U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: November 24, 2025

From: Biologist, Office of Pre-Market Additive Safety, Environmental Review Team

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2468

Notifier: Valtris Specialty Chemicals

To: Stevie N. Walters, Ph.D.
Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Lead Biologist,
Office of Pre-Market Additive Safety, Environmental Review Team

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S
Date: 2025.11.24 14:47:42 -05'00'

Attached is the FONSI for FCN 2468, which is for the use of 1,4-bis(2-ethylhexyl) benzenedicarboxylate (CAS Reg. No. 6422-86-2) as a component of food-contact articles. This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated September 10, 2025, 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.

Denis Wafula -S Digitally signed by Denis Wafula -S
Date: 2025.11.24 14:38:42 -05'00'

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

File: FCN No. 2468

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2468, submitted by Valtris Specialty Chemicals for the use of 1,4-bis(2-ethylhexyl) benzenedicarboxylate (CAS Reg. No. 6422-86-2) as a component of:

1. nitrile rubber.
2. plasticized vinyl chloride formulations.
3. paper or paperboard or coatings of such paper and paperboard.
4. adhesives.
5. pressure sensitive adhesives in contact with food.

The FCS may be used:

1. as a plasticizer at levels up to 15 percent by weight in repeated-use nitrile rubber articles in contact with all food types under Conditions of Use A through H, as described in Tables 1 and 2.
2. at levels not to exceed 55 percent by weight of finished plasticized vinyl chloride polymer formulations used in repeated-use applications in contact with all food types at temperatures not to exceed 100°C.
3. as a component of paper or paperboard, or coatings for such paper and paperboard intended for use in contact with dry foods with no free surface fats or oil in compliance with 21 CFR 176.180.
4. as a component of adhesives complying with the provisions of 21 CFR 175.105.
5. as a component of pressure sensitive adhesives complying with the provisions of 21 CFR 175.125.

The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

The Office of Pre-Market 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 September 10, 2025. 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 articles and will be sold to manufacturers engaged in the production of the finished food contact articles. Any waste materials generated in the process of fabricating food-contact articles containing the FCS 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 disposed of in landfills, combusted, or recycled in proportions corresponding to the patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: 2018 Fact Sheet." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. Because plasticizers such as the FCS are commonly used in polymers, they will not interfere with recycling patterns. Because of the aforementioned MSW landfill regulations and its chemical properties, the FCS is not expected to leach into the environment. Further, the FCS does not readily volatilize and therefore it is not expected to present any impact on the atmosphere. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws.

Total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS, are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration of the FCS at MSW combustion facilities.

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 substances already in use. It is reasonable to expect that the manufacture of the FCS and its fabrication into food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

No significant environmental impacts are expected from the 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 2468 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2025.11.24 14:38:12 -05'00'

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Approved by MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2025.11.24 14:49:07 -05'00'

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