An EA Revision Sheet has been prepared for this Environmental Assessment – See the FONSI for this Food Contact Notification

Attachment 13

Environmental Assessment

1. Date: August 31, 2018

2. Name of Applicant/Notifier: Eastman Chemical Company

3. Address:

Eastman Chemical Company
P.O. Box 511, B-54D
Kingsport, Tennessee 37662

All communications on this matter are to be sent in care of Counsel for Notifier:

Devon Wm. Hill, Partner
Keller and Heckman LLP
1001 G Street, NW, Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4279
Facsimile: (202) 434-4646
E-mail: hill@khlaw.com

4. Description of the Proposed Action:

The action requested in this Notification is to permit the use of the Notifier's food contact substance (FCS), Hydrocarbons, C6-C20, polymers, hydrogenated (CAS Reg. No. 69430-35-9), when used:

1. As a component of pressure sensitive adhesive formulations complying with 21 CFR 175.125;

2. As a component of resinous and polymeric coatings for polyolefin films complying with 21 CFR 175.320;

3. As a component of can-end cement formulations complying with 21 CFR 175.300(b)(3)(xxxi);

4. As a component of coatings for paper and paperboard complying with 21 CFR 176.170 and 21 CFR 176.180; and

5. As a component of adhesives for seals of food-contact, glass containers complying with 21 CFR 177.1210.

The food contact substance will be used at levels not to exceed 60 percent by weight of total polymer/formulation weight in contact with all types of food under Conditions of Use B through H.

Food-contact articles containing the FCS will be utilized in patterns corresponding to national population density and will be widely distributed across the country. In some of the above applications, specifically, can-end cement formulations, coatings for paper and paperboard, and seals for glass contains, the articles in which the FCS will be used may be collected for recycling. In the other of the above applications, namely, pressure sensitive adhesives and coated polyolefin films, the articles in which the FCS will be used are not expected to be collected for recycling to a significant extent, except potentially as a part of a mixed plastics recycling stream. Thus, it is estimated that approximately 80.4% of the materials will be deposited in land disposal sites and 19.6% will be combusted.[1, 2]

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

The FCS that is the subject of this Notification is a family of resins identified as Hydrocarbons, C6-C20, polymers, hydrogenated (CAS Reg. No. 69430-35-9).

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 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 FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of the subject FCS to fabricate packaging materials. In these applications, the FCS (*i.e.*, a family of hydrocarbon resins) is expected to be entirely incorporated into and remain with the finished food-contact

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[1] *See* the U.S. Environmental Protection Agency's (EPA) "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Compositing, Combustion with Energy Recovery and Landfilling in the United States," EPA530-R-17-01 (November 2016), at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report. As noted in Table 1 of EPA's fact sheet, of the total 258.5 million tons of municipal solid waste (MSW) generated in 2014, 52.6% was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting).

[2] Because the FCS is expected to be disposed primarily by landfill or combustion (*i.e.*, not recovered for recycling), we have calculated the disposal pattern based only on the quantities of MSW that are land disposed or combusted. Specifically, we estimate that 19.6% of food-contact articles containing the FCS will be combusted annually with the remaining 80.4% going into landfills (12.8% combusted ÷ (12.8% combusted ÷ 52.6% land disposed) = 19.6% combusted).

article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as a part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

We anticipate that disposal by the ultimate consumer of the finished articles containing the FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, incineration, or recovery for recycling.

The FCS is composed of carbon and hydrogen, elements that are commonly found in municipal solid waste. We compared the market volume information for the FCS, contained in a confidential attachment to this Notification (*see* **Attachment 14**), to the annual municipal solid waste (MSW) production (258.5 million tons MSW in 2014), and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect a significant environmental impact resulting from post-consumer disposal of articles that contain the FCS.

Further, the proposed use of the FCS and corresponding market volume show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which EPA has indicated to be 33.1 million tons, as of 2014.[3] Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and incineration of articles containing 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 and/or relevant state and local laws).

To evaluate the significance of the environmental impact of potential greenhouse gas (GHG) emissions, we refer to the Council on Environmental Quality's (CEQ) regulations under 40 C.F.R. § 1508.27, which define 'significantly' as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act reviews. Section 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." Of relevance, MSW combustion GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2 and subject to the annual 25,000 metric ton CO_2 equivalents reporting limit.

In this case, based on the confidential market volume information provided in **Attachment 14**, the expected carbon dioxide emissions from combustion of the FCS will amount to less than 25,000 metric tons of total CO_2 equivalents 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, the FCS will be used in place of other hydrocarbon resins already on the market. Thus, in practice, any emissions from combustion of the FCS would be substitutional in nature and would not represent an increase in emissions.

Finally, only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the

[3] *See* page 12 of EPA's fact sheet, cited in footnote 1.

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.

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, as the FCS is a hydrocarbon resin and, thus, non-volatile.

As indicated above in item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations. *See* **Attachment 14** for additional details.

(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 hydrocarbon resins. The fate of the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

(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 FCS. In particular, the resinous nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when finished articles are disposed. Furthermore, the very low production of the FCS for use in food-contact applications precludes any substantial release to the environment of its 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 FCS.

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 FCS. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

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 subject hydrocarbon resins consist of extremely small quantities of combustion products and leachables, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of packaging containing the FCS. 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 C.F.R. 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 FCS involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, because the FCS is intended to be used in place of similar hydrocarbon resins now on the market for use in food packaging applications. Hydrocarbon resins currently used in the applications in which the subject hydrocarbon resins is anticipated to be used include the resins cleared for use under FCN No. 56, which are permitted for the identical applications proposed in this Notification.

Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of other, similar FCSs. Furthermore, when the FCS is used in can-end cement formulations, coatings for paper and paperboard, and seals for glass contains, such types of articles already are collected for recycling, and the FCS will be a small component of such articles (food and beverage cans, paper and paperboard articles, and glass containers), and the FCS simply will replace comparable hydrocarbon resins already in use for the same applications. With regard to the other applications, pressure sensitive adhesives and coated polyolefin films, the finished articles in which the FCS may be used are not anticipated to be recovered for recycling, and such food-contact materials produced using the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used hydrocarbon resins. Thus, there will be no impact on 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 FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, and the insignificant impact on environmental concentrations of combustion products of the FCS.

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 materials that the subject FCS would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Devon Wm. Hill, J.D. and Masters in Chemistry, 20 years of experience related to all aspects of preparing Food Additive Petitions and Food Contact Notifications, Partner at Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

Lester Borodinsky, Ph.D. in Chemistry, 32 years of experience related to all aspects of preparing Food Additive Petitions and Food Contact Notifications, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

Kristin Price Wiglesworth, Ph.D. in Chemistry, 1 year of experience related to all aspects of preparing Food Contact Notifications, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

13. Certification

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

Date: August 31, 2018

[redacted]

Counsel for Eastman Chemical Company

14. References

1. U.S. Environmental Protection Agency, "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Compositing, Combustion with Energy Recovery and Landfilling in the United States," EPA530-R-17-01 (March 2018), available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

15. Attachments

1. Attachment 14, Confidential Addendum to Environmental Assessment