Environmental Assessment

1.	**Date:**	December 1, 2022
2.	**Name of Applicant/Petitioner:**	Allnex Austria GmbH
3.	**Address:**	All communications on this matter are to be sent in care of Counsel for the Notifier: Catherine R. Nielsen, Partner Keller and Heckman LLP 1001 G Street, N.W., Suite 500 West Washington, D.C. 20001 Telephone: (202) 434-4140 Facsimile: (202) 434-4646 E-mail: nielsen@khlaw.com

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), identified as tricyclodecanedimethanol (TCDM; CAS Reg. Nos. 26896-48-0 and 26160-83-8), when used in food-contact materials.

The FCS is intended for use as a monomer in the manufacture of (1) polyester resins for use as components of coatings for use on metal substrates and repeated-use food-contact surfaces, and (2) polyester resins for use in adhesives. When the FCS is used as a monomer in the manufacture of polyester resins as components of coatings, the coatings containing the FCS may contact non-alcoholic foods under the U.S. Food and Drug Administration's (FDA) 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").[1] When the FCS is used as a monomer in the manufacture of polyester resins for use in adhesives, the adhesives containing the FCS shall comply with 21 C.F.R. § 175.105 ("Adhesives") or 21 C.F.R. § 175.125 ("Pressure-sensitive adhesives") and will be used at room temperature or below. The finished food-contact materials containing the FCS are not for use in contact with infant formula and human milk, as these uses were not included as part of the intended use of the FCS in this notification.

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

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS that is the subject of this notification will be sold to food-contact article manufacturers.

B. Need for Action

The FCS is intended for use in the production of polyester resins that will be used in turn be used in food-contact materials. Use of the FCS monomer in polyesters provides high glass transition temperature and improved adhesion to metallic and other substrates.

C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (U.S. EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting), and 6.1% is directed to other food management pathways.[2] As the FCS is expected to be primarily disposed of through combustion or land-filling (*i.e.*, not composted, recycled, or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.[3] The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the articles in which they are used.

5. Identification of the Subject of the Proposed Action

The subject of the notification is tricyclodecanedimethanol (CAS Reg. Nos. 26896-48-0 and 26160-83-8). It is alternatively identified as bis(hydroxymethyl)tricyclo[5.2.1.0(2,6)]decane or hexahydro-4,7-methanolindandimethanol. The chemical formula of the FCS is $C_{12}H_{20}O_2$ and its molecular weight is 196 g/mol.

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 is aware of no information

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[2] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, December 2020, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[3] 11.8% Combusted ÷ (11.8% combusted + 50% land disposed) = 19.1% combusted.

suggesting the existence of any extraordinary circumstances[4] that would indicate a potential for significant adverse environmental impacts resulting from the manufacture of the 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 FCS is expected to be entirely incorporated into finished materials, and essentially all of the substance 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, is expected to be disposed as part of the finished article manufacturer's overall non-hazardous solid waste in accordance with established procedures. Disposal by the ultimate consumer of finished food-contact materials produced using the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The FCS consists of carbon, hydrogen, and oxygen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. The carbon content of the FCS has been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS (available in the confidential attachment to this Environmental Assessment). This potential amount of GHG emissions is below 25,000 metric tons carbon dioxide equivalent (CO_2-e) emission per MSW combustor on an annual basis.[5] Thus, the concentration of carbon dioxide in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food packaging applications.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment (*i.e.*, 40 C.F.R. Part 60, 40 C.F.R. Part 98.2, and/or relevant state and local laws). In this context, the U.S. EPA, under 40 C.F.R. Part 98, establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG. Stationary fuel combustion sources that emit 25,000 metric tons CO_2-e or more per year

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[4] 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 International 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.

[5] The U.S. Environmental Protection Agency reports there are 75 Municipal Solid Waste combustors. *See* U.S. Environmental Protection Agency: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), *available at*: https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw (last updated March 16, 2022).

must report their GHG emissions to the U.S. EPA (40 C.F.R. § 98.2(a)(3)). MSW combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). As the estimated GHG emissions resulting from combustion of articles containing the FCS in MSW combustion facilities are below the threshold for mandatory reporting, no significant environmental adverse impacts are anticipated. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

The U.S. EPA's regulations require all 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 and Appendix 2). These requirements are enforced by 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 FCS. Because the FCS is a monomer used in the production of high molecular weight polyester polymers, the FCS is not expected to readily volatize. Thus, no significant quantities of any substances will be released to the air upon the use and disposal of food-contact materials manufactured with the FCS.

As indicated above in Item 6, the FCS will replace a portion of the total MSW currently combusted. Therefore, 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.[6]

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills. Thus, the fate of finished food-contact materials 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

The factors discussed above support a conclusion that no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated due to the proposed use of the subject FCS. Virtually no leaching of components of the finished FCS

[6] *See* Confidential Attachment to this Environmental Assessment for additional details.

under normal environmental conditions is expected when these substances are landfill disposed because of the polymeric nature of the finished food-contact materials manufactured with the FCS. Furthermore, the estimated production of finished food-contact materials with the FCS, as discussed in the corresponding confidential attachment, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of these substances as a result of the proposed use of the 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.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment due to the use and disposal of the subject FCS in landfills and by combustion because only very small quantities of substances, if any, are expected to be introduced into the environment from the intended use of the FCS as discussed under Item 6. The use and disposal of 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 ("Criteria for Municipal Solid Waste Landfills") 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 involves 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 will be used in place of other food packaging materials.

Manufacture of the FCS, and its conversion to use in finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of chemically related resins. Articles and packaging materials produced from the FCS are expected to be disposed of according to the same patterns of currently marketed materials, when they are used in place of such materials. Thus, the use of this alternative product will have no significant impact on the use of resources and energy.

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 using the subject FCS. This is primarily due to the minute levels, if any, of the FCS components that may leach from finished materials containing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive polyester resins made with other alcohol monomers). Thus, no significant adverse impacts were identified that require mitigation measures.

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 anticipated environmental impact.

12. List of Preparers

Catherine R. Nielsen, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Ms. Nielsen has over 30 years of experience in preparing, supervising the preparation of, and counseling corporate entities on Food Additive Petitions and Food Contact Notification submissions, including Environmental Assessments.

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington D.C. 20001. Dr. Manning has over six years of experience drafting Food Contact Notification submissions, including Environmental Assessments.

13. Certification

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

Date: December 1, 2022

Catherine R. Nielsen
Counsel for Notifier

14. References

The following footnotes are found within the Environmental Assessment document:

1. FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, December 2020, *available at*: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

3. The U.S. Environmental Protection Agency reports there are 75 Municipal Solid Waste combustors. *See* U.S. Environmental Protection Agency: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), *available at*:

https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw (last updated March 16, 2022).

15. Attachments

1. Confidential Attachment