

## Environmental Assessment

1. **Date** August 17, 2016
2. **Name of Applicant** Henkel Corporation
3. **Address** Communications to be sent care of:  
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### 4. **Description of Proposed Action**

#### a. **Requested Action**

The action requested in this food contact notification (FCN) is to permit the use of a polyester-polyurethane adhesive formulated as follows: (a) polyurethane component prepared from isophthalic acid, diethylene glycol, adipic acid, 4,4'-diphenylmethane diisocyanate (CAS Reg. No. 101-68-8) and hexamethylene diisocyanate homopolymer (CAS Reg. No. 28182-81-2); and (b) Polyester-polyol component prepared from isophthalic acid, diethylene glycol, castor oil, propoxylated glycerol, propoxylated trimethylolpropane and caprolactam, as a laminating adhesive in flexible food packaging. The complete composition of the food contact substance (FCS) is described in the confidential attachment to this EA.

#### b. **Need for Action**

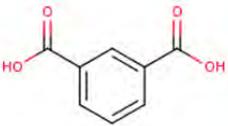
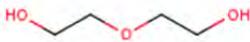
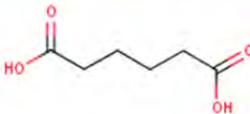
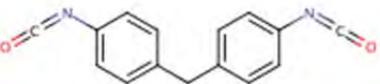
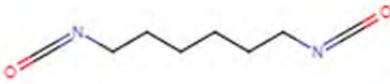
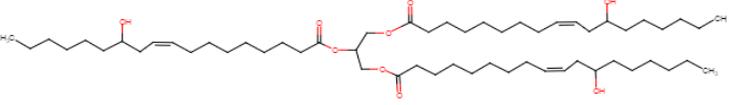
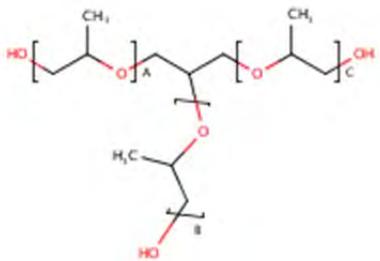
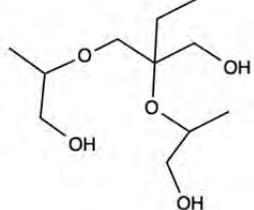
The action is needed to provide for an improved packaging material for high temperature laminate applications. The adhesive that is the subject of this FCN offers improved adhesion between the laminated layers, resulting in fewer lamination failures.

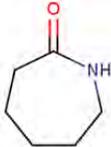
### 5. **Identification of Substances that are Subject of the Proposed Action**

The FCS is a polyurethane-polyester adhesive composed of: (a) polyurethane component prepared from isophthalic acid, diethylene glycol, adipic acid, 4,4'-diphenylmethane diisocyanate (4,4'-MDI) and hexamethylene diisocyanate homopolymer (HDI); and (b) Polyester-polyol component prepared from isophthalic acid, diethylene glycol, castor oil, propoxylated glycerol, propoxylated trimethylolpropane and caprolactam. The two components are mixed at a specified ratio, as described in the confidential attachment, and cured to form polymeric urea linkages. The cured molecular weight is essentially infinite, but cannot be accurately measured due to the insolubility of the FCS in solvent systems compatible with gel permeation chromatography (GPC). A representation of a segment of the cured substance is provided in the confidential attachment to this EA.

The FCS is intended to be used as an adhesive to join layers of high temperature laminate food contact materials. The FCS is intended for use in contact with all types of food under Conditions of Use B – H, including microwave reheating.

The chemical structures of the adhesive components, comprised of carbon, hydrogen, oxygen, and nitrogen, are as follows:

Component	Name	CAS Reg. No.	Structure
Polyurethane	Isophthalic acid	121-91-5	
	Diethylene glycol	111-46-6	
	Adipic acid	124-04-9	
	4, 4'-MDI	101-68-8	
	HDI homopolymer	28182-81-2	
Polyester-Polyol	Isophthalic acid Diethylene glycol Castor oil	See above for components other than castor oil.	
	Propoxylated glycerol	25791-96-2	
	Propoxylated trimethylol propane	25723-16-4	

	Caprolactam	105-60-2	
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## 6. Introduction of Substances into the Environment

### a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. Henkel Inc. asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatening a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); or (3) production associated with a proposed action that 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. 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 FCS as an adhesive or in the manufacturing of finished packaging materials. The FCS is expected to 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.

