

Environmental Assessment

1. **Date:** April 26, 2022
2. **Name of Applicant:** Novipax
3. **Address:** 2215 York Road, Suite 208
Oak Brook, IL 60523

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

Devon Wm. Hill, Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4279
Facsimile: (202) 434-4646
E-mail: hill@khlaw.com

4. **Description of the Proposed Action**

A. Requested Action

The action proposed in this Notification is to provide for the use of cross-linked 2-propenoic acid homopolymer, sodium salt as a fluid-absorbent component of food packaging materials intended to be used in contact with red meat, poultry, fish and seafood, and fruits and vegetables under FDA's Conditions of Use E through G (*i.e.*, room temperature, refrigerated, and frozen; no thermal treatment in the package).

B. Need for Action

Many food products available for sale in supermarkets are displayed in packaging that contains superabsorbent pads. These packages are regularly comprised of a tray that is overwrapped by a transparent plastic film. Such packages permit the consumer to check the product and, at the same time, protect the food from external contamination.

Fluids from washing and fluids discharged from the food products themselves can accrue inside the packaging. These fluids can potentially lead to the growth of microorganisms which could cause food to spoil if permitted to accumulate. Furthermore, fluid within the food packages can adversely impact the appearance that may lower the product's appeal to the consumer. Cellulose pads are commonly used to absorb excess fluid in food packaging; however, their absorption capacity is limited.

An absorbent core made of superabsorbent polymers, can be added to the pads to improve absorption capacity, and specifically the retention capacity of the fluids. These

superabsorbent polymers absorb excess fluids into the polymer matrix by swelling. The retention capability of the polymer prevents the squeezing out of liquid and minimizes food contamination by stagnant fluids. Thus, the polymer is intended to be used as an absorbent agent to increase the absorbent and retention capacity of composite structures for food packaging applications.

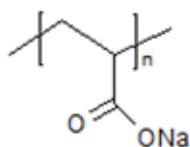
C. Location of Use and Disposal

The subject FCS will be sold to manufacturers who produce absorbent pads for food packaging. Food packaging produced with the FCS will be used in patterns corresponding to the national population density and will be widely distributed throughout the country. Thus, it is anticipated that discarding of such packaging will take place nationwide, with the food-contact article being land-disposed or combusted in proportions corresponding to those reported for municipal solid waste generally.

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

The subject FCS is a cross-linked, 2-propenoic acid homopolymer, sodium salt (CAS Reg. No. 9003-04-7). The chemical formula is depicted as follows: $[-CH_2-CH(CO_2Na)-]_n$. The structure of the base polymer is depicted as follows:

6. Introduction of Substance into the Environment



According to 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal of U.S. Food and Drug Administration (FDA)-regulated articles rather than the production of such articles. Nevertheless, information available to the Notifier suggests no extraordinary circumstances that would indicate a potential for significant adverse environmental impacts resulting from the manufacture of the FCS. Thus, information relating to the manufacturing site and compliance with relevant emissions requirements is not provided here.

The FCS is expected to be entirely incorporated into and remain with the finished food-contact article. Consequently, no significant environmental release is expected upon the use of the FCS to manufacture absorbent pads. Any waste material generated in the manufacturing process, *e.g.*, plant scrap, is expected to be disposed of in accordance with established procedures as part of the food-contact article manufacturer's overall non-hazardous solid waste disposal.

Discarding of absorbent pads containing the subject FCS by the eventual consumer will be by conventional rubbish disposal and, hence, primarily by landfill or incineration. Absorbent pads containing the FCS will be widely distributed across the country corresponding to the national population density. According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste is currently deposited in land disposal sites,

11.8% is combusted with energy recovery, 23.6% is recycled, and 8.5% is composted.¹ The use of the FCS in food-contact materials will have no impact on the disposal patterns of the packaging in which they are used.

Because the FCS is not recovered for recycling, we recalculate the disposal patterns here based on only the quantities of municipal solid waste that are land disposed or combusted. We therefore estimate the annual combustion amount of food packaging materials containing the FCS will be approximately 19.1%. This amount is estimated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. Therefore, it is anticipated that disposal will occur nationwide, with approximately 19.1% combusted. The remaining 80.9% will be land-disposed.

The FCS is composed of carbon, oxygen, hydrogen, and sodium, which are elements that are commonly found in municipal solid waste. We expect no extraordinary circumstances that would suggest a significant environmental impact resulting from post-consumer disposal of packaging that contains the FCS. We compared the projected fifth year market volume for the FCS, contained in a confidential attachment to this environmental assessment, to the annual municipal solid waste production (292 million tons municipal solid waste in 2018), and to the portion of that total that is landfilled, and conclude that the FCS will constitute an insignificant portion of the total municipal solid waste, as well as the amount of that total that is landfilled. Further, the proposed use of the FCS and corresponding projected market volume (provided in a confidential attachment to this environmental assessment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, estimated to be 11.8% of the 292 million tons total waste generated, or 34.5 million tons, as of 2018.² Thus, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant municipal solid waste combustors. Incineration of absorbent pads containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

