

Attachment 16: Environmental Assessment

1. **Date** November 10, 2021
2. **Name of Submitter** Shandong Rainwell New Materials Co., Ltd.

Counsel for Notifier:

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3. Description of 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 Bis(4-*tert*-butylbenzoate-O)hydroxyl aluminum (CAS Reg. No. 13170-05-3) as an additive to increase rigidity and impact modulus in polypropylene homopolymer and high propylene olefin copolymers. The FCS will be used use at levels not to exceed 0.1% by weight in polymers in contact with all food types, except for use in contact with infant formula and human milk, under Conditions of Use A through H.

b. Need for Action

The FCS is used as a component of finished food contact articles. The FCS increases rigidity and impact modulus of the food contact materials as well as the finished article. The food contact articles include food packaging and repeat-use articles, such as boxes and bags.

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. The notifier manufactures approximately one thousand metric tons of the notified substance annually in China as an additive to polypropylene homopolymer and high propylene olefin copolymers. Roughly 40% of such polymers containing the notified substance are for food contact uses and 60% of them are for non-food contact uses, mainly used in shells of household electronic appliances and in automobile parts.

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.

We consulted the data from EPA's Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020¹. 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 (Table 1). Further, among these solid waste of plastics, approximately 3,090,000 tons were "recycled, composted and managed by other food pathways: (Table 2); 5,620,000 tons were combusted with Energy Recovery (Table 3); and 26,970,000 tons were landfilled (Table 4).

We further refer to an article titled "An overview of chemical additives in plastics: Migration, release, fate and environmental impact during their use, disposal and recycling", authored by Hahladakis et al.². According to this article, polypropylene (PP) takes 21% in the total global annual production of plastics. We assume the demand for plastics in the U.S. follows the same pattern.

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:

$$(3,090,000/35,680,000) \times 21\% = 1.8\%$$

- 2) Combusted:

$$(5,620,000/35,680,000) \times 21\% = 3.3\%$$

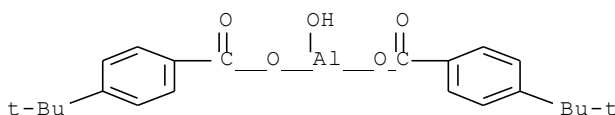
- 3) Landfilled:

$$(26,970,000/35,680,000) \times 21\% = 15.9\%$$

Therefore, it is anticipated that disposal will occur nationwide, with about 15.9% of the disposed solid waste containing the notified substance being deposited in land disposal sites, about 3.3% combusted, and about 1.8% recycled, composted and managed by other food pathways.

1) Identification of Substances that are Subject of the Proposed Action

The FCS is bis (4-tert-butylbenzoate-O) hydroxyaluminum (CAS Registry Number 13170-05-3). The molecular structure of the FCS is shown below.



The FCS is in the form of white powder. Its chemical structure can be identified with the infra-red spectrum as included in the FCN.

2) Introduction of Substances into the Environment

¹ [Advancing Sustainable Materials Management: 2018 Tables and Figures \(epa.gov\)](https://www.epa.gov/advancing-sustainable-materials-management-2018-tables-and-figures)

² <https://www.ncbi.nlm.nih.gov/pubmed/29035713>

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 (40 C.F.R. § 1508.27(b)(10)); 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 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 polypropylene substrate, and contains benzene ring, aluminum and other typical elements of organic substances, such as carbon, oxygen 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. The lack of any leaching is especially true due to the relative insolubility of the FCS.

3) 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. 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. In particular, the extremely low levels of maximum migration of components of the FCS, demonstrated by its insolubility, indicate that virtually no leaching of the components may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. 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.

4) 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 adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS.

5) 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.

6) 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.

7) Alternatives to the Proposed Action

No potential 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.

8) List of Preparers

Mr. Wilfred Feng, Dentons Law Offices LLP (Shanghai), 15F Shanghai Tower, 501 Yincheng Road (M), Shanghai, China 200120.

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 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.

9) Certification

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

Date: November 10, 2021

**Wilfred
Feng**

Wilfred Feng

Senior Counsel

