

# Environmental Assessment

1. **Date:** October 11, 2005
2. **Name of Submitter:** Stanelco, PLC
3. **Address:** Starpol Technology Centre  
North Road  
Marchwood, Southampton  
England SO40 4BL
4. **Description of the proposed action:**
  - a. **Requested action:** Accept the Submitter's Food Contact Notification regarding the use of 1,4-benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol, adipic acid, hexamethylene diisocyanate and not more than 1 percent by weight of the polyhydric alcohol as described in FCN 372. The purpose of this Notice is to permit the polyester to be used as a component in blends with polylactide (PLA) polymers described in FCN 178 at concentrations not to exceed 25% by weight of blend, for use in contact with dry solids having no free fat or oil and dry solids with surface containing free fat or oil, FDA Food Types VIII and IX. The packaging material is intended for use under Conditions of Use F and G
  - b. **Need for action:** The action is needed to provide for an improved packaging material for packaging of fresh meat, poultry and produce. Specifically, the FCS will be used to produce trays for packaging of meat, poultry and produce.
  - c. **Locations of use/disposal:** We believe that the food-contact articles fabricated with the subject polyester will be used in patterns corresponding to national population density, and will be widely distributed throughout the country. Consequently, we expect that disposal will occur nationwide, with approximately 76% of the containers being deposited in landfills and 24% being incinerated, according to current Environmental Protection Agency (EPA) projections. We predict that the types of environments present at and adjacent to the expected disposal locations are the same as for the disposal of any other retail food-packaging material currently in use. Therefore, there are no special considerations regarding the environment surrounding the disposal of containers made from the subject adhesive when the same is used as proposed herein.

The substance that is the subject of this Notice \_\_\_\_\_ was the subject of FCN 372 submitted by BASF Aktiengesellschaft. The information contained in that FCN, including the Environmental Assessment submitted as part of the FCN are hereby incorporated into this Notice and E A

**5. Identification of the substance that is the subject of the action:**

- a. **Name:** The Food Contact Substance that is the subject of this Notification is 1,4-benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol, adipic acid, hexamethylene diisocyanate and not more than 1 percent by weight of the polyhydric alcohol as described in FCN 372.
- b. **CAS Number:** 55231-08-8
- c. **Molecular Weight:** Molecular weight data was submitted to FDA as part of FCN 372. According to the EA for FCN 372, the  $M_w$ , and  $M_n$ , for the substance are approximately 137,000 Daltons and 36,000 Daltons, respectively, for a  $M_w/M_n$  of approximately 3.81.
- d. **Molecular Formula:**  $(C_{10}H_{10}O_4) \cdot (C_6H_{10}O_4) \cdot (C_4H_{10}O_2)_x$

**6. Introduction of substances into the environment:**

- a. **Introduction of substances into the environment as a result of manufacture:**

According to FDA's "Guidance for Industry, Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition," FDA does not routinely require information on environmental introductions resulting from the production of a food contact substance. Information on environmental introductions from the production process are required only when extraordinary circumstances pertain to the production process. Stanelco Plc has reviewed the production process and has confirmed that no extraordinary circumstances exist.
- b. **Introduction of substances into the environment as a result of use/disposal:**

The information provided to in the Environmental Assessment for FCN 372 is hereby incorporated by reference. We expect little or no introduction of substances into the environment as a result of the use of the FCS in finished food-packaging material because it is completely incorporated into the packaging material and essentially all is expected to remain with the packaging throughout its use. The FCS is expected to be distributed widely across the United States in patterns corresponding to national population density.

  - i. **Landfills:** We expect only very low levels of the FCS to leach into landfills based on migration tests done for FCN 372. Moreover, even if a very small

amount of the FCS migrates from the finished food packaging materials in landfills, we expect extremely low quantities to enter the environment. This finding is based on the regulations of the Environmental Protection Agency (EPA), in 40 C.F.R. Part 258, governing municipal solid waste landfills.

- ii. **Combustion.** The FCS is composed of compounds commonly found in municipal solid waste (MSW). Because the FCS will replace and compete with similar materials (see Format Item 9), adding the finished food-packaging materials containing the FCS to waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the low levels of combustion products compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion of products containing the FCS will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60).

**7. Fate of substances released into the environment:**

As we discussed under Format Item 6 above, only very small quantities of substances, if any, will be introduced into the environment as a result of use/disposal of the food packaging trays. Consequently, we do not need to provide information on the fate of substances released into the environment as a result of such use and disposal.

**8. Environmental Effects of Released Substances:**

We do not need to provide information on the environmental effects of the subject FCS released into the environment as a result of its use and disposal because, as we discussed under Format Item 6 above, only very small quantities of substances, if any, will be introduced into the environment as a result of use and disposal of products containing the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

**9. Use of Resources and Energy:**

The proposed use of the FCS will not have a significant impact on resources or energy because, as stated by the Notifier, it will replace other materials currently used in packaging trays for meat, poultry and produce

**10. Mitigation Measures:**

Since no potential adverse environmental impacts for the proposed action have been identified, no mitigation measures are required.

**11. Alternatives to the Proposed Action:**

Since no potential adverse environmental impacts for the proposed action have been identified, no alternatives to the proposed action need be considered.

**12. List of Preparers:**

Mr. Mark L. Itzkoff, J.D.  
Attorney-at-Law  
Olsson, Frank and Weeda, P.C.  
Suite 400  
1400 Sixteenth St., N.W.  
Washington, D.C. 20036

**13. Certification:**

The undersigned official certifies that the information presented in this document is true, accurate, and complete to the best of the knowledge of Stanelco, Plc.

A rectangular box with a red border, containing a redacted signature. The signature is illegible due to the redaction.

---

Mark L. Itzkoff  
Counsel for Stanelco Plc  
October 11, 2005

**14. References:**

No references are attached to this Environmental Assessment.

**15. Attachments:**

There are no attachments included with this E.A.