In accordance with 40 C.F.R. § 1508.27, the environmental impact analysis must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. Thus, according to 40 C.F.R. § 98.2(a)(3), stationary fuel combustion sources that emit 25,000 metric tons carbon dioxide (CO₂) equivalents (CO₂-e) or more per year must report their greenhouse gas (GHG) emissions to the EPA. Importantly, municipal solid waste combustion facilities are considered stationary fuel combustion sources

¹ *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Material Generation, Recycling and Disposal in the United States*, EPA 530-F-20-009, U.S. Environmental Protection Agency, Office of Land and Emergency Management (5306P), December 2020, available at: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf. According to this report, of the total 292.4 million tons of municipal solid waste generated in 2018, approximately 50.0% generally was land disposed, 11.8% was combusted with energy recovery, 23.6% is recycled, and 8.5% is composted. The remaining 6.1% consists of waste that was processed through other waste management pathways.

² *See Id.*

pursuant to 40 C.F.R. § 98.30(a). Greenhouse gas emissions resulting from the use and disposal of the FCS result from the incineration of articles containing the FCS in municipal solid waste combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. § 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 tons carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

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. The carbon dioxide emissions expected from combustion of the FCS were estimated in the confidential attachment to the environmental assessment from the fifth-year confidential market projection. These predicted emissions are far below 25,000 metric tons annually. Thus, no significant environmental impacts are anticipated to result from combustion of the FCS in municipal solid waste combustion facilities, because the estimated GHG emissions are far below the threshold for mandatory reporting.

Considering EPA’s regulations governing municipal solid waste landfills, extremely small amounts, if any, of the FCS are expected to enter the environment via landfill disposal of food-contact articles. EPA’s regulations require new municipal solid waste landfill units and lateral expansions of existing units to have protective elements such as composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems (*see* 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 still required to monitor groundwater and to take corrective action 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 because the FCS does not readily volatilize.

As indicated above under item 6, the FCS will make up a practically insignificant portion of the total municipal solid waste currently combusted. Therefore, the FCS will not meaningfully alter the emissions from 40 CFR 60-compliant municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations. See the confidential attachment to the environmental assessment for additional details.

B. Water

The proposed use of the subject FCS polymer will not result in any significant effects on the concentrations of, and exposures to, any substances in fresh water, estuarine, or marine ecosystems. With proper incineration of the polymer or upon its disposal in landfills, no significant quantity of any substance will enter water systems due to negligible levels of

migration of polymer components. 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

Based on the factors discussed above, no significant effects on the concentrations of and exposure to any substances in terrestrial ecosystems are expected due to the proposed use of the subject FCS. Virtually no leaching of the FCS components is anticipated when absorbent pads containing the FCS are disposed under normal environmental conditions due to the polymeric nature of the FCS. Thus, there is no expectation of any meaningful exposure to polymer-borne substances for terrestrial organisms due to 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 absorbent pads intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that could be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer are extremely small quantities of combustion products and negligible levels of migrating polymer components. Thus, no adverse effect on organisms in the environment is expected due to the disposal of absorbent pads containing the FCS. Therefore, no information needs to be provided on the environmental effects of substances released into the environment due to use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of absorbent pads containing the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the EPA's regulations in 40 CFR Parts 60 and 258.

9. Use of Resources and Energy

The production, use, and disposal of the FCS involves the use of natural resources (*e.g.*, petroleum products, coal, and the like) like other food packaging materials. However, the use of the subject FCS in the manufacture of absorbent pads 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 absorbent pads that will replace analogous articles now on the market.

Manufacture of the FCS, and its conversion to use in an absorbent pad, will consume energy and resources in amounts comparable to the manufacture and use of other equivalent FCSs. Additionally, the finished absorbent pad in which the FCS is used is not currently recovered for recycling. Food-contact materials manufactured using the subject FCS are anticipated to be disposed of according to the same patterns when they are used as replacements of the existing materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measures

No significant adverse environmental impacts are anticipated to result from the use and disposal of absorbent pads containing the FCS. This is based on the minute levels, if any, of leachable components of the FCS from the enclosed absorbent pad employing the FCS, as well as the inconsequential impact on environmental concentrations of combustion products of the FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would require alternative actions to those proposed in the Notification. The alternative of not approving the action proposed herein would merely result in the continued use of the material that the subject FCS would otherwise replace. Thus, such action would have no significant environmental impact.

12. List of Preparers

Devon Wm. Hill, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Juris Doctorate; many years of experience preparing environmental assessments related to Food Contact Notifications.

Mark A. Hepp, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Ph.D. (Chemistry); many years of experience preparing environmental assessments related to Food Contact Notifications.

13. Certification

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

Date: April 26, 2022



Devon Wm. Hill, Partner
Counsel for Novipax

14. List of References

1. Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations), Appendix V, Table 2: Conditions of Use, *available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-premarket-submissions-food-contact-substances-chemistry>*.

2. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2020, *available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf*.

15. List of Attachments

1. Confidential Environmental Assessment (Attachment 5).