Environmental Assessment

1. Date January 25, 2023 *

2. Name of Submitter Rianlon Corporation

Counsel for Notifier:
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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-trianzin-2yl]- 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

* Subsequent to this date, non-substantive revision was performed using Adobe text editor to reformat the EA to permit conformance with assistive technologies.

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%

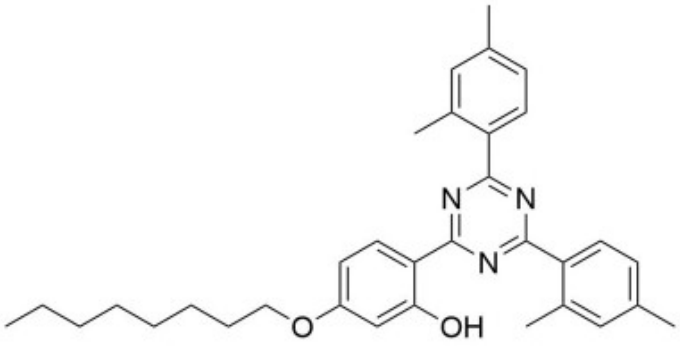
2) Combusted:
   (5,620,000/35,680,000) = 15.8%

3) Landfilled:
   (26,970,000/35,680,000) x 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-trianzin-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)

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

confidential annual market volume of the FCS (available in the confidential attachment to the EA) and have determined it is below 25,000 metric tons carbon dioxide equivalent (CO2-e) emissions on an annual basis. Thus, the concentrations of carbon dioxide in the environment will not be significantly altered by the proper incineration of finished food-contact items manufactured with the FCS. Furthermore, to evaluate significant 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 CFR Part 60, 40 CFR Part 98.2, and/or relevant state and local laws). In this context, the U.S EPA, under 40 CFR 98, "establishes mandatory GHG reporting 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 CFR 98.2) and identifies MSW combustors (MSWCs) as an included stationary fuel combustion source under 40 CFR 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.

6. 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 FCS does not volatilize and will not combust. The FCS consists of basic elements of carbon, hydrogen, oxygen and nitrogen. When subject to high temperature under incineration, it degrades into carbon dioxide, nitrogen gas and water. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles containing the FCS. As stated above, the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food contact material applications.

b. Water

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. As stated above, ultimate disposal is expected to be in a permitted municipal solid waste (MSW) landfill, or MSW combustion facility. Therefore, we do not expect disposal of the FCS to cause any significant impact to the aquatic environment.

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 FCS. Furthermore, the very low production of the FCS 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 the FCS as a result of its proposed use.

7. Environmental Effects of Released Substances

As discussed previously, we do not expect the FCS to be released 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 articles containing the FCS. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations e.g., EPA's regulations in 40 Parts 60 and 258.

8. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar substances already on the market. In particular, the FCS already is permitted for the same uses as those proposed in this Notification, most notably, effective FCN 2051. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Thus, the energy used for the production of the FCS is not significant.

As discussed in Item 3.c, about 8.7% of the food contact material containing the FCS may be recycld. However, we do not anticipate carbon monoxide-ethylene-propylene terpolymer, the substrate this FCS is intended to use in to be recycled.

9. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing the FCS. Therefore, mitigation is not required.

10. Alternatives to the Proposed Action

No potential significant adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed materials that the subject FCS would replace. Such action would not have significant impacts.

11. List of Preparers

Mr. Wilfred Feng, Dentons Law Offices LLP (Shanghai), 9th/24th/25th Floor, Shanghai World Financial Center, No.100 Century Avenue, Shanghai 200120, China.

Mr. Feng joined Dentons Shanghai Office as Senior Counsel in 2019. His practice focuses on global food and drug, agricultural and environmental laws, advising clients in the sectors of food, food packaging, dietary supplements, drug, medical device, tobacco products, cosmetics, pesticides, feed, veterinary drug, biotechnology, and chemicals.

Before joining Dentons, Mr. Feng spent 14 years at Keller and Heckman, an international regulatory law firm. As the first Chinese member joining its Shanghai Office, Mr. Feng has made significant contribution to its establishment and growth.

Before working at law firms, Mr. Feng gained extensive experience in regulatory affairs, government affairs, marketing and R&D at DuPont.

Mr. Feng earned B.Sc. (biology) from Fudan University, and master's degrees in agriculture and law from Chinese Academy of Agricultural Sciences and East China University of Law and Political Sciences. He is qualified to practice law in China

12. Certification

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

Date: January 25, 2023

Wilfred Feng

Senior Counsel

13. Attachments

A confidential attachment to this EA is enclosed.