

- 1. Date** July 17, 2016
- 2. Name of applicant/notifier** SHANGHAI MIKEN BIOTECH CO.,LTD
- 3. Address** Room 1006, Tower A, No.966, Huaxu Road, Qingpu District, Shanghai, China

#### **4. Description of proposed action**

The action required in this Food Contact Notification (FCN) is to permit the use of 1,2-benzisothiazolin-3-one (BIT; CAS Reg. No. 2634-33-5) at a maximum concentration of 0.05 weight-percent in the latex based on latex solids for use as a biocide in uncured liquid rubber latex used to manufacturer repeat-use rubber gloves intended for use in contact with all types of food.

The technical effect of BIT, the Food Contact Substance (FCS), is a biocide used in the raw latex solution to prevent bacterial degradation. The FCS functions as a preservative of the latex emulsion, and there is no preservative effect intended for the finished article, e.g., rubber gloves. The proposed use of the FCS is the same as FCNs 1208, 1111, 846 and 371.

The Notifier itself does not intend to produce finished food-contact items, such as gloves or other finished goods, which contain the FCS. However, the FCS will be added into formulations or be sold to glove manufacturers or other manufacturers of formulations that are used in the finished goods.

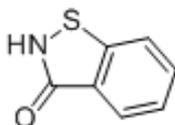
Disposal of the gloves containing the food-contact substance is expected to occur at the locations where they are used, with the FCS ultimately being deposited in municipal solid waste landfills or combusted in municipal waste combustors or commercial industrial solid waste incinerators.

#### **5. Identification of substance that is the subject of the proposed action**

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

CAS Reg. No.: 2634-33-5  
Molecular Formula: C<sub>7</sub>H<sub>5</sub>NOS  
Molecular weight : 151.2

Structural Formula:



#### **6. Introduction of substances into environment**

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 production of FDA-regulated articles. 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. Thus, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

Little or no introduction of the FCS entries is expected into environment because the FCS is completely incorporated into the fabricated food-contact gloves which, upon disposal by the consumer, 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.

Considering the market volume of the used FCS, it will not significantly affect the emissions from properly operating municipal solid waste combustor, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulation (40 CFR Part 60 or relevant laws). Comparing the expected market volume<sup>1</sup> with the total municipal solid waste currently combusted (estimated to be 32.7 million tons or 12.9 percent of 254 million tons in 2013), the FCS will make up a minute fraction of the total municipal solid waste currently combusted.

When the gloves are treated by sanitary landfills, no significant amount of leaching components from the product will introduce into environment. In terms of migration and exposure of BIT, we expect only very low levels of the FCS to leach or migrate from the gloves disposed of in landfills. This conclusion is based on the regulation of the U.S. Environmental Protection Agency (EPA) governing municipal solid waste landfills (MSWLF), 40 CFR Part 258, which requires new MSWLF 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. Though 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.

## **7. Fate of emitted substances in the environment**

As explained above, no releases to the environment are expected due to

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<sup>1</sup>The expected market volume is provided in confidential attachment to the Environment Assessment.

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 (USEPA, 2005; page 30):

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<sub>d</sub> 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<sub>ow</sub> 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<sub>7</sub>H<sub>5</sub>NOS), the usage of the FCS is expected to form greenhouse gases (GHG) carbon dioxide (CO<sub>2</sub>) and nitrous oxide (N<sub>2</sub>O). After consulting the Council on Environment Quality's draft revised guidance (CEQ, 2014) and Table ES-1 on page 3 of the Municipal Solid Waste in the United States statistics (USEPA, 2013), we found the annual emissions of CO<sub>2</sub>-e (CO<sub>2</sub> and N<sub>2</sub>O) from usage and disposal of our product is 857 metric tons<sup>2</sup>, which were calculated using U.S. EPA's Greenhouse Gas Equivalency Calculator<sup>3</sup>. Compared with the threshold of 25,000 metric tons provided by CEQ, the amount of CO<sub>2</sub>-e annual emissions from our products is much less than this threshold, and the further quantitative assessment is not warranted (CEQ, 2014).

