ENVIRONMENTAL ASSESSMENT
LYONDELLBASELL INDUSTRIES
FOOD CONTACT NOTIFICATION

1. Date: January 4, 2012

2. Name of Applicant/Notifier: LyondellBasell Industries

3. Address:

Equistar Chemicals, LP
(a subsidiary of LyondellBasell Industries)
Newtown Square Technology Center
3801 West Chester Pike
Newtown Square, Pennsylvania 19073

All communications on this matter are to be sent in care of Counsel for Notifier:
Joan Sylvain Baughan, Partner
Keller and Heckman LLP
1001 G Street, NW, Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4147
Facsimile: (202) 434-4646
E-mail: baughan@khlaw.com

4. Description of the Proposed Action

The action requested in this notification is to permit the use of "2-propenoic acid, butyl ester, polymer with ethene (CAS Reg. No. 25750-84-9)" as the basic polymer in articles that may contact food. The food contact substance (FCS) also is known as ethylene/n-butyl acrylate (n-BAc) copolymers.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the food-contact substance that is the subject of this Notification will be sold to formulators engaged in the production of finished food-contact articles. Food-contact articles produced with the food-contact substance 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 of the subject resin will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's 2009 update regarding municipal solid waste in the United States, 54.3% of municipal solid

waste generally was land disposed, 11.7% was combusted, and 34.0% was recovered for recycling.[1]

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the food-contact substance.

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

The FCS that is the subject of this Notification is: 2-propenoic acid, butyl ester, polymer with ethene (CAS Reg. No. 25750-84-9).

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. 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 environmental release is expected upon the use of the subject food-contact substance to fabricate food-contact materials. In these applications, the FCS (*i.e.*, copolymers) is expected to 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 food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles produced by 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, hydrogen, and oxygen, elements that are commonly found in municipal solid waste. The proposed use of the FCS and the market volume (available in a confidential attachment to the FCN) show that (1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 29 million tons or 11.9% of 243 million tons in 2009),[2] (2) the FCS will not significantly alter the

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[1] U.S. Environmental Protection Agency. Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2010. EPA-530-F-11-005, November, 2011, Washington DC. The percents noted above are based on municipal solid waste, excluding waste recovered for composting.

[2] *See* Footnote 1.

emissions from properly operating municipal solid waste combustors[3] and, therefore, (3) incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

Only extremely small amounts, if any, of the resin 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. 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. The lack of any leaching is especially true in this case, considering that the subject substances are polymers that contain only minute levels of extractable materia1 even under conditions that greatly exaggerate environmental exposure conditions.[4]

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. The food-contact substance is polymeric and does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the food-contact substance.

As indicated above in item 6, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly 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.

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[3] Paul M. Sullivan; Hallenbeck, W.H.; Brenniman, G.R. *Municipal Solid Waste Combustion;* University of Illinois at Chicago: Chicago, IL, 1993.

[4] This expectation is confirmed by the results of extraction studies described in the corresponding FCN.

(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 resin. 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, hydrocarbon nature of the food-contact substance is expected to result in virtually no leaching of components of the food-contact substance under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of the food-contact substance for use in food-contact applications as discussed in the corresponding confidential attachment 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 resin in the manufacture of articles 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. <u>Environmental Effects of Released Substances</u>

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 copolymer 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 articles 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 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. The use of the subject copolymer in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, however, because the substance is intended to be used in food-contact articles in place of similar polymers already on the market in food-contact applications. Polymers currently used in the applications in which the subject copolymer is anticipated to be used include other ethylene-containing copolymers, such as ethylene vinyl acetate (EVA) or other ethylene/acrylate copolymers.

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 finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances. Furthermore, the use proposed in this Notification for the subject food-contact substance, which is a family of ethylene/n-butyl acrylate copolymers, is as a replacement for polymers, *i.e.*, EVA or ethylene/acrylate copolymers, which are not currently recovered for recycling.

Importantly, the applications for which this Notification will be effective involve film applications, as the maximum thickness proposed for the FCS is 210 microns (μm), equivalent to approximately 0.00827 inch (8.27 mils) and, thus, will not replace bottles, given that the thickness of plastic bottles generally is greater than the maximum proposed thickness for the FCS. Consequently, articles fabricated from the FCS will not replace food or beverage bottles, which constitute a significant portion of the plastic recycle stream[5] and, thus, articles fabricated from the subject copolymer will be disposed of by means of sanitary landfill and incineration. 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. 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 food-contact materials 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 articles employing the food-contact substance, the insignificant impact on environmental concentrations of combustion products of the food-contact substance, and the similarity of the subject food-contact substance to the materials it is intended to replace. Thus, the use of the food-contact substance as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

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[5] *See* Footnote 1.

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 environmental impact. In view of the fact that the food-contact substance constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an effective Food Contact Notification to permit the use of the subject food-contact substance as described herein is environmentally safe in every respect.

12. List of Preparers

Lester Borodinsky, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

13. Certification

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

Date: January 4, 2012

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Joan Sylvain Baughan
Counsel for LyondellBasell Industries