

ENVIRONMENTAL ASSESSMENT

**ATTACHMENT 13 – ENVIRONMENTAL ASSESSMENT  
FOOD CONTACT NOTIFICATION**

1. **Date:** [September 14, 2007]

2 and 3. **Names and Addresses of Applicants/Notifiers:**

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Alcoa Technical Center  
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Alcoa Center, PA 15069

Amgraph Packaging, Inc.  
90 Inland Road  
Versailles, CT 06383

Ashland Specialty Chemical Company  
Post Office Box 2219  
Columbus, OH 43216

Bayer Polymers LLC  
100 Bayer Road  
Pittsburgh, PA 15205-9741

Bostik-Findley  
11320 Watertown Plank Road  
Wauwatosa, WI 53226-3434

Bryce Corporation  
4505 Old Lamar Avenue  
Memphis, TN 38118

Coating & Adhesives Corporation  
1901 Popular Street, NE  
Leland, NC 28451

Cognis Corporation  
300 Brookside Avenue  
Ambler, PA 19002-3498

**000426**

**0000390**

ENVIRONMENTAL ASSESSMENT

Crown Cork & Seal  
11535 South Central Avenue  
Aslip, IL 60803

Cytec Inc.  
Five Garret Mountain Plaza  
West Paterson, NJ 07424

Dart Container  
2148 Depot Street  
Holt, MI 48842

Dixie Packaging  
P.O. Box 820  
7354 Baltimore-Annapolis Road  
Glen Burnie, MD 21060

Energy Sciences Inc.  
42 Industrial Way  
Wilmington, MA 01887

FujiHunt  
40 Boroline Road  
Allendale, NJ 07401

Fusion UV Systems, Inc.  
910 Clopper Road  
Garthersburg, MD 20878

Gidue SpA  
Via Puecher, 26  
I 22078 TURATE CO ITALY

Graphic Packaging Corp.  
4455 Table Mountain Drive  
Golden, CO 80403

H.B. Fuller Company  
1200 Willow Lake Boulevard  
Vadnais Heights, MN 55110

INX International Ink Co.  
1760 Western Drive  
West Chicago, IL 60185-1864

000427

0000391

ENVIRONMENTAL ASSESSMENT

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21041 Albizzate (VARESE) ITALY

Liofol  
Henkelstrasse 67  
Duesseldorf, GERMANY

MeadWestvaco  
11013 West Broad Street  
Glen Allen VA 23060-5937

Nordson Corporation  
Container Systems Group  
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Amherst, OH 44001

PPG Industries  
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Allison Park, PA 15101

Petroferm Inc.  
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Gurnee, IL 60031

Pliant Corp  
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Bloomington, IN 47404

Printpack Inc.  
Post Office Box 43687  
4445 Wendell Drive, S.W.  
Atlanta, GA 30336-0687

Rahn USA Corporation  
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Aurora, IL 60504-8106

Rock-Tenn Company  
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Norcross, GA 30071

Rohm and Haas Company  
727 Norristown Road  
Spring House, PA 19477

**000428**

0000392

## ENVIRONMENTAL ASSESSMENT

Sartomer Company  
Oaklands Corporate Center  
502 Thomas Jones Way  
Exton, PA 19341

Sealed Air  
P.O. Box 464  
Duncan, SC 29334-0464

Siegwerk Group  
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Des Moines, IA 50321

Valspar Corporation  
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Pittsburgh, PA 15233

All communications on this matter are to be sent in care of Counsel for Notifier:  
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#### **4. Description of the Proposed Action**

The action requested in this notification is to permit the use of a mixture of one or more of the following: tripropylene glycol diacrylate (CAS Reg. No. 42978-66-5), trimethylolpropane triacrylate (CAS Reg. No. 15625-89-5), trimethylolpropane ethoxylate triacrylate (CAS Reg. No. 28961-43-5), hexanediol diacrylate (CAS Reg. No. 13048-33-4), and/or bisphenol A diglycidyl ether diacrylate (CAS Reg. Nos. 4687-94-9, 53814-24-7, 55127-80-5, 55818-57-0, or 37625-93-7) as monomer(s), and ESACURE ONE optionally as a photoinitiator. The mixture will be cured by either ultraviolet (UV) or electron beam (EB) irradiation. The cured resins may include substances permitted for the intended use by regulation in 21 CFR 170-189, substances generally recognized as safe, substances used in accordance with prior sanction approval, and substances that are the subject of other Food Contact Notifications permitted for the intended use. The cured resins are intended to be used as (1) coatings (including inks) or components of coatings (including inks) on polymeric substrates, paper and paperboard, metal substrates, or (2) as a component in adhesives, in contact with all food types under Conditions of Use A through H, as described in Tables 1 and 2 of 21 C.F.R. 176.170(c).

000429

0000393

## ENVIRONMENTAL ASSESSMENT

The action is needed to provide for a cured resin for use in applications for coatings (including inks) and adhesives, and this Environmental Assessment is intended to cover the adhesive applications.<sup>1</sup>

The Notifiers include companies that produce the raw materials that used to make up the cured resin, that formulate coatings, inks, and adhesives from the raw materials, that produce finished food packaging using the cured adhesive, and supply equipment used to cure the resins. Consequently, food-contact articles produced with the subject substance 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; 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.<sup>2</sup>

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 subject substance.

