

Environmental Assessment

1. **Date** August 13, 2019
2. **Name of Applicant/Petitioner** Innospec Ltd.
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier:
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4. **Description of Proposed Action:**

A. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), a mixture of 1-decene, polymer with sulfur dioxide (CAS Reg. No. 33990-98-6); 1,3-propanediamine, N1-(9Z)-9-octadecen-1-yl-, polymer with 2-(chloromethyl)oxirane (CAS Reg. No. 1010121-89-7); and dodecylbenzenesulfonic acid (CAS Reg. No. 27176-87-0), when used in the manufacture of food-contact materials. The FCS is intended for use as an antistatic agent in the production of polyethylene and polypropylene polymers and copolymers used in food-contact applications. More specifically, the FCS is intended:

(1) For use at levels not to exceed 20 parts per million (ppm) in polyethylene and polypropylene polymers and copolymers intended to be used in contact with all food types under all conditions of use, except for use in contact with infant formula and human milk.

(2) For use at levels not to exceed 4 parts per million (ppm) in high-density polyethylene and polypropylene polymers and copolymers intended for use in contact with infant formula and human milk under Conditions of Use A through H, as described in Table 2.

B. Need for Action

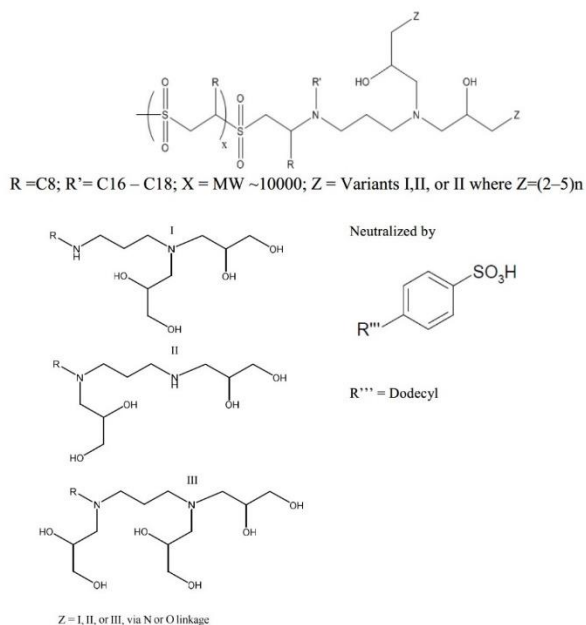
The FCS is intended to be used as an antistatic agent in the polymerization process to produce food-contact plastics. The FCS improves the yield from the polymerization process and results in increased throughput rates.

C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2015, approximately 52.5% of municipal solids waste is currently deposited in land disposal sites, 12.8% is combusted, and 34.7% is recovered (a combination of waste recovered for recycling and for composting).¹ The extremely low use level of the FCS in polyolefins will not impact the disposal patterns of the polymeric resins in which they are used.

5. Identification of the Subject of the Proposed Action

The subject of this notification is a mixture of 1-decene, polymer with sulfur dioxide; 1,3-propanediamine, N1-(9Z)-9-octadecen-1-yl-, polymer with 2-(chloromethyl)oxirane; and dodecylbenzenesulfonic acid. The structure of the polymer is as follows:



6. Introduction of Substances into the Environment

Under 21 C.F.R § 25.40(a) (“Environmental assessments”), 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 Notifier is not aware of any information to suggest that there are any extraordinary circumstances in this case indicative of

¹ *Advancing Sustainable Materials Management: Facts and Figures 2015*, U.S. Environmental Protection Agency, July 2018, available at https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf.

any adverse environmental impact as a result of the manufacture of the subject polymer. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected when the subject polymer is used in the manufacture of packaging materials. The polymer will be entirely incorporated into the finished article, and essentially all of it is expected to remain with these materials throughout the use of the plastics in the packaging applications and use/disposal by the consumer. Any waste material generated in this process, *e.g.*, plant scraps, is expected to be disposed as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

The FCS is composed of carbon, oxygen, hydrogen, nitrogen, and sulfur. Thus, the combustion products of the FCS may include the greenhouse gases (GHG) carbon dioxide and nitrous oxide. The carbon and nitrogen content of the FCS has been calculated based on the elemental composition of the FCS (available in a confidential attachment to the EA).

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) CO₂ equivalents (CO₂-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (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. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG.” Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 40 C.F.R. § 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 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.” GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulation (*i.e.*, 40 C.F.R. 60 and/or relevant state and local laws).

When combusted, there is nothing to suggest the FCS would threaten a violation of 40 C.F.R. Parts 60 and 62, the regulations governing municipal waste combustors, as carbon, hydrogen, oxygen, nitrogen and sulfur are either typical elements in MSW (*i.e.*, C, H, N and O) or are mitigated via these Clean Air Act regulations (*i.e.*, S may contribute to sulfur dioxide or SOX emissions, and MSW incineration units reduce the emissions of these harmful pollutants).

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 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, 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 collection systems, they are required to monitor groundwater and to take corrective actions as appropriate.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the polymer. The polymer is of high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact films manufactured with these polymers.

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 FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

B. Water

No significant effects on exposures to any substances from the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to its proposed use. 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 concentration of and exposure 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 FCS components under normal environmental conditions when the food packaging articles in which they are contained are disposed of. Furthermore, the very low production of the polymer 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 food-contact polyolefins. 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 above, the only substances that may be expected to be released into the environment upon the use and disposal of food packaging materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. None of these potential releases presents any toxicological concern at the low levels at which they could occur upon use and disposal of food-contact materials containing the FCS. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the polymer is not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

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 manufacturer of the FCS polymer will consume comparable amounts of energy and resources as similar products already being marketed, as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this alternative product will have no impact on the use of resources and energy.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles with or without antistatic agents. Because the FCS is used at an exceedingly low level in the manufacture of polyolefins, there will be no impact on current recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of articles fabricated within the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished food-contact materials, and the insignificant impact on environment concentrations of combustion products of the FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would replace. Such action would have no environmental impact.

12. List of Preparers

1. Cynthia B. Lieberman, J.D., 12 years of experience performing evaluations relating to all aspects of Food Contact Notifications, Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.
2. Peter Coneski, Ph.D. in Chemistry, 5 years of experience performing evaluations relating to all aspects of Food Additive Petitions and Food Contact Notifications, 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: August 13, 2019

Cynthia B. Lieberman



Counsel for Innospec Ltd.

14. List of References

The following footnotes are found within the Environmental Assessment document:

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2 at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm>.
2. *Advancing Sustainable Materials Management: Facts and Figures 2015*, U.S. Environmental Protection Agency, July 2018, available at https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf.

15. Attachments

1. Confidential Attachment to Environmental Assessment.