Environmental Assessment

1. Date: February 2, 2024

2. Name of Applicant/Notifier: Chitec Technology Co., Ltd

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

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), amines, bis(hydrogenated palm-oil alkyl)hydroxy (CAS Reg. No. 1374859-51-4), when used in food-contact materials. The FCS is intended for use as an antioxidant and/or stabilizer in olefin polymers intended for single and repeat food contact use. Specifically, the FCS will be used at levels not to exceed 0.1 percent of the finished olefin polymer. Polypropylene (with a density of 0.85-0.91 gram per cubic centimeter) and high density polyethylene (with a density not less than 0.94 gram per cubic centimeter) homopolymers and copolymers containing the FCS may be used in contact with food types I, II, IV-B, VI-A, VI-B, VII-B and VIII under Conditions of Use A through H as described in Tables 1 and 2, and food types III, IV-A, V, VI-C, VII-A, and IX under Conditions of Use B through H as described in Tables 1 and 2.[1] Other polyethylene (with a density less than 0.94 gram per cubic centimeter) homopolymers and copolymers containing the FCS may be used in contact with food under Conditions of Use B through H as described in Table 2. The FCS is not for use in contact with infant formula and human milk, as these uses were not specifically addressed in the FCN.

[1] FDA's food types and Conditions of Use are defined in Tables 1 and 2 at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

B. Need for Action

The FCS is intended to be used as an antioxidant in polymeric food-contact materials. The FCS is needed to minimize changes in the melt flow rate of olefin polymers and copolymers following multiple extrusions.

C. Location of Use/Disposal

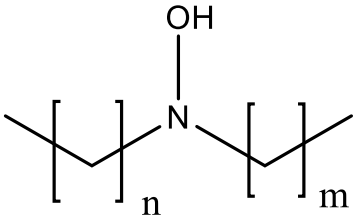
The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Thus, it is anticipated that disposal of food contact materials containing the FCS will occur nationwide. 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% was processed through other food management pathways.[2] 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.[3]

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

The FCS that is the subject of this Notification is amines, bis(hydrogenated palm-oil alkyl)hydroxy (CAS Reg. No. 1374859-51-4). The molecular formula for the predominant form of the FCS, *i.e.*, N,N-dioctadecylhydroxylamine, is $C_{36}H_{75}NO$. The molecular weight of this substance is 538 g/mol. A representative structure of this compound is:

[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* https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.*pdf*.

[3] By assuming that none of the FCS is recycled, composted, or handled through other food management pathways, we recalculate the fraction of FCS that is combusted as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted.



where n and m = 17

6. <u>Introduction of Substances into the Environment</u>

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 materials. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances in this case indicative of adverse environmental impacts resulting from the manufacture of the subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used in the manufacture of food-contact materials. The FCS is expected to be entirely incorporated into the finished food-contact materials and essentially of it is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Any waste materials generated during the manufacture of the finished articles, *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.

The FCS consists of carbon, hydrogen, nitrogen, and oxygen. When properly incinerated, the combustion products resulting from this mixture are expected to be carbon dioxide, nitrous oxide, and water. The carbon and nitrogen content of the FCS has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential anticipated annual market volume of the FCS (provided in confidential attachment to the EA) and is below 25,000 metric tons carbon dioxide equivalent (CO2-e) emission per MSW combustor (MWSC) on an annual basis.[4]

Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact materials, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW 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, "to have ground water monitoring systems and to take corrective action as appropriate (40 C.F.R. Part 258)." These requirements

[4] U.S. estimated 75 MSWCs. See US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), *available at*: https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentration of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS, as the FCS does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials 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, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and the incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations.

B. Water

No significant effects on exposures to any substances from the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of 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 concentration of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the chemical characteristics of the FCS are expected to result in virtually no leaching of the FCS components under normal environmental conditions when the food-contact articles in which they are contained are disposed of. 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 these substances 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. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introductions of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of the food-contact materials containing the FCS. In addition, the use and disposal of the polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency'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 contact materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The manufacturer of the FCS will consume comparable amounts of energy and resources as manufacturers of similar products already being marketed (*i.e.*, antioxidants permitted for use in olefin polymers), as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles with or without comparable additives. Because the FCS is used at an exceedingly low level in the production of food-contact materials, there will be no significant impact on current or future recycling programs. Further, in addition to this FCS, other antioxidants are found in a variety of food-contact materials and recycled plastics.

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. Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the produced action is not approved, the result would be the continued use of the materials that the subject FCS would replace. Such action would have no anticipated environmental impact.

12. List of Preparers

Kathryn C. Skaggs, J.D., Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C. 20001. Ms. Skaggs has 12 years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Dr. Coneski has 10 years of experience preparing FCN submissions and Environmental Assessments in support of the same.

13. Certification

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

Date: February 2, 2024

Kathryn C. Skaggs
Counsel for Notifier

14. References

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2 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, available at https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf..

3. US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW) available at https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw.

15. Attachment

1. Confidential Attachment to Environmental Assessment