Environmental Assessment

1. Date: October 19, 2020

2. Name of Applicant/Notifier: PPG Industries, Inc.

3. Address: All communications on this matter are to be sent in care of Counsel for Notifier:

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4. Description of the Proposed Action:

A. Requested Action

The action requested in this Notification is to permit the use of the Notifier's food contact substance (FCS), 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 Reg. No. 68975-83-7), which has the molecular formula $C_{54}H_{87}N_9O_9$, as a component of food-contact coatings for use on metal substrates in single-use food-contact applications and any suitable substrate in repeated-use food-contact applications, complying with 21 C.F.R. § 175.300(b)(3)(vii), except for use in contact with infant formula and human milk.

The FCS will be used in contact with all food types under Conditions of Use A ("High temperature heat sterilized (*e.g.*, over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared food intended to be reheated in container at the time of use").

B. Need for Action

The FCS will be used as a component of coatings on metal substrates in single-use food-contact applications and any suitable substrate in repeated-use food-contact applications, complying with 21 C.F.R. § 175.300(b)(3)(vii), except for use in contact with infant formula and human milk. The cross-linking agent allows for the use of polyester-based coatings as an alternative to epoxy-based coatings for single use metal food-contact articles and repeated-use articles. By utilizing the FCS as an alternative, finished coatings exhibit the following favorable characteristics:

- Exceptional gloss retention and non-staining from foods, even after a two-year exposure time;
- Excellent balance between hardness and flexibility. This property is especially important to achieve fabrication requirements and resistance to can damage. It is also

necessary in the applications where coated metal is embossed to obtain complex shapes; and

- Outstanding chemical resistance, which is particularly important for coatings on packaging for very aggressive food media.

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 of effective food contact notifications, it can be assured that polyester/polyurethane coatings meet the highest requirements in terms of chemical and technical performance.

C. Location of Use/Disposal

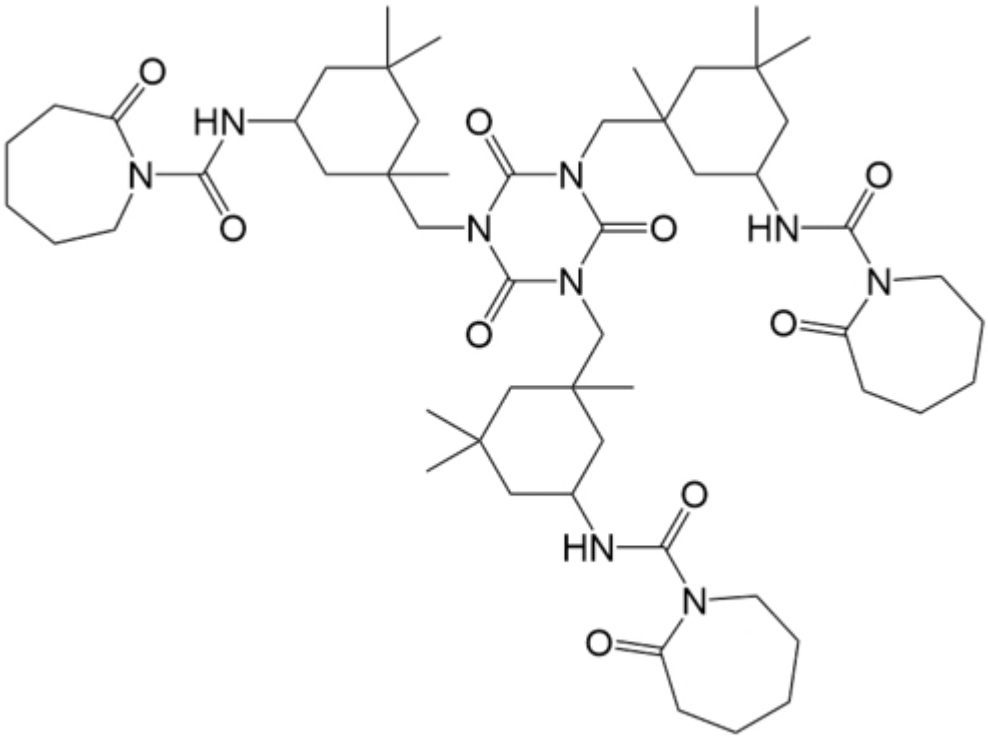
Food-contact coatings containing the FCS will be used to package food that will be distributed in patterns corresponding to the national population density. It is expected that the FCS will be widely distributed across the country upon use, and, therefore disposal will be widely distributed as well.

