Part IV (Environmental Information); Section B (Environmental Assessment)

☒An EA is required and has been prepared under 21 CFR 25.40 and is attached.

Note: An EA is a public document and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

Environmental Assessment

1. Date: August 2, 2019

2. Name of Applicant/Notifier: Flexpur – Polímeros de Poliuretano, S.A.

3. Address:

Flexpur – Polímeros de Poliuretano, S.A.
Rua da Estrada Nova, 785 – Apartado 15
3886-909 Esmoriz
PORTUGAL

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

Cynthia B. Lieberman, Partner
Keller and Heckman LLP
1001 G Street, NW, Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4114
Facsimile: (202) 434-4646
E-mail: lieberman@khlaw.com

4. Description of the Proposed Action:

The action requested in this Notification is to permit the use of the polyurethane resin produced by reacting a mixture of 2,4-toluene diisocyanate (CAS Reg. No. 584-84-9) and 2,6-toluene diisocyanate (CAS Reg. No. 91-08-7) with polyoxyethylene-polyoxypropylene glyceryl ether (CAS Reg. No. 9082-00-2) and 1,4-butanediol (CAS Reg. No. 110-63-4) as a component of agglomerated cork stoppers used as closures for bottles containing alcoholic beverages (*i.e.*, Food Types VI-A ("Beverages: Containing up to 8 percent of alcohol") and VI-C ("Beverages: Containing more than 8% alcohol")) under FDA's Conditions of Use D ("Hot filled or pasteurized below 150°F") through G ("Frozen storage (no thermal treatment in the container)").[1]

[1] FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm.

Agglomerated cork stoppers are composed of a combination of natural cork granules and synthetic components (typically particles), and it is necessary to use a binder or glue to adhere these substances together to form the finished closure. The food contact substance (FCS) resin is intended to serve this binding function.

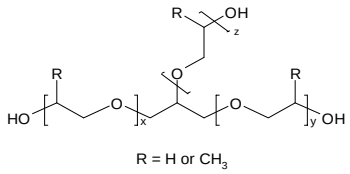
The Notifier produces the polyurethane binder resin for use by its customers in the manufacture of agglomerated cork stoppers. Closures containing the subject FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.[2]

Although cork stoppers may possibly be recycled,[3] this is not a widespread practice. Thus, environmental introductions of the FCS as a result of this disposal pathway are not further considered in this environmental assessment (EA).

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 a mixture of 2,4-toluene diisocyanate (CAS Reg. No. 584-84-9) and 2,6-toluene diisocyanate (CAS Reg. No. 91-08-7) with polyoxyethylene-polyoxypropylene glyceryl ether (CAS Reg. No. 9082-00-2) and 1,4-butanediol (CAS Reg. No. 110-63-4).

The structure of the polyoxyethylated-polyoxypropylated glycerol that is used as a starting reactant for the polyurethane resin may be depicted as follows:

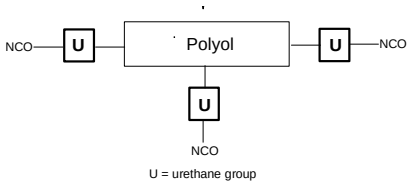


---

[2] *Advancing Sustainable Materials Management: Facts and Figures 2015. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, July 2018, *available at*: https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management. According to this report, of the total 262 million tons of municipal solid waste (MSW) generated in 2015, approximately 52.5% generally was land disposed, 12.8% was combusted, and 34.7% was recovered (a combination of waste recovered for recycling and for composting). If we assume that food-contact articles containing the FCS are expected to be disposed of by land-filling 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 19.6% of food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows: 12.8% combusted ÷ (12.8% combusted + 52.5% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

[3] *See, for example:* https://earth911.com/recycling-guide/how-to-recycle-corks/.

Reaction of this polyol with toluene diisocyanate (TDI) results in a polyurethane resin with the following general structure:



The FCS resin, prior to curing, has a weight average molecular weight in the range of 6000 – 9000 daltons and a number average molecular weight in the range of 1500 – 3000 daltons. The FCS undergoes further polymerization and cross-linking during the production and curing of the final stopper. Thus, in its final form as an integral component of the cork stopper, the FCS has an extremely high molecular weight.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), an EA 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 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 significant 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 bottle 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 nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of closures containing the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The FCS is composed of carbon, oxygen, nitrogen, and hydrogen. Thus, the combustion products of the FCS may include carbon dioxide and nitrous oxide. The carbon and nitrogen contents of the FCS have been calculated based on the elemental composition of the FCS (presented in the Confidential Attachment to the EA).

