Environmental Assessment

1. Date March 29, 2023 *

2. Name of Applicant Omya International AG and its Affiliates

3. Address Communications to be sent care of:

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4. Description of Proposed Action

The action requested in this Food Contact Notification (FCN) is to permit the use of the substance 2,5-furandione, dihydro-, mono-C_{15-20}-alkenyl derivs., (CASRN 68784-12-3), (hereinafter ASA, the food contact substance, or FCS) as a surface treatment for calcium carbonate, used as a pigment and/or filler in food contact materials and articles. The FCS contained in the calcium carbonate may be present at levels of up to 0.85 weight percent in polyethylene terephthalate (PET), polyethylene terephthalate glycol (PETG) and other polyester materials and articles, including, but not limited to: polyhydroxyalkanoate (PHA), polylactic acid (PLA), polybutylene succinate (PBS), polybutylene succinate adipate (PBSA), polybutylene terephthalate co-adipate (PBAT) and polybutylene adipate co-sebacate-co-terephthalate (PBASeT). The FCS is intended for use as a surface treatment for calcium carbonate at levels up to 1.7%. The calcium carbonate is intended for use as a pigment and/or filler at levels up to 50% in food contact polyester materials and articles. As a result, the FCS will be present in the finished materials and articles at a maximum use level of 1.7% × 50% = 0.85%. The finished materials and articles may be used in single or repeated use applications and are intended for contact with all food types under Conditions of Use A through H, as described in FDA's Table 2.[1] The FCS is not intended for use in contact with infant formula and human milk.

The use of the FCS to surface treat $CaCO_3$ improves the compounding process and mineral dispersion in polymers. The polymers that contain ASA-treated calcium carbonate demonstrate superior mineral dispersion and favorable mechanical properties.
Food-contact articles produced from the FCS may ultimately be subject to composting because some of the polymers are compostable. However, the Notifier understands that, while composting programs for items such as plastic cutlery and the like are increasing in small markets, they are not yet widely available

* = Subsequent to this date. this EA was edited using the Adobe text editor tool to make corrections of an editorial nature.

[1] U.S. Food and Drug Administration, Food Types & Conditions of Use for Food Contact Substances, *available at:* https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

on a national scale in the U.S.[2] Based on the limited number of composting facilities nationally at this time, the Notifier expects and conservatively assumes that the FCS will be disposed of almost entirely by landfill or combustion.[3] No significant environmental impact is anticipated due to the landfilling or incinerating of compostable polymers.[4]

The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials containing the FCS will be widely distributed across the country. Therefore, it is anticipated that disposal of food-contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste (MSW) generally. According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of MSW is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[5] As the FCS is expected to be primarily disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.[6]

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

The FCS, 2,5-furandione, dihydro-, mono-C15-20-alkenyl derivs., (CASRN 68784-12-3), also known as alkenyl succinic anhydride (ASA), is not a single substance, but rather a mixture of various alkenyl chain lengths depending on the manufacturing process. It can be represented by the following structure:

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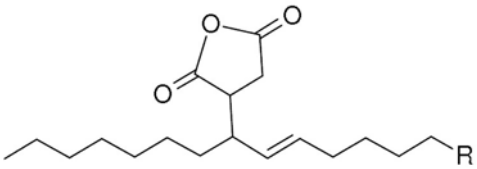
[2] For example, a BioCycle survey completed in 2018 identified a total of 185 full-scale food waste composting facilities in the U.S. *See, e.g.*, https://www.biocycle.net/food-waste-composting-infrastructure-u-s/

[3] This is further supported by the Environmental Protection Agency's (EPA) "Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Material Generation and Management in the United States", December 2020, pages 4 and 6, at: https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf, which confirms that food, yard trimmings, and other municipal solid waste (MSW) organic materials are the categories of waste that are composted in the U.S.; plastics are not included among the materials reported to be composted.

[4] The Notifier does not account for composting in our quantitative CO_2 assessment because the value determined based on incineration provides a worst-case scenario with respect to greenhouse gas emissions. In any event, should some composting of the FCS occur, the Notifier does not expect this to adversely impact the environment.

