

Memorandum

Date: May 8, 2024 *

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2346

Notifier: Polysecure GmbH

To: Vivian Gilliam, Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2024.05.08 09:00:23 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2346, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2346 is for the use of diyttrium dioxide sulfide (CAS Reg. No.: 12340-04-4)- doped with lanthanide ions, as an additive in all food-contact polymers, except for use in contact with infant formula and human milk (see below).

The FCS is for use as a fluorescent tracer at a maximum level of 200 ppm, in contact with all food types, under Conditions of Use B through H, as described in Tables 1 and 2. The FCS is intended to be used in both single and repeated use applications. The FCS is not intended for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated February 13, 2024, may be made available to the public. We will post digital transcriptions of the FONSI and the EA on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

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Date: 2024.05.08 08:48:08 -04'00'

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Attachment: Finding of No Significant Impact (FONSI)

* Subsequent to this date, this document was edited using the Adobe text editor tool to make several corrections to harmonize the FONSI to the final FCN regulatory language.

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2346, submitted by Polysecure GmbH for the use of diyttrium dioxide sulfide- doped with lanthanide ions, as an additive in all food-contact polymers, excluding contact with infant formula and human milk, as specified below.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated February 13, 2024. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

The FCS is expected to be entirely incorporated into and remain with the finished food-contact polymer and will be sold to manufacturers engaged in the production of the finished food contact articles. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures. Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population density and then disposed of nationwide via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*.¹ The EA indicates that the fate of articles containing the FCS within MSW is as follows: approximately 58.5% of municipal solids waste is currently deposited in land disposal sites, 13.8% is combusted, and 27.7% is recycled.

Post-consumer disposal of food-contact articles manufactured with the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively.

The FCS does not readily volatilize and is practically water insoluble; as such, it is unlikely to present any impact on the atmospheric, aquatic, or terrestrial environments. Upon combustion of the FCS, the lanthanide ions react with oxygen forming the relevant inert rare-earth oxides that deposit in slag of incineration which are followed by landfilling, while sulfur reacts with oxygen forming sulfur dioxide. The contribution of SO₂ emission through incineration of the FCS will make up an extremely small portion of the municipal solid waste currently combusted and of the total amount of SO₂ emissions currently generated.² Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA's regulations governing emissions from MWCs, no significant impacts are expected from incineration of the FCS at MWCs.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other polymer marking additives already in use. Manufacture of the polymeric materials containing the FCS will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

1 Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020. Available at: https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf.

2 Tiseo, Ian (2024) Annual sulfur dioxide (SO₂) emissions in the United States from 1970 to 2022, Jan 25, 2024. Available at: <https://www.statista.com/statistics/501303/volume-of-sulfur-dioxide-emissions-us/>

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2346 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by **Brittany Ott -S** Digitally signed by Brittany Ott -S
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