Attachment 15　Environmental Assessment

1. Date：　July 2, 2019

2. Name of Applicant/Notifier：　Matsumura Sangyo Co., Ltd.

3. Address：1-5-2, Uchikanda, Chiyoda-ku, Tokyo 101-0047 Japan

（All communication on this matter are to be sent to the US Technical Contact for the notifier, William A. Olson, 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 1,3-Benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt (1:1), polymer with dimethyl 1,4-benzenedicarboxylate and 1,2-ethanediol, for use in contact with all food types under FDA Conditions of Use A through H as new polymer additive for PET, PBT and PLA.

b. Need for Action

The notifier does not have the plan to manufacture finished food packaging materials or films from FCS. Rather, the FCS will be sold to manufacturers conducting production of compounds of polymers for manufacturing food contact articles. The FCS is a surface treatment agent for talc added to inhibit hydrolysis of food-contact polymers PET, PBT, and PLA. The subject polymer can improve the heat stability in the compounding or extruding process of PET, PBT and PLA by using with talc.

c. Location of Use/Disposal

Since finished food contact articles containing the FCS will be used widely in United States, the used packaging material and articles will be distributed widely across the nation depending on the population density of the United States.

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

According to the U.S Environmental Protection Agency's 2018 update regarding municipal solid waste in the United States, 52.5% of municipal solid waste generally was land disposed, 12.8% was combusted for energy recovery, 25.8% was recovered for recycling and 8.9% was recovered for composting.[1]

The FCS would be used for both recyclable and non-recyclable polymers with talc used as a nucleating agent or filler.
Accordingly, even if used with recyclable food contact materials, it would be difficult to classify into specific a 'recyclable' Resin Identification Code.

If it is used only for applications not covered by recycling, we estimated that 80.4% will be disposed of in the landfill and 19.6% will be combusted.[2]

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

a. Chemical Name :

1,3-Benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt (1:1), polymer with dimethyl 1,4-benzenedicarboxylate and 1,2-ethanediol,

b. CAS Registry Number : 27937-63-9

c. Trade or Common Name : Water soluble polyester,
PLAS COAT

d. Other Chemical Names :
none

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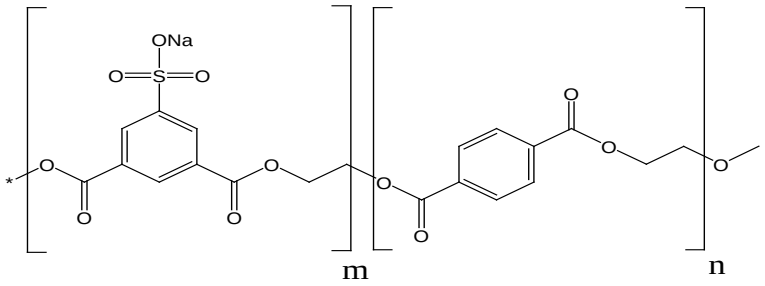
1. United States Environmental Protection Agency, Advancing Sustainable Materials Management: 2015 Tables and Figures, July 2018, at:
https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

2. The distribution of disposal is calculated as follows:
%Land disposed = 52.5%Land disposed/(12.8%Combusted+52.5%Land disposed)
= 80.4%Land disposed.

e. Molecular Formula



m=18 mol% n= 82 mol%

f. Molecular weight:

Mw = 5.7×104

Mn = 1.67×104

g. Physical Property

Acid Value	under 10 mgKOH/g
Softening point	135-140 ℃
Glass transition point	45-50 ℃
Viscosity	under 100 mPa・s

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.

Any waste materials generated in the 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.

b. Result of Disposal from Use

Disposal by the ultimate consumer of food contact articles contained 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, hydrogen, sulfur and sodium which are elements commonly found in municipal solid waste.

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

Since the FCS is only used in PET, PBT and PLA in the United States according to the intended use (refer to Attachment 16), the amount of FCS that is actually discarded will account for a very small portion of the total municipal solid waste currently combusted (estimated to be 33.5 million tons or 12.8% of million tons in 2015).[3]

Even though the FCS will account for a very small portion of MSW combusted, because carbon dioxide is a greenhouse gas (GHG) we have analyzed the potential contribution to GHG emissions in a confidential attachment to the EA (Attachment 16).

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 refer to CEQ regulations under 40 CFR 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in 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." The expected carbon dioxide equivalent emission, as shown in the confidential attachment (Attachment 16) to the EA, 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.

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3. see footnote 1.

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).

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 packaging 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 by polymer containing the FCS.

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 food packaging materials manufactured with the FCS consist of extremely small quantities of combustion products and leachable, 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 as same as other packaging materials, such as polyolefin, 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 the 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 action would have no environmental impact.

12. List of preparers

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

William A. Olson, Ph.D., more than 40 years' experience conducting 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 Matumura Sangyou Co., Ltd.

[redacted]

(date) ; July 2, 2019

Ryohei Watanabe
Genral manager
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Tokyo, Japan