

Environmental Assessment

1. Date: April 12, 2023 *
2. Name of Applicant/Notifier: UBE Corporation
3. Address: 1978-10, Kogushi, Ube-shi, Yamaguchi 755-8633, 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 Hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and 1,6-hexanediamine, for use in food-contact articles in contact with all food types under FDA's Conditions of Use A through H as a basic polymer.

- b. Need for Action

The notifier does not have the plan to manufacture finished food packaging materials or films 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.

The films will have a maximum thickness of 2 mil (0.002 inch, 51 µm).

- c. Location of Use/Disposal

Since finished food contact articles made from the food contact substance will be used widely in the United States, the used packaging material and articles will be being distributed widely across the nation depending on the population density of the United States. However, since the packaging material 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 national 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

* Subsequent to this date, this EA was amended using the Adobe text editor tool to reformat this document for conformity with Section 508 assistive technologies

recycling, and 8.5% was recovered for composting. ¹

Since we assume that the disposal of used packaging 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% is land disposed and 19.1% is combusted. ²

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

a. Chemical Name:

Hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and 1,6-hexanediamine

b. CAS Registry Number:

24993-04-2

c. Common Name:

Polyamide 6/66 (PA 6/66)
Nylon 6/66

e. Chemical Formula

$-(\text{NH}-\text{C}_5\text{H}_{10}-\text{CO})_n - (\text{NH}-\text{C}_6\text{H}_{12}-\text{NH}-\text{CO}-\text{C}_4\text{H}_8-\text{CO})_m$

Where:

n: 67–73 wt%

m: 27–33 wt%

¹ United States Environmental Protection Agency, Advancing Sustainable Materials Management: 2018 Fact Sheet, December 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 = 50.00% Land disposed / (11.8% Combusted + 50.0% Land disposed) = 80.9%

6. Introduction of Substance into the Environment

a. Result of Manufacture

The FCS is manufactured in Japan, Spain, and Thailand. Thus, the manufacturing residues will not introduce into the United States environment.

The production facilities for this food contact substance are operated in compliance with the environmental regulation in Japan, Spain, and Thailand. No extra-ordinary circumstances are reasonably 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 a basic polymer for the food packaging materials and articles, and it will be entirely incorporated into finished food contact products. Any waste materials generated in the process (e.g., plant scraps) are expected to be disposed of as part of the food contact product 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 with 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, and nitrogen which are elements commonly found in municipal solid waste. If these solid waste products are completely combusted, carbon dioxide, nitrogen oxides such like N₂O, NO and NO₂, 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).

Even though the FCS will make up a very small portion of MSW combusted,³ since carbon dioxide and nitrous oxide are greenhouse gas (GHG), we have analyzed the potential contribution to GHG emissions in confidential attachment to the EA.

³ see foot note 1

The 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 environment”. The expected carbon dioxide equivalent emissions analysis based upon the chemical composition of the FCS and the anticipated annual market volume combusted as presented in the confidential attachment to the Environmental Assessment, are far 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).

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.

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 FCS.

The FCS is a polymer having a high molecular weight greater than 10,000 Daltons by Number Average and not volatilize.

As described 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.

b. 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).

c. 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 leaching 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

FCS will provide new material as food contact substances. But the use of FCS is not expected to increase the use of energy and resources as the FCS is used replacing to other packaging substances previously used.

In addition, polyamide food packaging materials are not currently recovered for recycling. Therefore, it is expected that food contact materials produced using food contact substances subject to this FCN will be disposed of according to the same pattern as other polyamide products. Thus, there will be no impact on current recycling programs.

10. Mitigation measures

The use of Food contact substance is not expected to generate any new environmental impact that requires the mitigation measures of any kind based on the following reasons:

- (1) The amount of leaching components of the FCS from finished articles employing the FCS is at minute levels.
- (2) The impact on environmental concentrations of incineration products of the FCS is insignificant.
- (3) The FCS is intended to replace the similar existing packaging materials.

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 10 years' experience conducting Food Contact Notifications, Technical Director, DJK Corporation, Tokyo, Japan

Kristi O. Smedley, more than 20 years' experience conducting Food Additive Petitions or 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 UBE Corporation.



Naoyasu Yabu
UBE Corporation. Yamaguchi, Japan