

Part IV – Environmental Impact of Food Contact Substance (21 CFR Part 25)

Environmental Assessment

- 1) Date: January 23, 2013
- 2) Name of Notifier: Eastman Chemical Company
- 3) Address:

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:

Requested action:

It is proposed that the use of copolymers made from dimethyl terephthalate, 1,4-cyclohexanedimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (CAS Reg. No. 261716-94-3), containing repeat units consisting of terephthalate esters of 2,2,4,4-tetramethyl-1,3-cyclobutanediol at up to 40 mole percent (expressed as mole percent of the glycol component of the finished copolyesters) and 1,4-cyclohexanedimethanol at no less than 60 mole percent, and, optionally containing ≤ 0.5 percent (by weight of the finished resin) trimellitic anhydride (CAS Reg. No. 552-30-7) as a branching agent, be permitted as components of articles used in contact with food. Articles made with the subject food-contact substances (FCS) are intended for use in contact with Food Types I, II, III, IVA, IVB, VIA, VIB, VIC, VIIA, VIIB, and VIII as described in Table 1, under Conditions of Use C through H as described in Table 2.¹

Need for action:

The uses proposed in this Notification are an expansion of the uses covered by FCN 1041. FCN 1041 permits the use of the FCS in repeat use food-contact articles, in contact with all types of food at temperatures up to 100°C. The purpose of this Notification is to permit the use of the FCS in single-use food-contact applications in contact with all foods, except Food Types V and IX under Conditions of Use C through H.

¹ Tables 1 and 2 may be found on FDA's website at www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm109358.htm.

Location of use:

The FCS would be manufactured in the United States. The FCS will be used by Eastman's customers and incorporated into articles to be used as food contact materials at food-packaging production sites located throughout the United States.

Location of disposal:

Disposal of the food contact substance is expected to occur nationwide within the United States with the FCS ultimately being deposited in municipal solid waste landfills or combusted as a result of the disposal of the articles made from the resin. According to the U.S. Environmental Protection Agency's 2011 update regarding municipal solid waste in the United States, of the total of 249.8 million tons of municipal solid waste (MSW) generated in 2010, approximately 135.7 million tons (54.3%) generally was land disposed, 29.3 million tons (11.7%) was combusted, 64.8 million tons (25.9%) was recovered for recycling, and 20.2 million tons (8.75%) was recovered for composting.² 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 food-contact substance.

5) Identification of the chemical substances that are the subject of the proposed action:

CAS Name and Number:

Polymer of dimethyl terephthalate, 1,4-cyclohexanedimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (CAS Reg. No. 261716-94-3).

The versions that are branched with trimellitic anhydride use the same CAS names and numbers since the trimellitic anhydride is used at less than 2%.

Physical description:

The subject polymers have the appearance and handling characteristics of other colorless and odorless polymeric resins from which food-contact articles are typically made. They have a similar chemistry to widely-used commercial polyester resins.

Impurities:

This information is contained in Section II.B.3 of the FCN, associated attachments, as well as predecessor FCNs (FCNs 729 and 1041). Only very low amounts of these chemicals will be expected to enter the environment as a result of this action.

² U.S. Environmental Protection Agency. Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2010. EPA-530-F-011-005, November 2011, Washington DC.

6) Introduction of substances into the environment:

a) Introduction of substances into the environment as a result of manufacture:

These products will be manufactured in the United States and Malaysia. 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 food-contact substances. 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 copolymers. Consequently, information on the manufacturing sites and compliance with relevant emissions requirements is not provided here.

b) Introduction of substances into the environment as a result of use:

Little or no introduction of the polymer will result from its use because this substance is completely incorporated into articles or components of articles at industrial sites particular to the end-use application and essentially all of it is expected to remain with these articles throughout their lifetime.

c) Introduction of substances into the environment as a result of disposal:

i. Landfills:

No significant amount of the FCS is expected to leach from these materials into landfills. Moreover, even if a very small amount of the FCS migrates from the food packaging in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the Environmental Protection Agency's (EPA's) 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.

ii. Combustion:

The polymers are composed of carbon, hydrogen, and oxygen, elements commonly found in municipal solid waste. The proposed use of the FCS and the market volume (available in a confidential attachment to the FCN) show that (1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (29.3 million tons or 11.7% of 249.9 million tons in 2010³), (2) the FCS will not significantly alter the emissions from

³ U.S. Environmental Protection Agency. Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2010. EPA-530-F-011-005, November 2011, Washington DC. According to this report, of the total of 249.8 million tons of municipal solid waste (MSW) generated in 2010, approximately

properly operating municipal solid waste combustors,⁴ and, therefore, (3) incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

7) Fate of substances released into the environment:

No information need be provided on the fate of substances released into the environment as the result of use and disposal of the FCS because only small quantities of substances, if any, will be introduced into the environment from its use and disposal. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

8) Environmental effects of released substances:

No information need be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because only small quantities, if any, of substances will be introduced into the environment as a result of the use and disposal of this product. Therefore, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

9) Use of resources and energy:

As is the case with other food packaging materials, the production, use and disposal of the subject copolymer involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymer in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources. The copolymer is intended to be used mainly in place of other polymers now on the market for use in food packaging applications, including polycarbonate and polypropylene, and polyethylene terephthalate (PET) for applications other than single-use soda and water bottles. It is possible that the subject FCS could also replace glass or metal food packaging in certain small niche markets. Based on the confidential information set forth in Attachment 11, however, the FCS is not expected to replace a significant portion of the glass or metal used in single-service food packaging materials.

The partial replacement of other resins by the subject copolymer is not expected to have any adverse impact on the use of energy and resources because manufacture of the copolymer and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of the currently cleared alternative polymers.

135.7 million tons (54.3%) generally was land disposed, 29.3 million tons (11.7%) was combusted, 64.8 million tons (25.9%) was recovered for recycling, and 20.2 million tons (8.75%) was recovered for composting.

⁴ Paul M. Sullivan; Hallenbeck, W.H.; Brenniman, G.R. *Municipal Solid Waste Combustion*; University of Illinois at Chicago: Chicago, IL, 1993.

Articles made from the subject copolymer are expected to bear the resin identification code No. 07 ("Other"), and are not expected to be used in making soda or water bottles. Articles made with the FCS would not be expected to inadvertently enter the recycling stream. Furthermore, the polymers that may be replaced by the subject copolymer currently are not collected to any significant amount as a part of the recycled plastics stream.

For all of the foregoing reasons, the use of the FCS as described in this Notification will not have an adverse impact on energy and resources.

10) Mitigation measures:

We identify no adverse environmental effects, based upon our review of adequate and complete data and information.

11) Alternatives to the proposed action:

We identify no adverse environmental effects, based upon our review of adequate and complete data and information.

12) Preparer:

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13) Certification:

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

Date: 23 January 2013



Company