

Environmental Assessment

1. **Date** February 26, 2026*
2. **Name of Applicant** Buckman Laboratories, Inc.
3. **Address** All communications on this matter are to be sent to Counsel for Buckman,

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4. Description of the Proposed Action

The requested action in this Notification is the establishment of a clearance to permit the use of 2-Propanoic acid, 2-methyl, polymers with acrylamide, hydrolyzed poly(vinyl acetate) and 2-hydroxyethyl methacrylate (the “FCS”) as a creping agent in the manufacture of paper. The FCS is intended for use in contact with all food types under all conditions of use A through H as described in FDA Tables 1 and 2. The FCS is not for use in contact with infant formula and human milk.

More specifically, the FCS is used as a protective coating on the Yankee drying cylinder in the tissue paper making process. The FCS is diluted and then sprayed onto the Yankee cylinder to protect the metal surface against abrasion by the creping blade of the machine. The FCS provides high wet tack (bonding) that enables the Yankee cylinder to pick up the formed tissue sheet and hold it until it is creped by the doctor blade. The creping process gives tissue paper products their characteristic densities and textures. The tissue paper may be used in the packing or transport of food, e.g., bakery products. The FCS can be used as an alternative to traditional polyvinyl alcohol, which is hard to heat, difficult to stock and has a short shelf life.

5. Identification of Substances that are the Subject of the Proposed Action

The FCS (CAS No. 2349398-97-4) is produced by copolymerizing or grafting three monomers; namely 2-Propanoic acid, 2-methyl-, 2-hydroxyethyl ester (HEMA); 2-Propenamide (AM); and 2-Propanoic acid, 2-methyl-acrylic acid (MAA). The FCS is a high molecular weight polymer. The chemical formula and structure are contained in the Confidential Attachment.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make a minor correction of an editorial nature regarding the FCS name and limitations/specifications.

6. Introduction of the Food Contact Substance into the Environment

A. Manufacture

As set forth in 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the manufacturing, of FDA-regulated articles. However, FDA guidance directs that an EA should determine if any extraordinary circumstances pertain to the manufacture of the substance.¹ Extraordinary circumstances include situations where 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3) production associated with a proposed action may affect adversely 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.² The Notifier is not aware of data or information to suggest there may be extraordinary circumstances giving rise to adverse environmental impacts resulting from the manufacture of the FCS.

B. Use/Disposal

The Notifier does not intend to produce finished food-contact articles (tissues) from the FCS. Rather, the FCS will be used by paper mills in the production of finished tissue products. Food- contact articles produced with the FCS (tissue) will be used in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of tissue containing the FCS will occur nationwide, with the tissue land disposed, combusted, or recycled. According to the United States Environmental Protection Agency's 2020 update of data regarding municipal solid waste in the United States, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered for recycling or composting.³

No significant environmental release is expected when the FCS is used in the manufacture of food-contact materials (tissue). Approximately 15% of the FCS applied to the Yanke dryer is expected to be incorporated into the finished tissue and is expected to remain with these materials throughout the use/disposal of the finished materials by the consumer. Amounts remaining on the dryer during the manufacture of the finished tissue are disposed of as part of

¹ See United States Food and Drug Administration, *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition* (May 2006), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan>.

² *Id.*

³ See United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, available at: https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf.

the finished article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

7. Fate of Substances Released into the Environment

Air

No significant effects on the concentrations of or exposures to any substances in the atmosphere are anticipated from the proposed use of the FCS. As referenced in the Confidential Attachment, the FCS is a high molecular weight polymer and does not readily volatilize. 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. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations.

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 the FCS will enter water systems upon the proper disposal in landfills as the FCS is a high molecular weight polymer and because of the regulations in place to control leaching from landfills.

Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated due to the proposed use of the FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances from the proposed use of the FCS.

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 FCS in landfills and by combustion, because, as discussed under 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 FCS 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. Parts 60 and 258.

9. Use of Resources and Energy

As with most food contact articles, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The manufacture of the FCS will consume comparable amounts of energy and resources as the manufacture of similar creping agents that are already permitted for use in food contact articles, as the raw

materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this FCS will have no significant impact on the use of resources and energy.

10. Mitigation Measures

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 does not require mitigation measures.

11. Alternative 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 significant environmental impact.

12. List of Preparers

1. Laura Pearson
Director- Global Product Stewardship
Buckman Laboratories
31 years' experience in regulatory compliance
2. Geraldine Edens, Ph.D., J.D.
Counsel to Buckman
30 years' experience practicing environmental law

13. Certification

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

Dated: February 26, 2026



Geraldine Edens
Counsel for Buckman Laboratories, Inc.

14. REFERENCES

United States Food and Drug Administration, *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition* (May 2006), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan>.

United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, available at: https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

15. Attachments

A. Confidential Information