

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

1. **Date:** March 1, 2004
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-acid dianhydride adhesive formulated from the following:

- (a)(1) Polyesterpolyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in 21 C.F.R. § 175.300(b)(3)(vii) and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg No. 4098-71-9).
Additionally, 1,6-hexanediol may be used as a polybasic alcohol reactant.
- (2) Optional trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent by weight of the cured adhesive.

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- (b) (1) Urethane cross-linking agent, comprising not more than 12 percent by weight of the cured adhesive, and formulated from 3- isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate and/or trimethylol propane (CAS Reg. No. 77-99-6) adduct of 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 3634-83-1).
- (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 1 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 country. Therefore, it is anticipated that disposal will occur nationwide, with about 76% of the materials being deposited in land disposal sites, and about 24% combusted.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

¹ *Characterization of Municipal Solid Waste in the United States 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, May 1998.

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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-acid dianhydride adhesive formulated from the following:

- (a)(1) Polyesterpolyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in 21 C.F.R. § 175.300(b)(3)(vii) and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg No. 4098-71-9). Additionally, 1,6-hexanediol may be used as a polybasic alcohol reactant.
- (2) Optional trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent by weight of the cured adhesive.
- (c) (1) Urethane cross-linking agent, comprising not more than 12 percent by weight of the cured adhesive, and formulated from 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate and/or trimethylol propane (CAS Reg. No. 77-99-6) adduct of 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 3634-83-1).
- (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 1 percent by weight of the cured adhesive.

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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 articles produced by the subject copolymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject adhesive consists of carbon, hydrogen, nitrogen, and oxygen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

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Only extremely small amounts, if any, of the adhesive constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. 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 ground-water 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 collections 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 adhesives are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.²

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.

² This expectation is confirmed by the results of extraction studies described elsewhere in the Notification. As shown in Section II-F, when pouches fabricated using the adhesive were extracted with 10% ethanol at 135°C for 2 hours followed by 40°C for 10 days and with 95% ethanol at 121°C for 2 hours followed by 40°C for 10 days, minute levels of components of the subject adhesive were found in the extracts at levels ranging from non-detected at 0.36 parts per billion (ppb) to a maximum of 3.55 parts per million (ppm). Thus, the quantity of adhesive components in solid waste deposited in landfills will be extremely small.

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The products of complete combustion of the adhesive would be 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 adhesive 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

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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 copolymer 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

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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 and 349.

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.

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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.

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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: 3/1/04



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

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