

Environmental Assessment

1. **Date** March 28, 2024 *
2. **Name of Submitter** GCH Technology Co., Ltd.

Agent for Notifier:
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3. **Description of Proposed Action**

- a. **Requested Action**

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as 4-Cyclohexene-1,2-dicarboxylic acid, calcium salt (1:1) (CAS Reg. No. 57545-78-5) as a nucleating agent, for use at levels not to exceed 0.2% by weight in polypropylene articles, for contact with all food types under Conditions of Use A through H, except for use in contact with infant formula and human milk.

- b. **Need for Action**

The FCS is used as a component of finished food contact articles. The FCS increases impact modulus, provides higher heat deflection temperature for polypropylene, and provides thermal stability, dispersion, property of non-coloring and processing stability. The food contact articles manufactured with the FCS include food packaging and repeat-use articles, such as boxes and bags.

- c. **Location 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.

US EPA data for total plastics generated and used specifically in plastic containers and packaging is readily available in the EPA's Advancing Sustainable Materials Management: 2018 Tables and Figures publication, updated in December 2020 (see Table 8 of https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf).

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature and to format the text for conformance with Section 508 assistive technologies.

These total data and those for the polyolefin plastic resins HDPE, LDPE/LLDPE, PP and PS are reproduced below.

Resin	Generation (thousand tons)	Recycled (thousand tons)	Combusted (thousand tons)	Landfilled (thousand tons)
HDPE	3,790	560 (14.8% **)	***	***
LDPE/LLDPE	3,730	370 (9.9%)	***	***
PP	1,830	50 (2.7%)	***	***
PS	550	20 (3.6%)	***	***
Total Plastics in Containers & Packaging (all resins *)	14,530	1,980	2,460	10,090

* Value includes the listed polyolefins, PET, PLA and 'Other' resins

** Percent of the given resin type recycled

*** No data provided

These data show that the PP resins comprise 1,830 thousand tons (or 12.6%) of the total plastics generated and used specifically in plastic containers and packaging.¹ Not accounting for recycling, which is parsed out separately for each resin type, these data show that of the remaining waste streams 19.6% are combusted² and 80.4% are landfilled³. We anticipate that this disposal will occur nationwide.

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

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.

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 (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.

¹ Percent of resins that are polypropylene (PP) = $100 \times 1830 \div (14530) = 12.6\%$

² Percent that is combusted = $100 \times 2460 \div (14530 - 1980) = 19.6\%$

³ Percent that is land disposed = $100 \times 10090 \div (14530 - 1980) = 80.4\%$

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 within the matrix of the polypropylene substrate and contains benzene ring and other typical elements of organic substances, such as carbon, oxygen and hydrogen. As such, we anticipate the release of the greenhouse gas (GHG) carbon dioxide when articles manufactured with FCS are incinerated in municipal solid waste (MSW) combustion facilities. Based upon the elemental composition of the FCS and its estimated annual market volume, the worst-case releases of carbon dioxide equivalent (CO₂-e) emissions from the FCS have been calculated in a confidential attachment to this EA. These expected emissions are below 25,000 metric tons on an annual basis. To evaluate the significance of this 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.

GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2 and have a mandatory annual reporting threshold of 25,000 metric tons CO₂-e. As the FCS contains elements that are commonly found in MSW and as the estimated GHG emissions are well below the threshold for mandatory reporting, we anticipate that 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 packaging applications. Therefore, incineration of the FCS will not cause MSW combustion facilities to threaten a violation of applicable emission laws and regulations (i.e., 40 C.F.R. Parts 60 and 98, and/or relevant state and local laws). Accordingly, no significant adverse environmental impacts are anticipated resulting from the combustion of the FCS in MSW combustion facilities.

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. 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 because the FCS is bound into the finished polymer to perform its technical function thus extremely unlikely to cause landfill leaching.

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, chemical binding of the FCS to the polymeric substrate makes that virtually no leaching of the components may be expected 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 (See confidential attachment) 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 a significant amount of 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.

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. 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.

9. Mitigation Measures

The intended use of the FCS is not reasonably expected to create new environmental impacts that would require mitigation measures of any kind. Thus, no mitigation measures are necessary.

10. 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.

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, 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'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: March 28, 2024

**Wilfred
Feng**

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Wilfred Feng
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13. Attachments

Attachment: Confidential memo to the EA