Environmental Impact of Food Contact Substance (21 CFR Part 25)

Environmental Assessment

1. **Date:** January 5, 2018

2. **Name of Notifier:** Amorim & Irmãos

3. **Address:** Amorim & Irmãos
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All communication regarding this food contact notification (FCN) environmental assessment (EA) should be sent to the attention of the authorized representative:

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4. **Description of the proposed action:**

   a. **Requested action:**

   The action requested in this notification is to permit the use of a polyurethane-based adhesive as a food contact substance (FCS) and binder for cork granulate that is used in the production of Amorim & Irmãos' Neutrocork® micro-agglomerated corks (henceforth, Neutrocork® stopper). Neutrocork® stoppers are then used as closures for bottles containing wines and other alcoholic beverages. Neutrocork® stoppers are a so-called "technical" stopper recommended for wines intended for early consumption.

   b. **Need for action:**

The FCS, a polyurethane polymer, is intended for use as a binder of granulated cork in the production of micro-agglomerated corks that are used as stoppers for bottles of wines, sparkling wines, and select microbrewery beers. The FCS is 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 FCS has been specifically tailored to bind the granulated cork together while maintaining desirable viscoelastic properties of the stopper.

The flexibility and elasticity of polyurethane-based binders such as the FCS are preferred over existing epoxy or silicone based adhesives, exhibiting a rigidity and flexibility more suited to use in cork stoppers.

c. Locations of use/disposal:

Use: As a component of finished micro-agglomerated corks that are used as cork stoppers for bottles of wines, sparkling wines, and select microbrewery beers nationwide, the FCS is used in patterns corresponding to the needs and locations of wine, sparkling wine, and microbrewery beer bottling facilities. Closures containing the FCS will be widely distributed across the United States (U.S.), and will be utilized in patterns corresponding to the national population density.

Disposal: The FCS, along with the micro-agglomerated cork stopper, will be disposed of in municipal solid waste (MSW) systems throughout the U.S., including rural and urban residential neighborhoods, businesses, etc. According to the U.S. Environmental Protection Agency (EPA)'s 2014 data regarding MSW in the U.S., approximately 258 million tons of MSW are generated annually, with approximately 65.5%, or 169 million tons, discarded and disposed of in MSW landfills or combusted. More precisely, 33.14 million tons, or 12.8% of MSW were combusted with energy recovery in 2014, and 135.92 million tons, or 52.6%, were landfilled (U.S. EPA, 2016).

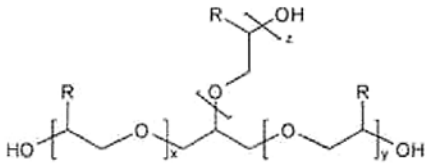
Assuming that food-contact articles containing the FCS are expected to be disposed of by landfilling or combustion, about 80.4% of the FCS materials will be deposited in land disposal sites, and about 19.6% will be combusted.[1]

[1] Utilizing figures cited in the 2016 EPA report, "Advancing Sustainable Materials Management," and assuming that food contact articles containing the FCS are expected to be disposed of by landfill or combustion (i.e. not recovered for recycling), we calculated the disposal pattern for the FCS based only on the quantities of MSW that are land disposed or combusted. On this basis, approximately 19.6% of food-contact articles containing the FCS will be combusted annually, according to the following calculation: 12.8% combusted ÷ (12.8% combusted + 52.6% land disposed) = 19.6% combusted. The remaining 80.4% will be land disposed.

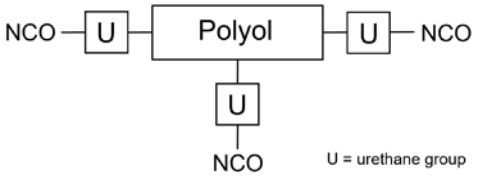
5. Identification of the substances that are the subject of the proposed action:

As described in Item 4(a), the FCS is a polyurethane polymer manufactured without solvents, which is designed as a binder for cork granulate in the production of micro-agglomerated cork stoppers. The FCS is 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 polyoxylated-polyoxypropylated glycerol that is used as a starting reactant for the polyurethane polymer may be depicted as follows:



Reaction of this polyol with toluene diisocyanate results in a polyurethane polymer with the following general structure:



6. Introduction of substances into the environment:

a. Introduction of substances into the environment as a result of manufacture:

The FCS and the finished micro-agglomerated cork stoppers are manufactured outside of the U.S. – in Portugal. Under 21 CFR §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 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.

b. Introduction of substances into the environment as a result of use and disposal:

The maximum yearly market volume of the FCS is based on fifth-year sales projections of finished micro-agglomerated cork stoppers in the United States (Confidential Appendix 2).

