Environmental Assessment

1. Date: March 8, 2022

2. Name of Applicant/Notifier: LyondellBasell Industries

3. Address:

LyondellBasell
Ricerche "G.Natta"
P.le Donegani, 12
Ferrara, ITALY 44100

All communications on this matter are to be sent in care of Counsel for Notifier:
Devon Wm. Hill, Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4279
Facsimile: (202) 434-4646
E-mail: hill@khlaw.com

4. Description of the Proposed Action

The action requested in this Notification is to permit the use of the Notifier's food contact substance (FCS), poly-1-butene homopolymer (CAS Reg. No. 9003-28-5) when used in food-contact materials. In addition, with respect to permitted uses in contact with infant formula and breast milk, the polymers may be used in repeated-use articles (excluding baby bottle nipples) intended for the feeding of infants (*e.g.*, baby bottles). Polymers of this type currently are permitted under 21 C.F.R. § 177.1570, as well as under FCN Nos. 146 and 1824. The objective of this FCN is to expand the upper boundary of the density specification from 0.92 g/cm^3 (in Section 177.1570 and FCN 146) or 0.93 g/cm^3 (in FCN 1824) to 0.94 g/cm^3. The other specifications will remain the same and the permitted uses will remain the same. The material made by the notifier would be a competitive replacement for the poly-1-butene homopolymers currently marketed in the US.

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in

the production of food-contact articles. Food-contact articles produced with the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. According to the U.S. Environmental Protection Agency's 2018 update regarding municipal solid waste in the United States, it is estimated that, of the 35.68 million tons of plastic containers and packaging present in municipal solid waste (MSW) generated in 2018, approximately 75.7% generally was land disposed, 15.8% was combusted, and 8.5% was recovered for recycling.[1] Recycling of articles manufactured with the FCS is not anticipated. As such, we have recalculated the disposal pattern based on only the quantities of plastic waste that are land disposed or combusted. On this basis, we estimate that 17.3% of food-contact materials containing the FCS will be combusted annually.[2]

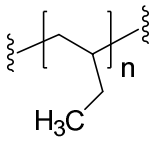
5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is poly-1-butene homopolymer (CAS Reg. No. 9003-28-5).

Chemical Abstracts Service (CAS) name: 1-butene, homopolymer

CAS Registry Number: 9003-28-5

Structural Formula:



Physical Description of FCS:
Density: 0.904-0.94 g/cm^3
Melt Flow Rate: 0.1-240 g/10 min

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 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. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal,

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[1] United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States*, November 2020 (Page 4, Table 1). Available at the following website: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[2] 15.8% combusted ÷ (15.8% combusted + 75.7% land disposed) = 17.3% combusted. The remaining 82.7% will be land-disposed.

State, or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. The FCS will be used as the basic polymer to fabricate all forms of food-contact articles and will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced by the subject polymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The subject polymer consists of carbon and hydrogen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case release of carbon dioxide from the FCS has been calculated in a confidential appendix to the Environmental Assessment, and an assessment of this worst-case release is also included in the same confidential appendix.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of packaging 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. Part 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 equivalents (CO2-e) emission threshold for required reporting.

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. The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis (provided in a Confidential Attachment to the Environmental Assessment). As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

Only extremely small amounts, if any, of the polymer constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills (40 C.F.R. Part 258). 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 groundwater monitoring systems. 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. Even if a very small amount of substances leach from the landfilled food-contact material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this FCS.

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. 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 in terrestrial ecosystems are anticipated as a result of the proposed use of the subject 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 subject FCS in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed under Item 6 above, significant 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 are not anticipated as 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 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-contact materials, the production, use, and disposal of the FCS involve the use of natural resources (e.g., petroleum products, coal, etc.). 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 it is intended to be used in place of poly-1-butene homopolymers now on the market for use in food-contact applications. Polymers of this type currently are permitted under 21 C.F.R. § 177.1570, as well as under FCN No. 146.

Manufacture of the FCS, and the final conversion of the FCS to finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of poly-1-butene homopolymers that are currently permitted. Packaging materials produced from the FCS are expected to be disposed of according to the same patterns when used in place of current materials. Neither the permitted poly-1-butene homopolymers nor the FCS are anticipated to be recovered for recycling. 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 food-contact materials fabricated from 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 food-contact substance would otherwise replace; such action would have no anticipated environmental impact.

12. List of Preparers

Kristin P. Wiglesworth, Ph.D. in Chemistry, 5 years of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 16 years of total experience in FDA regulated industries. Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C. 20001.

Devon Wm. Hill, J.D. and Masters in Chemistry, 20 years of experience related to all aspects of preparing Food Additive Petitions and Food Contact Notifications. Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

13. Certification

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

Date: March 8, 2022

Devon Wm. Hill
Counsel for LyondellBasell

14. References

1. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States*, November 2020 (Page 4, Table 1). Available at the following website: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

2. 40 C.F.R. Part 258.

15. Appendices

1. Confidential Environmental Information (**CONFIDENTIAL**) (Attachment 12).