EN

Environmental Assessment

FCN 000349

1. **Date:** September 29, 2003

2. **Name of Submitter:** Dainippon Ink and Chemicals, Inc.

3. **Address:** 35-58, 3-Chome, Sakashita, Itabashi-ku
   Tokyo, Japan

4. **Description of the proposed action:**

   a. **Requested action:** Accept the Submitter's Food Contact Notification (FCN 349) regarding the use of polyester-polyurethane resin-acid dianhydride adhesive as described at 21 C.F.R. §177.1390(c)(vii) for use as an adhesive in polypropylene/foil laminates intended for use in retortable food packaging intended for use in contact with fatty foods at temperatures that do not exceed 250° F. This would extend the current use of the adhesive which is cleared for use in the same application in contact with non-fatty foods under 21 C.F.R. §177.1390.

   b. **Need for action:** The action is needed to provide for an improved packaging material for retort applications. The adhesive that is the subject of the FCN offers improved adhesion between the polypropylene and foil layers, resulting in fewer lamination failures.

   c. **Locations of use/disposal:** We believe that the food-contact articles fabricated with the subject adhesives 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 Notifier stated in the EA from FAP 6B4496 that the use of the polyester-polyurethane resin-acid dianhydride adhesive that is the subject of this Notification as proposed will not affect the method of disposal of the finished article whether it is disposed of via sanitary landfill or incineration. As discussed under Format Item 6 below, only minute quantities of the adhesive components are expected to leach from articles placed in landfills, and no significant quantities of toxic combustion products will be produced upon incineration of the polymer.

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 a mixture of the following:

i. Polyesterpolyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in § 175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9). Additionally, dimethylol propionic acid and 1,6-hexanediol may be used alone or in combination as reactants in lieu of a polybasic acid and a polyhydric alcohol.

ii. Acid dianhydride formulated from 3a,4,5,7a-tetrahydro-7-methyl-5- (tetrahydro-2,5-dioxo-3-furanyl)-1,3-isobenzofurandione (CAS Reg. No. 73003–90–4), comprising not more than one percent of the cured adhesive.

iii. Urethane cross-linking agent, comprising not more than twelve percent by weight of the cured adhesive, and formulated from trimethylol propane (CAS Reg. No. 77–99–6) adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9) and/or 1,3- bis(isocyanatomethyl) benzene (CAS Reg. No. 363–48–31).

b. CAS Number: Not Available

c. Molecular Weight: The FCS is a cross-liked polyurethane/polyester resin. Due to the crosslinking, the resin is a macromolecule with ultra high molecular weight.

d. Molecular Formula: The molecular formula of this material was submitted to FDA as part of FAP 4B4496. That information is included into this EA by reference.

e. Physical Description: The adhesive is supplied as a two-part system. The first part, LX903 is a pale yellow fluid polyesterpolyurethane resin in ethyl acetate. The second component is the hardener, KG-75, is a pale yellow fluid polyisocyanate resin in ethyl acetate.

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. Dainippon Ink and Chemicals 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: 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.

c. Introduction of substances into the environment as a result of disposal: We expect disposal of finished food-packaging materials, containing the FCS, to occur nationwide with the packaging materials ultimately being deposited in municipal solid waste landfills or combusted.

i. Landfills: We expect only very low levels of the FCS to leach into landfills based on migration tests done for FAP 6B4496. 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 adhesive. 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 adhesives currently used in multilayer packaging.

10. Mitigation Measures:

We do not need to discuss mitigation measures since we have not identified potential adverse environmental impacts for the proposed action.

11. Alternatives to the Proposed Action:

We do not need to discuss alternatives to the proposed action since we have not identified potential adverse impacts for the proposed action.

12. List of Preparers:

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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 Dainippon Ink and Chemical, Inc.

9/29/03
September 29, 2003

Mark L. Itzkoff
Counsel for Dainippon Ink and Chemical, Inc.

14. References:

No references are attached to this Environmental Assessment.

15. Attachments:

Attachment 1 – Material Safety Data Sheet for LX 903H
Attachment 2 – Material Safety Data Sheet for KG-75 (hardener)