Environmental Assessment

1. Date	December 13, 2019
2. Name of Applicant/Petitioner	The Sherwin-Williams Company
3. Address	All communications on this matter are to be sent to: Judy Negley, Technical Writer, Regulatory The Sherwin-Williams Company 2000 Georgetown Drive Sewickley, PA 15143 Telephone: 724-940-3817 E-mail: Judy.negley@sherwin.com

4. Description of Proposed Action:

A. Requested Action

The action requested in this notification is to provide for the use of Food Contact Substance (FCS) "Blocked isophorone diisocyanate (IPDI) polymer consisting of trimer, pentamer, heptamer, and nonamer oligomers, with the primary component of interest being the trimer" (CAS Reg. No. 103170-26-9) as a component of food-contact coatings for use on metal substrates, except for use in contact with infant formula and human milk.

The FCS will be used as a cross-linking agent in polyester urethane food-contact coatings on metal substrates at a maximum concentration of 9.4% (weight solids). The coatings containing the FCS are intended for single-use 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 subject FCS is a cross-linking agent used in the polymerization of polyester urethane coatings for metal substrates. It is chemically a methyl ethyl ketone oxime (MEKO)-blocked IPDI trimer that provides the following positive characteristics to food-contact coatings in which it is used:

- Exceptional gloss retention and non-staining from foods, even after a two-year exposure time;
- Excellent balance between hardness and flexibility. This balance is important to achieving fabrication requirements and resistance to can damage. It is also necessary in applications where coated metal is embossed to obtain complex shapes;

- Outstanding chemical resistance, particularly important in coatings on packagingfor aggressive food media.

The combination of the technical advantages provided by the FCS allow for the use of polyester-based coatings as alternatives to BPA-based coatings for metal food-contact articles, while maintaining the chemical and technical performance requirements of such applications.

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 solids 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 composting).[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 Subject of the Proposed Action

The FCS that is the subject of this Notification is "Blocked isophorone diisocyanate polymer consisting of trimer, pentamer, heptamer, and nonamer oligomers, with the primary component of interest being the trimer" (CAS Reg. No. 103170-26-9). It is alternatively known as "cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl, homopolymer MeEt ketone oxime-blocked (solvent free)". The molecular formula of the FCS in the blocked form is $C_{48}H_{81}O_9N_9$; its molar mass is 927 g/mol.

When the FCS is used in manufacturing food-contact materials, the MEKO blocking groups are volatilized from the FCS. The blocked IPDI trimer initially contains three MEKO groups. The molecular formula of MEKO is C_4H_9NO and its molar mass is 87 g/mol. Therefore, when the three MEKO 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 molecular weight of the unblocked FCS is 666 g/mol. The unblocked IPDI trimer is completely reacted into the finished food-contact coating.

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[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/2017_facts_and_figures_fact_sheet_final.pdf

6. Introduction of Substances into the Environment

Under 21 C.F.R § 25.40(a) ("Environmental assessments"), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected when the subject FCS is used 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. Any waste material generated during the manufacture of the finished articles, e.g., plant scraps, are expected to be disposed 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 MEKO 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 MEKO blocking units and the confidential market volume of the FCS (available in the Confidential Attachment to the EA), the volatilization of MEKO from the FCS results in no significant environmental impact. Therefore, there are no extraordinary circumstances that pertain to the MEKO-deblocking step of the manufacture of food-contact materials containing the subject FCS.

Disposal by the ultimate consumer of the finished metal 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) show 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).

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[2] *See* footnote 1.

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 (CO2-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 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 CFR 60 and 62, the regulations governing municipal 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 regulation (i.e., 40 C.F.R. 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 MEKO 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 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). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective actions as appropriate.

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 substances 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 fate 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 concentration 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 FCS in the manufacture of food-contact materials. 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

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials coated with the FCS consist of very small quantities of MEKO blocking units and combustion products.

Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the materials containing the FCS is not expected to threaten a violation of applicable laws and regulations, 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 packaging materials, the production, use and disposal of the FCS involves 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 on metal substrates is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used as a component of polymerizations in which similar products, such as Sherwin-Williams' current Meko-Blocked IPDI trimer-containing coatings, along with other polyester-based coatings, may be used as alternatives to BPA-based coatings that are already on the market. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

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 cross-linking agents. When the FCS is used in coatings on metal articles, where such articles are already collected for recycling, the FCS will be a negligibly small component of such articles, and will replace comparable cross-linker products. Therefore, there will be no significant impact on current or future recycling programs 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 articles coated with the subject FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would replace. Such action would have no significant environmental impact.

12. List of Preparers

1. Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Dr. Manning has 3.5 years of experience preparing FCN submissions, including their Environmental Assessments.

2. Judith E. Negley, Technical Writer, Regulatory, The Sherwin-Williams Company, Sewickley, PA 15143. Ms. Negley has 7 years of experience preparing FCN submissions, including their Environmental Assessments.

13. Certification

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

Date: December 13, 2019

Judith E. Negley

Judith E. Negley Digitally signed by Judith E. Negley Date: 2019.12.13 13:25:33 -05'00'

Technical Writer, Regulatory

The Sherwin-Williams Company

14. List of References

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/2017_facts_and_figures_fact_sheet_final.pdf

15. Attachments

1. Confidential Attachment to Environmental Assessment.

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