Environmental Assessment

1. Date: March 31, 2025

2. Name of Applicant/Notifier: Milliken Chemical

3. Address: 920 Milliken Road, M-209
Spartanburg, SC 29303

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

Mitzi Ng Clark, Partner
Keller and Heckman LLP
Three Embarcadero Center, Suite 1420
San Francisco, CA 94111
Telephone: 415.948.2838
Email: clark@khlaw.com

4. Description of the Proposed Action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), 5-[[[*cis*-4-(1,1-dimethylethyl)cyclohexyl]carbonyl]amino]-N^1,N^3-bis[*cis*-4-(1-methylethyl)cyclohexyl]-1,3-benzenedicarboxamide (CAS Reg. No. 2649373-38-4), as a clarifying agent for polypropylene homopolymer and high-propylene olefin copolymers intended for use in food-contact applications. Specifically, the FCS may be used at up to 0.08% by weight of polypropylene homopolymer and high-propylene olefin copolymers, which will be used in contact with all food types, except those containing greater than 15% alcohol, under Conditions of Use A ("High temperature heat-sterilized (e.g., over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use") and Condition of Use J (microwave only, excluding susceptor applications).[1] The FCS may also be used in repeat-use articles intended for feeding infants, including baby bottles.

The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials produced from polypropylene homopolymer and high-propylene olefin copolymers. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of food contact materials containing the

[1] FDA's Food Types and Conditions of Use are defined at Tables 1 and 2 of "Food Types & Conditions of Use for Food Contact Substances," available at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

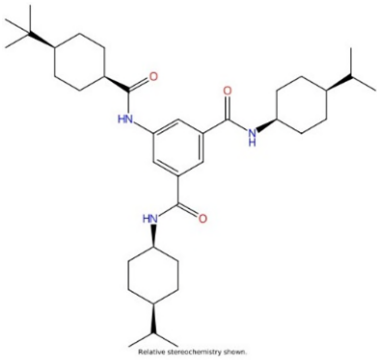
FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste (MSW) generally.[2]

According to the U.S. Environmental Protection Agency's (EPA) update regarding MSW in the U.S., it is estimated that, of the 292,360,000 tons of MSW generated in 2018, 50.0% of MSW was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.[3] Polypropylene containing the FCS as an additive is expected to be primarily disposed of through recycling, combustion, or land-filling (*i.e.*, not composted or handled through other food management pathways). Therefore, we recalculate the disposal pattern based on only the quantities of MSW that are land disposed, recycled, or combusted. On this basis, we estimate that 13.8% of food-contact materials containing the FCS will be combusted annually.[4]

5. Identification of the Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is 5-[[[*cis*-4-(1,1-dimethylethyl) cyclohexyl]carbonyl]amino]-N^1,N^3-bis[*cis*-4-(1-methylethyl)cyclohexyl]-1,3-benzene dicarboxamide. The CAS Registry Number is 2649373-38-4. The molecular formula is $C_{37}H_{59}N_3O_3$, and the corresponding molecular weight is 593.88 g/mole.

The molecular structure is as follows:



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[2] Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), last accessed March 31, 2025 at: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[3] *Id.*

[4] 11.8% MSW combusted ÷ (11.8 % MSW combusted + 23.6 % MSW recycled + 50% MSW land disposed) = 13.8% combusted.

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, rather than the production of, FDA-regulated food-contact materials. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. The FCS will be used as an additive in polypropylene homopolymer and high-propylene olefin copolymers which, in turn, are used to fabricate food-contact materials. The FCS will be entirely incorporated into the finished food-contact materials. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials containing the FCS will be by recycling or conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable, recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated.

The FCS consists of the elements carbon, hydrogen, oxygen, and nitrogen. Thus, the combustion products may include carbon dioxide, water, and nitrous oxide. The carbon and nitrogen contents of the FCS have been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS for food-contact use in the U.S. (available in the Confidential Environmental Information attachment).

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 GHG emissions to the EPA. Municipal solid waste (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.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the Confidential Environmental Information attachment, are below 25,000 metric tons on an annual basis. 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. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains only carbon, hydrogen, oxygen, and nitrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors 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).

Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact materials, 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, "to have ground water monitoring systems and to take corrective action as appropriate (40 CFR 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 FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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 subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this FCS.

As discussed above in Section 6, combustion of the FCS will not significantly alter the emissions from properly operating MSW combustors, and the incineration of food-contact materials containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (*see* Confidential Attachment for additional details).

B. Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact articles containing 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

Similarly, 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 materials.

8. Environmental Effects of Released Substances

As discussed under Item 6 above, significant environmental effects of substances released into the environment as a result of the use and disposal of the subject FCS in landfills and by combustion are not anticipated as 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 food-contact materials containing the subject FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the U.S. EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to MSW 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. However, the use of the subject FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because the FCS is intended to be used in food-contact resins in place of similar clarifiers now on the market for use in food-contact applications.

The replacement of other clarifiers by the subject FCS in food-contact resins is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, its use in resins, and the final conversion to finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of polypropylene containing other clarifying agents. Packaging materials produced from resins containing the FCS are expected to be disposed of according to the same patterns when it is used in place of current materials. Considering the low level (0.08%) at which the FCS is added to the polymer, no impact on current or future recycling programs is anticipated.

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, 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 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 subject FCS would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Mitzi Ng Clark, Partner, Keller and Heckman LLP, Three Embarcadero Center, Suite 1420, San Francisco, CA 94111. Ms. Clark has a J.D. and has over 25 years of experience counseling and representing corporate entities on food additive petitions and FCNs, including Environmental Assessments.

Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Foley has 40 years of experience preparing food additive petitions, FCN submissions, and environmental assessments.

13. Certification

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

Date: March 31, 2025

Mitzi Ng Clark, Counsel for Notifier
Milliken Chemical

14. References

1. FDA's Food Types and Conditions of Use are defined at Tables 1 and 2 of "Food Types & Conditions of Use for Food Contact Substances," available at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. EPA, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), available at: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.

15. Attachment

Confidential Environmental Information