The FCS is expected to be used in the manufacture of the Neutrocork® stopper, which are used as closures for bottles containing wines and other alcoholic beverages and will be entirely incorporated into and remain within the finished food contact article (Neutrocork® stopper). Waste materials generated in the production process 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, in this case outside the U.S.

As described in Item 4(c), food contact articles containing the FCS sold and distributed within the U.S. will be disposed of through municipal solid waste (MSW) systems throughout the country. Because the FCS is retained within the disposed micro-agglomerated cork stoppers after use, as described above, 100% of the FCS contained within the micro-agglomerated cork stoppers is expected to be discarded in MSW landfills or incinerated in MSW combustors.

Based on the maximum FCS use level and considering the projected fifth-year sales estimates, the FCS is demonstrated to comprise a negligible component ([redacted]) of annual MSW discards. Calculations supporting this determination are included in Confidential Appendix 2.

When disposal of the entire finished cork article is considered using projected fifth-year sales estimates, the contribution of finished corks to annual MSW discards also accounts for a negligible component ([redacted]). Calculations supporting this determination are included in Confidential Appendix 2. Therefore the requested use of the FCS will not significantly alter the magnitude, composition, or risk of environmental releases from MSW disposed of in landfills.

Likewise, the FCS is demonstrated to comprise a negligible component of the amount of MSW combusted annually ([redacted]). Calculations supporting this determination are included in Confidential Appendix 2. The FCS is composed of carbon, hydrogen, nitrogen, and oxygen, elements commonly found in MSW. Air emissions from large and small MSW combustors are regulated by EPA with standards of performance and emissions guidelines (40 CFR Part 60). Additionally, emissions of certain "criteria air pollutants," e.g., carbon monoxide and nitrogen

oxides, are controlled via National Ambient Air Quality Standards set by EPA (40 CFR Part 50). Ultimately, due to its negligible addition to the MSW stream and components, which are typical of MSW, incineration of the FCS will not significantly alter the emissions from properly-operating MSW combustors or result in a violation of applicable emissions laws and regulations for MSW combustors.

Because the above described composition of the FCS, incineration of articles manufactured with the FCS in MSW combustion facilities are expected to generate greenhouse gas (GHG) emissions such as carbon dioxide and nitrous oxide. As such, we have analyzed GHG emissions using the projected market volume and EPA's Greenhouse Gas Equivalencies Calculator (U.S. EPA, 2017). This analysis is provided in Confidential Appendix 2.

In accordance with 40 CFR 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, the greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. 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 to GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

Based on the information provided in Confidential Appendix 2, combustion of the FCS would result in GHG emissions well below the EPA threshold for mandatory reporting. As such, no significant environmental impact is anticipated resulting from the combustion of the FCS in MSW combustion facilities.

Moreover, MSW landfills are regulated by the U.S. EPA (40 CFR Part 258) to restrict movement of waste into the environment, including location restrictions, composite liner requirements, leachate collection and removal systems, operating practices, groundwater monitoring requirements, and closure and post-closure care requirements (U.S. EPA, 2017a).

No significant introduction, if any, of the FCS constituents are expected to enter the environment as a result of landfill disposal of food-contact items containing the FCS, 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 CFR Part 258). Based upon confidential migration testing of the FCS-containing cork material, very low levels of residual monomers were detected following extraction with 3% acetic acid. This testing also showed that no significant levels of total non-volatiles extractives. The reference to the studies supporting these determinations is included in Confidential Appendix 2. Therefore, we do not expect the FCS to enter aquatic bodies as a result of this route of disposal.

Based on the information in Item 6 and Confidential Appendix 2, no significant environmental introductions of the FCS are anticipated as a result of use and disposal of articles manufactured with the FCS.

7. Fate of substances released into the environment:

a. Air

No significant effect on the concentration of and exposure to any substance in the atmosphere is anticipated due to the proposed use of the FCS. As discussed in Item 5 above, the FCS is a polymer and therefore characteristically non-volatile.

