ENVIRONMENTAL ASSESSMENT
MITSUBISHI GAS CHEMICAL COMPANY, INC.
FOOD CONTACT NOTIFICATION 1841

1. Date: November 20, 2017

2. Name of Applicant/Notifier: Mitsubishi Gas Chemical Company, Inc.

3. Address:

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4. Description of the Proposed Action:

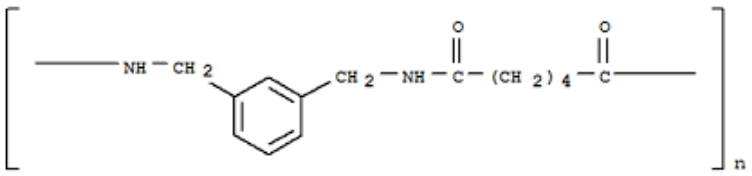
The action requested in this notification is to permit the use of Hexanedioic acid polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1), the polyamide resin produced from the reaction of adipic acid (CAS Reg. No. 124-04-9) with meta-xylylenediamine (CAS Reg. No. 1477-55-0), in food-contact articles in contact with all foods under FDA's Conditions of Use A through H, as defined in Table 2 at: http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm. The FCS is currently authorized by numerous food contact notifications when used in blends with polymers such as PET, or as a standalone FCS, subject to certain limitations. Hexanedioic acid polymer with 1,3-benzenedimethanamine is also cleared for selected applications as described in 21 C.F.R. 177.1500 ("Nylon resins"), 21 C.F.R. 177.1390 ("Laminate structures for use at temperatures of 250°F and above") and 21 C.F.R. 177.1630 ("Polyethylene phthalate polymers"). As noted above, the current notification would permit the use of nylon MXD-6 in direct contact with food at Conditions of Use A-H, with no limitations on food type.

Hexanedioic acid polymer with 1,3-benzenedimethanamine serves as an excellent oxygen and carbon dioxide barrier when used to produce food-contact articles, and enhances the gas barrier properties of food-contact articles when blended with other polymers such as PET (*i.e.*, polyethylene terephthalate).

The Notifier does not intend to produce finished food-contact articles containing the subject FCS. Rather, the FCS will be sold to customers engaged in the manufacture of food-contact articles produced from the FCS. Food-contact articles containing the subject FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. The FCS may be used as the primary component of food-contact articles that are not ultimately recycled by the user. In addition, the FCS may be used in blends with other polymers to produce food-contact articles that are not recycled. Finally, the FCS may be used in polymers such as PET that are ultimately recycled. When used exclusively in applications not subject to recycling, we estimate that 80.4% will be disposed of in a landfill and 19.6% will be combusted.[1] Because these estimates exclude recycling of the FCS, both landfill-disposed and combustion values can be seen as upper-bound estimates for the purposes of this notification. Any contributions from recycling will necessarily reduce the amount of the FCS that is disposed of in a landfill or combusted.

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

The FCS that is the subject of this Notification is hexanedioic acid polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1) also known as nylon MXD-6 (the polyamide resin produced from the reaction of adipic acid (CAS Reg. No. 124-04-9) with meta-xylylenediamine (CAS Reg. No. 1477-55-0)). The FCS is composed of the elements carbon, hydrogen, nitrogen and oxygen. In addition, the FCS is a relatively high molecular weight polymer and, therefore, it is inherently non-volatile. The chemical structure for nylon MXD-6 is shown in the image below.



[1] *See* EPA's 2014 internet summary of "Advancing Sustainable Materials Management: Facts and Figures", November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures. *See also* "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", November 2016 at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, 52.6% was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting). As the FCS is expected to be disposed primarily 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 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% landfill disposed) = 19.6% combusted. The remaining 80.4% will be landfill disposed.

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 articles. In these applications, the FCS (*i.e.*, a polymer) is expected to be used in the manufacture of food-contact articles and will be entirely incorporated into and remain with 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 containing the subject food-contact substance will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are recyclable (*i.e.*, PET bottles), recycling processes will compete with conventional rubbish disposal and therefore reduce the amount of the FCS that is landfilled or incinerated. We estimate that approximately 31% of PET bottles are recycled.[2] In 2010 (with revisions in 2013 and 2014), ASTM published Standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification." This standard provides a guide for plastic manufactures to mark the final plastic article with an identification code that informs users/recyclers what resin the final plastic article is made with. The standard includes a designation for PETE+ "reserved for manufactured articles produced from poly(ethylene terephthalate) that also contain at least one additional layer of a different material." Additionally, it includes an "OTHER" category "reserved for manufactured articles produced from any polymer chemistry not described by any other Code." Furthermore, the FCS has been approved for blending with PET in effective FCNs, and has been contended with in the industry for at least a decade. Therefore, since good manufacturing practices (properly labeling the final polymer composition of a final plastic article) would prevent contamination of the PET recycling stream; and because the recycling industry has considered and deals with the FCS in PET products, there is nothing specific to this FCN that would impact current recycling streams.[3]

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[2] *See* http://www.container-recycling.org/index.php/factsstatistics/plastic. (1,798 million pounds recycled ÷ 5,764 million pounds total x 100% = 31% recycled).

