

## Environmental Assessment

1. **Date:** July 28, 2025
2. **Name of Applicant/Notifier:** DRT (Les Derives Resiniques et Terpeniques)
3. **Address:** All communications on this matter are to be sent in care of Counsel for Notifier:  
  
Kathryn C. Skaggs, Partner  
Keller and Heckman LLP  
1001 G Street, N.W., Suite 500 West  
Washington, DC 20001  
Telephone: (202) 434-4247  
E-mail: skaggs@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), terpenes and terpenoids, turpentine-oil, 3-carene fraction, polymers with phenol (CAS Reg. No. 705265-37-8) as a tackifier in adhesives authorized under 21 C.F.R. § 175.105 ("Adhesives) and pressure-sensitive adhesives authorized under 21 C.F.R. §175.125 ("Pressure-sensitive adhesives").

The Notifier does not intend to produce finished food packaging from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact articles. Food-contact materials containing the FCS 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 of the FCS will occur nationwide, with the material being land disposed, or combusted in quantities similar to those reported for municipal solid waste generally.<sup>1</sup>

According to the U.S. Environmental Protection Agency's (EPA) 2020 update regarding municipal solid waste (MSW) in the United States, it is estimated that, of the 292.36 million tons of MSW generated in 2018, 50.0% of MSW generated was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.<sup>2</sup> As the food-contact materials containing the FCS are expected to be primarily disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways), we recalculate the disposal pattern based on

---

<sup>1</sup> *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed October 2024, at [https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_ff\\_fact\\_sheet.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf).

<sup>2</sup> *Id.*

only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.<sup>3</sup>

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

The FCS that is the subject of this Notification is: Terpenes and terpenoids, turpentine-oil, 3-carene fraction, polymers with phenol (CAS Reg. No. 705265-37-8).

## **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 food-contact materials. The Notifier is aware of no information suggesting the existence of extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from manufacture of the FCS. Such extraordinary circumstances would include: 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; 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 significant environmental release is expected upon the use of the FCS in food-contact materials. The FCS will be used as a component in adhesive and pressure-sensitive adhesives authorized under 21 C.F.R. § 175.105 (“Adhesives”) and 21 C.F.R. § 175.125 (“Pressure-sensitive adhesives”) and will be entirely incorporated into the finished food-contact articles and is expected to remain with these materials throughout the use of the FCS in food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact material manufacturer’s overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS for food-contact use in the U.S. is provided in the Confidential Attachment to the Environmental Assessment.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable, recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated.

---

<sup>3</sup> 11.8% Combusted ÷ (11.8 % combusted + 50% land disposed) = 19.1% combusted. The remaining 80.9% will be land disposed.

The subject polymers consist of carbon, hydrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case release of carbon dioxide from the FCS has been calculated in a confidential appendix to the Environmental Assessment, and an assessment of this worst-case release is also included in the same confidential appendix.

In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 C.F.R. § 98.2(a)(3) requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO<sub>2</sub> equivalents (CO<sub>2</sub>-e) or more per year to report their GHG emissions to the EPA. Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the Confidential Environmental Information attachment, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, hydrogen, and oxygen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

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 materials, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW 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, "to have ground water monitoring systems and to take corrective action as appropriate (40 C.F.R. Part 258)." These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the FCS is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

## **7. Fate of Emitted Substances in the Environment**

### **A. Air**

No significant effect on the concentrations of and exposures to any of the substances in the atmosphere are anticipated due to the proposed use of the subject FCS. The FCS does not readily volatilize during use, and the analysis discussed above in Item 6 demonstrates that no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this FCS.

## **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 the FCS, nor upon its disposal in landfills.

## **C. Land**

Due to 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 polymeric nature of the FCS is expected to result in virtually no leaching of components of the finished FCS under normal environmental conditions when these substances are disposed. Furthermore, the estimated low production volume anticipated for the FCS in food-contact applications precludes any substantial release to the environment of its components. Thus, we have no expectation of any meaningful exposure to terrestrial organisms of 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 food-contact materials.

## **8. Environmental Effects of Released Substances**

As discussed under Item 6 above, significant environmental effects of substances released into the environment as a result of the use and disposal of the subject FCS in landfills and by combustion are not anticipated as only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of food-contact articles and films containing the subject FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the U.S. EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to MSW combustors and Part 258 that pertain to landfills.

## **9. Use of Resources and Energy**

As is the case with other food-contact materials, the production, use, and disposal of the FCS involve the use of natural resources. 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 will be used in place of other food packaging materials.

Manufacture of the FCS and the final conversion to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture of chemically related resins. Articles and packaging materials produced from the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed materials. Thus, there will be no impact on current recycling programs.

For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this Notification becoming effective.

**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 from the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem 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 the materials that the subject FCS would otherwise replace; such action would have no anticipated environmental impact.

**12. List of Preparers**

Kathryn C. Skaggs, JD, MPH, Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500W, Washington, DC 20001. Ms. Skaggs has 14 years of experience with Environmental Assessments for FDA submissions and a background in epidemiology and biostatistics.

Jade C. Williams, Ph.D. in Chemistry, 1 year of experience performing evaluations relating to all aspects of preparing Food Contact Notifications, and 4 years of total experience in FDA-regulated industries. Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Experienced in preparing environmental assessments for FCNs

**13. Certification**

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



Date: 7/28/2025

Kathryn C. Skaggs  
Counsel for Notifier

**14. References**

1. FDA’s Food Types and Conditions of Use are defined at Tables 1 and 2 of “Food Types & Conditions of Use for Food Contact Substances,” available at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.
2. EPA, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), available at: [https://www.epa.gov/sites/default/files/2020-11/documents/2018\\_ff\\_fact\\_sheet.pdf](https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf).

15. **Attachment**

1. Confidential Attachment – **Attachment 14**