Environmental Assessment

1.	**Date**	November 25, 2025 *
2.	**Name of Applicant**	Troy Corporation, an Arxada Company
3.	**Address**	Agent for Notifier: Joseph M. Dages, Partner Steptoe LLP 1330 Connecticut Avenue, N.W. Washington, D.C. 20036

4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as 1,2-benzisothiazolin-3-one (BIT; CAS Reg. No. 2634-33-5) (1) as a biocide preservative in aqueous latex/silicone formulations used for coatings on metal substrates complying with 21 C.F.R. § 175.300 and on polypropylene (PP) films complying with 21 C.F.R. § 175.320; and (2) as an antimicrobial agent in can-end and side-seam cements, excluding use in contact with infant formula and human milk.

When used as a biocide preservative, the FCS may be used at a level not to exceed 5 weight-percent of the preservative formulation, and the formulation may be added to the latex/silicone formulations at a level not to exceed 0.3 weight-percent. Coatings containing the FCS may not exceed an applied coating rate of 7.74 mg/in^2. The FCS is intended for contact with all food types, under Conditions of Use A through H, as described in Food and Drug Administration's (FDA's) Tables 1 and 2[1].

When used as a can-end and side-seam cement antimicrobial, the FCS is intended for use at levels not to exceed 0.015 percent by weight (150 parts per million, ppm) in can-end and side-seam cements that will contact aqueous, acidic, low alcoholic (up to 8 percent v/v alcohol content) and fatty food under the FDA's Conditions of Use A through H, and high alcoholic food (greater than 8 percent alcohol content) under Conditions of Use C through G, as described in Tables 1 and 2.

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

[1] *See* Food Types and Conditions of Use for Food Contact Substances, US Food and Drug Administration, available at https://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature and to remove reference to a withdrawn CEQ guidance document.

b. Need for Action

The FCS is intended for use as a preservative used in the production of food-packaging materials. The food contact substance will be sold to manufacturers engaged in the production of polymer solution preparations that will be sold to other companies to make coatings that are applied to food contact articles. The FCS will preserve these polymer solution formulations. The FCS has no function in final food contact articles.

The FCS is an antimicrobial preservative that is regulated by the U.S. Environmental Protection Agency (US EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Troy has current registrations of the FCS with US EPA.

c. Locations of Use/Disposal

The polymer and metal container production plants that purchase the FCS to add as a preservative to their food-contact articles are located outside of the United States. Local surface waters may receive liquid production wastes. Such emissions would be regulated under the jurisdiction of those locations.

It is expected that food-contact articles that contain the FCS will be utilized in patterns corresponding to the national population density and widely distributed across the country. It is expected that end consumers will either recycle, or dispose of metal cans into the trash where they will ultimately end up in landfills, at current observed recovery rates.[2] The EPA's current data for municipal solid waste generation, recycling and disposal indicate that there was no significant recycling of flexible packaging.[3] It is expected that end consumers will dispose of the flexible packaging in the trash, which will end up in the landfills. Per EPA, 2020, 10% of flexible packaging is recycled, 72.4% is landfilled, and 17.6% is combusted with energy recovery. As to metal cans, EPA's 2020 information on MSW recovery indicate recycling for steel cans to be 70.9%, 23.4% landfilled, and 5.7% combusted with energy recovery.[4]

5. Identification of Substances that are Subject of the Proposed Action

The FCS that is the subject of this Notification is 1,2-benzisothiazolin-3-one (BIT).

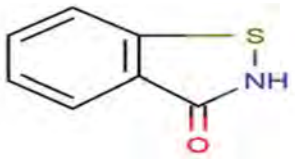
CAS Reg. No.: 2634-33-5

Molecular Formula: C_7H_5NOS

Molecular weight: 151 g/mol

[2] EPA, *Advancing Sustainable Materials Management: 2018 Tables and Figures*, https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf.
[3] *Ibid*. Page 10, Table 8 (Plastics in Products In MSW, 2018).
[4] *Ibid*. Page 8, Table 7 (Metal Products In MSW, 2018).

Structural Formula:



Physical description: off white crystalline solid

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. 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 articles. Moreover, information available to the manufacturer 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 food-contact substance. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Disposal by the end consumer of the FCS will be by landfill, combustion and recycling facilities. Based on the molecular composition of the FCS, emissions of carbon, nitrogen and sulfur oxides may be expected during combustion of articles containing the FCS. However, based on confidential market volume estimates provided in a confidential attachment to this EA, the proposed use of the FCS is expected to make up a very small portion of the total municipal solid waste (MSW) currently combusted and will not present any unique emissions. Therefore, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (under 40 C.F.R. Part 60 or relevant state and local laws). Also, based on those market volume estimates, the FCS will only account for a marginal amount of total MSW discards. 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 groundwater 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 ground water and to take corrective action as appropriate. As such, no unique or significant amounts of landfill leachates are anticipated.

The analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion

sources which emit 25,000 metric tons (mT) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). MSW combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). Based on the market volume in the confidential attachment, the carbon dioxide equivalent emissions are below 25,000 metric ton. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulations (i.e., 40 C.F.R. Parts 60 and 98, and/or relevant state and local laws). Therefore, no significant environmental adverse impacts are anticipated resulting from the combustion of the FCS in MSW combustion facilities.

