

**ENVIRONMENTAL ASSESSMENT  
VALTRIS ENTERPRISES  
FOOD CONTACT NOTIFICATION**

1. **Date** September 10, 2025
2. **Name of Applicant/Notifier** Valtris Enterprises
3. **Address** Lankro Way  
Eccles, Greater Manchester M30 0LX  
United Kingdom

All communications to this matter as to be sent in care of agent for Notifier:

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4. **Description of the Proposed Action**

The action requested in this notification is to permit the uses of 1,4-bis(2-ethylhexyl) benzenedicarboxylate as a plasticizer: (1) in nitrile rubber at levels not exceeding 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 of 21 Title 21 Code of Federal Regulations (CFR) §176.170(c); (2) in contact with all food types at levels not exceeding 55 percent by weight of finished plasticized vinyl chloride polymer formulations used in repeated-use, food-contact applications at temperatures no greater than 100 °C; (3) as a component of paper and 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; and, (4) as a component of pressure sensitive adhesives complying with the provisions of 21 CFR §175.125.

The action is needed to provide for an alternative supplier of 1,4-bis(2-ethylhexyl) benzenedicarboxylate for use in each of the proposed applications. The use of the FCS at levels not to exceed 15% in nitrile rubber articles and 55% by weight in plasticized vinyl chloride polymer formulations for repeat-use food-contact applications below 100 °C are types of uses that are equivalent to the actions which are categorically excluded under 21 CFR §25.32(j). These types of actions under §25.32(j) have been shown as a class to neither individually nor cumulatively have a significant effect on the human environment. Further, there are no extraordinary circumstances relating to these uses. Therefore, no significant impacts are expected as a result of the use in nitrile rubber articles or plasticized vinyl chloride polymer formulations for repeat use food-contact applications below 100 °C.

Thus, the remainder of the environmental assessment will focus on the uses of the FCS as a component of paper and paperboard, or coatings for such paper and paperboard, intended for use in contact with dry foods with no free surface fats or oil; as a component of adhesives; and, as a component of pressure sensitive adhesives, as described above.

The Notifier does not intend to produce finished food-contact articles from the subject FCS. Rather, the FCS that is the subject of this Notification will be sold to formulators engaged in the production of finished food-contact articles. Food-contact articles produced with the FCS 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 the subject resin will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's latest update regarding municipal solid waste in the United States<sup>1</sup>, of the total of 292.4 million tons of municipal solid waste (MSW) generated in 2018, approximately 146 million tons (50.0%) generally was land disposed, 35 million tons (11.8%) was combusted, 69 million tons (23.6%) was recycled and 25 million tons (8.5%) were composted. In addition, the remainder of the waste was managed by other methods such as: animal feed, bio-based materials/biochemical processing, co-digestion/anaerobic digestion, donation, land application and sewer / wastewater treatment.

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the FCS.

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

The FCS that is the subject of this Notification is:

1,4-bis(2-ethylhexyl) benzenedicarboxylate (CAS Reg. No. 6422-86-2).

## **6. Introduction of Substances into the Environment**

Under 21 C.F.R. § 25.40(a), 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. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject FCS to fabricate food-contact materials. In these applications, the FCS is expected to be used as a component of packaging used in contact with food, and the FCS will be entirely incorporated into the finished packaging. Any waste materials generated in this process, e.g., plant scraps, are

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<sup>1</sup> [EPA: National Overview: Facts and Figures on Materials, Wastes and Recycling](#)

expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of the food packaging produced with the subject FCS will be by conventional rubbish disposal and, hence, primarily by recycling, sanitary landfill, or incineration. As this FCS is being offered as an alternate supplier, it will not increase the environmental impact of using this FCS. The FCS is composed only of carbon, hydrogen, and oxygen; elements that are commonly found in municipal solid waste. (1) The proposed use of the FCS support that the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 35 million tons or 11.8% of 292.4 million tons in 2018)<sup>2</sup>; (2) paper or paperboard, including adhesives uses in the manufacture of them represent 12.16%, or 4.2 million tons in 2018 of the total municipal solid waste that is combusted, carbon represents 73.81% of the molecular mass of the proposed FCS, meaning that greater than 37 thousand tons of the FCS would need to be combusted to exceed 25 thousand metric tons carbon to the environment<sup>3</sup>. This amount of combusted FCS would require the FCS to represent 0.9% of the total US market of paper and paperboard, where this FCS is only a minor contributor to the final article; and (3) incineration of 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).