In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) carbon dioxide equivalents (CO_2-e) or more per year to report their greenhouse gas (GHG) emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by

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 MT CO_2-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. 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.

Based on the confidential market volume, the expected CO2-e emissions, as shown in the confidential attachment to the EA, are below 25,000 MT on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Moreover, as the FCS only contains carbon, oxygen, nitrogen, and hydrogen, elements that are commonly found in MSW, the presence of the FCS in MSW will not significantly alter the emissions from properly operating MSW combustion facilities. Therefore, based on the foregoing points, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (*i.e.*, 40 C.F.R. § 60 or relevant state and local laws).

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 articles, 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, and to have ground-water monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active MSW landfills that were constructed before October 9, 1993, are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

7. <u>Fate of Emitted Substances in the Environment</u>

(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, a polymer, as it does not readily volatilize.

As indicated in the Confidential Attachment to the EA, the FCS will make up a very small portion of the total MSW currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. § 60-compliant operating MSW combustors, and incineration of the FCS will not cause MSW 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 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 above.

(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, the polymeric nature of the FCS is expected to result in virtually no leaching of the FCS components under normal environmental conditions following the disposal of finished stoppers. Furthermore, the very low production of the FCS for use in food-contact applications (as noted in the Confidential Attachment to the EA) precludes any substantial release to the environment of the FCS 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 FCS in the manufacture of agglomerated cork stoppers intended for use in contact with food. Therefore, the environmental fate of FCS components 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 above, 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 FCS 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 FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and 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 disposal of closures containing the FCS. Therefore, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.,* EPA's regulations in 40 C.F.R. Parts 60 and 258.

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 and coal. However, the use of the subject FCS in the fabrication of agglomerated cork stoppers is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in closures that will be used in place of similar articles already on the market for use in food-contact applications. In particular, the FCS that is the subject of this Notification is cleared for the same intended use under effective FCNs filed by other Notifiers. This Notification, if it becomes effective, will allow additional manufacturers of

agglomerated cork stoppers to use the FCS resin in the production of their products. These closures will be used in the same applications as closures produced by the Notifiers of the existing effective FCNs.

The production of FCS-containing stoppers by other manufacturers, in addition to (or in partial substitution for) the production of FCS-containing stoppers by the manufacturers authorized under other effective FCNs is not expected to have any adverse impact on the use of energy and resources. Production of the FCS, and its conversion to use in a finished stopper, will consume energy and resources in comparable amounts regardless of which manufacturer produces the final agglomerated cork stopper.

Furthermore, the finished stoppers containing the FCS are not currently recovered for recycling to a significant extent. Food-contact materials produced using the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current recycling programs.

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 FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished closures employing the polyurethane binder, and the insignificant impact on environmental concentrations of combustion products of the FCS. Thus, no significant adverse environmental impacts were identified that require mitigation measures of any kind.

11. Alternatives to the Proposed Action

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

12. List of Preparers

Cynthia B. Lieberman, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Over 11 years of experience in preparing Food Contact Notifications, and Environmental Assessments for the same.

Holly H. Foley, Senior Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Over 35 years of experience in preparing Food Additive Petitions and Food Contact Notifications, including the Environmental Assessments for the same.

13. Certification

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

Date: August 2, 2019

[redacted]

Cynthia B. Lieberman
Counsel for Flexpur – Polímeros de Poliuretano, S.A.

14. List of References

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2, *available at*: http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm.

2. *Advancing Sustainable Materials Management: Facts and Figures 2015*, U.S. Environmental Protection Agency, July 2018, *available at*: https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf.

3. EPA's Greenhouse Gas Equivalencies Calculator, *available at*: https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator.

4. Earth 911, *How to Recycle Corks* (2018), *available at*: https://earth911.com/recycling-guide/how-to-recycle-corks/.

15. List of Attachments

1. Confidential Attachment