Environmental Assessment

1. Date: June 16, 2020

2. Name of Applicant/Notifier: Adeka Corporation

3. Address:

Adeka Corporation
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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:

The action requested in this Notification is to permit the use of the Notifier's food contact substance (FCS), a polymeric additive, C_{10-14}-branched, C_{11}-rich, reaction products with ethylene oxide, [(2-propenyloxy)methyl]oxirane and sulfamic acid (CAS Reg. No. 905843-50-7) composed primarily of poly(oxy-1,2-ethanediyl), alpha-sulfo-omega-[1-(hydroxy-methyl)-2-(2-propenyloxy)ethoxy]-, C_{11}-rich C_{10-14}-branched alkyl ethers, ammonium salts (CAS 403983-53-9), when used as a reactive emulsifier at up to 3% in adhesive formulations.

Food-contact packaging 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 packaging containing the FCS will occur nationwide. It is estimated that, of the 267,790,000 tons of total municipal solid waste (MSW) generated in 2017, approximately 52.1% generally was land disposed, 12.7% was combusted, and 35.2% was recovered for recycling.[1]

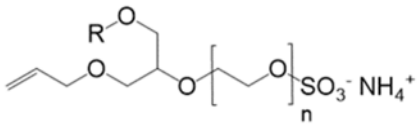
5. Identification of the Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is alcohols, C_{10}-C_{14}-branched, C_{11}-rich, reaction products with ethylene oxide, [(2-propenyloxy)methyl]oxirane and sulfamic acid (CAS Reg. No. 905843-50-7). The FCS is composed primarily of poly(oxy-1,2-ethanediyl), α-sulfo-ω-[1-

[1] *Advancing Sustainable Materials Management: 2016 and 2017 Tables and Figures*, U.S. Environmental Protection Agency, November 2019, accessed March 2020 at: https://www.epa.gov/sites/production/files/2019-11/documents/2016_and_2017_facts_and_figures_data_tables_0.pdf.

(hydroxymethyl)-2-(2-propen-1-yloxy)ethoxy]-, C_{11}-rich, C_{10-14}-branched alkyl ethers, ammonium salts (CAS Reg. No. 403983-53-9).

Structural Formula:



R = alkyl, C10-C14 branched, C11 rich;
N = 10, 20 or 30 depending on SR grade

Physical Description of FCS:

ADEKA REASOAP SR-10 is a viscous liquid with a density of 1.1 g/cm^3 and a viscosity of 7200 mPa sec (at 25°C). The viscosity of ADEKA REASOAP SR-20 is 10,000 mPa sec (at 25°C). The viscosity of ADEKA REASOAP SR-30 is even higher and this product is marketed as a 25% aqueous solution.

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 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 adverse environmental release is expected upon the use of the subject FCS in the manufacture of food-contact packaging materials. In these applications, the FCS is expected to be entirely incorporated into the finished adhesive. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as a part of the food-contact packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

The subject FCS consists of the elements carbon, hydrogen, nitrogen, sulfur, and oxygen. Thus, carbon dioxide and nitrous oxide are expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide and nitrous oxide from the FCS have been calculated.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of packaging containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency ("U.S. EPA") under 40 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalents (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations in 40 C.F.R. § 1508.27, which define 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. Moreover, 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. The expected carbon dioxide equivalent emissions have been calculated in a confidential attachment to this EA. The calculation, based upon the FCS elemental composition and estimated annual market volume, shows that the expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the food-contact packaging containing the FCS in MSW combustion facilities.

Only extremely small amounts, if any, of the substances from the finished food-contact packaging, containing the FCS, are expected to enter the environment as result of the landfill disposal, in light of the Environmental Protection Agency's (EPA) 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 groundwater monitoring systems. 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate. Even if a very small amount of substances leach from the landfilled food packaging 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

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 packaging manufactured with this FCS.

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. 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. 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 packaging intended for use in contact with food.

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 fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because it will replace use of other packaging materials.

Manufacture of the FCS, and the final conversion of the FCS to finished food-contact packaging will consume energy and resources in amounts comparable to the manufacture and use of other resins. Packaging materials produced from the FCS are expected to be disposed of according to the same patterns when used in place of current materials. Thus, there will be no impact on current recycling programs.

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 measures are 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

Mitzi Ng Clark, Partner, Keller and Heckman LLP, Three Embarcadero Center, Suite 1420, San Francisco, CA 94111. Over 17 years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

Michael A. Hubbard, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Over 1 year of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, 28 years of total experience in FDA regulated industries.

13. Certification

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

[redacted]

Mitzi Ng Clark
Authorized Counsel for Adeka Corporation
Date: June 16, 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

Confidential Attachment – Attachment 14