7. Fate of Emitted Substances in the Environment

As explained above, no releases to the environment are expected due to existing regulations governing landfill disposal and waste combustion; besides, as shown below, according to EPA's Reregistration Eligibility Decision on BIT, the FCS is hydrolytically stable, and is unlikely to cause ground water contamination or to bioaccumulate:[5]

> The environmental fate assessment for 1,2-benzisothiazolin-3-one was based on limited information; data were only available for hydrolysis, aerobic soil metabolism, and adsorption/desorption. These data indicate that 1,2-benzisothiazolin-3-one is hydrolytically stable (half-life > 30 days), but breaks down fairly quickly in aerobic soils (half-life < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one shows moderate to strong binding to soils, with adsorption K_d values estimated to be between 1.24 and 9.56. If used outdoors, 1,2-benzisothiazolin-3-one may possibly move with soil during rainfall events and potentially reach surface waters. However, it breaks down aerobically on the surface soils. Since it has a moderate binding potential to soils, it is not likely to migrate into the ground and there is low potential for ground water contamination. Furthermore, with a K_{ow} value of 20 at 25°C, 1,2-benzisothiazolin-3-one is unlikely to bioaccumulate in aquatic organisms.

a. Air

Based on FCS's molecular structure (C_7H_5NOS), the combustion of the FCS may form greenhouse gases (GHG) carbon dioxide (CO_2) and nitrous oxide (N_2O). As noted

[5] EPA, Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one, September 29, 2005, p. 30 https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-098901_29-Sep-05.pdf.

above the annual emissions of CO_2-e (CO_2 and N_2O) from combustion of materials containing the FCS will be well below the EPA mandatory reporting threshold of 25,000 metric tons and thus further quantitative assessment is not warranted.

Considering the proposed use and the main disposal of the FCS, primarily sanitary landfills or incineration, there will be no significant effect on concentrations of and exposures to any substance in the air. The EPA regulation 40 C.F.R. Part 60 requires that the emission limits for sulfur dioxide contained in the gases discharged to the atmosphere from a designated facility is 29 parts per million by volume or 25 percent of the potential sulfur dioxide emission concentration (75 percent reduction by weight or volume), corrected to 7 percent oxygen (dry basis). Meanwhile, emission limits for nitrogen oxides from these designated facilities are listed on Table 1 in Subpart Cb of 40 C.F.R. Part 60. Because the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste contributors, and therefore not threaten a violation of applicable emissions laws and regulations (i.e., 40 C.F.R. Part 60).

b. Water

BIT is highly water soluble.[6] However, the materials present in the consumer products are bound in the polymer matrix of can, or film coatings, and would not be released under normal environmental conditions. Any leachates of the FCS from the polymeric matrix that occur are expected to break down quickly under normal environmental conditions. Although BIT is considered to be mobile to moderately mobile in soils, with the potential to contaminate ground water,[7] in light of EPA's regulations governing municipal solid waste landfills (40 C.F.R. Part 258), 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 manufactured with the FCS. 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. Landfills also are required to have ground-water monitoring systems. Although owners and operators of existing 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. The FCS measured value of log K_{ow} is 1.4 which is lower than the risk concern level (log K_{ow} of 3.2); therefore, the FCS is not expected to accumulate in the food chain due to its low K_{ow} bioconcentration potential.[8] Therefore, no significant release of the FCS to fresh water,

[6] US EPA, 2014. 1,2-Benzisothiazolin-3-one (BIT) Preliminary Work Plan Registration Review: Initial Docket Case Number 3026, Docket No. EPA-HQ-OPP-2014-0159, p. 23-24, https://www.regulations.gov/document/EPA-HQ-OPP-2014-0159-0002.

[7] *Ibid*., p. 41.

[8] *Ibid*.

estuarine, or marine ecosystems is anticipated as a result of the proposed use and proper disposal of the FCS according to EPA's regulations governing landfills, e.g., 40 C.F.R. Part 258 or relevant regulations.

c. Land

Considering the factors discussed above, no significant introductions of the FCS to terrestrial ecosystems are anticipated as a result of the proposed use and disposal of the subject FCS. As discussed above, EPA's regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate. Furthermore, the low production of the FCS for use in food-contact applications precludes any substantial release to the environment of the 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.

Therefore, we respectfully state that there is no reasonable expectation of a significant impact on any substance in the environment due to the proposed use of the FCS in articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, only very small quantities of the substance, if any, will be introduced into the environment from its use and disposal. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the food contact substance. Any residual amounts of the FCS entering the environment would degrade rapidly to non-toxic and non-persistent substances with no potential bioaccumulation.

Therefore, as no significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6, a quantitative evaluation of the environmental effects of the proposed use of the FCS is not required.

9. Use of Resources and Energy

The use of the FCS in food-contact materials is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in place of the same FCS or similar substances now on the market, such as FCN 1108.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. Therefore, mitigation measures of any kind are not required.

11. Alternatives to the Proposed Action

No potential significant adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact 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

Ms. Patricia Kinne, Environmental Specialist, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036 with over 10 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joseph M. Dages, Partner, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036, with 19 years of experience working in the food regulatory arena, including over ten years as an attorney working on FCN submissions and environmental assessments.

13. Certification

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

Date: November 25, 2025

(b) (4)

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Joseph M. Dages, Partner

14. References

US EPA, Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one, September 29, 2005.

US EPA, 2014. 1,2-Benzisothiazolin-3-one (BIT) Preliminary Work Plan Registration Review: Initial Docket Case Number 3026, Docket No. EPA-HQ-OPP-2014-0159.

US EPA Report: Advancing Sustainable Materials Management: 2018 Tables and Figures. December 2020.

US FDA, Food Types & Conditions of Use for Food Contact Substances, available at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

15. Attachments

Confidential Attachment