Environmental Assessment

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 uses of BIT are: (1) at a maximum concentration of 300 ppm as an anti-microbial preservative (alone or in combination with other biocides) to preserve aqueous preparations of adhesives and polymers that will be used to fabricate layers or adhesives for laminate structures in compliance with 21 CFR 177.1390 and 21 CFR 177.1395 or an effective FCN for laminate structures, and (2) at a maximum concentration of 300 ppm as an anti-microbial preservative (alone or in combination with other biocides) to preserve aqueous preparations of adhesives that will be used in pressure sensitive adhesives in compliance with 21 CFR 175.125 or an effective FCN for a pressure sensitive adhesive to be used on labels to be affixed directly to food.

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 are manufactured using 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 most food contact articles with pressure sensitive adhesives and food contact articles with layered/laminate structures that are manufactured using the FCS are expected to be disposed of mainly by landfill or to be combusted at a municipal solid waste combustion (MSW) facility (with lower amounts recycled) at current observed disposal patterns (EPA 2019)[2].

This report provides MSW data for plastics used in containers and packaging, specifically. In 2017, 14,490,000 tons (13,145,111 metric tons) were generated in MSW. Of that amount, 1,890,000 tons or 1,714,580 metric tons (13.0%) were recycled; 2,470,000 tons or 2,240,747 metric tons (17.0%) were combusted with energy recovery; and 10,130,000 tons or 9,189,784 metric tons (69.9%) was disposed in landfills[3]. The maximum use

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[1] https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm
[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 4. https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.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. https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf (Table 4).

level of the FCS is 300 ppm (0.03%). If it is assumed that all plastic used in packaging and containers contained the FCS, 567 tons or 514 metric tons of the FCS were recycled, 741 tons or 672 metric tons of the FCS were combusted with energy recovery, and 3,039 tons or 2,757 metric tons of the FCS were landfilled. The proposed uses and use levels of the FCS are expected to result in very small portions of the total municipal MSW currently recycled (0.0008%), combusted (0.0022%), and landfilled (0.0022%). 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:

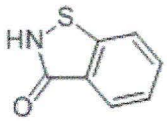
a) Complete nomenclature: 1,2-benzoisothiazolin-3-one

b) Chemical Abstracts Service (CAS) registration number: 2634-33-6

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 Section 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 the use of the FCS: No release of the FCS into the environment is expected to result from the use of the FCS or other constituents of the formulation used to manufacture layered/laminate structures and pressure sensitive adhesives to be used on labels to be affixed directly to food because the FCS is expected to be completely incorporated into the finished articles. 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 food contact articles with laminated/layered structures manufactured with the FCS or pressure sensitive adhesive containing the FCS will be by landfill and incineration at municipal solid waste combustion facilities that receive food contact articles manufactured with the FCS.

The FCS is composed of carbon, hydrogen, oxygen, nitrogen, sulphur, nitrogen, and oxygen. 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. 40 CFR 98.2(a)(3) requires stationary fuel combustion sources that emit 25,000 metric tons CO_2 equivalents or more per year to report their greenhouse gas emissions to the US EPA. Municipal solid waste combustion facilities are stationary fuel combustion sources.

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.

Due to the composition of the FCS, combustion at MSW incinerators will result in the production of sulfur and nitrogen oxides. 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.

Small amounts of the FCS are anticipated to enter the environment due to disposal of food contact articles by landfill. EPA regulations require all 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:

According to EPA (2020)[4]

> "Based on the current use patterns for BIT, no terrestrial exposures are expected. Several of the use patterns could result in aquatic exposure, however. Of these, the water cooling tower, pulp and paper mill, and paint uses are expected to result in the highest aquatic exposures and were modeled in this assessment."

(a) Air
No significant effect on the concentrations of and exposures to the FCS in the atmosphere are anticipated to result from the proposed use of the food-contact substance. The food-contact substance will make up a very small portion of the total municipal solid waste currently combusted. The FCS does not readily volatilize, but if it were to volatilize, it will undergo degradation in a reaction with photochemically generated hydroxyl radicals.[5]

(b) Water
EPA's regulations governing landfills (40 CFR Part 258) would prevent contamination of groundwater and aquatic ecosystems. Some of the safeguards mandated by EPA's regulations include landfill liners, leachate collection systems and groundwater monitoring. 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 FCS. The FCS is not expected to accumulate in the food chain. The FCS undergoes photodegradation in water with a half-life of 9.1 hours at pH 5 and 0.7 hour at pH 7 and 9.[6]

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[4] EPA (2020) Reregistration Review Draft Risk Assessment for 1,2-benzisothiazolin-3-one https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0159-0007

[5] PubChem 1,2-Benzisothiazoline-3-one (Compound). https://pubchem.ncbi.nlm.nih.gov/compound/1_2-Benzisothiazol-3_2H_-one#section=Environmental-Fate-Exposure-Summary

[6] EPA (2020) Reregistration Review Draft Risk Assessment for 1,2-benzisothiazolin-3-one https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0159-0007

(c) Land
Considering the factors discussed above, no significant effects on the concentrations of or exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS. Extremely low use levels of the FCS in layered/laminate structures and a pressure sensitive adhesive to be used on labels to be affixed directly to food are expected to result in the release of no or very small amounts of the FCS into the environment. 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. Because there is no expectation that use and disposal of materials manufactured from the FCS will affect the concentration of any substance in the terrestrial environment, we respectfully suggest that no further consideration of environmental fate in the terrestrial environment is necessary.

In summary, no significant impact of the FCS when used in aqueous preparations of adhesives and polymers that will be used to fabricate layered/ laminate structures and pressure sensitive adhesives to be used on labels to be affixed directly to food that are in compliance with 21 CFR 177.1390 and 21 CFR 177.1395 or an effective FCN for use in layered/laminate structures and a pressure sensitive adhesive to be used on labels to be affixed directly to food. The maximum concentration to be used in these formulations is 300 ppm.

8. Environmental effects of released substances:

As discussed previously, negligible quantities of the FCs may be expected to be released to the environment upon the use and disposal of layered/laminate structures and pressure sensitive adhesive to be used on labels to be affixed directly to food containing the FCS. Any residual amounts of the FCS entering the environment would degrade rapidly to non-toxic and non-persistent substances 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. In addition there is no expectation that the use and disposal of layered/laminate structures and a pressure sensitive adhesive to be used on labels to be affixed directly to food that contain the FCS would violate relevant laws and regulations.

9. Use of resources and energy:

The FCS is intended to replace the same and similar anti-microbial preservatives currently allowed in 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 layered/laminate structures and a pressure sensitive adhesive to be used on labels to be affixed directly to food.

10. Mitigation measures:

No significant adverse environmental impact has been identified as a result of the proposed use of the FCS and the disposal of layered/laminate structures and a pressure sensitive adhesive to be used on labels to be affixed directly to food 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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14 years experience in regulatory affairs

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of his 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 attachments in the FCN are relevant to this environmental assessment. Attachments which are considered confidential are indicated below.

"Confidential Attachment to Environmental Assessment"