In addition, as discussed above in Item 6, the FCS is demonstrated to comprise a negligible component of the amount of MSW incinerated annually. Further, no significant emissions from the combustion of the FCS-containing cork stoppers in MSW combusted is anticipated, and will not cause municipal waste combustors to violate any applicable laws or emissions regulations.

b. Water

No significant effect on the concentration of and exposure to any substance in fresh water, estuarine or marine ecosystems is anticipated due to the proposed use of the FCS. As mentioned above, the FCS is entirely incorporated into and remains within the manufactured food-contact article/closures. The FCS is not anticipated to dissolve or be removed from finished articles. Manufacture occurs entirely outside the U.S., and disposal is anticipated to be in municipal landfills or incineration facilities. As such, no introduction of the FCS into aquatic environments is anticipated, and the fate of the FCS in aqueous environments does not need to be addressed.

c. Land

As discussed in Item 6 above, no significant effect on the concentration of or exposure to substances in terrestrial ecosystems is anticipated from the proposed use of the FCS. The polymeric nature of the FCS, again, is anticipated to result in virtually no leaching of the FCS components into the environment under normal conditions and proper adherence to use and disposal protocols. Therefore, there is no anticipated exposure of terrestrial organisms to the FCS as a result of its use in cork stoppers.

Considering all above information, we respectfully submit that there is no reasonable expectation of significant impact on the concentration of any substance in the environment due to the proposed use of the FCS in cork stoppers manufactured outside the U.S. and internally distributed.

8. Environmental effects of released substances:

Because no significant amounts of the FCS are expected to be released into the environment as the result of use and disposal, and because food contact materials manufactured with the FCS consist of extremely small quantities of combustion products and leachables, if any, it is unlikely that the FCS will be a risk to aquatic or terrestrial organisms. Therefore, we do not further discuss fate or effects of the FCS in the environment.

9. Use of resources and energy:

The FCS will replace and/or compete with similar food contact substances currently in the market. As is the case with other food contact materials, the production, use and disposal of the FCS will involve the use of energy and natural resources such as petroleum products, coal, etc. However, the use of this FCS is not anticipated to result in a net increase in the use of energy or resources within the U.S., as the FCS is intended for use in cork stoppers which will be used in place of similar articles, such as 100% synthetic bottle closures.

As described in Item 6(a), the FCS is manufactured outside of the U.S. – in Portugal. For context, annual polyurethane production is estimated at 17.9 million metric tons worldwide, with 3.5 million metric tons being produced in the European Union (EU) (CIEC Promoting Science, 2017). When compared to the Global and European markets for polyurethane, the manufacture of the FCS for the requested use is negligible ([redacted]) and is therefore not anticipated to impact the energy and other resources required for the manufacture of such materials at the site of manufacturing.

In the U.S., the use and subsequent disposal of the FCS is not expected to result in a net increase in the energy and resources required to transport and/or dispose of wastes, as the amount of FCS disposed of annually in the U.S. is estimated to comprise a negligible component of MSW streams (see Item 6).

For the described reasons, the requested use of the FCS is not anticipated to have an adverse impact on energy and resources.

10. Mitigation measures:

As shown above, no significant adverse environmental impacts are expected to result from the se and disposal of the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in environmental problems requiring mitigation measures.

11. Alternatives to the proposed action:

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. The alternative of not approving the action proposed herein would simply be the continued use of materials such as 100% synthetic closures that are currently on the market. As such, the action would have no environmental impact.

12. List of Preparers:

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Dr. Tran has more than 20 years of experience in exposure and risk assessment, and has evaluated the safety of foods and food ingredients, additives, and contaminants extensively.

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Ms. Wilken specializes in EPA FIFRA and state regulatory processes, with a robust interdisciplinary research background in aquatic ecology and environmental science.

13. Certification:

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

Signature: [redacted]

Nga Tran
Principal Scientist, Exponent, Inc.

Date: January 5, 2018

14. References:

CIEC Promoting Science. (2017). Polyurethanes. In *The Essential Chemical Industry online*. The Centre for Industry Education Collaboration (CIEC). Last updated April 24, 2017. Available at: http://www.essentialchemicalindustry.org/polymers/polyurethane.html

U.S. Environmental Protection Agency (EPA). (2017). Greenhouse Gas Equivalencies Calculator. Last updated September, 2017. Available at: http://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator

U.S. Environmental Protection Agency (EPA). (2016). Advancing Sustainable Materials Management: 2014 Fact Sheet: Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States. Washington, D.C., Office of Solid Waste and Emergency Response, EPA530-R-15-003. Available at: https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf

U.S. Environmental Protection Agency (EPA). (2017a). Wastes – Non-Hazardous Waste - Municipal Solid Waste Landfills. Last updated September 28, 2017. Available at: https://www.epa.gov/landfills/municipal-solid-waste-landfills#regs

15. Attachments:

Appendix 1: FCS Material Safety Data Sheet (MSDS)

CONFIDENTIAL Appendix 2: Market Volume Projections and Associated Estimates (Separate Enclosure)