

ZEON CORPORATION
ENVIRONMENTAL ASSESSMENT

**ENVIRONMENTAL ASSESSMENT
ZEON CORPORATION
FOOD CONTACT NOTIFICATION**

1. **Date** March 8, 2016
2. **Name of Applicant/Notifier** ZEON Corporation
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Tokyo, 100-8246 Japan

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**

The action requested in this notification is to permit the use of cyclopentene, polymer with 1-butene, (2E)-2-butene, (2Z)-2-butene, 2-methyl-1-propene and 1,3-pentadiene as a component of pressure-sensitive adhesives used as the food-contact surface of labels and/or tapes applied to food, as described in 21 C.F.R. § 175.125. When used in these applications, the resin is intended to provide tackifying properties to the adhesive formulations in which it is used.

The Notifier does not intend to produce finished food-contact articles from the subject FCS. Rather, the FCS that is the subject of this Notification will be sold to formulators engaged in the production of finished food-contact articles. Food-contact articles produced with the FCS will be used in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of the subject resin will occur nationwide, with about 80.4% of the materials being disposed of in land disposal sites, and about 19.6% combusted.¹

¹ *Advancing Sustainable Materials Management: 2013 Fact Sheet, Assessing Trends in Material Generation, Recycling and Disposal in the United States*, EPA530-R-15-003, U.S. Environmental Protection Agency, Solid Waste and Emergency Response (5306P), June 2015. See http://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_fs.pdf.

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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 FCS.

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

The FCS is a non-hydrogenated petroleum hydrocarbon resin manufactured from the C5 and C4 fractions of petroleum cracking. The resins may be described chemically as cyclopentene, polymer with 1-butene, (2E)-2-butene, (2Z)-2-butene, 2-methyl-1-propene and 1,3-pentadiene (CAS Reg. No. 220543-67-9). The **Confidential Appendix** to this Environmental Assessment further describes the chemical composition of the FCS, specifically the typical ratios of the starting monomers and the corresponding amount of Carbon contained in the FCS.

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 materials. 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 herein.

No environmental release is expected upon the use of the subject FCS to fabricate food-contact materials. In this application, the FCS is expected to be used as a component of pressure-sensitive adhesives that are used in the production of labels that may be applied to food. The FCS is expected to be entirely incorporated into the finished adhesive label. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

See also http://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_rpt.pdf. According to this report, of the total 254.1 million tons of municipal solid waste (MSW) generated in 2013, approximately 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 adhesive labels containing the food-contact substance (FCS) are expected to be disposed of by land-filling or combustion (*i.e.*, not recovered for recycling), we will recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that approximately 19.6% of labels containing the FCS will be combusted annually. This amount is calculated as follows: $12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

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Disposal by the ultimate consumer of food-contact labels produced with the subject FCS will be by conventional rubbish disposal means, primarily by sanitary landfill or incineration. The FCS is composed only of carbon and hydrogen, elements that are commonly found in municipal solid waste. The proposed use of the FCS and the confidential market volume show that the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 32.8 million tons or 12.9% of 254.1 million tons in 2013).² The FCS thus will not significantly alter the emissions from properly operating municipal solid waste combustors, and therefore, 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 and/or relevant state and local laws).

Pursuant to the Council on Environmental Quality (CEQ) “Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts,”³ a quantitative analysis is required if greenhouse gas (GHG) emissions from the action are expected to exceed 25,000 metric tons CO₂ equivalent on an annual basis. Based on market volume information provided in the **Confidential Appendix**, the expected carbon dioxide emissions from combustion of adhesive labels containing the FCS are below 25,000 metric tons on an annual basis; therefore, no quantitative analysis is required for this action.

Only extremely small amounts, if any, of the FCS 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 entering ground and surface water, and to have ground-water monitoring systems.⁴ 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. The FCS is a polymer and does not readily volatilize.

As indicated above in item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not

² See *id.*.

³ Council on Environmental Quality (CEQ). *Revised Draft Guidance on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change*. December 18, 2014. https://www.whitehouse.gov/sites/default/files/docs/nepa_revised_draft_ghg_guidance.pdf.

⁴ 40 C.F.R. Part 258.

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cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations. The fate of the FCS in the atmosphere does not need to be addressed because no significant introductions of substances into the air are identified, as discussed under Item 6.⁵

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of food packaging employing the subject substance, nor upon its disposal in landfills due to the anticipated extremely low levels of aqueous extraction of the subject substance (the FCS has a very low water solubility). The fate of the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment are identified, as discussed under 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, because of its low water solubility, only extremely low levels of aqueous extraction of the subject substance are expected to occur under normal environmental conditions when finished food-contact materials are disposed. In addition, 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 in the manufacture of articles intended for use in contact with food. Therefore, the fate of the FCS in the terrestrial environment does not need to be addressed because no significant introduction of substances into the environment resulting from 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 adhesive labels fabricated with the subject polymer consist of extremely small quantities of combustion products and leachates, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of adhesive labels 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 the substance will be introduced into the environment as a result of use and/or disposal of the FCS.

⁵ In addition, no net increase in carbon dioxide emissions is expected.

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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. The use of the subject polymer as a component of pressure-sensitive adhesives is not expected to result in a net increase in the use of energy and resources, however, because the substance is intended to be used as a substitute for similar polymers that are already on the market in these same food-contact applications. Such polymers may include, *e.g.*, hydrocarbon resins that are cleared under 21 C.F.R. Section 175.125 (“Pressure-sensitive adhesives”) or under effective FCNs covering these applications – the latter include, *e.g.*, FCNs 56, 57, 161, 482, and 1375.

