



Environmental Assessment

- 1. Date** September 4, 2024
- 2. Name of Applicant/Notifier** BASF Corporation
- 3. Address** BASF Corporation
500 White Plains Road
Tarrytown, NY 10591-9005
Telephone: (914) 506-2488
- 4. Description of and Need for the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of Fatty acids, C16-18, [9-(acetyloxy)-3,8,10-triethyl-7,8,10-trimethyl-1,5-dioxo-9-azaspiro[5.5]undec-3-yl]methyl esters (CAS Reg. No. 1422729-07-4) for use as a rheology modifier in olefin polymers complying with 21 CFR 177.1520; intended for single and repeat food contact use. The use of this FCS is needed to manufacture olefin polymers with modified properties (such as the melt flow index) to permit greater flexibility in manufacturing processes.

The FCS will be used at a level not to exceed 0.099 percent by weight of the polyolefin polymers. Food contact articles manufactured with polyolefin polymers modified with the food contact substance may be used in contact with all types of food under conditions of use A through H as described in Tables 1 and 2, unless restricted by applicable regulations for the polyolefin polymers. The finished polyolefin polymer must comply with the specifications and use limitations in 21 CFR 177.1520(c).

The FCS is not for use in contact with infant formula and human milk, as these uses were not specifically addressed in the FCN.

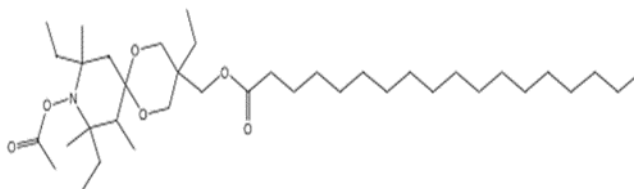
The Notifier does not intend to produce finished food-contact articles, as the FCS is an additive that is used in the manufacture of food contact article for food-contact applications. The FCS will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with 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 polyolefin resins containing the FCS will occur nationwide. It is estimated that, of the 9,350,000 tons of polyolefin plastic containers and packaging present in municipal solid waste (MSW) generated in 2018, approximately 88.4% generally was land disposed, 1.1% was combusted, and 10.5% was recovered for recycling.¹

¹ United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures, Assessing Trends in Material Generation, and Management in the United States*, December 2020. Available at the following website: https://www.epa.gov/sites/production/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

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

Chemical Name:	Fatty acids, C16-18, [9-(acetyloxy)-3,8,10-triethyl-7,8,10-trimethyl-1,5-dioxo-9-azaspiro[5.5]undec-3-yl]methyl esters
CAS Registry Number:	1422729-07-4
Chemical Formula:	C38H71NO6

Chemical Structure:



6. Introduction of Substances into the Environment

a. Introduction of Substances 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. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

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; or 3) production associated with a proposed action 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.

b. Use in Polymer Manufacture

No significant environmental release is expected upon the use of the subject FCS to fabricate food-contact articles. In these applications, the FCS (*i.e.*, an additive for polymers) 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 a part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established

procedures.

c. Introduction of Substances into the Environment as a Result of Use/Disposal

Air: (Combustion)

The subject FCS consists of the elements carbon, hydrogen, nitrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from 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. To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide and assumed that 1.1% of the market volume will be combusted.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the 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 equivalent (CO₂-e) emission threshold for required reporting. 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. Based on confidential market volume data, the expected carbon dioxide equivalent (CO₂-e) emissions are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Soil and Water: (Landfill)

Only extremely small amounts, if any, of the FCS is 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 regulations require all 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 and Appendix 2). These requirements are enforced by 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

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food-contact articles containing the FCS.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic, or terrestrial environmental compartments.

Accordingly, because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental Effects of Released Substances

As discussed above, no significant releases of the FCS are expected to occur to the environment. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, 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 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 in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because the FCS is intended to be used in food-contact article in place of similar, rheology modifiers now on the market for use in food-contact applications.

The replacement of other rheology modifiers by the subject FCS in food-contact article is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, its use in resins, and the final conversion to finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of the current stabilizers. Food contact articles produced from resins containing the FCS are expected to be disposed of in the same pattern as currently seen for article include recycling. Food contact articles already contain rheology modifiers, and this notified use would be substitutional to these other authorized uses. Therefore, significant impacts to recycling are not anticipated.

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 from the use of the FCS. Thus, no mitigation is required.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the currently marked materials; such action would have no significant environmental impact.

12. List of Preparers

John C. Hand, Ph.D in Biochemistry, 5 years of experience related to the preparation of Food Contact Notifications, 14 years' experience generating data for Food Contact Notifications and 20 years working in FDA regulated industries.
Product Regulation Specialist, Senior, BASF Corporation 500 White Plains Road, Tarrytown, NY 10591.

13. Certification

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



John C. Hand
Date: September 4, 2024

14. List of References

United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures, Assessing Trends in Material Generation, and Management in the United States*, December 2020. Available at the following website:
https://www.epa.gov/sites/production/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

15. List of Attachments

1. Confidential Environmental Assessment.