Attachment 05

Environmental Assessment

BASF Corporation

1. Date: January 30, 2020

2. Name of Notifier: BASF Corporation

3. Address: All communications should be sent to:

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4. Description of the Proposed Action

a. Requested Action

The action requested in this Notification is to establish a clearance for the food contact substance (FCS) of 1,4-benzenedicarboxylic acid, (or dimethyl ester), polymer with 1,4-butanediol, adipic or sebacic acid, hexamethylene diisocyanate and further reacted with no more than 1 percent by weight of the polyhydric alcohol described in the notification. The FCS is intended for use in single-use polyester films, coatings, and molded articles, except for use in contact with infant formula and human milk.

b. Need for Action

The FCS is intended for use in contact with all food types under conditions A through H as described in Tables 1 and 2 of 21 CFR 176.170 (c).

The FCS is a compostable polyester resin which may be used as flexible food packaging films or as coatings or as molded articles. Examples of food packaging materials that may be made from the FCS include, but are not limited to, garbage bags intended for composting, coatings used on clamshell containers intended for use in serving food, and stand-alone films for use as food wraps.

The Notifier does not intend to produce finished food packaging materials from the subject FCS. Rather, the Notifier plans to produce resin of the subject FCS, which will be sold to manufacturers

engaged in the production of food-contact films, coatings, and molded articles.

c. Location of Use/Disposal

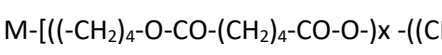
Food contact materials produced with the FCS in the United States will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide.
According to the U.S. Environmental Protection Agency's (EPA) report November 2019 regarding municipal solid waste (MSW) in the United States the total of 267.8 million tons of municipal waste (MSW) was generated in 2017 in the United States. 52.1% of MSW generally was land disposed, 12.7% was combusted and 35.2% with energy recovery was recovered for recycling or composting[1].

The materials in which the FCS will be used are not expected to be collected for recycling or composting to a significant extent[2]. Excluding this means of disposal and assuming, that all food contact articles made from the FCS are land-disposed or combusted, it is estimated that approximately 80% of the materials will be deposited in land disposal sites and about 20% will be incinerated[3].

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

The FCS that is the subject of this notification is 1,4-benzenedicarboxylic acid, (or dimethyl ester), polymer with 1,4-butanediol, adipic or sebacic acid, hexamethylene diisocyanate and further reacted with no more than 1 percent by weight of the polyhydric alcohol described in the notification. The chemical structures for the FCS are shown in the image below:

- 1,4-benzenedicarboxylic acid, (or dimethyl ester), polymer with 1,4-butanediol, adipic acid, hexamethylene diisocyanate



[1] U.S. Environmental Protection Agency.
Advancing Sustainable Materials Management 2017 Fact Sheet. Found at:
https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf
The percent noted above are based on municipal solid waste, excluding waste recovered for composting.

[2] EPA, 2019. *Advancing Sustainable Materials Management: 2016 and 2017 Tables and Figures* (https://www.epa.gov/sites/production/files/2019-11/documents/2016_and_2017_facts_and_figures_data_tables_0.pdf) see p. 34 Table 22, which does not include a distinct category for flexible multi-layer packaging; additionally, various publications such as the following detail that while technically feasible, recycling flexible multi-layer packaging is not currently mainstream (Favaro, et. al., *PET and aluminum recycling from multilayer food packaging using supercritical ethanol*, J. of Supercritical Fluids 75 (2013) 138–143. See https://doi.org/10.1016/j.supflu.2012.12.015

[3] The distribution of disposal is adjusted as follows: %Combusted = 12.7% combusted / (12.7% combusted + 52.1% land disposed) =19.6 %.
% land disposed = 52.1% land disposed/ (12.7% combusted + 52.1% land disposed) = 80.4% land disposed.

- 1,4-benzenedicarboxylic acid, (or dimethyl ester), polymer with 1,4-butanediol, sebacic acid, hexamethylene diisocyanate

  M-[((-CH_2)$_4$-O-CO-(CH_2)$_8$-CO-O-)x -((CH_2)$_4$-O-CO-Ø-CO-O-)y]n

where M = HOCO-NH-(CH_2)$_6$-NH-COOH, Ø = benzyl, C_6H_4

6. Introduction of Substances into the Environment

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

Under 21 C.F.R. 25.40(a), an environmental assessment ordinarily should focus on the relevant environmental issues relating to the use and disposal after use of the FCS, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances indicative of adverse environmental impact that may result from the manufacture of the FCS. Consequently, information on manufacturing site and compliance with relevant emissions requirements is not provided herein.

b. Introduction of the substance into the environment as a result of use/disposal:

No significant environmental release is expected upon the use of the subject FCS to fabricate packaging materials. In these applications, the FCS will be entirely incorporated into the finished food package. 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 FCS will be by conventional rubbish disposal and, hence, primarily by incineration or sanitary landfill.

The subject FCS consists of carbon, oxygen, hydrogen, and nitrogen - elements that are commonly found in municipal solid waste. The products of complete combustion would be carbon dioxide, water and potentially nitrogen oxides or nitrous oxide. Since carbon dioxide and nitrous oxide are greenhouse gases (GHG), a GHG analysis has been provided in a confidential attachment to the EA to determine whether the GHGs emitted from incineration of the FCS at MSW combustion facilities will significantly impact the environment. Background information and a summary follow.

