

Environmental Assessment

1. Date January 23, 2024 *

2. Name of applicant/notifier RIANLON CO.LTD

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4. Description of proposed action

a) Requested Action

The action requested in this Notification is to establish a clearance for the food contact substance (FCS) of Octadecyl-3-(3', 5'-di-tert-butyl-4'-hydroxyphenyl) (CAS No.2082-79-3) which will be used as: (a)an antioxidant in polyolefin polymers and styrene block polymers with 1,3-butadiene, hydrogenated (SEBS; CAS Reg. No. 66070-58-4); (b) A stabilizer for flexible polyvinyl chloride (PVC) except for use in contact with infant formula and human milk.

Specifically, the FCS will be used as:

1. An antioxidant in SEBS (CAS Reg. No. 66070-58-4) at levels not to exceed 0.07 percent by weight of SEBS. Articles containing the FCS may contact all food types under conditions of use A through H, as described in Tables 1 and 2;
2. An antioxidant for olefin polymers complying with 21 CFR 177.1520(c), item 3.6, at levels not to exceed 0.25 percent by weight of the finished articles that may contact all food types under Conditions of Use A through H as described in Tables 1 and 2.
3. A stabilizer in flexible PVC film at levels not to exceed 0.006 percent by weight of flexible PVC film (maximum thickness shall not exceed 1 mil) that may contact food types I, II, IV-B, VI-B, VII-B and VIII under Conditions of Use A through H as described in Tables 1 and 2.

b) Need for Action

The FCS is intended to be used as an antioxidant in polymeric food-contact materials. The FCS inhibits oxidation, and thus deterioration of technical performance, of polymers used in food-contact materials. Octadecyl-3-(3', 5'-di-tert-butyl-4'-hydroxyphenyl) is currently cleared for the uses

listed above under FCNs 181, 386, 768, 830, 1557, 1605, 1935 and 2035. The FCS made by the notifier would be a competitive replacement for the material currently marketed in the US.

c) Locations of Use/Disposal

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials and articles. Food contact articles produced with the FCS in the U.S. 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 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% is directed to other food management pathways.¹ 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.²

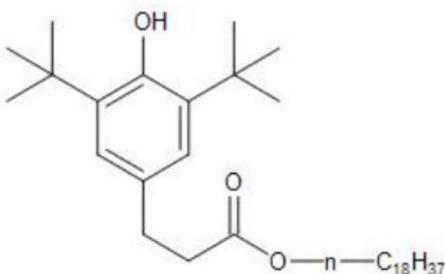
5. Identification of substance that is the subject of the proposed action

The FCS that is the subject of this Notification is Octadecyl-3-(3', 5'-di-tert-butyl-4'-hydroxyphenyl) (CAS No.2082-79-3). Chemical information on this substance is presented below:

| | |
|-------------------|--|
| CAS Reg. No.: | 2082-79-3 |
| Chemical Formula: | C ₃₅ H ₆₂ O ₃ |

¹ Table 35 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

² This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.



Structural Formula:

Appearance: White powder

Melting Point: 50-55°C

6. Introduction of substances into environment

a) 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. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances³ in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b) As a Result of Use and Disposal

No significant environmental release is expected upon the use of the FCS in the manufacture of food-contact articles. In these applications, the FCS will be entirely incorporated into the finished food-contact articles. Any waste materials generated in the process (e.g., plant scraps) are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The FCS is expected to remain in the food-contact articles and, therefore, its disposal by the ultimate consumer will be by conventional rubbish disposal, and thus, primarily by sanitary landfill or incineration.

³ Such extraordinary circumstances would include: 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 adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on Intentional Trade in Endangered Species of Wild Fauna to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated.

Air (Combustion):

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 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. Considering the proposed use and use level of the FCS described under 4(a),, it can be concluded that the FCS will make up an insignificant portion of the plastic containers and packaging presented in the total municipal solid waste (MSW) currently combusted.⁴

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, a GHG analysis was performed. This analysis is presented in the confidential attachment to the EA and is based upon the elemental composition of the FCS and assumes that 19.1% (described under 4(c)) of the annual market volume will be combusted.

MSW combustion facilities are regulated by the U.S. EPA under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG" and sets an annual 25,000 metric tons carbon dioxide equivalent (CO2-e) emission threshold for required reporting at 40 CFR 98.2 of this regulation. From this analysis (contained in the confidential attachment to the EA), the expected CO2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

As the FCS will not alter the emissions from properly operating MSW combustors and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable Federal, State or local emissions laws and regulations (i.e., 40 CFR 60, 40 CFR 98). 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. As indicated above, the FCS will make up a small portion of the total MSW currently combusted. Thus, no significant adverse environmental introductions will result from the proper incineration of the FCS in the amounts utilized in the notified applications.

Landfill:

⁴ The comparison is contained in a confidential attachment.

Only extremely low levels, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA's 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 ground-water monitoring systems (40 C.F.R. Part 258). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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.

Water

No significant effect on the concentrations of and exposure to any substances 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.

Further, we compared the maximum annual market volume of the food-contact polymers containing the FCS,⁵ to the annual plastic containers and packaging waste (14,530 thousand tons in 2018 from EPA), and concluded that the FCS and the food-contact polymers containing the FCS will constitute a very small portion of the plastic containers and packaging waste in the MSW. Therefore, we do not expect there are any extraordinary circumstances which would otherwise suggest a significant environmental impact on the aqueous environment resulting from post-consumer disposal of food-contact articles that contain the FCS due to the proposed use.

7. Fate of emitted substances in the environment

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food-contact articles containing the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic or terrestrial environmental compartments.

⁵ The comparison is contained in a confidential attachment.

Accordingly, because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental effects of released substances

As discussed previously, only extremely small and insignificant quantities of the FCS may be expected to be released to the environment during use and disposal of food-contact articles containing the FCS.

Based on these considerations, no adverse effect on organisms in the environment, or the environment itself, is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

9. Use of resources and energy

The proposed use of the FCS in this Notification will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace similar substances already on the market. Food-contact materials and articles containing the FCS are expected to be disposed according to the same patterns when it is used in place of current materials. .

The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of other similar polymer antioxidants. Furthermore, the use of the subject FCS proposed in this Notification is as replacement for similar polymer antioxidants.

The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is insignificant.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles containing the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished item; the insignificant impact on environmental concentrations of

combustion products of the FCS; and the close similarity of the FCS to the products it is intended to replace. Thus, the use of the FCS as proposed is not reasonably expected to result in any significant environmental problem requiring mitigation measures of any kind.

11. Alternatives to proposed action

No potential 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 materials which the FCS would otherwise replace; such action would have no anticipated environmental impact.

12. List of preparers

Gabbie Wang, 6 years of experience related to the preparation of Food Contact Notifications and food packaging compliance matters under FDA food contact regulations.

13. Certification

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

14. Attachment

- Confidential Attachment to the Environmental Assessment (Attachment 12 in this Notification)

Date: January 23, 2024

Gabbie Wang, Regulatory analyst



Consultant for RIANLON CO.LTD