Environmental Assessment

1. The proposed use of the food contact substance (FCS) in conveyer belts qualifies for categorical exclusion under 21 *CFR* 25.32(j), as stated in our original submission dated February 6, 2002. This environmental assessment (EA) concerns the proposed use of the FCS in polyvinyl chloride (PVC) gloves.

2. **Date** [March 28, 2002]

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 40°C.

The technical effect of the subject substance is to plasticize or soften vinyl chloride polymers which otherwise are rigid polymers. Plasticizers reduce molecular binding forces in the polymer and make the product more flexible.

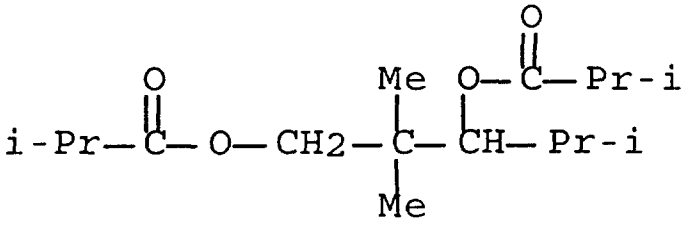
The Notifier does not intend to produce finished food-contact material, such as gloves or other finished articles that may be used in contact with food, that contain the subject plasticizer. Rather, TXIB will be sold to glove manufacturers. Glove manufacturers are located at various locations world wide, 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 2,2,4-trimethyl-1,3-pentanediol diisobutyrate (TXIB):

Chemical Abstracts Service (CAS) Registry Name:
propanoic acid, 2-methyl-, 2,2-dimethyl-1-(1-methylethyl)-1,3-propanediyl ester
CAS Reg. No.: 6846-50-0
Molecular weight: 286.4
Molecular formula: $C_{16}H_{30}O_4$
Structural formula:



Physical description: clear liquid

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

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 the migration studies performed 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 migrates 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.[1]

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[1] 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,

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.

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

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 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 are 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.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Petition. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which 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 which 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.

12. 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.

Guidance provided by Layla Batarseh, Ph.D., Supervisor, Environmental Review Group (ERG), Division of Chemistry Research and Environmental Review (HFS-246), Food and Drug Administration

13. Certification

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

Date: March 28, 2002

Joan Sylvain Baughan

Counsel for Eastman Chemical Company