

Environmental Assessment

- 1. Date** February 3, 2016
- 2. Name of Applicant** Eastman Chemical Company
- 3. Address** Communications to be sent care of:
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4. Description of Proposed Action

a. Requested Action

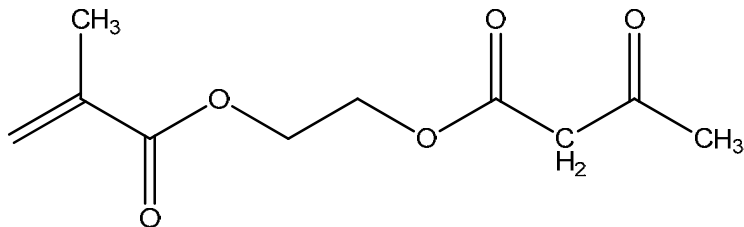
The action requested in this food contact notification (FCN) is to permit the use of the substance butanoic acid, 3-oxo-, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl ester (CAS Reg. No. 21282-97-3) (the food contact substance or FCS) as a monomer in the production of resins that are intended for use as food contact adhesives. The Notifier does not intend to produce the food contact adhesives, rather the substance that is the subject of the proposed action will be sold to adhesive manufacturers. Adhesives produced with the FCS may be used in accordance with the provisions of 21.C.F.R. Section 175.105(a)(2), in single use applications.

b. Need for Action

Use of the FCS in polymers used to manufacture adhesives provides several technical advantages. Resins containing the FCS have reduced glass transition points, lower viscosity, enhanced adhesion to metals, and cross-linking versatility, resulting in improved packaging material.

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

The FCS is butanoic acid, 3-oxo-, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl ester (CAS Reg. No. 21282-97-3), with a chemical formula of $C_{10}H_{14}O_5$, a molecular weight of 214.22, and the following structure:



The FCS is intended for use as a monomer in the production of resins for use in food contact adhesive applications.

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 ordinarily 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. The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, state or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 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. 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 to produce adhesives or in the manufacturing of finished packaging materials. The FCS is expected to be entirely incorporated into the adhesive, while the adhesive also 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.

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

The Notifier does not intend to produce finished food packaging from the subject FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food contact adhesives. These adhesives will, in turn, be used in the production of food contact articles. Finished articles produced with adhesives containing the FCS are expected to be utilized in patterns corresponding to the national population density and 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.¹ Thus, based on the above numbers, 80.4% of the material not recycled is land disposed and 19.6% is combusted.² Adhesives produced with the FCS are intended as alternatives to other 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 chemically similar adhesives for similar or identical uses.

¹ 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.

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

Disposal by the ultimate consumer of food contact articles containing the FCS will be primarily by sanitary landfill or incineration. The subject resin consists of carbon, hydrogen, and oxygen, elements commonly found in municipal solid waste.

To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we consider that the combustion product of most concern would be the greenhouse gas carbon dioxide. We have assumed that available carbon in the FCS would be converted to this gas and that 19.6% of the market volume will be combusted. Based on the anticipated market volume of the FCS and calculations regarding the maximum introduced level of carbon dioxide (provided in a confidential attachment to the FCN), we have concluded that combustion of 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). Further, 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 (CO₂-e) emissions are estimated to be below 25,000 metric tons.³ Based upon the analysis in the confidential attachment described above, the expected CO₂-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 finished articles produced with adhesives 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. The lack of any leaching is especially true considering that adhesives containing the FCS are expected to be highly cross-linked resins with a high molecular weight, resulting in very low levels of low molecular weight resin components that have the potential to leach.

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 in food contact adhesive applications. Finished adhesives containing the FCS are expected to be highly cross-linked and of high molecular weight, and are not expected to be volatile. As described above, the emission of carbon dioxide 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 finished articles manufactured with the FCS.

³ 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.

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 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 low levels of potential migration of the FCS as calculated in the FCS indicate that virtually no leaching of this substance may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Furthermore, the very stringent regulatory limitations on leachate from landfills preclude any substantial release to the environment of the FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

On these bases, 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 FCS in food contact adhesive applications.

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 manufactured with the FCS 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 finished articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors or and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food contact substances, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The FCS already is commercially manufactured for use in a variety of applications, so the additional use in food contact applications is not expected to significantly increase the consumption of energy and resources. Manufacture of adhesives containing the FCS, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other adhesives already on the market. Finished articles containing the FCS are expected to be disposed of according to the same patterns as alternative materials.

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 commodity chemicals that the subject FCS would replace. Such action would have no environmental impact. The addition of the FCS as a monomer for use in food contact adhesives 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.

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Attwood has six years of experience preparing environmental submissions to FDA for the use of food contact substances.

13. Certification

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

Date: February 3, 2016


Mitchell Cheeseman, PhD

14. References

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

15. Attachments

Attachment 07: Confidential Attachment to the Environmental Assessment.