Environmental Assessment

1. Date 04 February 2026

2. Name of notifier Cotek Specialties (Taicang) Co., Ltd.

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4. Description of the proposed action

a) Requested action

The action requested in this food contact substance (FCS) notification is to establish a clearance for the use of 2-methyl-4-isothiazolin-3-one (MIT; CAS Reg. No. 2682-20-4) as an antimicrobial in uncured liquid rubber latex used to manufacture repeat-use rubber gloves.

Limitations/Specifications

The FCS may be used in contact with all food types, excluding infant formula and human milk. The maximum level of the FCS in latex emulsions for the manufacture of repeat-use gloves is 250 ppm.

b) Need for action

The FCS functions as an antimicrobial preservative within the uncured rubber latex solution, preventing bacterial degradation during the manufacturing process. In this application, the FCS will be entirely incorporated into the glove. It is important to note that this preservative effect is intended solely for the latex emulsion and has no function in final manufactured food-contact articles (e.g., rubber gloves). The proposed use of MIT would be substitutional for its use as outlined in the effective FCNs 2081, 1308 and 286.

c) Locations of use/disposal

The notifier does not manufacture finished food-contact articles. The FCS that is the subject of this notification will be supplied to glove manufacturers or to manufacturers who produce the latex compounds used in glove manufacturing.

It is expected that food-contact articles like gloves that contain the FCS will ultimately be utilized in patterns corresponding to the national population density and widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide. Gloves containing the FCS are expected to be disposed of at the point of use, with the final disposal pathway being municipal solid waste landfills, municipal waste combustion facilities, or commercial/industrial solid waste incinerators. The environmental setting of these disposal locations is typical for end-of-life food-contact articles currently in commerce. Therefore, no special environmental circumstances are anticipated with respect to either the use or disposal of these gloves.

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

The identity of the FCS is summarized below:

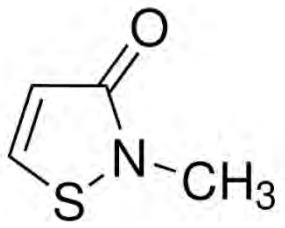
Substance Name: 2-methyl-4-isothiazolin-3-one

CAS Registry Number: 2682-20-4

Molecular Formula: C_4H_5NOS

Molecular Weight: 115.16 g/mol

Structural Formula:



6. Introduction of substances into the environment

a) Introduction of substances into the environment as a result of manufacture

The FCS does not readily volatilize and will be cured within a food-contact article; as such, it is unlikely to present any significant impact on the atmospheric environment. Moreover, 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.

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. 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

No significant environmental release is expected upon the use of the FCS or the other chemicals in the formulation in the manufacture of food-contact articles. The FCS is expected to be entirely incorporated into and remain with the finished food-contact articles under the intended use. Any waste materials generated during the glove manufacturing process are expected to be managed in accordance with standard waste disposal procedures.

The FCS is expected to remain within the food-contact articles. Consequently, end-of-life disposal by consumers will follow conventional solid waste management pathways, primarily landfilling or incineration. Since the current notification pertains to a substitutive use of the same FCS under the effective FCNs 2081, 1308, and 286, the intended use of notifier's FCS is not expected to result in increase in the overall environmental burden (e.g., landfill volume or combustion emissions).

Confidential market volume estimates (provided in a confidential attachment) indicate that the FCS will only account for a marginal amount of total municipal solid waste (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 groundwater and surface water contamination, 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.

Confidential market volume estimates (provided in a confidential attachment) indicate that the FCS is expected to constitute a minor fraction of the total 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).

Greenhouse gas (GHG) emissions associated with the use and disposal of the FCS are expected to originate primarily from the incineration of end-of-life articles in MSW combustion facilities. These facilities are subject to mandatory GHG reporting requirements established by the U.S. EPA under 40 CFR Part 98, which applies to facilities whose annual emissions meet or exceed a threshold of 25,000 metric tons of carbon dioxide equivalents (CO2-e). An estimation of annual GHG emissions attributable to the intended use of the FCS, based on confidential market data, is provided in the confidential attachment to this Assessment. The estimated emissions are significantly below the reporting threshold. Therefore, no significant environmental impacts are anticipated from the combustion of the FCS in MSW facilities.

7. Fate of substances released into the environment

Based on its physical and chemical properties, MIT is highly water-soluble, stable against chemical degradation (hydrolysis and photodegradation), rapidly degraded by metabolism in the environment, unlikely to volatize from water into air, and will be present mostly in water in the presence of sediment (U.S. EPA, 2014). The low log Kow value of MIT indicates that sorption to soil, sludge, and sediments, as well as bioconcentration in aquatic organisms, is expected to be limited (U.S. EPA, 2014).

As discussed previously, no significant quantities of the FCS are anticipated to be released during the manufacture, use, or disposal of food-contact articles containing it. Furthermore, confidential market volume data indicate that only extremely low levels of the FCS would be disposed of in MSW. Should the FCS reach aquatic or terrestrial environments, it would not be expected to persist due to its rapid potential for biodegradation (U.S. EPA, 2014).

Based on the foregoing assessment, we respectfully conclude that there is no reasonable basis to anticipate significant effects on the concentrations of, or exposures to, any substances within the atmospheric, aquatic, or terrestrial environmental compartments. As the FCS is not expected to be introduced into the environment through its proposed use, we propose that a detailed analysis of its environmental fate may be omitted from this Environmental Assessment.

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

No significant change in energy use is expected based on the approval of the requested use, since the proposed use of the FCS would be substitutional for the same FCS or similar latex preservatives (e.g., 1,2-benzisothiazolin-3-one) that are presently available in the market.

10. Mitigation measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact gloves containing the FCS. The FCS would substitute for the same or similar substances and would not be expected to cause new environmental issues. 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 clearing 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. Prepared by

Lehao Zhou, M.Sc., Regulatory Affairs Consultant, Hangzhou REACH Technology Group Co., Ltd. Many years of experience with FCN submissions and food packaging compliance matters.

13. Certification

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

(b) (4)

Lehao Zhou
Hangzhou REACH Technology Group Co., Ltd.
February 4, 2026

14. Reference

U.S. EPA. (2014, December). *Methylisothiazolinone/Chloromethylisothiazolinone Final Work Plan*. EPA-HQ-OPP-2013-0605-0045. https://www.regulations.gov/document/EPA-HQ-OPP-2013-0605-0045

15. Attachments

- Confidential Attachment to the Environmental Assessment