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

Environmental Assessment

1. Date July 7, 2017

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), poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/or 5, neutralized with dodecylbenzenesulfonic acid, when used in the manufacture of food-contact materials. The polymer is intended for use as an antistatic agent in the polymerization process to produce food contact plastics (polypropylene (PP), and polyethylene (PE)) at a maximum level of 50 parts per million (ppm) (20 ppm active) relative to total polymer. The finished materials containing the FCS are intended for use with all types of food under Conditions of Use A ("High temperature heat-sterilized (*e.g.*, over 212°F) through H (Frozen and refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"), and J ("Cooking at temperatures exceeding 250°C").[1]

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.

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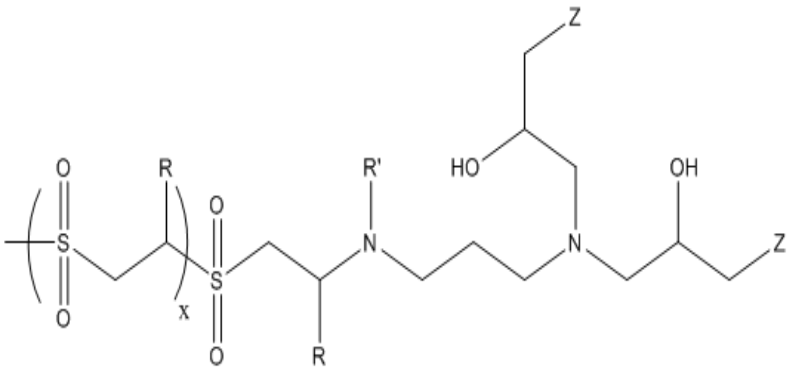
[1] FDA's food types and Conditions of Use are defined in Tables 1 and 2 at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm.

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 2014, approximately 52.6% of municipal solids waste is currently deposited in land disposal sites, 12.8% is combusted, and 34.6% is recovered (a combination of waste recovered for recycling and for composting).[2] 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.

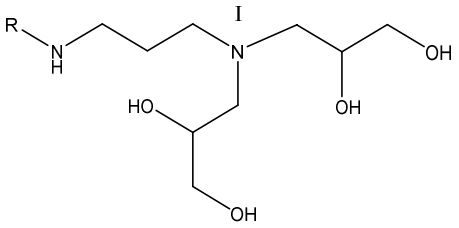
5. Identification of the Subject of the Proposed Action

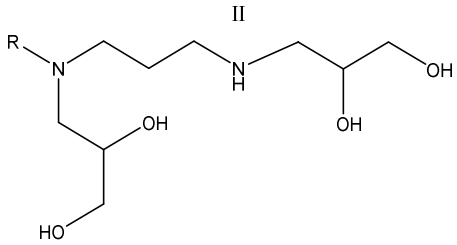
The subject of this notification is poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/or 5, neutralized with dodecylbenzenesulfonic acid. The structure of the polymer is as follows:

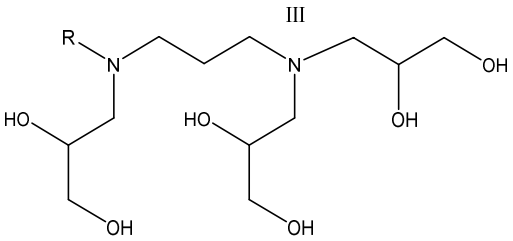


R =C8; R'= C16 – C18; X = MW ~10000; Z = Variants I,II, or II where Z=(2–5)n

[2] *Advancing Sustainable Materials Management: Facts and Figures 2014*, U.S. Environmental Protection Agency, November 2016, *available at* https://www.epa.gov/sites/production/files/2016-11/documents/*2014*_smmfactsheet_508.pdf.

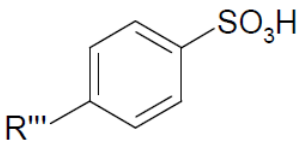






Z = I, II, or III, via N or O linkage

Neutralized by



R''' = Dodecyl

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 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.

Food-contact materials manufactured using the subject polymer are expected to be disposed of either by conventional rubbish disposal (i.e., sanitary landfill), recycling, or incineration. The subject copolymers consist of carbon, oxygen, sulfur, nitrogen, 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 Environmental Assessment, to the annual municipal solid waste (MSW) production (258.5 million tons in 2014),

and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there are any extraordinary circumstances that would otherwise suggest a significant environmental impact resulting from post-consumer disposal of food-contact materials containing the FCS. Further, the proposed use of the FCS and corresponding market volume (available in the Confidential Attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, estimated to be 12.8% of 258.5 million tons, or 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 packaging 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).

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance[4] to agencies regarding addressing GHG emissions and climate change impacts in NEPA documents. This guidance is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effects of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action" (CEQ, 2016 p. 3). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 CFR Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Section 2 of this Part (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO2-e emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 CFR 1508.27(b)(10) states that, when evaluating the 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 CFR 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons 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.

Only extremely small amounts, if any, of the FCS is 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

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[3] *Id.*

[4] Council on Environmental Quality (CEQ), Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews, August 1, 2016, *available at* https://ceq.doe.gov/docs/ceq-regulations-and-guidance/nepa_final_ghg_guidance.pdf.

composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater 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 action 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 products of complete combustion of the polymer would be carbon dioxide, nitrous oxide, and water; the concentrations of these substances in the environment will not be significantly altered by the 40 CFR 60-compliant incineration of the polymers in the amounts utilized for food packaging applications. Additional details are provided in the Confidential Attachment to this Environmental Assessment.

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 is 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 or future recycling programs.

10. Mitigation Measures

The intended use of the FCS is not reasonably expected to create new environmental problem that would require mitigation measures of any kind. As discussed above, the use and disposal of food-contact materials fabricated with the FCS is not expected to result in significant adverse environmental impacts. This is primarily due to the very low levels of potential migrants that could leach from the finished article, the insignificant impact on environmental concentrations from the polymer's combustion products, and the lack of adverse effects of recycling of polyolefins in which it is used.

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. Considering the excellent properties of the FCS for use in food-contact applications, the fact that its constituents are not expected to enter the environment in more than minute quantities upon 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 FCN to permit the use of the subject polymer as described herein is environmentally safe in every respect.

12. List of Preparers

1. Joan Sylvain Baughan, J.D., 24 years of experience performing evaluations relating to all aspects of Food Additive Petitions and 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, 4 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: July 7, 2017

Joan Sylvain Baughan

[redacted]

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 2014*, U.S. Environmental Protection Agency, November 2016, *available at* https://www.epa.gov/sites/production/files/2016-11/documents/*2014*_smmfactsheet_508.pdf.

3. *Id.*

4. Council on Environmental Quality (CEQ), Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews, August 1, 2016, *available at* https://ceq.doe.gov/docs/ceq-regulations-and-guidance/nepa_final_ghg_guidance.pdf.

15. Attachments

1. Attachment 35B, Confidential Attachment to Environmental Assessment.