

Environmental Assessment

1. **Date:** February 7, 2024*
2. **Name of Applicant/Petitioner:** Tronox Holdings plc
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

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), identified as a mixture of alcohols, C₁₂-C₁₆, with a degree of ethoxylation between 2.5 – < 40 moles ethylene oxide (EO), when used in food-contact applications.

The FCS is intended for use at concentrations not to exceed 532 parts per million (ppm) as an emulsifier in surface-treated titanium dioxide pigments, which in turn are intended for use as colorants for polymers at levels up to 15% by weight of polymer. Finished polymers containing the FCS are intended to contact all food types under FDA’s Conditions of Use A (“High temperature heat-sterilized (e.g., over 212°F)”) through H (“Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use”).¹ The FCS is not intended for use in contact with infant formula and human milk, as such uses were not included as part of the intended use of the substance in the FCN.

The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this notification will be sold to manufacturers engaged in the production of food-contact materials. 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. Therefore, it is anticipated that disposal of food-contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or

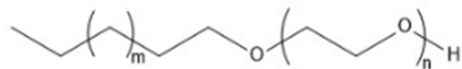
¹ See United States Food and Drug Administration, “Food Types & Conditions of Use for Food Contact Substances,” available at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

* Subsequent to this date, this EA was amended using the Acrobat direct edit tool to add various clarifying text. No additional analysis was made.

recycled in quantities similar to those reported for municipal solid waste (MSW) generally. According to the Environmental Protection Agency (EPA), it is estimated that, as of 2020, of the 292.36 million tons of MSW generated, approximately 50.0% of MSW is deposited in land disposal sites; 11.8% is combusted; 23.6% is recycled; 8.5% is composted; and 6.1% is directed to other food management pathways.² Because there is a wide variation in the rates of recycling of polymeric resins,³ to estimate the worst-case environmental introduction, it is conservatively assumed that the FCS is expected to be primarily disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.⁴

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

The FCS may be described as a mixture of alcohols, C₁₂–C₁₆, with a degree of ethoxylation between 2.5 – < 40 moles ethylene oxide (EO). The chemical formula is C_{12–16}H_{25–33}O(C₂H₄O)_{2.4–40}H and its maximum molecular weight is 2,002 g/mol. The chemical structure of the FCS is shown below.



(where m is 8 – 12 and n is 2.5 – 40)

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 is not aware of any information to suggest that there are any extraordinary circumstances that would indicate the potential for significant 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; 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

² See U.S. Environmental Protection Agency (EPA), “Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Materials Generation and Management in the United States” December 2020, Table 35, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

³ *Ibid.* Table 8 - Subcategory: Total Plastics in Containers & Packaging, by resin. Rates of recycling range from negligible (PVC, PLA and Other resins) to 25.4% (PET) with overall 13.6% recycling.

⁴ By assuming that none of the FCS is recycled, we recalculate the fraction of FCS that is combusted as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

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

No significant adverse environmental release is expected upon the use of materials containing the FCS. In these applications, the polymer will be entirely incorporated into the finished food-contact article. In these applications, the FCS is expected to be entirely incorporated into the finished food-contact article. 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. The annual projected market volume of the FCS is provided in the confidential attachment to the EA.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable, recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated. ASTM standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification" provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made.⁵ We anticipate the articles manufactured with the FCS would be so marked and, thus, coded for recycling.

The FCS is composed of the elements carbon, hydrogen, and oxygen. Thus, the combustion products of the FCS may include carbon dioxide and water. The carbon content of the FCS (57.5% C) has been used to calculate the worst-case potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (Provided in a Confidential attachment to the EA) and is below 25,000 metric tons carbon dioxide equivalent (CO₂-e) emission per MSW combustor (MSWC) on an annual basis.⁶ Thus, the concentrations of carbon dioxide in the environment will not be significantly altered by the proper incineration of the polymers in which the FCS is used, in the amounts utilized for food packaging applications, as the host polymers will be incinerated whether or not they contain the FCS.

Furthermore, to evaluate the significance of the environmental impact, we considered whether the action threatens a violation of federal, state, or local laws or requirements imposed for the protection of the environment (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws). In this context, the EPA, under 40 C.F.R. § 98.1, "establishes mandatory GHG reporting

⁵ ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

⁶ See Environmental Protection Agency, "Energy Recovery from the Combustion of Municipal Solid Waste (MSW)," available at: <https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw>.

requirements for owners and operators of certain facilities that directly emit GHG.” This regulation describes that facilities must report GHG emissions and sets an annual 25,000 metric ton CO₂-e threshold for required reporting (40 C.F.R. § 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 C.F.R. § 98.30(a). As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental adverse impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

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 MSW landfills. EPA’s regulations require new MSW 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 to take corrective action as appropriate (40 C.F.R. Part 258).” These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

7. Fate of Emitted Substances in the Environment

A. Air

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 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 the FCS.

B. Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the 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 are anticipated as a result of the proposed use of the subject FCS. Thus, the fate of finished food-contact articles containing the FCS 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 FCS.

Considering the foregoing, the environmental fate 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 was identified as discussed under Item 6.

8. Environmental Effects of Released Substances

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 FCS-containing polymer consist of small quantities of combustion products and leachables, if any. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. 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 the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

As is the case with other food contact materials, the production, use and disposal of the FCS involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS as an emulsifier in a surface treatment for titanium dioxide colorants for food-contact polymers is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used as a component of food-contact materials in which similar products that are already on the market are used (*e.g.*, pigment dispersants regulated under 21 C.F.R. § 178.3725 ("Pigment dispersants")).

For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this notification becoming effective.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive regulated pigment dispersants). Thus, no significant adverse 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 FCS would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Cynthia B. Lieberman, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Ms. Lieberman has over 14 years of experience counseling and representing corporate entities on Food Contact Notifications, including their Environmental Assessments.

Rachel D. Deese, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Dr. Deese has over two years of experience preparing FCN submissions and Environmental Assessments in support of the same.

13. Certification

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

Date: February 7, 2024

Signature:



14. References

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2 at United States Food and Drug Administration, "Food Types & Conditions of Use for Food Contact Substances," *available at*: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.
2. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), *available at*: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.
3. ASTM, Standard Practice for Coding Plastics Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.
4. Environmental Protection Agency, "Energy Recovery from the Combustion of Municipal Solid Waste (MSW)," *available at*: <https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw>.

15. Appendices

1. Confidential Addendum to Environmental Assessment