

**ATTACHMENT 11 - ENVIRONMENTAL ASSESSMENT
DAINIPPON INK AND CHEMICALS, INC. FOOD CONTACT
NOTIFICATION**

1. **Date:** April 23, 2007
2. **Name of Applicant/Notifier:** Dainippon Ink and Chemicals, Inc.
3. **Address:** 35-58, Sakashita 3-chome, Itabashi-ku
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JAPAN

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4. **Description of the Proposed Action**

The action requested in this notification is to permit the use of a polyester-polyurethane resin adhesive formulated from the following:

- (a)(1) Urethane cross-linking agent, comprising not more than 75% by weight of the cured adhesive, prepared by the reaction of a mixture of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate, homopolymer (CAS Reg No. 53880-05-5) and 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 25854-16-4), and a polyester prepared by the reaction of a mixture of acids and alcohols listed in 21 C.F.R. § 175.300(b)(3)(vii).

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- (a)(2) Optional use of 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 3 percent by weight of the cured adhesive.
- (a)(3) Optional trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent by weight of the cured adhesive.
- (b)(1) Polyesterdiol resins prepared by the reaction of a mixture of acids and alcohols listed in 21 C.F.R. § 175.300(b)(3)(vii). Additionally, 1,6-hexanediol may be used as an alcohol reactant.
- (b)(2) Optional use of 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 3 percent by weight of the cured adhesive.
- (b)(3) Optional trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent by weight of the cured adhesive.

The action is needed to provide for an improved packaging material for retort applications. The adhesive that is the subject of this Notification offers improved adhesion between the laminated layers, resulting in fewer lamination failures.

The Notifier does not intend to produce finished food packaging from the subject adhesive. Rather, the adhesive will be sold to manufacturers engaged in the production of retort pouches for food. Food-contact articles produced with the copolymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the

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country. Therefore, it is anticipated that disposal will occur nationwide; according to the U.S. Environmental Protection Agency's (EPA) 2005 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 13.6% was combusted, and 32.1% was recovered for recycling and composting.¹

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the adhesive.

5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is a polyester-polyurethane resin adhesive formulated from the following:

- (a)(1) Urethane cross-linking agent, comprising not more than 75% by weight of the cured adhesive, prepared by the reaction of a mixture of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg No. 53880-05-0) and 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 25854-16-4), and a polyester prepared by the reaction of a mixture of acids and alcohols listed in 21 C F.R. § 175.300(b)(3)(vii).

¹ *Municipal Solid Waste in the United States. 2005 Facts and Figures*, EPA530-R-06-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2006.

(a)(2) Optional use of 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 3 percent by weight of the cured adhesive.

(a)(3) Optional trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent by weight of the cured adhesive.

(b)(1) Polyesterdiol resins prepared by the reaction of a mixture of acids and alcohols listed in 21 C.F.R. § 175.300(b)(3)(vii). Additionally, 1,6-hexanediol may be used as an alcohol reactant.

(b)(2) Optional use of 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 3 percent by weight of the cured adhesive.

(b)(3) Optional trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent by weight of the cured adhesive.

6. 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 the adhesive. Consequently, information

on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject adhesive to fabricate packaging materials. In these applications, the adhesive is expected to be used to fabricate retortable food-contact articles, and will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials (*i.e.*, retortable food-contact articles) containing the subject adhesive resin will be primarily by sanitary landfill or incineration. The subject resin consists of carbon, hydrogen, oxygen, and nitrogen. Based on the elemental composition of the FCS, the nitrogen content in the FCS has been calculated (available in a confidential attachment to the FCN). With regard to carbon, hydrogen, and oxygen, these are elements that are commonly found in municipal solid waste. With regard to nitrogen, this element could potentially form combustion products that could be toxic at levels much higher than could be present from combustion of this FCS. Based on the proposed use of the FCS, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum introduced level of nitrogen containing combustion products (available in a confidential attachment to the FCN), we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and

incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the adhesive resin's constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles. EPA's 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. (40 C.F.R. Part 258.) 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. The lack of any leaching is especially true considering that the subject substance is a high molecular weight adhesive resin that contains only low levels of low molecular weight resin components, the portion of the resin that can potentially be leachable.

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the adhesive. The adhesive is of high

molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the adhesive.

The products of complete combustion of the adhesive resin are carbon dioxide and water, along with small amounts of nitrogen oxides; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the resin in the amounts utilized for food packaging applications.

(b) Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject adhesive. No significant quantities of any substance will be added to these water systems upon the proper incineration of food packaging employing the adhesive, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of adhesive components.

(c) Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject adhesive. In particular, the extremely low levels of maximum migration of components of the adhesive, demonstrated by the food simulating extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of the adhesives for use in food-contact applications

precludes any substantial release to the environment of their components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the adhesive.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the adhesive in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the use of the subject adhesive consist of extremely small quantities of combustion products and extractables. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the adhesive. In addition, the use and disposal of food-contact articles containing the adhesive 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. Part 60 that pertain to municipal solid waste combustors, and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the adhesive involves the use of natural resources such as petroleum products, coal, and the like.

However, the use of the subject adhesive in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the adhesive is intended to be used in packaging which will be used in place of similar adhesive materials now on the market for use in food packaging applications. Adhesives currently used in the applications in which the subject adhesive is anticipated to be used include those that are permitted under 21 C.F.R. § 177.1390 (“Laminate structures for use at temperatures of 250°F and above”) and under effective Food Contact Notification Nos. 123, 349, and 413.

The partial replacement of these types of materials by the subject adhesive is not expected to have any adverse impact on the use of energy and resources. Manufacture of the adhesive, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of the other adhesives. Furthermore, the use proposed in this Notification is for the use of the subject adhesive in retort-only applications. Thus, it will not be used in applications that may be replacements for polyethylene terephthalate (PET) soda bottles or high density polyethylene (HDPE) milk bottles, as neither carbonated soft drinks nor milk are retort sterilized. As PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as the subject adhesives will not be used in such applications, articles fabricated from the subject adhesives will be disposed of by means of sanitary landfill and incineration. Packaging materials produced using the subject adhesives are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated using the subject adhesive. This is primarily due to the minute levels of leaching of potential migrants from finished articles employing the adhesive, the insignificant impact on environmental concentrations of combustion products of the adhesive, and the close similarity of the subject adhesive to the materials they are intended to replace. Thus, the use of the adhesive 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 that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject adhesive would otherwise replace; such action would have no environmental impact. In view of the fact that the adhesive constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an effective Food Contact Notification to permit the use of the subject adhesive as described herein is environmentally safe in every respect.

12. List of Preparers

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

13. Certification

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

Date: 4/23/07

[Redacted Signature Line]

Joan Sylvain Baughian
Counsel for Dainippon Ink and Chemicals, Inc.

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