ware.

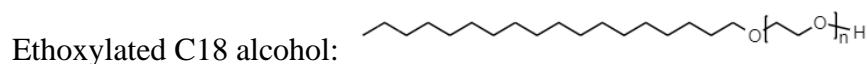
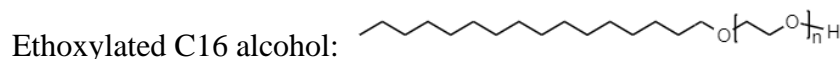
¹ FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. It is estimated that, of the 14,530,000 tons of plastic packaging present in municipal solid waste (MSW) generated in 2018, approximately 69.9% generally was land disposed, 17.0% was combusted, and 13.1% was recovered for recycling.² The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the articles in which they are used.

5. Identification of the Subject of the Proposed Action

The subject FCS is alcohols, C16-18, ethoxylated (CAS Reg. No. 68439-49-6). The FCS has the following molecular structure:



The FCS is derived from a fatty alcohol. As is typical of fatty acids and their corresponding alcohols, the alcohol starting reactant contains a range of alkyl chain lengths, with C16 and C18 alcohols being the predominant species. Thus, although two structures and formulas are shown above, the FCS is not a mixture of two distinct substances; rather, it contains both ethoxylated C16 and C18 alcohols because the alcohols occur together.

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 materials. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently,

² *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, November 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used in the manufacture of food-contact materials. The FCS is expected to be entirely incorporated into finished materials, and essentially all of it is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Any waste material generated during the manufacture of the finished articles, e.g., plant scraps, is expected to be disposed as part of the finished article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of the finished food-contact materials will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, incineration, or recovery for recycling.

The FCS is composed of carbon, hydrogen, and oxygen, elements commonly found in MSW. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide resulting from incineration of materials containing the FCS have been calculated in a confidential appendix to the Environmental Assessment, and an assessment of these worst-case releases is also included in the same confidential appendix.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of packaging 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. Part 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 equivalents (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations in 40 C.F.R. § 1508.27, which define 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. Moreover, 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." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis (see Confidential Attachment to Environmental Assessment). As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

Only extremely small amounts, if any, of the substances from the finished food-contact materials containing the FCS are expected to enter the environment as a result of landfill disposal, in light of the EPA's 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 groundwater monitoring systems. Even if a very small amount of substances leach from the landfilled food-contact material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

7. Fate of Emitted Substances in the Environment

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with this FCS.

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills. Similarly, 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.

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 subject FCS in the manufacture of food-contact articles and packaging intended for use in contact with food.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other FCSs, 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 as a dispersant in polyolefins is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to replace other similar products that are already on the market (i.e., competitive additive dispersants). Therefore, the use of the FCS will have no significant impact on the use of resources and energy.

Food-contact materials containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used materials with or without comparable additive dispersants.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated with the subject FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No significant adverse 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 significant impact.

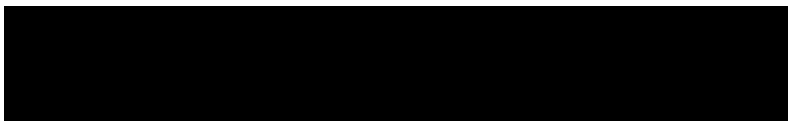
12. List of Preparers

1. Cynthia B. Lieberman, JD, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500W, Washington, DC 20001. Ms. Lieberman has over 13 years of experience with Food Contact Notifications, including their Environmental Assessments.
2. Holly H. Foley, Senior Staff Scientist (Food Packaging), Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Foley has approximately 40 years of experience preparing food additive petitions and Food Contact Notifications, including their Environmental Assessments.

13. Certification

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

Date: June 1, 2021



Cynthia B. Lieberman
Counsel for Cytex Industries Inc.

14. List of References

The following footnotes are found within the Environmental Assessment document:

1. FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

2. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, November 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

15. Attachments

1. Confidential Attachment