Environmental Assessment

1. Date: 23 March, 2023

2. Name of applicant/notifier:

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3. Address:

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4. Description of the proposed action

The action requested in this notification is to permit the use of a polyurethane resin produced by reacting 2,4-toluene diisocyanate (CAS Reg. No. 584-84-9) with Polyolpolyether (Propylene oxide ethylene oxide polymer, ether with glycerol) (CAS 9082-00-2) as a binder in agglomerated cork stoppers production. The produced agglomerated cork stoppers are used as closures for bottles containing alcoholic beverages, *i.e.,* Food Types VI-A and VI-C, under FDA's Conditions of Use E through G, as defined in Tables 1 and 2 at Food Types & Conditions of Use for Food Contact Substances | FDA.

Agglomerated cork stoppers are composed of a combination of natural cork granules and a minor percentage of particulate polymeric material, and it is necessary to use a binder or glue to adhere these substances together to form the finished closure.

The Notifier intends to produce finished food-contact articles containing the subject food contact substance (FCS). Closures containing the subject 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 will occur nationwide, with about 80.9% of the materials being deposited in land disposal sites, and about 19.1% combusted[1].

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

The FCS that is the subject of this Notification is a polyurethane resin produced by reacting 2,4-toluene diisocyanate (CAS Reg. No. 584-84-9) with Polyolpolyether (Propylene oxide ethylene oxide polymer, ether with glycerol). It is a polymerization process. The free OH groups present in the Polyolpolyether react with the free NCO groups in the 2,4-toluene diisocyanate to originate the polymer. Some remained unreacted NCO molecules will react with the OH groups (from cork and environmental humidity) during the cork stopper production process.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), 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 circumstances in this case indicative of any adverse environmental

[1] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and manage in the United States, EPA530-F-20-009*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), December 2020, available at Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov). According to this report, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted with energy recovery, 32.1% was recovered (a combination of waste recovered for recycling and for composting) and 6.1% processed through other food management pathways. If we assume that food-contact articles containing the FCS are expected to be disposed of by landfilling or combustion (i.e., not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19.1% of food-contact articles containing the FCS will be combusted annually. 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.

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.

No environmental release is expected upon the use of the subject FCS to fabricate bottle closures. In these applications, the FCS *(i.e.,* a polymer) is expected to be used in the manufacture of predominantly cork-containing closures and will be entirely incorporated into and remain with the finished food-contact article/closure. 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. Migration tests, designed to simulate the notified use conditions were performed and are referenced in the EA's confidential attachment. Total non-volatile extractives (TNEs), including those for 2,4-toluene diisocyanate, 2,4-toluene diamine (TDA), ethylene oxide, propylene oxide, and glycerol were 448 µg/g stopper. TDA-related extractives were determined to be 18.816 µg/g stopper. Given an average stopper weight of 5.68x10^6 µg, the migration of TNEs and TDA-related extractives from finished stoppers are as follows:

TNEs: (448 µg extractives / g stopper x 5.58 g stopper) x 100% / (5.68x10^6 µg/g stopper) = 0.04% migration

TDA-Related Extractives: (18.816 µg extractives / g stopper x 5.68 g stopper) x 100% / (5.68x10^6 µg / stopper) = 0.002% migration

Given the stated nationwide disposal and assumed further dilution in any receiving environmental compartment (i.e. soil, water, air), any environmental introduction of these residues would not have a significant impact. Therefore, no further analysis is considered in this EA.

To access the significance of these impacts, we considered the environmental impact analysis must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. Thus, according to 40 C.F.R. § 98.2(a)(3), stationary fuel combustion sources that emit 25,000 metric tons carbon dioxide (CO2) equivalents (CO2-e) or more per year must report their greenhouse gas (GHG) emissions to the EPA. Importantly, municipal solid waste combustion facilities are considered stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). Greenhouse gas emissions resulting from the use and disposal of the FCS result from the incineration of articles containing the FCS in municipal solid waste combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. § 98, which establishes mandatory 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 tons carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

The carbon dioxide emissions expected from combustion of the FCS were estimated in the confidential attachment to the environmental assessment from the confidential market projection. These predicted emissions are far below 25,000 metric tons annually (CO_2-e = 2,942 metric ton/year). Thus, no significant environmental impacts are anticipated to result from combustion of the FCS in municipal solid waste combustion facilities, because the estimated GHG emissions are far below the threshold for mandatory reporting.

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

7. Introduction of Substances into 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 food-contact substance, as the FCS is a polymer and does not readily volatilize. The food-contact substance will make up a very small portion (0.00081%, see

Environmental Assessment Confidential Attachment) of the total municipal solid waste currently combusted. Therefore, the food-contact substance will not significantly alter the emissions from 40 C.F.R. 60-compliant operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

(b) Water
No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject polymer. The fate of the food-contact substance 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 food-contact substance. In particular, the polymeric nature of the food-contact substance is expected to result in virtually no leaching of FCS components under normal environmental conditions when finished stoppers are disposed of. Furthermore, the very low production of the polymer 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 food contact substance.

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 polymer in the manufacture of stoppers intended for use in contact with food. Therefore, the environmental fate of substances 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 were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed in item 6, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer consist of extremely small quantities of combustion products and leachables, if any.
Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of stoppers containing the food-contact substance. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of closures containing 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 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 packaging materials, the production, use and disposal of the food-contact substance involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject food-contact substance in the fabrication of bottle closures is not expected to result in a net increase in the use of energy and resources, since the food-contact substance is intended to be used in closures which will be used in place of similar articles already on the market for use in food-contact applications, such as 100% synthetic, i.e., plastic, bottle closures. Further, other granulated cork products not produced by the Notifier are expected to make use of similar binders. The partial replacement of these types of materials by the subject food-contact substance is not expected to have any adverse impact on the use of energy and resources. Manufacture of the food-contact substance, and its conversion to use in a finished closure, will consume energy and resources in amounts comparable to the manufacture and use of other, similar food-contact substances. Furthermore, the finished stopper in which the FCS is used is not currently recovered for recycling.

Food-contact materials produced using the subject food-contact substance are expected to be disposed of according to the same patterns when they are used in place of the current materials. In addition, 19.1% of the disposed of FCS products (i.e. the cork stoppers) are expected to be combusted. Study has shown that incineration of polyurethane is an efficient heat recovery method. It was calculated that 1 kg polyurethane burning can produce calorific value of about 7000 kcal/kg, which can provide heat equivalent to the same weight of coal provides energy (Yang et al., 2012). Thus, there will be no (negative) impact on use of resources and energy.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of closures fabricated using the subject food-contact substance. This is primarily due to the minute levels, if any, of leaching of components of the food-contact substance from finished closures employing the food-contact substance, and the insignificant impact on environmental concentrations of combustion products of the food-contact substance. Thus, no significant adverse environmental impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No significant 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 anticipated environmental impact.

12. Certification

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

Date: 23-03-2023

Signature: 

13. List of Preparers

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14. List of References

1. EPA, 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.
2. Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and manage in the United States, EPA530-F-20-009, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), December 2020, available at https://19january2021snapshot.epa.gov/sites/static/files/2020-11/documents/2018_ff_fact_sheet.pdf.
3. W. Yang, Q. Dong, S. Liu, H. Xie, L. Liu and J. Li, Recycling and disposal methods for polyurethane foam wastes. Recycling and disposal methods for polyurethane foam wastes, Procedia Environmental Sciences 16 (2012) 167 – 175. Available at : https://www.sciencedirect.com/science/article/pii/S1878029612005610

15. Confidential Attachments