Environmental Assessment

1. Date: September 22, 2021

2. Name of Applicant/Notifier: Songwon International – Americas, Inc.

3. Address:

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All communications on this matter are to be sent in care of Counsel for Notifier:

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4. Description of the Proposed Action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine (CAS Reg. No. 32687-78-8), as a stabilizer and antioxidant in polyolefin polymers and copolymers, except for use in contact with infant formula and human milk. Specifically, the FCS will be used:

1. In high density polyethylene (HDPE) at levels not to exceed 0.12 wt.-% in contact with all food types under Conditions of Use B through H.[1]

2. In polypropylene (PP) and PP copolymers at levels not to exceed 0.12 wt.-% in contact with all food types under Conditions of Use B through H.

3. In polyethylene copolymers as described in 21 C.F.R. § 177.1520(c), item 3.2a at levels not to exceed 0.18 wt.-% in contact with aqueous and acidic foods under Conditions of Use B through H.

4. In polyolefin repeat-use articles at levels not to exceed 0.12 wt.-% in contact with all food types with no temperature limitation.

[1] FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

1,2-Bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine is currently cleared for the uses listed above under FCNs 39, 316, and 366. The FCS made by the notifier would be a competitive replacement for the material currently marketed in the US.

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 utilized in patterns corresponding to the national population density and 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 generally.[2] According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (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.[3] 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.[4]

5. Identification of the Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine (CAS Reg. No. 32687-78-8).

Chemical Abstracts Service (CAS) name: 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine

CAS Registry Number: 32687-78-8

Molecular Formula: $C_{34}H_{52}N_2O_4$

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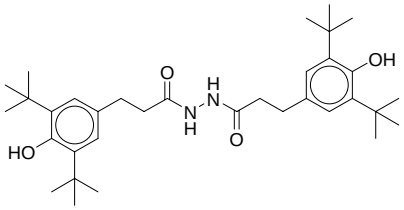
[2] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *see* Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov).

[3] *Id.*

[4] 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

Structural Formula:



Physical Description of FCS:

Physical Form: solid

Melting Point: 221-232°C

6. Introduction of Substances into the Environment

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 food-contact materials. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for 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 (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a 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. 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 the FCS in food-contact materials. In these applications, the FCS is expected to be entirely incorporated into the finished food-contact materials. Any waste materials generated in this process, ***e.g.***, plant scraps, are expected to be disposed of as part of the food-contact material manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact materials containing 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.

The FCS is composed of carbon, oxygen, nitrogen, and hydrogen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case release of carbon dioxide from the FCS has been calculated in a confidential

attachment to the Environmental Assessment, and an assessment of this worst-case release is also included in the same confidential attachment. Greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by EPA under 40 C.F.R. § 98.1, which "establishes mandatory greenhouse gas (GHG) reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (NEPA) documents. Moreover, 40 C.F.R. § 1508.27(b)(10) states that, when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. The expected carbon dioxide emissions are below 25,000 metric tons on an annual basis (*see* Confidential Attachment to Environmental Assessment). As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

Only extremely small amounts, if any, of the FCS or its constituents are expected to enter the environment as a result of the landfill disposal of food-contact materials containing the FCS, in light of the 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 and to take corrective action as appropriate (40 C.F.R. Part 258).

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Because the FCS is a high melting point solid (mp > 221°C), the FCS does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS.

As indicated above in Item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and the incineration of food-contact materials containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment 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. 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 and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. Furthermore, the use of the FCS as a stabilizer and antioxidant is a replacement for other identical antioxidants already on the market for use under FCNs 39, 316, and 366 and precludes any substantial increase in release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to this substance as a result of the proposed use of the FCS.

Considering the foregoing, we respectfully submit that 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 subject FCS in the manufacture of food-contact materials.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the FCS in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The use of the subject FCS in 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 plastics in place of other identical antioxidants already on the market for use under FCNs 39, 316, and 366.

The replacement of identical or similar antioxidants by the subject FCS is not expected to have any significant adverse impact on the use of energy and resources. Manufacture of the FCS, its use in resins, and the final conversion of the resin to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture and use of the other cleared FCSs. Packaging materials produced from resins containing the FCS are expected to be disposed of according to the same patterns when they are used in place of current materials. Thus, there will be no impact on current or future recycling programs.

For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this Notification becoming effective.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive antioxidants and stabilizers). Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the material already cleared by FCNs 39, 316, and 366 that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

George G. Misko, J.D., Partner, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Mr. Misko has over 30 years of experience drafting food additive petitions, FCN submissions, and environmental assessments.

Colleen M. Evale, J.D., Counsel, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Evale has over 20 years of experience drafting FCN submissions and environmental assessments.

Kristin P. Wiglesworth, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Wiglesworth has over 4 years of experience drafting FCN submissions and environmental assessments, and 15 years of total experience in FDA regulated industries.

13. Certification

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

Date: September 22, 2021

[redacted]

Counsel for Notifier

14. References

1. FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *see* Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov).

3. *Container Recycling Institute's Plastics Facts & Statistics* are available at http://www.container-recycling.org/index.php/factsstatistics/plastic.

15. Attachment

1. Confidential Attachment – Attachment 8