MSW combustion facilities are regulated by the EPA under 40 CFR 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG”. Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions and

sets an annual 25,000 metric ton CO_2-e emission threshold for required reporting. To evaluate the significance of the environmental impact of these GHG emissions, we refer to the Council on Environmental Quality (CEQ) regulations under 40 CFR 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (NEPA) documents. 40 CFR 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 CFR 98.2. Based on projected market volume information provided in the confidential attachment to the EA and on information about the operation of MSW combustion facilities in the US, the expected carbon dioxide equivalent emissions resulting from the disposal FCS by combustion will not result in significant environmental impacts.

Again, as the subject FCS consists of carbon, oxygen, hydrogen, and nitrogen - elements that are commonly found in municipal solid waste - the action requested in this FCN is also not expected to significantly alter the emission from properly operating MSW combustors. Furthermore, based on the proposed use of the FCS and the expected market volume[4], the FCS will make up a very small portion of the total municipal waste currently combusted (estimated to be 34 million tons or 12.7% of 267.8 million tons in 2017[5]. In sum, 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. 98.2, 40 C.F.R. part 60 under/or relevant state and local laws).

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of the food contact articles comprised of the FCS. 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. Landfills are also required to have ground-water monitoring systems. (40 C.F.R. Part 258). Although owners and operators of existing municipal solid waste landfills that were constructed before October 9th,1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

[4] The expected market volume is provided in a confidential attachment to the Environmental Assessment
[5] U.S. Environmental Protection Agency.
Advancing Sustainable Materials Management 2017 Fact Sheet. Found at:
https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf
The percent noted above are based on municipal solid waste, excluding waste recovered for composting.

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 FCS. The FCS is a high molecular weight polymer 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 FCS.

As indicated above in item 6 the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

Additionally, because the use of the FCS proposed in this FCN is the same as the use of the similar FCS's already authorized by FDA (e.g. 21 CFR §177.1500, FCN 907 & 916), the FCN is intended to compete with and replace other polyester polymers already used as proposed. Consequently, no new emissions are expected when this notification becomes effective.

b. Water

No significant effect on the concentrations of and exposures to the FCS or its constituents in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS or the disposal of food contact articles made from the FCS. No significant quantities of the FCS will be added to these systems upon the proper incineration of the FCS, nor upon its disposal in landfills equipped with composite lines and leachate monitoring protocols.

As noted under Section 6 above, even if small amounts of the FCS or its constituents were to transfer from a disposed food contact article into landfill leachate, EPA's regulations governing landfills (40 C.F.R. Part 258) will minimize migration of the leachate into the natural environment. MSW landfills must comply with the federal regulations in 40 C.F.R. Part 258 or equivalent state regulations.

The federal standards include composite liner requirements, leachate collection and removal systems, ground water monitoring requirements and closure and post closure requirements.

The environmental fate of substances in the aquatic environment does not need to be addressed, because no significant introduction of substances into the aquatic environment as a result of the proposed use of the FCS is identified.

c. Land

Considering the factors discussed above, no significant effect on the concentrations of, and exposure to, any substances in terrestrial ecosystems are anticipated as result of the proposed use of the FCS and its proper disposal. Only very small amounts of leaching of the FCS may be expected to occur under normal environmental conditions when finished food contact materials are disposed of. Furthermore, as noted above, if the FCS were to migrate from the discarded food contact articles, the leachate will be prohibited from entering adjacent ecosystems by proper environmental controls in place at landfill sites.

Thus, there is little expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

8. Environmental effects of released substances

No significant adverse environmental effects are expected as a result of the anticipated release of substances into the environment. No significant quantities of any substance are expected to be released to the environment as a result of the proposed use of the subject FCS. 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 FCS consist of extremely small quantities of combustion products and leachables, if any.

Accordingly, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles 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/or disposal of the FCS because, as discussed under item 6, only extremely small quantities of substances, if any, 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 contact substance 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 FCS involves the use of natural resources such as petroleum products and biobased products. 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 FCS is anticipated to be used include other FCS’s

already authorized by FDA (e.g. 21 CFR §177.1500, FCN 907 & 916).
The partial replacement of these materials by the subject FCS is not expected to have any significant adverse impact on the use of energy and resources. Manufacture of the FCS and its conversion to finished food contact materials, will consume energy and resources in amounts comparable to the manufacture and use of the other FCS. Furthermore, the use of the subject FCS proposed in this Notification is as a replacement for the same polymers, which are not currently recovered for recycling. Therefore, we expect no impacts to recycling practices.

Importantly, the applications for which this Notification will be effective involve film applications. Consequently, articles fabricated from the FCS will not replace food or beverage bottles - generally with a greater thickness than that proposed for the FCS - which constitute a significant portion of the plastic recycling stream. Instead, articles fabricated from the subject copolymer will be disposed of by means of sanitary landfill and incineration. 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.

10. Mitigation measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. This is primarily due to (1) the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, (2) the insignificant impact on the environmental concentrations of combustions products of the FCS, and (3) the similarity of the subject FCS to the materials it is intended to replace. Thus, the use of the FCS as proposed is not expected to result in any significant environmental impact requiring mitigation.

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 actions proposed herein would simply result in the continues use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of preparers

Dr. Anke Mueller, Ph.D. in Macromolecular Chemistry, 11 years of experience related to food contact compliance review and registrations. Global Regulatory Affairs Manager, BASF SE, Ludwigshafen, Germany

Dr. Li Zhang, Ph.D. in Insecticide Toxicology, 12 years of experience related to food contact

compliance review and registrations. Senior Product Regulatory Specialist, BASF Corporation, Florham Park, NJ 07932

13. Certification

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

Date: January 30, 2020

[redacted]

Li Zhang, Ph.D.
Senior Product Regulatory Specialist

14. Attachments

Confidential attachment – Attachment #06