Attachment 18
Environmental Assessment

1. **Date:** August 31, 2018

2. **Name of Applicant/Notifier:** Diam Bouchage SAS

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 hexamethylene diisocyanate homopolymer (CAS Reg. No. 28182-81-2) with castor oil (CAS Reg. No. 8001-79-4) as a component of agglomerated cork stoppers used as closures for bottles containing alcoholic beverages, *i.e.*, Food Types VI-A and VI-C, under FDA's Conditions of Use D through G, as defined in Tables 1 and 2 at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypeConditionsofUse/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 Notifier intends to produce finished food-contact articles containing the subject 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 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.[1]

We anticipate that cork stoppers may be recycled[2]; however, it is not a widespread practice. As such, environmental introductions of the FCS as a result of this disposal pathway are not considered in the 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 hexamethylene diisocyanate (HDI) homopolymer (CAS Reg. No. 28182-81-2) with castor oil (CAS Reg. No. 8001-79-4).

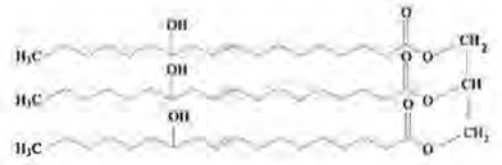
Polyurethane resins may be produced by polymerization of a polyisocyanate with a polyol. The polyol from which the FCS is produced is castor oil, which contains a high level of ricinoleic acid, a hydroxy-functional fatty acid. Due to the presence of OH groups on the ricinoleic acid moieties, castor oil is capable of reacting with isocyanate groups on the HDI homopolymer to produce a highly cross-linked polyurethane resin.

Due to the complex nature of the polymer, which is expected to be highly cross-linked in its final form, it is not possible to depict the exact molecular structure of the final resin. However, the molecular structures of HDI monomer and castor oil are depicted below.

HDI monomer; 504.588 g/mol ($C_{24}H_{36}N_6O_6$)	

[1] *Advancing Sustainable Materials Management: 2014 Facts Sheet. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, available at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf. According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, approximately 52.6% generally was land disposed, 12.8% was combusted, and 34.6% 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 + 52.6% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

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

Castor Oil; 933.4396 g/mol ($C_{57}H_{104}O_9$)	

The molecular weights of the starting monomers are shown in the table above. Because the resin is cured in the production of the agglomerated cork stopper, the resin does not achieve its full molecular weight until it is in its final cured form in the finished stopper. After curing, the resin is intermingled with the cork particles that make up the bulk of the stopper, so it is not possible to measure the molecular weight of the final resin. However, the cured resin as it is present in the stopper is expected to be of extremely high molecular weight due to extensive cross-linking within the polyurethane resin itself and with the cork particles.

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 impact as a result of the manufacture of the food-contact substance. 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 food-contact substance 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 nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of closures containing the subject food-contact substance 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 (available in a 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) CO_2

equivalents (CO_2-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 CFR 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 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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (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 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. Further, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (*i.e.*, 40 CFR 60 and/or relevant state and local laws).

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors as the FCS contains carbon, oxygen, nitrogen, and hydrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (*i.e.*, 40 CFR 60 and/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 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). Although owners and operators of existing active municipal solid waste 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. Fate of Emitted Substances in 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. As discussed in Section 5 above, the polymer is expected to be of extremely high molecular weight in its final, cured form in the finished stopper due to extensive cross-linking. Further, the starting reactants from which the polymer is made are themselves are of low volatility. HDI monomer has a boiling point of 213°C and vapor pressure of 0.05 mm Hg at 25°C. Castor oil has a reported boiling point of 313°C.[3] It follows that the resin produced by the polymerization of the starting monomers will be of even lower volatility, and thus is not expected to volatilize.

The food-contact substance will make up a very small portion 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. See Confidential Attachment for additional details.

(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 (as noted in the confidential attachment to the EA) 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

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[3] *See*, the Hazardous Substance Data Bank, https://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB.

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 previously, 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. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency'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 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. 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. Urethane-based resins are currently authorized for use in agglomerated cork stoppers that are currently recycled. 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 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 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 significant environmental impact.

12. List of Preparers

George G. Misko, Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Mr. Misko has over 30 years of experience drafting food additive petitions, FCN submissions, and environmental assessments.

Jason P. Schmidt, Ph.D. in Chemistry, Senior Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

Holly H. Foley, Senior Staff Scientist (Food Packaging), Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Holly Foley has over 35 years of experience preparing food additive petitions and Food Contact Notifications, including their Environmental Assessments.

13. Certification

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

Date: August 31, 2018

Counsel for Diam Bouchage SAS and Henkel AG & Co. KGaA

14. List of References

1. *Advancing Sustainable Materials Management: 2014 Facts Sheet. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, *available at* https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

2. Advancing Sustainable Materials Management: Facts and Figures, Materials and Waste Management in the Unites States Key Facts and Figures (internet summary), U.S. Environmental Protection Agency, November 2016, *available at* https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures.

3. EPA, *Energy and the Environment: Greenhouse Gas Equivalence Calculator* (last updated September 15, 2016), *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/.

5. Hazardous Substance Data Bank, https://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB.

15. Attachments

1. Confidential Attachment to Environmental Assessment.