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

The food contact substance that is the subject of this Notification is a mixture of one or more of the following: tripropylene glycol diacrylate (CAS Reg. No. 42978-66-5), trimethylolpropane triacrylate (CAS Reg. No. 15625-89-5), trimethylolpropane ethoxylate triacrylate (CAS Reg. No. 28961-43-5), hexanediol diacrylate (CAS Reg. No. 13048-33-4), and/or bisphenol A diglycidyl ether diacrylate (CAS Reg. Nos. 4687-94-9, 53814-24-7, 55127-80-5, 55818-57-0, or 37625-93-7) as monomer(s), and ESACURE ONE optionally as a photoinitiator. The mixture will be cured by either ultraviolet (UV) or electron beam (EB) irradiation. The cured resins may include substances permitted for the intended use by regulation in 21 CFR 170-189, substances generally recognized as safe, substances used in accordance with prior sanction approval, and substances that are the subject of other Food Contact Notifications permitted for the intended use.

### 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 Notifiers does not suggest that there are any extraordinary circumstances in this case indicative of any adverse

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<sup>1</sup> The proposed use of the food contact substance (FCS) in coatings (including inks) qualifies for categorical exclusion under 21 CFR 25.32(i). Hence, this environmental assessment (EA) concerns the proposed use of the FCS in the other application (adhesives).

<sup>2</sup> *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.

000430

0000394

## ENVIRONMENTAL ASSESSMENT

environmental impact as a result of the manufacture of the subject substance. Consequently, information on the manufacturing sites and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject substance to fabricate packaging materials. In these applications, the subject substance is expected to be used to fabricate coatings (including inks) and adhesives, 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.*, articles employing coatings (including inks) and adhesives containing the subject substance) will be primarily by sanitary landfill or incineration. The subject substance consists of carbon, hydrogen, and oxygen. These are elements that are commonly found in municipal solid waste. Based on the proposed use of the FCS and the anticipated market volume (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 subject substance 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.

**000431**

000-395

## ENVIRONMENTAL ASSESSMENT

### 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 subject substance. The substance is a cured resin that is a solid and, therefore, does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the subject substance.

The products of complete combustion of the subject substance are carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the subject substance 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 substance. No significant quantities of any substance will be added to these water systems upon the proper incineration of food packaging employing the subject substance, nor upon its disposal in landfills due to the anticipated extremely low levels of aqueous extraction expected of the subject substance, a cured polymeric resin.

#### (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 substance. In particular, because of the low solubility in water of polymeric resins, extremely low levels of aqueous extraction of the subject substance are expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of the subject substance for use in food-contact applications precludes any substantial release to the environment of the subject substance. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to this substance as a result of its proposed use.

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 subject substance 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 substance consist of extremely small quantities of combustion products and extractables.

000432

0000306

## ENVIRONMENTAL ASSESSMENT

Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the subject substance. In addition, the use and disposal of food-contact articles containing the subject substance are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the EPA'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 subject substance involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject substance 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 subject substance is intended to be used in packaging which will be used in place of other resins used as coatings (including inks) and adhesives now on the market for use in the same food packaging applications. Coatings and adhesives currently used in the applications in which the subject substance is anticipated to be used include those that are permitted under 21 C.F.R. §§ 175.105 ("Adhesives"), 175.300 ("Resinous and polymer coatings"), 175.320 ("Resinous and polymer coatings for polyolefin films"), 176.170 ("Components of paper and paperboard in contact with aqueous and fatty foods"), and under various effective Food Contact Notifications.

The partial replacement of these resins by the subject substance is not expected to have any adverse impact on the use of energy and resources. Manufacture of the subject substance, and its use in the conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of the other resins. Furthermore, the use proposed in this Notification is for the use of the subject substance in applications involving food packaging applications for coatings (including inks) and adhesives. Thus, with regard to plastic articles, 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 PET and HDPE bottles are the predominant plastic food packaging articles recovered for recycling, and as the subject substance will not be used in such applications, articles fabricated from the subject substance will be disposed of by means of sanitary landfill and incineration, except as noted below. With regard to use on metal and paper food packaging articles, the subject substance will be used as a replacement for the currently used coatings or adhesives, and it is expected that the metal or paper food-contact articles that employ the subject substance will replace other metal or paper articles, respectively. It is expected that the metal and paper articles that employ the subject substance will be recovered for recycling interchangeably with the articles that they replace. Packaging materials produced using the subject substance are expected to be disposed of according to the same patterns when they are used in place of the currently used plasticizers in the applications for which clearance of the subject substance is being sought in this Notification. 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 substance. This is primarily due to the minute levels of leaching of potential migrants expected from finished

000433

000397



ENVIRONMENTAL ASSESSMENT

articles employing the subject substance, the insignificant impact on environmental concentrations of combustion products of the subject substance, and the absence of an impact on current or future recycling programs. Thus, the use of the subject substance 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 coatings and adhesives that the subject substance would otherwise replace; such action would have no environmental impact. In view of the fact that the subject substance is 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 substance as described herein is environmentally safe in every respect.

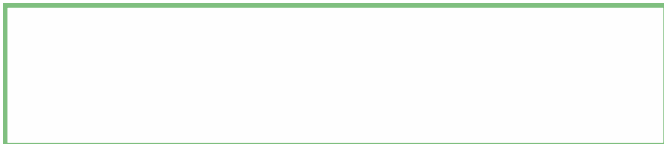
**12. List of Preparers**


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. 9/21/07



Martha E. Marrapese   
Counsel for the Notifiers

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