

An EA Revision Sheet has been prepared for this Environmental Assessment
See the FONSI for this Food Contact Notification

Environmental Assessment

FCN 1733

1. **Date:** March 8, 2017
2. **Name of submitter:** Lanxess Corporation
3. **Address:** 111 RIDC Park West Dr., Pittsburgh, PA 15275-1112

All communications on this matter are to be agent/consultant for Lanxess:

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4. **Description of the proposed action:**

a. **Requested action:**

The action requested in this Food Contact Notification (FCN) is the establishment of a clearance to permit the use of 2-methyl-4-isothiazolin-3-one (MIT) antimicrobial preservative as a component in the manufacturing of food contact articles.

Intended Use

As: (1) a preservative in aqueous formulations of adhesives that will be used under use conditions defined in 21 CFR 175.105; (2) a preservative in aqueous coating formulations to be used on paper under use conditions defined in 21 CFR 176.170; (3) a preservative in aqueous additive formulations (latex emulsions, fillers, binders, pigment slurries, and sizing solutions) used in paper and paperboard manufacturing to produce paper in compliance with 21 CFR 176.170 and 176.180; and (4) as a slimicide in the wet end of paper manufacturing to produce paper in compliance with 21 CFR 176.170 and 176.180. The FCS is not for use in contact with infant formula and human milk (see Limitations/Specifications).

Limitations/Specifications

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 The maximum level of the FCS: (1) in adhesives is 150 ppm; (2) in paper coating formulations is 150 ppm, with the exception of latex coatings where the maximum level is 250 ppm; (3) in aqueous additive formulations for use in paper is 150 ppm (4) as a slimicide used in the wet end of paper manufacture is 150 ppm in the process water. The FCS is not for use in contact with infant

¹ Available at
<https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm>

formula or human milk. Such uses were not included as part of the intended use of the substance in the FCN.

b. Need for action:

This FCS is a preservative used in the production of food-packaging materials. The food contact substance will be sold to manufacturers engaged in the production of adhesives and paper and paperboard. The FCS has no function in final food contact articles.

The FCS is an anti-microbial preservative that is normally regulated by the U.S. Environmental Protection Agency (US EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Lanxess has not registered any products with the FCS with US EPA. Lanxess intends to sell the FCS to customers outside the United States where a FIFRA registration is not necessary.

c. Locations of use/disposal:

The polymer, adhesive, and paper production plants that purchase the FCS to use as a preservative or slimicide are located outside of the United States. Should there be any environmental impacts from use of the FCS during production of food contact articles, these will be under the jurisdiction of a foreign nation and are not occurring in the global commons. Therefore, an evaluation of the impacts is outside the scope of this environmental assessment (EA), and information on production sites and compliance is not provided.

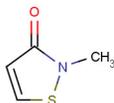
It is expected that food-contact articles that contain the FCS will ultimately be imported into the U.S. market and utilized in patterns corresponding to the national population density and widely distributed across the country. As explained in the confidential attachment, it is anticipated that virtually all of the FCS resulting from FCN 1733 will be used in paper packaging. It is expected that end consumers will either recycle or dispose of treated paper and paperboard products into the trash, which will ultimately end up in landfills or combusted at a municipal solid waste combustion (MSW) facility at current observed disposal patterns (EPA, 2016). Antimicrobials are typical components of paper and paperboard products; there is nothing about this FCS in particular which would uniquely impact paper recycling operations. Therefore there is no likely impact of the use of this preservative on recycled paper.

5. Identification of substances that are the subject of the proposed action:

The identity of the FCS is summarized below:

- a) Complete nomenclature (IUPAC): 2-methyl-2H-isothiazolin-3-one
- b) Chemical Abstracts Service (CAS) registration number: 2682-20-4
- c) Molecular weight: 115.2 g/mol
- d) Molecular formula: C₄H₅NOS

e) Structural (graphic) formula:



f) Physical description: off-white and to be 9/1 10Y (value, chroma and hue respectively, 100%), pale amber and to be 8/4 7.5Y (value, chroma and hue respectively, 57.3% purity)

6. Introduction of substances into the environment:

a. Introduction of substances into the environment as a result of manufacture:

Under 21C.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 manufacture of the FCS. 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 confidential market volume estimates provided in a confidential attachment to the EA (Attachment 36), 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 the elemental composition is typical of those in MSW (C, H, N, O, S). Therefore, incineration of food contact articles containing the FCS is not expected to cause MSW combustion facilities to threaten a violation of applicable emissions laws and regulations (under 40 C.F.R. Part 60 or relevant state and local laws).

Based on market volume estimates provided in a confidential attachment, 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 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 ground water and to take corrective action as appropriate. Therefore, based on MSW landfill regulations preventing leaching, the FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

On August 1, 2016, the Council on Environmental Quality (CEQ, 2016) issued final guidance to agencies regarding addressing GHG emissions and climate change impacts in NEPA documents. This guidance is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effects of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action" (CEQ, 2016 p. 3). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the

U.S. Environmental Protection Agency (U.S. EPA) under 40 CFR 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG”. Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 CFR 1508.27(b)(10) states, that when evaluating intensity of an impact, one should consider “whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.” GHG emissions from MSW combustion facilities are regulated under 40 CFR 98.2. Based on the confidential market volume, the expected CO₂-e emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Based on the discussion above, we do not expect the FCS (MIT) to have a significant impact on the environment. Similarly, EPA is not planning to conduct an ecological risk assessment for MIT-containing pesticide products because of MIT’s lack of persistence in the environment (as we will outline further in Item 7 below) (EPA, 2014).

