Environmental Assessment for Food Contact Notification

1. Date: November 10, 2020

2. Name of submitter: Lanxess Corporation

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4. Description of the proposed action:

The action requested in this Food Contact Notification (FCN) is the establishment of a clearance to permit the use of 1, 2-benzoisothiazolin-3-one (BIT) antimicrobial preservative (CAS No. 2634-33-5) as a component in the manufacturing of food contact articles. The proposed use of BIT is as a preservative in aqueous additive formulations (latex emulsions, fillers, binders, pigment slurries, and sizing solutions) that are in compliance with 21 CFR.176.170, 176.180 or an effective FCN for use in paper and paperboard manufacturing. The maximum concentration to be used in these formulations is 300 ppm.

The Food Contact Substance (FCS) is not 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. The FCS may be used in contact with all food types under Conditions of Use A through H, as described in Table 2 in FDA guidelines .[1] It is expected that food contact articles that contain the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. It is anticipated that end consumers will either recycle treated paper and paperboard products, dispose of treated paper and paperboard products into trash, which will ultimately end up in landfills, or treated paper and paperboard products will be combusted at a municipal solid waste combustion (MSW) facility at current observed disposal patterns (EPA, 2019)[2].

This report provides MSW data for paper and paperboard used in containers and packaging, specifically. In 2017, 41,060,000 tons (37,249,016 metric tons) were generated. Of that amount, 30,080,000 tons (27,288,125; 73%) were recycled; 2,160,000 tons (1,959,520 metric tons, 5.3%) were combusted with energy recovery; and 8,820,000 tons (8,001,372 metric tons, 21.5%) was disposed into landfills.[3] The maximum use level of the FCS is 300 ppm (0.03%). If we assume that all paper/paperboard contained the FCS, then the FCS would be expected to account for 0.03% of total p/pb in MSW; 0.02% of this MSW that was recycled; 0.002% of this MSW that was combusted with energy recovery; and 0.001% of this MSW that was landfilled. Environmental conditions and considerations for the disposal locations are the same for other food contact substances.

5. Identification of substances that are the subject of the proposed action:
a) Complete nomenclature: 1,2-benzoisothiazolin-3-one

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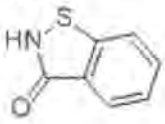
[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances
[2] EPA, 2019. Advancing Sustainable Materials Management: 2017 Tables and Figures, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States. Table 5B. https://www.epa.gov/sites/production/files/2019-11/documents/2016_and_2017_facts_and_figures_data_tables_0.pdf
[3] EPA, 2019. Advancing Sustainable Materials Management: 2017 Tables and Figures, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States.

b) Chemical Abstracts Service (CAS) registration number: 2634-33-5
c) Molecular weight: 151.18 g/mol
d) Molecular formula: C_7H_5NOS
e) Structural formula:



6. Introduction of substances into the environment:

Resulting from the manufacture of the FCS: Under 21 CFR 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 articles. 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. As a result, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

Resulting from use of the FCS: No release of the FCS into the environment is expected to result from the production and use of the FCS or other constituents of the formulation used to manufacture paper or paperboard because the FCS is expected to be completely incorporated into the food contact paper and paperboard. Essentially all of the FCS is expected to remain with the finished products throughout their use. Waste materials produced in the manufacturing of the FCS will be disposed of by the manufacturing facility as part of its overall waste management plan in accordance with the protocols that the company has developed and established regulations.

Resulting from disposal of the FCS: Disposal of the FCS will be by recycling, combustion, and landfill facilities that receive paper and paper board containing the FCS that have been discarded in rubbish by the end consumer. As described in Section 4, the FCS accounted for fractional proportions of paper and paperboard wastes disposed of by recycling (0.02%), combustion (0.002%) and landfilling (0.001%).

For the portion of MSW that is combusted, the proposed uses and use levels are not expected to change the emissions of properly functioning combustors. In addition, the elements comprising the FCS (e.g., C, H, O, N and S) are elements generally found in MSW. Incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (i.e., 40 CFR Part 60). As a result, no significant environmental impacts are anticipated to result from combustion of the FCS in MSW combustion facilities.

EPA regulations require all new 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 CFR Part 258 Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the FCS is not expected to reach the aquatic and terrestrial environment when disposed by landfill.

7. Fate of substances released into the environment:

(a) Air
No significant effects on the concentrations of and exposures to the FCS in the atmosphere are anticipated to result from the proposed use of the FCS. As discussed in Section 6, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted.

Based on the molecular structure of BIT (C_7H_5NOS), combustion of the FCS will result in production of the greenhouse gases carbon dioxide (CO_2) and nitrous oxide (N_2O). To assess the significance of this impact, we

consider the extent to which this action threatens a violation of federal, state, or local laws established for the protection of the environment. Per 40 CFR 98.2(a)(3) stationary fuel combustion sources that emit 25,000 metric tons CO_2 equivalents (CO2-e) or more per year are required to report their greenhouse gas emissions to the US EPA. Municipal solid waste combustion facilities are stationary fuel combustion sources. The combustion of articles containing the FCS will also result in the formation of sulfur dioxide and nitrogen oxides. The emissions of these gases are regulated in properly operating MSW incinerators under 40 CFR part 60.

An analysis of the total annual greenhouse gas CO_2 emissions is provided in the confidential attachment to the Environmental Assessment. The annual greenhouse gas emissions are below the EPA 25,000 metric tons CO_2-e greenhouse gas emissions threshold for mandatory reporting as described under 40 CFR 98.2.

Any emissions of sulfur and nitrogen oxides in MSW combustion facilities will be regulated under 40 CFR 60. Therefore, no significant impacts on the environment are anticipated. Combustion of the FCS will account for a very small fraction of the total emission from the large MSW combustion units.