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 Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste 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 collections systems, they are 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. The FCS has a boiling point of approximately 400°C and therefore does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS.

As indicated above in item 5, the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the

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<sup>2</sup> See footnote 1.

<sup>3</sup> 25,000 metric tons carbon is equivalent to 27,558 tons carbon, meaning that 37,336 tons of the FCS will need to be combusted to release 27,558 tons of carbon.

emissions from properly operating 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. The fate of the FCS in the atmosphere does not need to be addressed because no significant introductions of substances into the air are identified, as discussed under Item 5.

**b. 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 subject FCS. No significant quantities of the any substance will be added to these water systems upon the proper incineration of food packaging employing the subject substance, nor upon its disposal in landfills due to the anticipated extremely low levels of aqueous extraction of the subject substance (the FCS has a very low water solubility). The fate of the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment are identified, as discussed under Item 5.

**c. Land**

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, because of its low water solubility, only extremely low levels of aqueous extraction of the subject substance are expected to occur under normal environmental conditions when finished food-contact materials are disposed. In addition, the very low production of the FCS for use in food-contact applications as discussed in the corresponding confidential 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, 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 articles intended for use in contact with food. Therefore, the fate of the FCS in the terrestrial environment does not need to be addressed because no significant introduction of substances into the environment resulting from the proposed use of the FCS were identified, as discussed under Item 5.

**8. Environmental Effects of Released Substances**

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer consist of extremely small quantities of combustion products and leachates, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of food-contact paper containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as

a result of use and/or disposal of the FCS because, as discussed under Item 5, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

## **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. The use of the FCS as a plasticizer in the fabrication of food-contact paper and paperboard packaging, and as a component of adhesives, including pressure sensitive adhesives, is not expected to result in a net increase in the use of energy and resources, however, because the substance is intended to be used in food-contact paper and paperboard and in adhesives and pressure sensitive adhesives in place of 1,4-bis(2-ethylhexyl) benzenedicarboxylate already on the market in these same food-contact applications.

The partial replacement of 1,4-bis(2-ethylhexyl) benzenedicarboxylate already marketed by other manufacturers by the subject FCS will not have any adverse impact on the use of energy and resources. Manufacture of the food-contact substance, and its conversion to finished food-contact materials, will consume the same energy and resources as the manufacture and use of the same substance already marketed under FCNs 770, 1056, and 1473. Furthermore, the use proposed in this Notification for the subject FCS, which is used as a component of paper and paperboard, and as a component of adhesives and pressure sensitive adhesives is not expected to have an impact on current or future recycling programs because the subject FCS will be used in place of the identical plasticizer already authorized by FCNs 770, 1056, and 1473. Thus, the use of the FCS will not have an impact on current or future recycling programs.

As described above, the FCS is already authorized for use in food-contact, pressure-sensitive adhesives by FCNs 770 and 1473. Thus, allowing this notification to become effective will neither expand the number of authorized substances that may be used as components of pressure-sensitive adhesives nor negatively impact the development of recycling-compatible pressure-sensitive adhesives for food packaging.

## **10. Mitigation Measures**

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the food-contact substance from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the fact that it is intended to compete with and replace the identical substance already authorized for such use. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

**11. Alternatives 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

**12. Certification**

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

Date: September 15, 2025



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Jonathan Walsh  
Regulatory Agent for Valtris Enterprises