

Environmental Assessment

1. **Date** January 25, 2023 *
2. **Name of Submitter** Rianlon Corporation
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3. Description of the Proposed Action

a. Requested Action

The action requested in this food contact notification (FCN) is to permit for the use of the food contact substance (FCS) identified as 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy) phenol (CAS Reg. No. 2725-22-6) as a UV absorber in carbon monoxide-ethylene-propylene terpolymer (CAS No. 88995-51-1) intended for single or repeated use, except for use in contact with infant formula and human milk. The FCS will be used at levels not to exceed 0.5 weight percent of the finished polymer in contact with all foods, except infant formula and human milk, under the Conditions of Use A through H as described in Table 2.¹

b. Need for Action

The FCS is used as a component of finished food contact articles. The FCS serves as a UV light stabilizer. The food contact articles include single and repeat-use articles.

c. Locations of Use / Disposal

The Notifier does not intend to produce finished food packaging materials from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials and articles. 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.

As the notifier only manufactures the notified substance as an additive, it is beyond their knowledge as to what portion of the materials and articles containing the notified substance would eventually make their ways to the United States. We therefore conservatively assume that 100% of such materials and articles are exported to the U.S.

¹ <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>

We consulted the data from EPA's Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020.² In 2018, in the United States, approximately 292,360,000 tons of municipal solid waste (MSW) were generated, in which 35,680,000 tons were plastics (see footnote, Table 1).

Further, among these solid waste of plastics, approximately 3,090,000 tons were "recycled, composted and managed by other food pathways: (see footnote, Table 2); 5,620,000 tons were combusted with Energy Recovery (see footnote, Table 3); and 26,970,000 tons were landfilled (see footnote, Table 4).

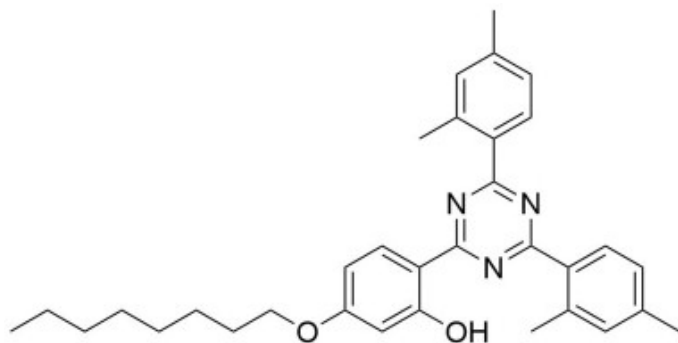
Taking the EPA data above into account, we then calculate the possible fate of the materials and articles containing the notified substance in MSW as follows:

- 1) Recycled, composted and managed by other food pathways:
 $(3,090,000/35,680,000) = 8.7\%$
- 2) Combusted:
 $(5,620,000/35,680,000) = 15.8\%$
- 3) Landfilled:
 $(26,970,000/35,680,000) \times 21\% = 75.6\%$

Therefore, it is anticipated that disposal will occur nationwide, with about 75.6% of the disposed solid waste containing the notified substance being deposited in land disposal sites, about 15.8% combusted, and about 8.7% recycled, composted and managed by other food pathways.

4. Identification of Substances that are Subject of the Proposed Action

The FCS is 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2yl]-5-(octyloxy) phenol (CAS Reg. No. 2725-22-6). The molecular structure of the FCS is shown below.



The FCS is in the form of white powder.

² [Advancing Sustainable Materials Management: 2018 Tables and Figures \(epa.gov\)](https://www.epa.gov/advancing-sustainable-materials-management-2018-tables-and-figures)

5. 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 should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants outside of the United States, which otherwise meet local environmental regulations. The Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements; or 3) production associated with the 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.

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

No significant environmental release is expected upon the use of the FCS in a 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 recycled by the manufacturer or disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials containing the FCS will be by conventional trash disposal and, hence, primarily by sanitary landfill or incineration. The FCS exists as small molecules incorporated with the matrix of the polymer substrates, and contains benzene ring, and other typical elements of organic substances, such as carbon, oxygen, nitrogen, and hydrogen. The FCS is not combustible; thus, no airborne emission products are expected to be released into the environment as a result of the incineration of the materials manufactured with the FCS. Only extremely small amounts, if any, of the FCS's 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 groundwater monitoring systems. 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. The lack of any leaching is especially true due to the relative insolubility of the FCS (according to the data from the website of the European Chemical Agency, the estimated water solubility of the FCS at 25°C is 0.003318 mg/l)³. We have calculated the potential greenhouse gas (GHG) emissions derived from combustion of the

³ <https://echa.europa.eu/registration-dossier/-/registered-dossier/14173/4/9>