As a result, no significant environmental impacts are expected from incineration of paper or paperboard food contact articles containing the FCS.

(b) Water
EPA's regulations governing landfills (40 CFR Part 258) would prevent contamination of groundwater and aquatic ecosystems. Some of the safeguards provided mandated by EPA's regulations include landfill liners and leachate collection systems and groundwater monitoring.

Although BIT is hydrolytically stable and has a half-life of greater than 30 days, it undergoes fairly rapid breakdown in aerobic soils (EPA, 2005). The half-life of BIT in aerobic soils is less than 24 hours. BIT has been observed to show moderate to strong binding to soils and the absorption K_d values of BIT are estimated to fall between 1.24 and 9.56. When used outdoors, BIT may travel with soil during rainfall and may reach surface waters. BIT undergoes aerobic breakdown on surface soils. Given BIT's moderate binding potential to soils, the likelihood of it migrating to the ground and contaminating ground water is low. In addition, the K_{ow} value is 20 at 25°C; therefore, BIT is not likely to bioaccumulate in aquatic organisms (EPA, 2005)[4].

Given the disposal patterns and regulatory controls previously described, no significant effects on the concentration of and exposures to the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The FCS is not expected to accumulate in the food chain. BIT undergoes photodegradation in water; at pH 5 the half-life of 9.1 hours and pH 7 and pH 9, the half-life is 0.7 hours. The photolytic degradation products of BIT include hydroxy BIT, saccharin, 2-sulfobenzamide, and 1,2-benzthiazolin-2-one[5]. In general, photodegradation is not a primary route of dissipation into the environment due to sorption, shading, and suspended sediment in water.[6]

(c) Land
Considering the factors discussed above, no significant effects on the concentrations of or exposures in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS. As summarized in the Reregistration Eligibility Decision (RED) for BIT (EPA, 2005) acute toxicity studies have revealed that BIT has low to moderate toxicity in birds and mammals, is moderately toxic to freshwater fish, and is highly toxic to marine estuarine invertebrates. The no observed adverse effect level (NOAEL) in a rat developmental study

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[4] EPA (2005) Reregistration Eligibility Decision (RED) for Benisothiazoline-3-one
https://nepis.epa.gov/Exe/ZyPDF.cgi/P1009GUF.PDF?Dockey=P1009GUF.PDF
[5] EPA (2020) Registration Review Draft Risk Assessment for 1,2-benzisothiazolin-3-one (BIT) pg. 53
https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0159-0007
[6] EPA (2020) Registration Review Draft Risk Assessment for 1,2-benzisothiazolin-3-one (BIT)
https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0159-0007

was 50 mg/kg/d and no chronic toxicity studies on aquatic organisms were identified at that time. One published acute toxicity study in algae reported that BIT is highly toxic to green algae.

The maximum amount of BIT permitted for use as an inert ingredient in pesticide products is small (not more than 0.1% of the formulation and 0.02 lbs per acre). Extremely low use levels of the FCS in paper and paperboard (at 300 ppm or 0.03%) are expected to result in the release of no or very small amounts of the FCS into the environment. As cited above, BIT breaks down rapidly in aerobic soils and has a half-life of less than 24 h in sandy loam soil. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the components of the food-contact substance as a result of the proposed use. EPA's regulations governing landfills (40 CFR Part 258) will prevent, minimize, or mitigate any migration of the FCS out of properly operating landfills. Owners and operators of municipal solid waste landfill (MSWLF) units are required to install a final cover system in order to minimize infiltration and erosion for protection of soil and water. As discussed in Part 6, leachate resulting from disposal of paper or paperboard products containing the FCS will be prevented from entering adjacent ecosystems using proper controls at landfill sites. The action that has been proposed and proper dispersal are not anticipated to result in significant contamination of the land (See EPA's regulation on landfills in 40 CFR Part 258).

In summary, no significant environmental impacts of the FCS when used in aqueous additive formulations (latex emulsions, fillers, binders, pigment slurries, and sizing solutions) that are in compliance with 21 CFR.176.170, 176.180 or an effective FCN for use in paper and paperboard manufacturing is expected.

8. Environmental effects of released substances:

As discussed in sections 6 and 7, negligible quantities of the FCS may be expected to be released to the environment upon the use and disposal of paper and paperboard containing the FCS. The regulations described in 40 CFR Parts 258 and 60 are protective of the environment for MSW LF units and MSW combustion facilities, respectively. The FCS is not expected to be released into the environment due to use of or disposal of the articles containing the FCS. Any residual amounts of the FCS entering the environment would degrade rapidly based on information described in the EPA (2005) Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS.

9. Use of resources and energy:

The FCS is intended to replace the same and similar anti-microbial preservatives currently allowed in the Inventory of Effective Food Contact Notifications, and so no significant net increase in energy use is expected based on the approval of the requested use in food contact paper and paperboard.

10. Mitigation measures:

No significant adverse environmental impact is expected to result from the proposed use of the FCS and the disposal of food contact paper and paperboard containing the FCS. The FCS would substitute for the same or similar substances and would not be expected to cause new environmental issues. Therefore, no mitigation measures are necessary.

11. Alternatives to the proposed action:

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the FCS would otherwise replace; such action would have no environmental impact.

12. List of preparers:

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Qualifications:
B.S. in Biology
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14 years of experience in regulatory affairs

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of her knowledge."
November 10, 2020

[redacted]

Kara Lewis, Ph.D.
Director of Scientific Affairs
GRAS Associates, LLC
Consultant to the Lanxess Corporation

13. Attachments

The following attachment in the FCN is relevant to this environmental assessment. This attachment, which is considered confidential, is indicated below.

"Confidential Environmental Assessment Attachment Lanxess FCN for BIT in Paper and Paperboard"