The partial replacement of the currently cleared resins by the FCS will not have any adverse impact on the use of energy and resources. Manufacture of the food-contact substance, and its conversion to finished food-contact materials, will consume the same energy and resources as the manufacture and use of the similar polymers already marketed for this use. Furthermore, the use proposed in this Notification for the subject FCS, as a component of pressure-sensitive adhesives for labels or tapes that may be applied directly to food, is not expected to have an impact on current or future recycling programs because the final food-contact articles – adhesive labels applied to food – are not currently recovered for recycling. Nor are they expected to be recovered for recycling in the future, given the small size of the labels and the fact that they are not part of a larger food package that will be recycled. Thus, the use of the FCS will not have an impact on current or future recycling programs.

Nevertheless, because FDA has previously requested information on the potential impact that pressure-sensitive adhesives might have on recycling programs if the labels were to be collected for recycling, we address this topic as follows. Note, however, that the issues discussed below with regard to challenges raised by such materials in the recycling stream are not expected to be encountered by the FCS, as it is not expected to be recycled.

More specifically, some pressure-sensitive adhesive products are reported to cause challenges for mills that transform recovered paper, including food-contact paper, into recycled pulp and paper. Specifically, pressure-sensitive adhesives that are not compatible with paper re-pulping processes can fragment into small particles during the re-pulping process, deform under heat and pressure, and become lodged on papermaking equipment or the paper itself. This can increase the cost of operating a re-pulping mill and reduce the prices received by recovered paper collectors.

Pulping of reclaimed paper involves using water to separate fibers from contaminants by the mechanical action of a spinning rotor in a large tank. Products containing pressure-sensitive adhesives are broken up into small particles that may be separated from the fibers by screening through slots or holes. Smaller particles are more difficult to screen. Many factors affect the screening efficiency including slot size, flow rate, turbulence, temperature, and pressure drop across the screen. In addition to these factors, adhesive formulation can significantly impact the

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pressure-sensitive adhesive particle size produced from re-pulping and therefore its screenability.⁶

Published results on hot-melt pressure-sensitive adhesives indicate that a threshold cohesive strength exists below which hot melt pressure-sensitive adhesives readily fragment to sizes that are difficult to remove from re-pulping operation via screening.⁷ Cohesive strength in hot-melt pressure-sensitive adhesives is temperature dependent. Thus, formulating environmentally benign hot-melt pressure-sensitive adhesives requires that the phase behavior of the adhesive be properly controlled through choice of base polymer, tackifying resin, plasticizer, and other additives. Formulating adhesives for recycling compatibility continues to be an active area of research for adhesive formulators.⁸

The development of recycling-compatible, pressure-sensitive adhesives for food-contact applications requires formulating adhesives to meet the performance, production, and esthetic demands of food-packaging applications while employing only such components in the formulations that are safe for use in contact with food. In addition, the formulation should produce appropriate sized particles when subjected to the re-pulping process. Thus, authorizing the safe use of additional substances that may be used as components of pressure-sensitive adhesives for food-contact applications, such as the FCS, provides adhesive manufacturers with increased flexibility in developing recycling-compatible, pressure-sensitive adhesives for food packaging applications. This increases the likelihood that more adhesives meeting these stringent requirements will become available for the food packaging markets. As described above, the other polymers are already authorized for use in food-contact, pressure-sensitive adhesives. Thus, allowing this notification to become effective will expand the number of authorized substances that may be used as components of pressure-sensitive adhesive formulations thereby increasing the likelihood that new, finished adhesives will not negatively impact re-pulping mill operations.

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 food-contact substance from finished articles employing the FCS and the insignificant impact on

⁶ R. A. Venditti, B. E. Lucas, H. Jameel, *The Effects of Adhesive Properties on the Removal of Pressure Sensitive Adhesive Contaminants in Paper Recycling*, *Progress in Paper Recycling*, **16(3)**, 18-31, 2007.

⁷ Nowak, M. J.; Severtson, S. J.; Wang, X.; Kroll, M. S. *Properties Controlling the Impact of Styrenic Block Copolymer Based Pressure-Sensitive Adhesives on Paper Recycling*. *Ind. Eng. Chem. Res.* **42(8)**, 1681-1687, **2003**.

⁸ S. Severtson, J. Guo, J. Wang, G. Pu, L. Gwin and C. Houtman, *Development of Recycling Compatible Pressure-Sensitive Adhesives and Coatings, Final Scientific Report for Project DE-FC36-04GO14309*, Office of Scientific and Technical Information, Department of Energy, available at: <http://www.osti.gov/scitech/servlets/purl/975049>.

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environmental concentrations of combustion products of the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problems requiring 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 those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of similar polymers produced under 231 CGR 175.125 and effective food-contact notifications in the same applications. Such action would have no environmental impact. In view of the fact that the FCS constituents are 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 its use, the establishment of an effective Food contact Notification to permit the use of the subject FCS as described herein is environmentally safe in every respect.

12. List of Preparers

Mitzi Ng Clark, Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

Mark Hepp, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. As a former FDA staff member, primary and secondary review of environmental submissions accompanying indirect food additive petitions assigned to the Office of Food Additive Safety's Special Project Team were among Dr. Hepp's routine duties.

Holly Foley, 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 her knowledge.

Date: March 8, 2016


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Counsel for ZEON Corporation