[5] *See* U.S. Environmental Protection Agency (EPA), "Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States" (EPA530-F-20-009) December 2020, Table 1, *available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

[6] By assuming that none of the FCS is recycled, we recalculate the fraction of FCS that is combusted as follows: 11.8% combusted (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.



R = CH_3 - C_6H_{13}

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. The FCS may be manufactured in plants both inside and outside of the United States. When manufactured in the U.S., the plants meet all applicable federal, state and local environmental regulations.

Notifier asserts that there are no extraordinary circumstances that would indicate the potential for significant 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 that may significantly 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. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of materials containing the FCS. 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 disposed of as part of the food-contact article manufacturer's overall non-hazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS is provided in a separate Confidential Attachment to the Environmental Assessment.

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

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable, recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or

incinerated. ASTM standard number D7611 “Standard Practice for Coding Plastic Manufactured Articles for Resin Identification” provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made. We anticipate the articles manufactured with the FCS would be so marked and, thus, coded for recycling.

The FCS is composed of the elements carbon, hydrogen, and oxygen. Thus, the combustion products of the FCS may include carbon dioxide and water. The carbon content of the FCS has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (available in the Confidential Attachment to the Environmental Assessment) and is below 25,000 metric tons carbon. To evaluate 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. 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 listed 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 stated above, the estimated GHG emissions are below the threshold for mandatory reporting. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations. Thus, no significant adverse environmental impacts are anticipated from combustion of the FCS in MSW combustion facilities.

7. Fate of Emitted Substances in the Environment

a. Air

As described above, no significant quantities of any substances will be released to the atmosphere upon the use and disposal of finished articles manufactured with the FCS. Therefore, an assessment of the environmental fate of these substances is not required.

As indicated above in Item 6, the FCS will make up a very small portion of the total MSW currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating MSW combustors, and the incineration of food-contact materials containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (i.e., 40 CFR Part 60). *See* the Confidential Attachment to the Environmental Assessment for additional details.

b. Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills. Similarly, no significant effects on the concentrations of and exposures to any substances are anticipated as a result of the proposed use of the subject FCS. Thus, the fate of finished food-contact articles containing the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

c. Land

Considering the factors discussed above, no significant effects on the concentrations of land exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. As discussed above, EPA's regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate (i.e., 40 CFR Part 258). On these bases, there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the FCS in the production of food contact articles.

8. Environmental Effects of Released Substances

No significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified above. Therefore, an evaluation of the environmental effects of the proposed use of the FCS is not required. Thus, 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 finished articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors or and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food contact substances, the production, use, and disposal of the FCS involves the use of natural resources such as petroleum products and coal. The use of the 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 articles and will be used in place of similar mineral dispersant materials now on the market for use in food contact applications. The partial replacement of these types of materials by products containing the FCS is not expected to have any adverse impact on the use of energy and resources.

Manufacture of the FCS, and manufacture of the finished food-contact materials will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances. For this reason, the intended use of the FCS will have no significant adverse effect on the use of natural resources and energy.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food contact materials fabricated using the subject FCS. Therefore, the use of the FCS is not reasonably expected to result in any significant adverse impacts issues that require mitigation measures.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this FCN. 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 have no significant environmental impact.

12. List of Preparers

Daniel C. Rubenstein, Partner, Steptoe & Johnson LLP, 1330 Connecticut Ave., N.W., Washington, D.C. 20036 with 12 years of experience with Food Additive Petitions, FCN submissions, and environmental assessments.

Patricia Kinne, Environmental Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036 has over 10 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

13. Certification

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

Date: March 29, 2023

Daniel C. Rubenstein, Partner

14. References

U.S. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States* (EPA530-F-20-009), December 2020

U.S. Food and Drug Administration, *Food Types & Conditions of Use for Food Contact Substances*.

15. Attachments

Confidential Attachment to the Environmental Assessment