Attachment 19 Environmental Assessment

1. Date : March 25, 2021

2. Name of Applicant/Notifier : Mitsubishi Engineering-Plastics Corp.

3. Address : 5-6-2, Higashiyawata, Hiratsuka, Kanagawa 254-0016, Japan

   (All communication on this matter are to be sent to the US Technical Contact for the notifier, Kristi O. Smedley, Center for Regulatory Services, Inc., 5200 Wolf Run Shoals Road, Woodbridge, VA 22192-5755 (Telephone No. 703 590 7337))

4. Description of the Proposed Action

   a. Proposed Action

   The action requested in this Notification is to obtain the authorization as the Food Contact Substance (FCS) of poly(tetramethylene terephthalate) (PTMT, IUPAC Name : Polybutylene terephthalate (PBT)) as manufactured from terephthalic acid and 1,4-butanediol, for use in contact with all food types under FDA Conditions of Use A through H as base polymer.

   b. Need for Action

   The notifier does not have the plan to manufacture finished food contact materials or articles from the FCS. Rather, the food contact substance that is the subject of this notification will be sold to manufacturers engaged in the production of food contact articles or films for single use.

   c. Location of Use/Disposal

   Since finished food contact materials or articles made from the food contact substance will be used widely in the United States, the used articles will be distributed widely across the nation depending on the population density of the United States.

   However, since the mateial and articles in which the FCS will be used are not expected to be collected for recycling or composting to a significant extent, we assume that the disposal of all food contact materials and articles made from the FCS will be land-disposed or combusted.

   Therefore, it is anticipated that disposal will occur nation wide.

According to the U.S Environmental Protection Agency's 2020 update regarding municipal solid waste in the United States, 50.0% of municipal solid waste generally was land disposed, 11.8% was combusted for energy recovery, 6.1% was processed by other food management pathways, 23.6% was recovered for recycling, and 8.5% was recovered for composting.[1]

Since we assume that the disposal of used food contact material and articles manufactured with the FCS will be conducted without other food management pathways, recycling or composting, as described above, we assume that 80.9% will be land disposed and 19.1% combusted.[2]

5. Identification of substance that is the subject of the proposed action

a. Chemical Name :

Poly(tetramethylene terephthalate) as manufactured from terephthalic acid and 1,4-butanediol

b. CAS Registry Number :

24968-12-5

26062-94-2

c. Trade Name or Other Chemical Name :

1,4-Benzenedicarboxylic acid, polymer with 1,4-butanediol

Polybutylene terephthalate

Poly(butylene terephthalate)

PBT

d. Chemical formula :

-(O-C4H8-O-CO-C6H4-CO)n-

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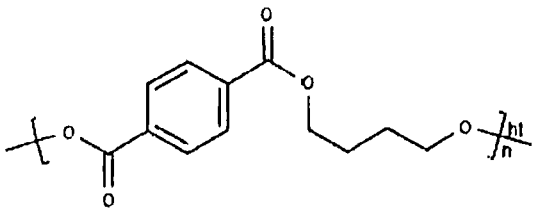
1. United States Environmental Protection Agency, Advancing Sustainable Materials Management: 2018 Fact Sheet, November 2020, at:
https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

2. The distribution of disposal is calculated as follows:
%Land disposed = 50.0%Land disposed/(11.8%Combusted+50.0%Land disposed)
= 80.9%Land disposed.

e. Molecular formula :



6. Introduction of Substance into the Environment

a. Result of Manufacture

The FCS is manufactured in Japan. Thus, the manufacturing residues will not be introduced into the United States environment. The production facilities for this food contact substance are operated in compliance with the environmental regulation in Japan.

No extra-ordinary circumstances are known to exist for the manufacture of the FCS that would cause or threaten to cause non-compliance with such regulations.

b. Result of Use

No environmental release is expected upon the use of the FCS to fabricate food contact materials and articles. The FCS is used as basic polymer and it will be entirely incorporated into finished food contact products. Any waste materials generated in the process (e.g. plant scraps) are disposed of together with the food contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

c. Result of Disposal from Use

Disposal by the ultimate consumer of food contact articles produced the FCS will primarily be by conventional rubbish disposal and, thus, will primarily be by landfill or incineration.

The FCS is composed of carbon, oxygen and hydrogen which are elements commonly found in municipal solid waste.

If these solid waste products are completely combusted, carbon dioxide, which is a greenhouse gas, and water would be produced.

Based on the proposed use of the FCS and the expected market volume (refer to confidential attachment of Environmental Assessment) , the FCS will make up a very small portion of

the total municipal solid waste (MSW) (292.4 million tons in 2018).[3]

Even though the FCS accounts for a very small portion of MSW, since carbon dioxide is a greenhouse gas (GHG), we have analyzed the potential contribution to GHG emissions in a confidential attachment to the EA.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of materials containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 CFR 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 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." The expected carbon dioxide equivalent emissions analysis based upon the FCS formula composition and the anticipated annual market volume combusted as presented in the confidential attachment to the Environmental Assessment, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting regulated under 40 CFR 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 CFR 60, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

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 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 also are required to have groundwater monitoring systems (40 CFR Part 258).

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3. see footnote 1.

Although owners and operators of existing 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 ground water and to take corrective action as appropriate.

7. Fate of Substance released into the environment

The main disposal method of the material is expected to be a landfill and some combustion.

7-1. 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 FCS. The FCS is a polymer having a high molecular weight greater than 10,000 Daltons by Number Average and not volatilize. As mentioned above emissions from MSW combustion facilities are regulated under 40 CFR 60. Therefore no significant environmental impacts are expected from combustion of the FCS in MSW combustion facilities.

As described above in Item 6, the incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations and GHG emissions are below the EPA level for mandatory reporting. Therefore, no significant quantities of any substances will be released upon the use and disposal of finished materials manufactured with the FCS.

7-2. Water

No significant effect on the concentrations of, and exposures to FCS in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of FCS or the disposal of food contact articles made from the FCS.

The FCS is a high molecular weight polymer, and the exposure of any substance which will be released into the aqueous environment water (river, lake and sea) will be expected to be very small amounts as the results of proposed use and disposal (landfill).

7-3. Land

No significant effects on the concentrations of, and exposures to, any substances in terrestrial ecosystems are anticipated as a result of the propose use of the FCS and its proper disposal.

Only very small amounts of leachate, if any, of the FCS may be expected to occur under normal environmental conditions when finished food contact materials are disposed of. Furthermore, 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.

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 materials manufactured with the FCS consist of extremely small quantities of combustion products and leachates, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of finished materials containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 CFR Parts 60 and 98 that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of resources and energy

The use of the FCS is not expected to result in an increase in the use of energy and resources, since the FCS is intended to be used the same as other materials, such as polyolefins and polyester, sourced from similar materials.

10. Mitigation measures

Based on the analysis in the EA and confidential attachment, the use of Food contact substance is not expected to generate any environmental impact that requires mitigation.

11. Alternative 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 FCS would otherwise replace, such as described above. Such action would have no significant environmental impact.

12. List of preparers

Hiroshi Ishiwata, more than 5 years' experience conducting Food Contact Notifications, Technical Director, DJK Corporation, Tokyo, Japan

Kristi O. Smedley Ph.D., Vice president of Center for Regulatory Services having more than 40 years' experience of Food Additive Petitions and Food Contact Notifications, Center for Regulatory Services, Inc., VA, U.S.A

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Mitsubishi Engineering-Plastics Corp.

[redacted]

(date) ; March 25, 2021

Tatsuya Watari
Group Manager
Mitsubishi Engineering-Plastics Corp.
Kanagawa, Japan