Articles containing the FCS may be collected for recycling. According to U.S. Environmental Protection Agency (EPA) data for 2017, approximately 52.1% of municipal solid waste is currently deposited in land disposal sites, 12.7% is combusted, and 35.2% is recovered (a combination of waste recovered for recycling and for compositing).[1] For the "metals" material class, approximately 55.1% is deposited in land disposal sites, 11.7% is combusted, and 33.3% is recovered (a combination of waste recovered for recycling and for composting).

5. Identification of the 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- (CAS Reg. No. 68975-83-7). The molecular formula of the FCS in the blocked form is $C_{54}H_{87}N_9O_9$; its molar mass is 1006.34 g/mol.

[1] Advancing Sustainable Materials Management: 2017 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilled in the United States, U.S. Environmental Protection Agency, November 2019. *See* https://www.epa.gov/sites/production/files/2019-11/documents/2016_and_2017_facts_and_figures_data_tables_0.pdf.



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

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 food-contact materials. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for significant adverse environmental impacts resulting from the manufacture of the FCS such as: 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 (40 C.F.R. § 1508.27(b)(10)); 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 International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of the subject FCS in the manufacture of food-contact materials. The unblocked FCS is expected to be entirely incorporated into finished materials, and essentially all of it is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Caprolactam will be volatilized during the curing of the can coatings. Upon combustion, the volatilized caprolactam may form greenhouse gases such as carbon dioxide and/or nitrous oxide. Any waste material generated during the manufacture of the finished articles, *e.g.*, plant scraps, are expected to be disposed of as part of the finished article manufacturer's overall nonhazardous 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 and the confidential market volume of the FCS (available in the Confidential Attachment to the EA), the volatilization and decomposition of the blocking agent 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.

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 and its corresponding confidential market volume (available in the Confidential Attachment to the EA) shows that the FCS will make up a very small portion of the total municipal solid waste (MSW) production of 267.8 million tons (in 2017), 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 and corresponding confidential market volume (available in the Confidential Attachment to the EA) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, estimated to be 12.7% of the total 267.8 million tons total waste generated, or 34.0 million tons, as of 2017.[2]

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 (available in the Confidential Attachment to the EA).

In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-e) or more per year to report their Greenhouse Gas (GHG) emissions to the U.S. Environmental Protection Agency (EPA). MSW combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). The GHG emissions resulting from the

[2] *See* footnote 1.

use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 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." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, when the FCS is combusted, there is nothing to suggest the FCS would threaten a violation of 40 C.F.R. Parts 60 and 62, the regulations governing municipal solid waste combustors, as carbon, hydrogen, oxygen, and nitrogen are typical elements in MSW (*i.e.*, C, H, O, and N). Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

Based on the confidential market volume (available in the Confidential Attachment to the EA), the expected carbon dioxide equivalent emissions, as shown in the confidential attachment, are below 25,000 metric tons on an annual basis. The carbon dioxide equivalents evaluation considered the impact from both the blocking group volatilization step and any potential combustion of the unblocked FCS. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Only very small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW landfill units and lateral expansions of existing units to have composite liner 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). Even if a very small amount of substances leach from the landfilled food-contact material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

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 FCS. Thus, no significant quantities of any substance will be released upon the use and disposal of food-contact materials manufactured with the FCS.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. As discussed above under Item 6, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations.

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 FCS. The fact of the FCS 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 FCS.

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 subject FCS in the manufacture of food-contact articles. 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

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS in the preparation of food-contact coatings is not expected to result in a net increase in the use of energy and resources because it will replace use of other similar products.

Food-contact materials containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used materials with or without comparable products. Thus, no significant impact on current or future recycling programs are anticipated due to the intended use of the FCS.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the FCS. Thus, mitigation is not required.

11. Alternatives to the Proposed Action

No significant 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 significant impact.

12. List of Preparers

Devon Wm. Hill, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Over 20 years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Seven years of experience preparing FCN submissions, including their Environmental Assessments.

13. Certification

The undersigned certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Devon Wm. Hill
Counsel for the Notifier
Date: October 19, 2020

14. References

1. United States Environmental Protection Agency (EPA), *Advancing Sustainable Materials Management: 2016-2017 Tables and Figures, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, November 2019. Available at the following website: https://www.epa.gov/sites/production/files/2019-11/documents/2016_and_2017_facts_and_figures_data_tables_0.pdf.

15. Appendices

1. Confidential Environmental Information