

Environmental Assessment

- 1. Date** September 12, 2008
- 2. Name of Applicant/Notifier** The Dow Chemical Company
- 3. Address** All communications on this matter are to be sent to Mr. Garry M. Wiltshire, The Dow Chemical Company, 1803 Building #416, Midland, Michigan 48674. Telephone: (986) 638-1557
- 4. Description of the Proposed Action**

The action requested in this notification is to permit the use of 1,2-benzisothiazolin-3-one (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 manufacture repeat-use rubber gloves intended for use in contact with all types of food.

The food contact substance (FCS) technical effect is as a biocide used in the raw latex solution to prevent bacterial degradation. The FCS functions as a preservative of the latex emulsion.

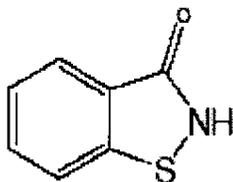
The Notifier does not intend to produce finished food-contact articles, such as gloves or other finished articles that may be used in contact with food that contain the food contact substance. Rather, the FCS will be sold to manufacturers engaged in the production of gloves or to manufacturers of formulations used to produce gloves. Gloves are produced worldwide, predominantly in the Asia Pacific region. According to the U.S. Environmental Protection Agency's 2005 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 13.6% was combusted, and 32.1% was recovered for recycling and composting.¹

The types of environments present at and 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 food-contact gloves.

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).

¹ *Municipal Solid Waste in the United States: 2005 Facts and Figures*, EPA530-R-06-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2006.



Empirical formula: C₇H₅NOS

Molecular weight: 151.9

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 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 gloves containing 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 FCS, or the other chemicals in the formulation, to fabricate food-contact gloves. In these applications, the FCS will be entirely incorporated into the glove. Any waste materials generated in this process are expected to be disposed of as part of the glove manufacturer's overall solid and liquid waste in accordance with established procedures.

The FCS is expected to remain with the gloves and, therefore, its disposal by the ultimate consumer will be parallel to the disposal of the of food-contact gloves; specifically, by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration (80% and 20%, respectively). The proposed use of the FCS is the same as FCN 371, thus the FCS will be substitutional. Moreover, 1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 33 million tons or 14% of 236 million tons in 2003)¹ 2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors², and 3) incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 CFR part 60 and/or relevant state and local laws.

Only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food-contact gloves, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. 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

² Paul M. Sullivan; William H. Hallenbeck; Gary R. Brenniman, *Municipal Solid Waste Combustion*; University of Illinois at Chicago: Chicago, IL, 1993.

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 groundwater and to take corrective action as appropriate. Even if a very small amount of FCS leach from the landfilled food-packaging gloves into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

7. Fate of Emitted Substances in the Environment

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Format Item 6. Consequently, evaluation of the environmental fate of the FCS or its combustion products is not required.

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant introduction of substances into the aqueous environment is anticipated as a result of the proposed use of the FCS as discussed in Format Item 6.

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the food-contact substance in the manufacture of gloves intended for use in contact with food.

8. Environmental Effects of Released Substances

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6. Consequently, evaluation of the environmental effects of the proposed use of the FCS is not required.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use and disposal of the food-contact substance involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the FCS in the fabrication of food-contact gloves 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.

Manufacture of the FCS and conversion to finished food-contact gloves will consume energy and resources in amounts comparable to the manufacture of other similar FCS's. Moreover, the FCS will replace food-contact substances that are not currently recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Gloves containing our FCS are expected to be disposed of according to the same patterns that are used in place of gloves containing the FCS from other manufacturers or of similar materials.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact gloves fabricated from the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished article; the insignificant impact on environmental concentrations of combustion products of the FCS; and the similarity of the subject FCS to the materials they are intended to replace. 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 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. In view of the excellent qualities of the subject food-contact substance for use in food-contact gloves, the fact that the FCS constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact gloves, and the absence of any significant environmental impact which would result from their use, the clearance of the use of the FCS as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

Garry M. Wiltshire, Product Regulatory Technical Leader, The Dow Chemical Company, 1803 Building #416, Midland, MI 48674,

13. Certification

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

Date: September 12, 2008

Garry M. Wiltshire