### b. Introduction of Substances into the Environment as a Result of Use/Disposal

Henkel, Inc. 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 high temperature laminate structures for packaging 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. According to the US Environmental Protection Agency's (EPA) 2013 update regarding municipal solid waste in the United States, which is the most recent data available, 65.7% of MSW was not recycled, of which 52.8% of MSW was disposed in landfills or elsewhere and 12.9 % was combusted.<sup>1</sup> Thus, based on the above numbers, 80.4% of the material not recycled is land disposed and 19.6% is combusted.<sup>2</sup> The types of environment present at and adjacent to these disposal locations are the same as for the disposal of any

<sup>1</sup> U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: Facts and Figures 2013*, June 2015, pg. 16. Available at [http://www.epa.gov/epawaste/nonhaz/municipal/pubs/2013\\_advncng\\_smm\\_rpt.pdf](http://www.epa.gov/epawaste/nonhaz/municipal/pubs/2013_advncng_smm_rpt.pdf).

<sup>2</sup>  $12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 19.6\% \text{ combusted}$ . The remaining 80.4% will be land-disposed.

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.

Disposal by the ultimate consumer of food-contact materials containing the subject adhesive resin will be primarily by sanitary landfill or incineration. The subject adhesive consists of carbon, hydrogen, oxygen, and nitrogen. With regard to carbon, hydrogen, and oxygen, these are elements that are commonly found in municipal solid waste. The FCS is intended to replace chemically similar food-contact adhesives currently permitted under FDA regulations and effective food contact notifications. There is no reason to believe that disposal patterns for food packaging containing the FCS will be different from current disposal patterns of other similar adhesives for identical uses.

To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide, determined the carbon dioxide equivalent from the nitrogen content of the FCS, assuming all the nitrogen forms nitrous oxide, and assumed that 19.6% of the market volume will be combusted. In accordance with the Council on Environmental Quality's (CEQ) revised draft guidance on greenhouse gas emissions and climate change impacts, quantitative disclosure is not warranted if annual carbon dioxide equivalent (CO<sub>2</sub>-e) emissions are estimated to be below 25,000 metric tons.<sup>3</sup> Based upon Henkel's anticipated market volume of the FCS and calculations demonstrating the maximum introduced level of carbon dioxide (provided in a confidential attachment to the FCN), the expected CO<sub>2</sub>-e emissions fall below the CEQ threshold for quantitative disclosure.

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of food-contact articles containing the FCS. 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.

## **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. As described above, the emission of carbon dioxide or nitrogen oxides due to the combustion of finished articles containing the FCS is not expected to be significantly increased. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the adhesive.

### **(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

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<sup>3</sup> Council on Environmental Quality's *Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts*, December 2014, available at [https://www.whitehouse.gov/sites/default/files/docs/nepa\\_revised\\_draft\\_ghg\\_guidance\\_searchable.pdf](https://www.whitehouse.gov/sites/default/files/docs/nepa_revised_draft_ghg_guidance_searchable.pdf).

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. As discussed above, EPA's regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate. Furthermore, the very low production of the subject adhesive for use in food-contact applications, as evidenced by the market volume described in the confidential attachment, precludes any substantial release to the environment of the 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 leachables. 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 and under effective FCNs. 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. Moreover, the intended use of the FCS proposed here is such that there is no possibility that food contact materials incorporating the adhesive will replace any food packaging materials that are currently recycled. A February 2013 report by the Canadian Packaging Industry Association demonstrates that recycling of multi laminate films in North America is negligible.<sup>4</sup> Therefore, we do not expect packaging manufactured with the adhesive to be recycled. Packaging materials produced using the subject adhesives are expected to be disposed of according to the same

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<sup>4</sup> Reclay StewardEdge Product Stewardship Solutions, et al., *Analysis of Flexible Film Packaging Diversion Systems*, February 2013, available at: [http://www.moorerecycling.com/Flexible\\_Film\\_Report.pdf](http://www.moorerecycling.com/Flexible_Film_Report.pdf).

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 discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of FCS. Therefore, the FCS is not reasonably expected to result in any new environmental issues that require 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 that proposed in this FCN. If the proposed action is not approved, the result would be the continued use of the currently marketed adhesives that the subject FCS would replace. Such action would have no environmental impact. The addition of the adhesive to the options available to food packaging manufacturers is not expected to increase the use of such adhesives or the food packaging materials into which they are incorporated.

#### **12. List of Preparers**

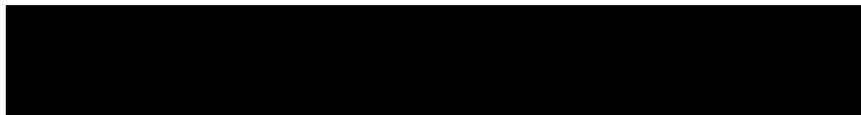
Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011.

#### **13. Certification**

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

Date: August 17, 2016



Mitchell Cheeseman, PhD

#### **14. References**

Council on Environmental Quality's *Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts*, December 2014.

Reclay StewardEdge Product Stewardship Solutions, et al., *Analysis of Flexible Film Packaging Diversion Systems*, February 2013.

U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: Facts and Figures 2013*, June 2015.

15. **Attachments**

Confidential Attachment to the Environmental Assessment.