Environmental Assessment

1.	**Date**	4/8/2024
2.	**Name of applicant/notifier**	Wanhua Chemical Group Co., Ltd.
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4. Description of proposed action

a) Requested Action

The action requested in this Notification is to establish a clearance for the food contact substance (FCS) of 1H-Azepine-1-carboxamide, N,N',N"-[(2,4,6,trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)triyl)tris[methylene(3,5,5-trimethyl-3,1-cyclohexanediyl)]]tris[hexahydro-2-oxo- (CAS: 68975-83-7) which will be used as a reactant with one or more of the polybasic acids or polyhydric alcohols in the formation of coatings on metal substrates in single-use food-contact applications and any suitable substrate in repeated-use food-contact applications, complying with 21 CFR 175.300(b)(3)(vii), in contact with all food types under Conditions of Use A through H as described in Tables 1 and 2 of FDA's "Definitions of food types and conditions of use for food contact substances".

b) Need for Action

The FCS will be used as a component of coatings for metal food-contact articles. Under stoving conditions, caprolactam in the FCS is freed from IPDI trimer and vaporizes. The IPDI trimer acts as a cross-linking agent in the polymerization of polyester/polyurethane coatings. By utilizing the FCS, finished coatings exhibit favorable characteristics, for example, good adhesion, machinability and outstanding chemical resistance.

Therefore, with the addition of the FCS as an essential component of coatings on metal substrates in combination with food contact substances cleared for the intended use by FDA under 21 C.F.R. Section 175.300 or other applicable regulations or effective food contact notifications, it can be assured that polyester/polyurethane coatings meet the higher requirements in terms of chemical and technical performance.

c) Locations of Use/Disposal

Food-contact coatings containing the FCS will be used to package food that will be distributed in patterns corresponding to the national population density. It is expected that the FCS will be widely distributed across the country upon use, and, therefore disposal will be

widely distributed as well.

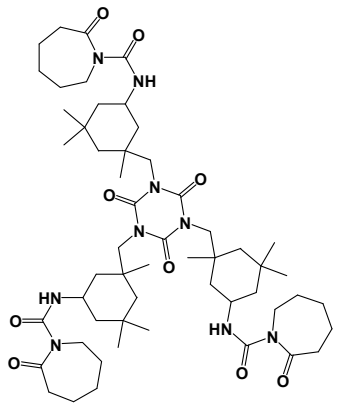
According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[1] For the "metals" material class, approximately 54.4% is deposited in land disposal sites, 11.5% is combusted, and 34.1% is recovered (a combination of waste recovered for recycling and for composting)[2].

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

The FCS that is the subject of this Notification is 1H-Azepine-1-carboxamide, N,N'N"-[(2,4,6,trioxo-1,3,5-triazine-1,3,5 (2H, 4H, 6H)triyl)tris[methylene(3,5,5-trimethyl-3,1-cyclohexanediyl)]]tris[hexahydro-2-oxo-. Chemical information on this substance is presented below:

CAS Reg. No.: 68975-83-7

Structural Formula:



In the manufacturing process, IPDI trimer and caprolactam were reacted under a certain temperature to obtain the target product (Caprolactam-blocked IPDI trimer). When the FCS is used in manufacturing food-contact materials, the caprolactam blocking groups are volatilized from the FCS. The blocked isophorone diisocyanate (IPDI) trimer initially contains three caprolactam groups. The molecular formula for caprolactam is $C_6H_{11}NO$ and its molar mass is 113 g/mol. Therefore, when the three caprolactam blockers are volatilized from the blocked FCS during manufacture, the remaining molecular formula of the unblocked FCS is $C_{36}H_{54}O_6N_6$; the molar mass of the unblocked FCS is 666 g/mol. The

[1] Table 35 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

[2] Table 7 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

unblocked IPDI trimer is completely reacted into the finished food-contact coating.

