

Environmental Assessment

1. **Date:** October 25, 2016
2. **Name of Applicant/Notifier:** DIC Corporation
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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**

A. Requested Action

The action requested in this Notification is to permit the use of a food-contact substance that is a polyurethane adhesive formulated from (a) Polyester resins prepared by the reaction of a mixture of acids and alcohols listed in 21 C.F.R. § 175.300 (b)(3)(vii); (b) Isocyanate hardeners consisting of one or more of the following (1) m-xylene diisocyanate (CAS Reg. No. 3634-83-1), (2) m-xylene diisocyanate-trimethylol propane prepolymer (CAS Reg. No. 51852-81-4), (3) aliphatic alcohol reaction products with 1,6-diisocyanatohexane, (4) 1,6-diisocyanatohexane (CAS Reg. No. 822-06-0), and (5) prepolymers of them; (c) Optional use, in either the urethane hardener or polyester resin, of trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups comprising not more than 3 percent by weight of the cured adhesive and/or the triethoxysilane coupling agent described in the notification at the level indicated; (d) Option use of inorganic filler as described in the Notification.

The polyurethane food-contact substance is intended for use as a laminating adhesive and oxygen barrier on both conventional and metallized films. The finished article will contact all types of food under Conditions of Use A through H.

B. Need for Action

The action is needed to provide for an alternative laminating adhesive.

C. Location of Use/Disposal

The Notifier does not intend to produce finished food packaging from the subject adhesive. Rather, the substance will be sold to manufacturers engaged in the production of laminated films. 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, with about 80% of the materials being deposited in land disposal sites, and about 20% combusted.¹

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

The food contact substance (FCS) that is the subject of this Notification is a polyurethane adhesive formulated from:

(a) Polyester resins prepared by the reaction of a mixture of acids and alcohols listed in 21 C.F.R. § 175.300 (b)(3)(vii);

(b) Isocyanate hardeners consisting of one or more of the following (1) *m*-xylylene diisocyanate (CAS Reg. No. 3634-83-1), (2) *m*-xylylene diisocyanate-trimethylol propane prepolymer (CAS Reg. No. 51852-81-4), (3) aliphatic alcohol reaction products with 1,6-diisocyanatohexane, (4) 1,6-diisocyanatohexane (CAS Reg. No. 822-06-0), and (5) prepolymers of them;

(c) Optional use, in either the urethane hardener or polyester resin, of trimethoxysilane coupling agents containing amino, epoxy, ether, or mercapto groups comprising not more than 3 percent by weight of the cured adhesive and/or the triethoxysilane coupling agent described in the notification at the level indicated;

¹ *Advancing Sustainable Materials Management: 2013 Facts and Figures*, EPA530-R-15-003, U.S. Environmental Protection Agency, Solid Waste and Emergency Response (5306P), June 2015, available at http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_fs.pdf. The percents noted above are based on municipal solid waste, including waste recovered for composting. According to this report, of the total of 254 million tons of municipal solid waste (MSW) generated in 2013, 52.8% generally was land disposed, 12.9% was combusted, and 34.3% was recovered (a combination of waste recovered for recycling and for composting). As the food-contact substance (FCS) is expected to be disposed primarily by land-filling or combustion (*i.e.*, not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 20% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows:

$12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 20\% \text{ combusted}$. The remaining 80% will be land-disposed.

(d) Option use of inorganic filler as described in the Notification.

The structural formula for the FCS components is provided in a confidential attachment to the EA. The polyurethane adhesive is a relatively high molecular weight polymer and, therefore, not expected to be volatile. The FCS can be physically described as a polyester-polyurethane.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) (“Environmental assessments”), 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, the Notifier is not aware of information that suggests that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the subject FCS. Specifically, as set forth in FDA’s guidance,² extraordinary circumstances include situations where (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. To the best of the knowledge of the Notifier, no situations such as these apply to the manufacture of the FCS. 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 substance to fabricate food-contact materials. In these applications, the subject substance is expected to be used to fabricate laminated films, 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.

Food-contact materials containing the subject substance (*i.e.*, articles employing the adhesives) are expected to be disposed of either by conventional rubbish disposal (*i.e.*, sanitary landfill) or incineration. The subject substance consists of carbon, oxygen, hydrogen, and nitrogen, and optionally silicon. With regard to carbon, hydrogen, and oxygen, these are elements that are commonly found in municipal solid waste.

² *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition*, Food and Drug Administration, May 2006, at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081049.htm>.

