

Environmental Assessment

FCN 835

1. This environmental assessment (EA) concerns the proposed use of the FCS in polyvinyl chloride (PVC) gloves that will be used in food contact applications. Much of the information in this assessment relies on the EA for FCN 597 where the use conditions for that FCS were very similar. The FCS for FCN 835 is in the process of being registered under FIFRA and will not be sold for this use until all needed EPA registrations are in place. When that is achieved the FCS would qualify for the exemption under 21 CFR 25.32 (q) and will not be sold until the conditions for this exemption have been met.
2. **Date:** August 26, 2008
3. **Name of Notifier:** Lanxess Corporation
4. **Address:** 111 RIDC Park West Dr., Pittsburgh, PA 15275-1112

All communications on this matter are to be agent/consultant for Lanxess:

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5. Description of the Proposed Action

The action requested in this Food Contact Notification (FCN) is the establishment of a clearance to permit the use of 1, 2- benzisothiazol-3(2H)-one (BIT) biocide in uncured liquid rubber latex at a weight of 0.05% to manufacture rubber gloves intended for use contact with all types of food for use in food handling establishments. The vinyl chloride polymers containing BIT will be used at temperatures not to exceed 100°C.

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 subject plasticizer. Rather, BIT will be sold to glove manufacturers or manufacturers of other finished articles or manufacturers of formulations used in the finished articles. Glove manufacturers are located at various locations world wide, predominantly in the Asia Pacific region; currently, most of the food contact substance that will be used in the manufacture of gloves will be used in Taiwan and China.

Disposal of the food contact substance is expected to occur at locations where PVC gloves are used with it ultimately being deposited in municipal solid waste landfills or

combusted in municipal waste combustors or commercial industrial solid waste incinerators.

6. Identification of Substance that Is the Subject of the Proposed Action

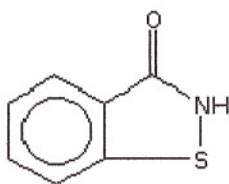
The additive that is the subject of this Notification is 1, 2- benzisothiazol-3(2H)-one

CAS Reg. No.: 2634-33-5

Molecular weight: 151.18

Molecular formula: C₇H₅NOS

Structural formula:



7. 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 BIT. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here. However, it should be noted that large quantities of the FCS are in production around the world for many biocide uses. The use proposed by this FCN uses only a very small percentage of the FCS produced. Little or no introduction of the FCS into the environment will result from its use because this substance is almost completely incorporated into the PVC and essentially all of it is expected to remain with the gloves throughout their use.

Based on migration migration estimates used to demonstrate human safety of the proposed use and reported elsewhere in the FCN, we expect only very low levels of the FCS to leach from the gloves in landfills. Moreover, even if a very small amount of the FCS were to migrate from the gloves in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the regulations of the Environmental Protection Agency (EPA) governing municipal solid waste landfills.

The United States Environmental Protection Agency's (EPA) regulations require new 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 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 collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

New food contact materials generally comprise a small fraction of the overall amount of waste combusted in the United States. Therefore, we believe that the combustion products from new food contact materials usually will not alter significantly the emissions from municipal waste combustors or commercial industrial solid waste incinerators, and that any such emissions are governed by EPA's regulations on combustors in 40 CFR Part 60. This also would be the case for PVC gloves manufactured using BIT, as no increase in the annual market volume of PVC gloves used for food handling is expected as a result of the proposed use of BIT becoming effective. The reason that no increase is expected in the annual market volume of PVC gloves used for food handling is that BIT does not impart any beneficial effect to the final glove article but merely preserves the liquid latex used in the manufacture of gloves.

8. Fate of Emitted Substances in the Environment

No information need be provided on the fate of substances released into the environment as the result of use and disposal of the gloves containing BIT because, as discussed under format Item 7, only very small quantities of substances, if any, will be introduced into the environment from its use and disposal. Therefore, we do not expect the use and disposal of BIT-containing PVC gloves to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

EPA has reviewed the available on properties of BIT that relate to its environmental fate and their summary follows (EPA, 2005):

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_d 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_{ow} value of 20 at 25°C, 1,2-benzisothiazolin-3-one is unlikely to bioaccumulate in aquatic organisms.

9. Environmental Effects of Released Substances

No information need be provided on the effect of substances released into the environment as the result of use and disposal of the BIT-containing PVC gloves because only very small quantities, if any, will be introduced into the environment from its use and disposal. Therefore, the use and disposal of PVC gloves containing BIT are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

EPA has reviewed the available on data on toxicity of BIT to species that are viewed as sentinels for potential environmental effects and their summary follows (EPA, 2005):

The available ecological effects data for 1,2-benzisothiazolin-3-one are somewhat limited. Based on acute toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebrates.

10. Use of Resources and Energy

BIT is intended to preserve latex emulsions used in the manufacture of gloves for the food processing industry such that there is essentially no effect on the use of natural resources and energy or the quantity of PVC gloves, themselves, produced using biocides. The use of BIT will not increase the demand for PVC gloves. Therefore there will be no increase in utilization of natural resources.

Moreover, PVC gloves containing BIT are not recovered for recycling, but are disposed of by means of sanitary landfill and incineration. Gloves containing BIT are expected to be disposed of according to the same patterns when they are used in place of gloves that do not contain BIT. Thus, there will be no impact on current or future recycling programs.

11. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact gloves containing BIT. This is primarily due to the minute levels of leaching of BIT from gloves; the insignificant impact on environmental concentrations of combustion products of BIT in disposed gloves, and the fact that the use of BIT in gloves is small compared to use of BIT in other products. Thus, the use of BIT as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

12. 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 herein would be to not use BIT to preserve latex. The alternative action would have adverse environmental consequences because a certain amount of spoiled latex would continued to be needed to be disposed. In view of the fact that the substance is 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 that would result from its use, the clearance of the use of BIT as described herein by allowing this Notification to become effective is environmentally safe in every respect.

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13. Preparer

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Qualifications:

BS Chemistry
Ph.D. Pharmacology
30 years experience in toxicology and regulatory affairs

14. Certification

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

August 26, 2008

✓ **Richard Kraska**
Kraska Consultants, Inc.
Consultant to the Lanxess Corporation

1. References

EPA, 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one (BIT). Environmental Protection Agency, September 29, 2005

2. Attachments

A product MSDS for BIT-85 is attached.