

Environmental Assessment

1. **Date:** September 8, 2023
2. **Name of Applicant/Notifier:** Mitsui Chemicals, Inc.
3. **Address:** 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**

A. **Requested Action**

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS) identified as 2,5-furandione, polymer with 1-propene (CAS Reg. No. 25722-45-6) for use as a component in blends with polyolefins for use in contact with all food types under Conditions of Use A through H.¹ The FCS will be used such that the level of the FCS (fraction by weight of polyolefin) multiplied by the thickness of the polyolefin layer containing the FCS in micrometers (μm) does not exceed the value of 6.35.

B. **Need for Action**

The FCS will be used as an adhesion promoter to adhere nonpolar polymers to polar polymeric materials such as polyamides and ethylene vinyl alcohol (EVOH), as well as metals. The resulting laminated products are suitable for food containers such as bags, cups, and bottles because of the high gas barrier property.

Materials with similar functions are currently permitted for use in the same applications for which the FCS is proposed. Use of the FCS in the production of multilaminate structures will substitute for the use of materials currently cleared for such applications.

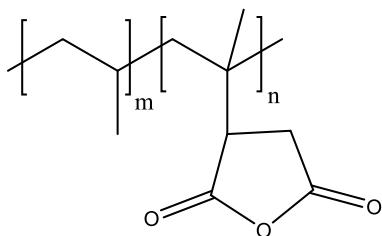
¹ FDA Food Types and Conditions of Use are defined in Tables 1 and 2 at:
<https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and they will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. 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, 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 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 this notification is 2,5-furandione, polymer with 1-propene (CAS Reg. No. 25722-45-6).



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 materials. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact as a result of the manufacture of the subject 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 articles. In the intended applications, the FCS will be used as a tie layer in the production of multilaminate structures. Thus, it is expected to be entirely incorporated into and remain with the finished food-contact article throughout the use/disposal of the finished materials by the consumer. Any waste material generated during the manufacture of the finished polymer, *e.g.*, plant scrap, will be disposed as part of the manufacturing facility’s overall nonhazardous solid waste in accordance with established procedures.

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.

Disposal by the ultimate consumer of the finished food-contact materials will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The FCS is composed of carbon, hydrogen, and oxygen. Thus, the combustion products of the FCS may include carbon dioxide. The carbon content of the FCS has been calculated based on the elemental composition of the FCS (presented 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) CO₂ equivalents (CO₂-e) or more per year to report their greenhouse gas (GHG) emissions to the U.S. 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. Such facilities are regulated by the 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 equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 40 C.F.R. § 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (NEPA) documents. 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 FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. 60 and/or relevant state and local laws).

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, 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 carbon, hydrogen, and oxygen, 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 are expected to enter the environment as a result of the landfill disposal of food-contact articles, 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, and to have ground-water monitoring systems (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 required to monitor groundwater and to take corrective actions as appropriate.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. When used as a component of laminated products, the FCS will be physically entrapped within polymeric matrices minimizing its ability to be liberated from the base resins to which it is added. Further, the FCS is a polymer of high molecular weight and will 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. Additional details are presented in the Confidential Environmental Information Attachment.

B. Water

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject FCS. 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

Considering the factors discussed above, no significant effects on the concentration of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the high molecular weight of the FCS is expected to result in virtually no leaching of the FCS from the laminate structures in which it is used under normal environmental conditions when food-contact materials are disposed. Furthermore, the low production volume anticipated for the FCS in food-contact applications (as noted in the Confidential Environmental Information Attachment) precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Considering the foregoing, the environmental fate does not need to be addressed because no significant introduction of substances into the environment as a result of the proposed use of the FCS was identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food-contact materials containing the FCS consist of very small quantities of combustion products and extractables, if any. None of these potential releases presents any significant toxicological concern at the low levels at which they could occur upon use and disposal of food-contact materials containing the FCS. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of food-contact materials containing the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA'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 packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS as a tie layer in 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 as a substitute for chemically identical or similar resins that are already on the market for use in the same or similar applications. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Food-contact materials containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used materials.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated with the subject FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No significant adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the FCS in accordance with the terms of FCN 631. Such action would have no environmental impact.

12. List of Preparers

1. George G. Misko, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Mr. Misko has over 30 years of

experience drafting food additive petitions, FCN submissions, and Environmental Assessments.

2. Peter N. Coneski, Ph.D., Senior Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Coneski has approximately 10 years of experience preparing FCNs, including 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: September 8, 2023



George G. Misko
Counsel for Mitsui Chemicals, Inc.

14. References

The following sources are referenced within this Environmental Assessment document:

1. FDA Food Types and Conditions of Use, 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.

15. Attachment

Confidential Environmental Information Attachment