[3] *See* ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2014. DOI:10.1520/D7611_D7611M-13. https://www.astm.org/Standards/D7611.htm and ASTM Standardiztion News, https://www.astm.org/standardization-news/?q=features/modernizing-the-resin-identification-code-ja13.html. *See also* APR Design for Recyclability Guidelines Section Excerpt, http://www.plasticsrecycling.org/images/pdf/PET-Resins/PET-Bottles/PET_Bottle_Design_Guidance.pdf.

As noted above, the FCS is composed of carbon, hydrogen, nitrogen and oxygen, elements that are commonly found in municipal solid waste. Accordingly, the disposal of the FCS does not threaten a violation of 40 C.F.R. Part 60, which establishes emissions requirements for certain stationary sources, because the FCS is composed of elements commonly found in MSW. In addition, the regulations at 40 C.F.R. Part 258 prevent leaching of the FCS from sanitary landfills. More specifically, only extremely small amounts, if any, of the FCS 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.

As secondary support that disposal of the FCS will not significantly impact the environment, we compared the market volume information for the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual municipal solid waste (MSW) production (258 million tons MSW in 2014), and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there is a significant environmental impact resulting from post-consumer disposal of food-contact articles that contain the FCS. Further, the proposed use of the FCS and corresponding market volume (available in the Confidential Attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which EPA has indicated to be 33.1 million tons, as of 2014.[4]

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 (CO_2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to the regulations under 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." MSW combustion GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions for the FCS, as shown in the

[4] *See* Footnote 1.

confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Incineration of food-contact articles containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws) because the FCS contains elements commonly found in MSW, and the amount of the FCS combusted represents a marginal amount of combusted MSW, as shown in the confidential attachment to the EA.

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 thus non-volatile.

The composition of the FCS is similar to other MSW incinerated at MSW combustion facilities, and the analysis in the confidential attachment to the EA supports the use of the FCS as described in the Notification will not exceed the EPA GHGRP threshold of 25,000 metric tons carbon dioxide equivalents.

(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. EPA's regulations at 40 C.F.R. 258 require MSW owners to operate their facilities to prevent leaching from sanitary landfills. Further, the polymeric nature of the food-contact substance is expected to result in virtually no leaching of the components under normal environmental conditions when food-contact articles containing the FCS are disposed in sanitary landfills. Furthermore, the very low production of the food-contact substances for use in food-contact applications precludes any substantial release to the environment of their 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 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. 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 organisms in the environment are expected to be exposed to the FCS as a result of the use and disposal of food-contact 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 food-contact articles containing the FCS.

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 others. However, the use of the subject food-contact substance in the fabrication of food-contact articles 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 articles which will be used in place of similar articles already on the market for use in food-contact applications.

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 food-contact article, will consume energy and resources in amounts comparable to the manufacture and use of other, similar food-contact substances. Finished articles in which the FCS are used (e.g., PET bottles) may be recovered for recycling. However, as discussed previously, there will be no significant impacts on PET recycling streams. The remaining food-contact articles produced using the subject food-contact substance are not typically subject to recycling and 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 recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use 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 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 environmental impact.

12. List of Preparers

Cynthia B. Lieberman, B.A. Biology, JD, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001; 10 years of experience counseling and representing corporate entities on Food Contact Notifications, and assisting in the preparation of same, including 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; 8 years of experience evaluating and preparing Food Contact Notifications, including 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: November 20, 2017 [redacted]

14. List of References

1. 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.

2. Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Land and Emergency Management (5306P), November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

3. Container Recycling Institute, Plastic Facts & Statistics, available at: http://www.container-recycling.org/index.php/factsstatistics/plastic.

4. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2014. DOI:10.1520/D7611_D7611M-13. https://www.astm.org/Standards/D7611.htm

5. ASTM Standardization News, https://www.astm.org/standardization-news/?q=features/modernizing-the-resin-identification-code-ja13.html.

6. APR Design for Recyclability Guidelines Section Excerpt, http://www.plasticsrecycling.org/images/pdf/PET-Resins/PET-Bottles/PET_Bottle_Design_Guidance.pdf

15. List of Attachments

1. Confidential Attachment