

Attachment 4 - Environmental Assessment

1. The proposed use of the food contact substance (FCS) in repeated use applications qualifies for categorical exclusion under 21 C.F.R. § 25.32(j), and its use in coatings for paper and paperboard qualifies for a categorical exclusion under 21 C.F.R., § 25.32 (i). This environmental assessment (EA) concerns the proposed use of the FCS in polyvinyl chloride (PVC) gloves.
2. **Date** December 29, 2005
3. **Name of Notifier** Eastman Chemical Company
4. **Address** 100 North Eastman Road
Kingsport, Tennessee 37662-5280
All communications on this matter are to be sent in care of Counsel for Notifier, Joan Sylvain Baughan, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.
Telephone: (202) 434-4147.

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 2,2,4-trimethyl-1,3-pentanediol diisobutyrate (TXIB) as a plasticizer in vinyl chloride polymers used in repeated-use food-contact applications at a level not to exceed 10% by weight of the polymer. The vinyl chloride polymers containing TXIB will be used at temperatures not to exceed 100°C.

The technical effect of the subject substance is to plasticize or soften vinyl chloride polymers, which otherwise are rigid polymers. Plasticizers make the product more flexible.

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, TXIB 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.

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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 TXIB, 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 TXIB becoming effective. The reason that no increase is expected in the annual market volume of PVC gloves used for food handling is that TXIB would replace other substances currently being used with PVC in gloves for the same intended effect, as described below in Item 10.

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 TXIB 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 TXIB-containing PVC gloves to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

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 TXIB-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 TXIB are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

10. Use of Resources and Energy

TXIB is intended to compete with and replace other plasticizers used in 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 plasticizers. For example, TXIB is expected to compete with and replace plasticizers that are currently employed in PVC, such as di(2-ethylhexyl)phthalate and di(2-ethylhexyl)adipate. As is the case with other plasticizers, the production, use and disposal of TXIB involves the use of natural resources such as petroleum products, coal, and the like. The replacement of currently used plasticizers by TXIB is not expected to have any adverse impact on the use of energy and resources.

Manufacture of TXIB and its use in PVC gloves will consume energy and resources in amounts comparable to the manufacture and use of other plasticizers. Moreover, PVC gloves

are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

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containing TXIB are not recovered for recycling, but are disposed of by means of sanitary landfill and incineration. Gloves containing TXIB are expected to be disposed of according to the same patterns when they are used in place of gloves containing other plasticizers. 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 TXIB. This is primarily due to the minute levels of leaching of TXIB from gloves; the insignificant impact on environmental concentrations of combustion products of TXIB in disposed gloves, and the close similarity of TXIB to plasticizers it is intended to replace. Thus, the use of TXIB 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 simply result in the continued use of the materials that TXIB would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of TXIB for use in food-contact gloves, 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 TXIB as described herein by allowing this Notification to become effective is environmentally safe in every respect.

13. List of Preparers

Lester Borodinsky, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

14. Certification

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

Date: December 29, 2005


Devon Wm. Hill
Counsel for Eastman Chemical Company

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