Environmental Assessment

1. Date April 3, 2024

2. Name of Applicant/Petitioner ADEKA CORPORATION

3. Address

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Hasbrouck Heights, NJ 07604

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

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4. Description of Proposed Action

The action requested in this submission is to establish a clearance for the food-contact substance (FCS), L-Aspartic acid, N-benzoyl-, sodium salt (1:2) (CAS Reg. No. 2092399-70-5). The FCS is for use as a β-nucleating agent added to polypropylene homopolymers and co-polymers at a maximum level of 0.3% w/w. The maximum thickness of the polypropylene will be 2 mm and the polypropylene will be used as food contact films and molded articles. The FCS as a component of the polypropylene would come into contact with all food types under conditions of use A-H as described in the FDA Guidance for Industry: Preparation of Premarket Submission for Food Contact Substances (Chemistry Recommendations). The highest intended temperature that the FCS would be exposed to is 230˚C during manufacturing, and the maximum food-contact time is 121˚C for 2 hours followed by long term storage at room temperature.

The FCS is intended to assist in the process of accelerating crystallization to improve stiffness, impact strength and tensile strength of a polymer. The Notifier does not intend to provide finished food packaging from the FCS, as the FCS is an additive that is used in the manufacture of polypropylene homopolymers and copolymers used for food-contact applications. Polypropylene homopolymers and copolymers containing the FCS will then be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the polypropylene polymers 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 the polypropylene polymers containing the FCS will occur nationwide, with the material being land disposed, recycled, or combusted in quantities similar to those reported for municipal waste generally.[1] According to the U.S.

[1] Advancing Sustainable Materials Management: Facts and Figures 2018, U.S. Environmental Protection Agency, accessed March 2023, at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

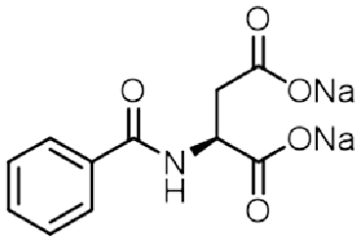
Environmental Protection Agency's (EPA) 2020 update regarding municipal solid waste (MSW) in the United States, it is estimated that, of the 292.36 million tons of MSW generated in 2018, 50.0% of MSW generated was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.[2] As the food-contact materials containing the FCS are expected to be primarily disposed of through combustion, recycling, or land-filling (*i.e.*, not composted or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed, recycled, or combusted. On this basis, we estimate that 13.8% 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 the notification is L-Aspartic acid, N-benzoyl-, sodium salt (1:2). Chemical information on this substance is presented below:

CAS Registry Number: 2092399-70-5

Structural Formula:



6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), an environmental assessment (EA) 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 produces the FCS in Japan and complies with all relevant environmental regulations in Japan. 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 subject FCS in food-contact materials. In these applications, the FCS (i.e., an additive for polymers) is expected to be entirely incorporated into the finished food-contact material. Any waste materials generated in this process, e.g., plant scraps, are expected to be disposed of as a part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

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[2] *Id.*

[3] 11.8% Combusted ÷ (11.8 % combusted + 50% land disposed + 23.6% recycled) = 13.8% combusted.

Disposal of finished food-contact materials containing the FCS will be by recycling or conventional rubbish disposal, i.e., 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 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.[4] We anticipate that articles manufactured with the FCS will be so marked and, thus, coded for recycling.

The subject FCS consists of the elements carbon, hydrogen, oxygen, nitrogen, and sodium, which are elements that are commonly found in municipal waste. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS have been calculated. The concentrations of carbon dioxide in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food packaging applications.

To evaluate the significance of the 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. Greenhouse gas (GHG) emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. The expected carbon dioxide equivalent emissions related to combustion of the FCS are based upon the projected confidential FCS market volume and are below 25,000 metric tons on an annual basis (as calculated in the Confidential Addendum to Environmental Assessment).

Furthermore, to evaluate the significance of the 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 (i.e., 40 C.F.R. Part 60 and/or relevant state and local laws). In this context, the EPA, under 40 C.F.R. § 98.1, "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." This regulation describes that facilities must report GHG emissions and sets an annual 25,000 metric ton CO_2-e threshold for required reporting (40 C.F.R. § 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 C.F.R. § 98.30(a). As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental adverse impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

EPA regulations require all 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 and Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of

[4] ASTM, ASTM D-7511/D7611M-21: Standard Practice for Coding Plastic Manufactured Articles for Resin Identification.

these requirements, the FCS is not expected to reach aquatic or terrestrial environment when disposed via landfill.

7. 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. Use and disposal of food-contact materials manufactured with the FCS will not significantly alter the emissions from solid waste combustion facilities operating under 40 C.F.R. Part 60.

As indicated above in Item 6, the FCS will replace a 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 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 and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject 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. 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, the environmental fate does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS was identified as discussed under Item 6.

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 subject substance 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 regulation, e.g., the 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 ("Criteria for Municipal Solid Waste Landfills") 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 involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject 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 polypropylene homopolymers and copolymers in place of similar polypropylene homopolymers and copolymers now on the market for use in food-contact applications.

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

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from polypropylene homopolymers and copolymers containing the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the 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 that the subject FCS would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Malcolm Driffield, Ph.D., Exponent International, Ltd. Harrogate, North Yorkshire, GBR.

13. Certification

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

Date: April 3, 2024

Signature:

Malcolm Driffield, Ph.D.

14. References

ASTM, Standard Practice for Coding Plastics Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

Environmental Protection Agency, Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States (December 2020), available at: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.

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.

15. Appendices

A. Confidential Attachment to the Environmental Assessment