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 CFR Part 60 requires that the emission limits for sulfur dioxide contained in

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<sup>2</sup>Detailed calculation process is recorded in confidential attachment to the Environment Assessment.

<sup>3</sup>USEPA's Greenhouse Gas Equivalency Calculator. Available at <http://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator>

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 CFR Part 60. When the FCS is combusted completely in these designated facilities, the products will be nitrogen oxides, carbon dioxide, sulfur dioxide, nitrogen oxides and water. Besides, given the amount of the combusted products based on the excepted market volume, it will be a very small fraction of the total emission from the large MSW combustion units.

Based on the analysis above, the annual emissions of the combusted products from the FCS will not harm the atmosphere significantly.

#### (b) Water

According to the MSWLF units required by EPA's regulation in landfills on 40 CFR Part 258, the FCS is not expected to cause contamination of the groundwater or surface water, or cause leachate depth on the liner to exceed 30-cm for assuring protection of human health and the environment. Besides, a leachate collection system, which is monitoring the depth of the leachate persistently, is to protect the groundwater from being contaminated. Furthermore, there is a groundwater monitoring systems, which is built to yield ground-water samples from the uppermost aquifer to detect the groundwater contamination. 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. Thus, even though a very small fraction of FCS releases to the environment, it will be monitored by these systems and then be treated by corrective actions timely.

Therefore, no significant release of the FCS to fresh water, estuarine, or marine ecosystem 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 CFR Part 258 or relevant regulations.

#### (c) Land

As the requirement of 40 CFR Part 258, owners or operators of all MSWLF units must install a final cover system, which is designed to minimize infiltration and erosion for protecting the soil and water. Furthermore, as analyzed in Item 7 (b), though very small amount of leaching of the FCS may be expected to occur when the used gloves are disposed, the leachate will be prohibited from entering adjacent ecosystems by proper controls in place at landfill sites. Our proposed action and proper disposal are not expected to

significantly contaminate the land in the requirement of EPA's regulation on landfills in 40 CFR Part 258 and Part 60.

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

## **8. Environmental effects of released substances**

Accordingly, given regulations that are protective of the environment for MSW LF units and MSW combustion facilities at 40 CFR Parts 258 and 60, respectively, the FCS is not expected to release into environment during the use and disposal of food-contact rubber gloves containing the FCS. Based on the analysis under Item 6 and 7, no information is needed to be provided on the environmental effects of the FCS released into environment as a result of usage and/or disposal of the FCS. Furthermore, any residual quantity reaching the environment would be degraded in short term based on the properties of BIT, which is according to Reregistration Eligibility Decisions Database on 1,2-Benzisothiazolin-3-one (BIT) published on 2005.

## **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 for use in food-contact gloves, see FCSs 1208, 1111, 846 and 371.

## **10. Mitigation measures**

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact gloves containing the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

## **11. Alternatives to proposed action**

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the current preservatives that the FCS would otherwise replace; such action would have no environmental impact.

## **12. List of preparer**

Mia Gao, M.S., Regulatory analyst, 9 years' experience conducting ecological risk assessments.

Cimmy Zeng, M.S., Regulatory analyst, 5 years' experience conducting ecological risk assessments.

Alice Wu, Ph.D., Regulatory analyst, 2 years' experience conducting ecological risk assessments.

Maxine Liu, M.S., Regulatory analyst, 6 years' experience conducting ecological risk assessments.

### **13. Certification**

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

Date: Aug. 03,2016



Signed: Alice Wu

## **14. References**

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

USEPA, 2013. Advancing Sustainable Materials Management: Facts and Figures 2013, Assessing Trends in Material Generation, Recycling and Disposal in the United States, EPA 530-R-15-002, June 2015.

CEQ, 2014. Revised Draft Guidance on the Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in NEPA Reviews. Available at <https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance>

## **15. Attachment**

There is a confidential attachment to this Environment Assessment, which is including the market volume information for the FCS and the detailed calculation process of greenhouse gases emissions from the FCS.