

Environmental Assessment

FCN 2081

1. **Date:** August 28, 2020
2. **Name of submitter:** Lanxess Corporation
3. **Address:** 111 RIDC Park West Dr., Pittsburgh, PA 15275-1112

All communications on this matter go to the 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, CAS 2682-20-4) as a preservative in formulations of uncured liquid rubber latex used to manufacture repeat-use rubber gloves. The food contact substance (FCS) is not for use in contact with infant formula and human milk.

Limitations/Specifications

The FCS may be used in contact with all food types. The maximum level of the FCS is 250 ppm in the latex emulsion. The 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.

- b. **Need for action:**

This FCS is a preservative in raw latex solutions used to manufacture rubber gloves. In this application, the FCS will be entirely incorporated into the glove. The gloves will be used by workers in food processing plants.

The FCS is an antimicrobial preservative that is regulated by the U.S. Environmental Protection Agency (U.S. EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Lanxess has registered with US EPA a manufacturing use product and end-use products that contain this FCS as part of their formulation.

c. Locations of use/disposal:

The Notifier itself does not intend to produce finished food-contact items (e.g., repeat-use rubber gloves) which contain the FCS. Rather, the FCS will be marketed to manufacturers to be added to uncured liquid rubber latex formulations used by glove manufacturers.

The production plants that purchase the FCS to add as a preservative to their food-contact articles 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.

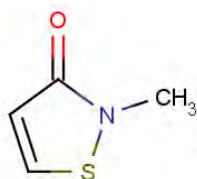
It is expected that food-contact articles like gloves that contain the FCS will ultimately be imported into the U.S. market and utilized in patterns corresponding to the national population density and widely distributed across the country. It is expected that end consumers will dispose of gloves and these will be either land disposed in municipal solid waste (MSW) landfills subject to 40 CFR Part 258 or incinerated at MSW combustion facilities that comply with 40 CFR Part 60. Gloves used in an industrial setting will be disposed of in an industrial waste landfill governed by Subpart D of the Resource Conservation and Recovery Act (RCRA) recorded in 40 CFR 257.2.

The only rubber product that is accounted for in U.S. EPA's most recent MSW database¹ is tires. Recycling and recovery of the rubber from food-contact gloves are not expected.

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:



- i.
- 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)

¹ Advancing Sustainable Materials Management: 2017 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States. November 2019; EPA 530-F-19-007. Available at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf (Accessed Aug. 28, 2020)

6. Introduction of substances into the environment:

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

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 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 or combustion. Based on confidential market volume estimates provided in a confidential attachment to the 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 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 CFR 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 all 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 CFR Part 258). 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 or terrestrial environment when disposed of via landfill.

Greenhouse gas (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 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalents (CO₂-e) emission threshold for required reporting. Because we anticipate such emissions, we have analyzed GHG emissions based upon the confidential market volume of the FCS. This analysis is provided in a confidential attachment to the EA.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations in 40 C.F.R. § 1508.27, which define 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. When evaluating intensity of an impact, 40 C.F.R. § 1508.27(b)(10) states that one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." As stated above,

GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. As the estimated carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis (i.e., the EPA threshold for mandatory reporting), no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

7. Fate of substances released into the environment:

a. Physical/chemical properties

Based on the physical and chemical properties summarized in Table 1 below, 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). According to the EPA Final Work Plan on MIT (EPA, 2014), MIT is not susceptible to hydrolysis at acidic, neutral, or alkaline pH and no formaldehyde release was detected. The combustion products are expected to be oxides of carbon, hydrogen, sulfur, and nitrogen.

Table 1. Physical and chemical properties

Water solubility ^a	>76.0% w/w @ 20.0 ± 0.5°C; 49.8 – 76.0% w/w @10 ± 0.5°C
Dissociation constant in water ^a	-0.32 (predicted by SPARC version 4.6)
n-octanol/water partition coefficient	K _{ow} = 0.3 ^a or 0.5 ^b
Vapor pressure	1.2 Pa at 25 °C ^c or 6.2 x 10 ⁻⁴ torr ^b
Henry's Law constant ^d	1.36 x 10 ⁻⁹ Pa-m ³ /mol
Photostability at pH 7 ^e	DT ₅₀ (aqueous, sunlight, 50 °N): 5.2 DT ₅₀ (aqueous, sunlight, 30-40 °N): 5.0
Soil adsorption, desorption ^a	Mean log ₁₀ K _{oc} : 0.778 Adsorption coefficient: 6.00

a., c., d., and e. Information obtained through internal testing and provided in confidential data reports (citations provided in the confidential attachment to this EA)

b. EPA, 2014

b. Environmental depletion mechanisms

Based on the use pattern of the FCS (as a component of food-contact articles 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).

i. 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.

ii. Water

The preservative that is the subject of this notification is 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. As explained above, based on the use pattern, no significant introductions of the FCS into the environment are expected (see Item 6 above).

iii. Land

Considering the factors discussed above (propensity to partition to water, unlikelihood of absorbing to sediment or soil, marginal amount of FCS disposed of 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:

MIT would substitute for other similar latex preservatives such as 1,2-benzisothiazolin-3-one currently allowed by FCNs. 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. Prepared by:

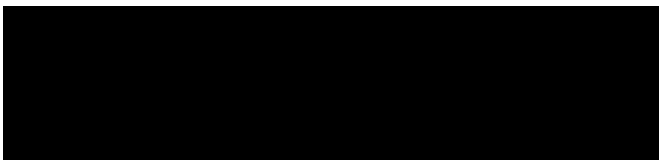
Leslie E. Patton, Ph.D.

Qualifications: Ph.D. Toxicology; B.S. Natural Resources. 13 years of experience in toxicology and regulatory affairs

13. Certification:

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

Date: August 28, 2020



Leslie E Patton, Ph.D., Senior Toxicologist.
TSG Consulting
Consultant to the Lanxess Corporation

14. References:

EPA. 2019. *Advancing Sustainable Materials Management: 2017 Fact Sheet: Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*. November 2019, EPA 530-F-19-007, Available at - https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

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>

15. Attachments:

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

Attachment 16. Confidential Environmental Assessment, Lanxess FCN 2081