7. Fate of substances released into the environment:

a. Physical/chemical properties

Based on the physical and chemical properties summarized in Table 1 above, MIT is highly water soluble and therefore would be expected to remain in water (rather than volatilize to the air, based on its low Henry’s law constant). However, if in soil, the FCS could volatilize to air based partially on its vapor pressure and its low Log Kow, which indicates it is unlikely to sorb to soil or sediment. The low Log Kow also suggests bioaccumulation of the FCS is unlikely (EPA, 2014).

Table 1. Physical and chemical properties^a

Water solubility	≥22.59 grams at 25°C in 100 mL water
Octanol-water partition coefficient (Log Kow)	-0.486 at 24°C in log P (PAI)
Vapor Pressure	6.2x10 ⁻² mm Hg
Henry's law constant at 25 °C CALCULATED ^B	4.16 x 10 ⁻⁸ atm-m ³ /mol

^aMIT Final Work Plan (EPA, 2014 Table 4, p. 10 and 11)

b. Environmental depletion mechanisms

Based on the use pattern of the FCS (as a component of food-contact articles recycled, landfilled or combusted), the FCS is not expected to reach the environment. Additionally, based on the market volume information provided in the confidential attachment only extremely low levels of the FCS would be disposed of in MSW. However, if the FCS reaches water or soil, it is expected to rapidly biodegrade and therefore would not significantly affect terrestrial or aquatic organisms (EPA, 2014).

(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 food-contact substance. The food-contact substance will make up a very small portion of the total MSW currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors (as it is composed of elements typical of MSW), and therefore not threaten a violation of applicable emissions laws and regulations (i.e., 40 CFR Part 60 and 40 CFR Part 98). Additionally, as indicated above the FCS is not expected to volatilize into air from the aquatic environment. Although the FCS may volatilize from terrestrial environment, it is not expected to reach the terrestrial environment (see below), and therefore this route of introduction is not considered further in the EA.

(b) Water

The preservatives which are the subject of this notification are highly water soluble. However, if the FCS reaches the aquatic environment, due to its lack of persistence, it is not expected to have a significant impact on the aquatic environment. FCS. As explained above, based on the use pattern, no significant introductions of the FCS into the environment are expected (see Item 6 above).

(c) Land

Considering the factors discussed above (propensity to partition to water, unlikely to absorb to sediment or soil, marginal amount of FCS disposed compared and the regulations at 40 CFR Part 258 which prevent leaching from landfills), we do not expect the FCS to reach the terrestrial environment as a result of the proposed use of the food contact substance. 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.

8. Environmental effects of released substances:

As discussed previously, the FCS is not expected to be introduced into the environment upon the use and disposal of food contact articles containing the FCS. At most, extremely small quantities of combustion products and FCS containing leachates might reach the environment, and if they did, rapid biodegradation is expected. As no significant introductions of the FCS into the environment as a result of the proposed use of the FCS were identified under Item 6, and, as provided in Item 7 any residual amounts of the FCS entering the environment would degrade rapidly to non-toxic and non-persistent substances with negligible potential for bio-accumulation. Therefore, no significant adverse environmental effects are expected as a result of the use

and disposal of articles containing the food contact substance.

9. Use of resources and energy:

The food contact substance is intended to replace other similar polymer preservatives such as 5-Chloro-2-methyl-4-isothiazolin-3-one (CMIT), 1,2-Dibromo-2,4-dicyanobutane, and other anti-microbial preservatives currently allowed in Inventory of Effective Food Contact Notifications, and so no significant change in energy use is expected based on the approval of the requested use.

10. Mitigation measures:

No potential significant adverse environmental impact has been identified as a result of the proposed action. Therefore, identification of mitigation measures is not 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 action, as described in the FCN 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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Heather Adams, Ph.D.
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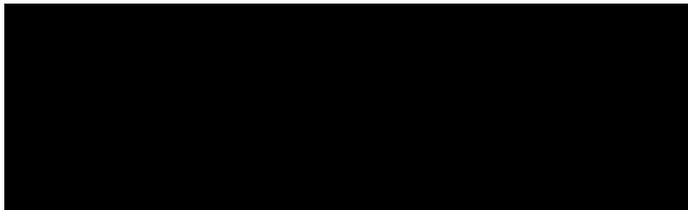
Amy Anstead, M.S.
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M.S. Biology
15 years experience in environmental science

13. Certification:

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

March 8, 2017



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Co-Founder
GRAS Associates, LLC
Consultant to the Lanxess Corporation

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14. References:

EPA, 2014. Methylisothiazolinone/Chloromethylisothiazolinone Final Work Plan, Registration Review: Initial Docket Case No. 3092. EPA-HQ-OPP-2013-0605 (December 2014).
<https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0605-0045>

CEQ, 2016. *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews*, August 1, 2016, Available at
https://www.energy.gov/sites/prod/files/2016/08/f33/nepa_final_ghg_guidance.pdf

EPA, 2016. *Advancing Sustainable Materials Management: 2014 Tables and Figures, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*
<http://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report>

15. Attachments:

The following attachments in the FCN are relevant to this environmental assessment. Attachments which are considered confidential are indicated below.

Confidential Environmental Assessment Attachment, Lanxess FCN 1733