

Environmental Assessment

- 1. Date** May 28, 2024
- 2. Name of Notifier** Cotek Specialities (Taicang) Co., Ltd.
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4. Description of the proposed action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), 1,2-benzisothiazolin-3-one (BIT; CAS Reg. No. 2634-33-5), as a biocide in uncured liquid rubber latex to manufacture repeat-use rubber gloves intended for use in contact with all types of food, excluding infant formula and human milk. The clearance established by this Notification would permit the use of the FCS at a maximum concentration of 0.05 percent by weight of the latex solids.

The technical effect of the FCS, is a biocide used in the raw latex solution to prevent bacterial degradation. The FCS functions as a preservative for the latex emulsion during the manufacturing process, and there is no preservative effect intended for the finished article, e.g., rubber gloves. The proposed use of BIT would be substitutional for its use as outlined in the effective FCNs 371, 846, 1111, 1208, and 1686.

The Notifier itself does not intend to produce finished food-contact articles, like gloves or other goods containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to glove manufacturers or manufacturers of formulations that are used to produce gloves.

Disposal of the gloves containing the food-contact substance is expected to occur at the locations where they are used, with the FCS ultimately being deposited in municipal solid waste landfills or combusted in municipal waste combustors or commercial industrial solid waste incinerators.

The types of environments present at or adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of the food-contact gloves.

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

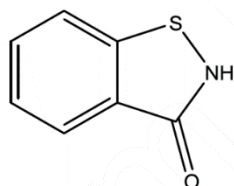
The FCS that is the subject of this Notification is 1,2-benzisothiazolin-3-one.

CAS Registry Number: 2634-33-5

Molecular Formula: C_7H_5NOS

Molecular Weight: 151.19

Structural Formula:



6. Introduction of substances into the environment

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 materials. 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. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject FCS, or the other chemicals in the formulation, to fabricate food-contact gloves. In these applications, the FCS is expected to be entirely incorporated into and remain with the finished food-contact articles. Any waste materials generated during the glove manufacturing process are anticipated to be managed according to standard waste disposal protocols.

Disposal by the ultimate consumer of rubber gloves containing the FCS will be by conventional rubbish disposal and, therefore, primarily through municipal solid waste (MSW) landfills subject to 40 CFR Part 258, or incineration at MSW combustion facilities that comply with 40 CFR Part 60. Gloves used in industrial settings are expected to be disposed of in compliance with industrial landfill regulations under Subpart D of the Resource Conservation and Recovery Act (RCRA) recorded in 40 CFR 257.2.

As stated above, the proposed use of the FCS would be substitutional for the use of BIT in the effective FCNs 371, 846, 1111, 1208, 1686. The FCS will not significantly alter the emissions from properly operating municipal solid waste combustors. The incineration of the FCS will not result in municipal waste combustors threatening a violation of any relevant emissions laws and regulations (40 CFR Part 60 and/or corresponding laws). An estimation of the total annual greenhouse gas emissions is provided in the confidential attachment to the Environmental Assessment. Considering the market volume of the FCS, it will make up a very small portion of the total MSW currently

combusted (total estimated to be 34.6 million tons or 11.8% of 292.4 million tons in 2018)¹. Compared with the threshold of 25,000 metric tons provided by the Council on Environmental Quality (CEQ), the amount of CO₂-e annual emissions from the subject of the FCS is much less than this threshold, therefore, mandatory reporting, as described under 40 CFR 98, is not required.

Only extremely low levels, if any, of the FCS are expected to enter into the environment from gloves disposed of in sanitary landfills. The U.S. Environmental Protection Agency (EPA) has stringent regulations under 40 CFR Part 258 for municipal solid waste landfills (MSWLFs), mandating that new units and expansions have composite liners and leachate collection systems to prevent ground and surface water contamination, as well as groundwater monitoring systems. 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 groundwater and to take appropriate corrective action. Consequently, it is anticipated that only extremely low quantities, if any, of the FCS will migrate from gloves disposed of in landfills into the environment.

7. Fate of substances released into the environment

As discussed above, negligible releases to the environment are expected due to existing regulations governing landfill disposal and waste combustion; besides, the FCS is hydrolytically stable, and is unlikely to cause ground water contamination or to bioaccumulate, according to EPA's Reregistration Eligibility Decision for 1,2-Benzisothiazolin-3-one².

(a) Air

No significant effect on the concentrations of and exposures to the FCS in the air are anticipated to result from the proposed use. As discussed in Format Item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted. Furthermore, the FCS does not readily volatilize, but if released to air, it will undergo degradation in a reaction with photochemically-produced hydroxyl radicals³.

(b) Water

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated as a result of the proposed use and proper disposal of the FCS. As discussed in Format Item 6, EPA's regulations and mandated safeguards would prevent contamination of groundwater and aquatic ecosystems. Furthermore, any of the FCS that would reach the aquatic environment will be rapidly photodegraded in water with a half-life of 9.1 hours at pH 5 and 0.7 hour at pH 7 and 9⁴.

¹ USEPA, 2020. Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States.

² USEPA/OPPTS, 2005. Reregistration Eligibility Decisions (REDs) on 1,2-Benzisothiazolin-3-one (BIT) (2634-33-5). EPA-739-R-05-007.

³ PubChem 1,2-Benzisothiazoline-3-one (Compound). Available at: <https://pubchem.ncbi.nlm.nih.gov/compound/17520#section=Environmental-Fate-Exposure-Summary>

⁴ USEPA, 2020. Reregistration Review Draft Risk Assessment for 1,2-benzisothiazolin-3-one

(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.

Furthermore, the very low use level of the FCS in the liquid rubber latex and entirely incorporated into and remain with the finished food-contact articles, are expected to result in the release of no or very small amounts of the FCS into the environment.

In summary, no significant impact on the concentrations of, and exposures to, any substance in terrestrial ecosystem is anticipated as a result of the propose use of 1,2-benzisothiazolin-3-one and its proper disposal.

8. Environmental effects of released substances

No significant introductions of substances into the environment during the use and disposal of food-contact rubber gloves were identified under Format Item 6 and 7. Consequently, no information is required to be provided on the environmental effects of the FCS released into the environment as a result of usage and disposal of the FCS. Moreover, any residual quantity reaching the environment would be degraded in short term based on the properties of BIT, according to EPA's Reregistration Eligibility Decision on 1,2-Benzisothiazolin-3-one (BIT)⁵. Therefore, the disposal of articles containing the FCS is not expected to adversely affect organisms in the environment.

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 proposed use of the FCS would be substitutional for the same FCS or similar substances that are presently available in the market for use in food-contact gloves, as referenced by effective FCNs 371, 846, 1111, 1208, and 1686.

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, 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 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.

⁵ USEPA/OPPTS, 2005. Reregistration Eligibility Decisions (REDs) on 1,2-Benzisothiazolin-3-one (BIT) (2634-33-5). EPA-739-R-05-007.

12. List of preparers

Michael Chang, Ph.D., DABT. Chief Technology Officer, Hangzhou REACH Technology Group Co., Ltd. Over 15 years of experience in chemistry, toxicology and regulatory affairs.

Zhou Lehao, M.Sc., Regulatory analyst, 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 his knowledge.



Michael Chang, Ph.D.

Hangzhou REACH Technology Group Co., Ltd.

Date: May 28, 2024

14. Attachment

- Confidential Attachment to the Environmental Assessment