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance³ to agencies regarding addressing greenhouse gas (GHG) emissions and climate change impacts in NEPA documents. As stated in the guidance, the document is “intended to help Federal agencies ensure their analysis of potential GHG emissions and effect of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action.” The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG.” Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states, that when evaluating intensity of an impact, one should consider “whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.” GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Furthermore, based on the elemental composition of the FCS, the nitrogen content in the FCS has been calculated (available in a confidential attachment to the Notification). Nitrogen could potentially form combustion products that could be toxic at levels much higher than could be present from combustion of this FCS. The combustion product of silicon is silicon dioxide, a substance that is the same composition as sand, a substance commonly found in municipal solid waste. Based on the proposed use of the FCS and the anticipated market volume (available in the confidential attachment to the EA), incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (*i.e.*, 40 C.F.R Part 60 and/or relevant state and local laws).

Only extremely small amounts, if any, of the substance’s 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

³ Council on Environmental Quality (CEQ) Final Guidance for Federal Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Review, dated August 1, 2016, *available at*: https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf

entering ground and surface water, as well as groundwater monitoring systems. 40 C.F.R. Part 258 (“Criteria for municipal solid waste landfills”). 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 polymer 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 FCS. The substance is polymer 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 FCS 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

As mentioned in Item 6, due to the regulations found at 40 C.F.R. Part 258, no environmental releases are expected from land disposal of items containing the FCS. No significant effects on 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 and regulations in 40 C.F.R. Part 258.

(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. As mentioned in Item 6, due to regulations at 40 CFR Part 258, no environmental releases are expected from land disposal of items containing the FCS. 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 the 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

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion, because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertains 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 FCS 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 in place of similar materials now on the market for use in the same food packaging applications. Adhesives currently used in the applications in which the subject substance is intended for use include those that are permitted under 21 C.F.R. §§ 175.105 and 177.1390, as these two regulations permit the use of other polyester-polyurethanes with which the FCS will compete for use in comparable applications, as well as under various effective Food Contact Notifications (FCN), including FCNs 1597, 1596, 1584, 1583, 1531, 1505, 766, 733, 448, 413, 349, 123.

The partial replacement of these adhesives 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 adhesives. Furthermore, the use proposed in this Notification for the subject FCS, which is used as a laminating adhesive, is not expected to have an impact on current or future recycling programs because the subject FCS will be used in place of other adhesives already authorized under 21 C.F.R. §§ 175.105 and 177.1390, and under various effective Food Contact Notifications. Thus, the use of the FCS will not have an impact on current or future recycling programs. This conclusion is supported by the Canadian Plastics Industry Association Packaging Industry Report of 2013,⁴ which demonstrates that recycling of multilaminate films in North America is negligible. Because recycling of food-contact materials containing the FCS will be negligible, the intended use of the FCS is not expected to impact recycling operations.

⁴ Reclay StewardEdge Product Stewardship Solutions, et al., Analysis of Flexible Film Plastics Packaging Diversion Systems, February 2013, available at: http://www.moorerecycling.com/Flexible_Film_Report.pdf.

10.1 Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject substance. This is primarily due to the minute levels of leaching of potential migrants from the finished articles employing the subject substance, the insignificant impact on environmental concentrations of combustion products of the substance, and the close similarity of the subject substance to the adhesives it is intended to replace. 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.

11.1 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 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 their 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.

12.1 List of Preparers

Lester Borodinsky, Ph.D. in Chemistry, more than 30 years of experience performing evaluations relating to all aspects of Food Additive Petitions and Food Contact Notifications, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20010

13.1 Certification

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

Date: October 25, 2016

Joan Sylvain Baughan
Counsel for DIC Corporation

14.1 List of References

- 1.0 *Advancing Sustainable Materials Management: 2013 Facts and Figures*, EPA530-R-15-003, U.S. Environmental Protection Agency, Solid Waste and Emergency Response (5306P), June 2015, available at http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_fs.pdf. The

percents noted above are based on municipal solid waste, including waste recovered for composting. According to this report, of the total of 254 million tons of municipal solid waste (MSW) generated in 2013, 52.8% generally was land disposed, 12.9% was combusted, and 34.3% was recovered (a combination of waste recovered for recycling and for composting). As the food-contact substance (FCS) is expected to be disposed primarily by land-filling or combustion (*i.e.*, not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 20% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows:

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3. Council on Environmental Quality (CEQ) Final Guidance for Federal Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Review, dated August 1, 2016, *available at*: https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf.

15. **List of Attachments**

1. Confidential Attachment