6. Introduction of substances into environment

a) As a Result of Manufacture

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[3] in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b) As a Result of Use and Disposal

No significant environmental release is expected upon the use of the FCS in the manufacture of food-contact articles. In these applications, the FCS will be entirely incorporated into the finished food-contact articles. Any waste materials generated in the process (*e.g.*, plant scraps) are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

When the FCS is used in manufacturing food-contact materials, the blocking groups are intended to be volatilized from the blocked FCS, leaving the unblocked FCS. The unblocked material is completely reacted into the finished food-contact coating. Based on the chemical composition of the blocking units, the volatilization and decomposition of the blockingagent from the FCS results in no significant environmental impact. Therefore, there are no extraordinary circumstances that pertain to the deblocking step of the manufacture of food-contact materials containing the subject FCS.

Air (Combustion):

Disposal by the ultimate consumer of the finished food-contact materials will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, incineration, or recovery for recycling. The FCS is composed of carbon, hydrogen, oxygen, and nitrogen; elements that are commonly found in municipal solid waste. The proposed use of the FCS

[3] Such extraordinary circumstances would include: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on Intentional Trade in Endangered Species of Wild Fauna to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

shows that the FCS will make up a very small portion of the total municipal solid waste (MSW) production of 292.36 million tons (in 2018), as well as the total amount that is landfilled. Therefore, we expect no extraordinary circumstances that would suggest a significant environmental impact resulting from post-consumer disposal of food-contact coatings containing the FCS. Further, the proposed use of the FCS shows that the FCS will make up a very small portion of the total municipal solid waste currently combusted, estimated to be 11.8% of the total 292.36 million tons total waste generated, or 34.6 million tons, as of 2018[4].

Based on the chemical composition of the FCS, the combustion products of the FCS may include carbon dioxide and nitrous oxide. The carbon and nitrogen content of the FCS have been calculated based on the elemental composition of the FCS.

MSW combustion facilities are regulated by the U.S. EPA under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG" and sets an annual 25,000 metric tons carbon dioxide equivalent (CO2-e) emission threshold for required reporting at 40 CFR 98.2 of this regulation. From this analysis, the expected CO2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

As the FCS will not alter the emissions from properly operating MSW combustors and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable Federal, State or local emissions laws and regulations (i.e., 40 CFR 60, 40 CFR 98). 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. As indicated above, the FCS will make up a small portion of the total MSW currently combusted. Thus, no significant adverse environmental introductions will result from the proper incineration of the FCS in the amounts utilized in the notified applications.

Landfill:

Only extremely low levels, 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 EPA's 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). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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[4] Table 2 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substance in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS.

Water

No significant effect on the concentrations of and exposure to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS nor its disposal in landfills. Similarly, no significant effects on the concentrations of and exposures to any substances are anticipated as a result of the proposed use of the subject FCS.

Therefore, we do not expect there are any extraordinary circumstances which would otherwise suggest a significant environmental impact on the aqueous environment resulting from post-consumer disposal of food-contact articles that contain the FCS due to the proposed use.

7. Fate of emitted substances in the environment

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food-contact articles containing the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic or terrestrial environmental compartments. Accordingly, because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental effects of released substances

As discussed previously, only extremely small and insignificant quantities of the FCS may be expected to be released into the environment during use and disposal of food-contact articles containing the FCS.

Based on these considerations, no adverse effect on organisms in the environment or the environment itself, is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

9. Use of resources and energy

The proposed use of the FCS in this Notification will not require additional energy resources

for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace similar substances already on the market. Food-contact materials and articles containing the FCS are expected to be disposed according to the same patterns when it is used in place of current materials. Therefore, there will be no anticipated impact on current or future recycling programs.

The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of other similar caprolactam-blocked IPDI trimer coatings. Furthermore, the use of the subject FCS proposed in this Notification is as replacement for these similar coating products.

The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is insignificant.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles containing the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished item; the insignificant impact on environmental concentrations of combustion products of the FCS; and the close similarity of the FCS to the products it is intended to replace. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to 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 which the FCS would otherwise replace; such action would have no anticipated environmental impact.

12. List of preparers

Maxwell Song, 3 years of experience related to the preparation of Food Contact Notifications and food packaging compliance matters under FDA food contact regulations.

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13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

14. Attachment

Confidential Attachment to the Environmental Assessment (Attachment 12 in this Notification)

Date: 4/8/2024

Maxwell Song, Regulatory analyst

Consultant for Wanhua Chemical Group Co., Ltd.