Attachment 11
Environmental Assessment

1. Date February 9, 2018

2. Name of Applicant/Notifier Clariant Plastics & Coatings USA Inc.

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

This EA has been amended in consultation with the Notifier to correct the reference annotations for confidential information cited. No modification or additional analysis to the original EA has been made. FDA Environmental Review Team 04/03/2018

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4. Description of the Proposed Action

The action requested in this notification is to provide for the use of 1,3-benzenedicarboxamide, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)- (CAS Reg. No. 42774-15-2) as a processing stabilizer in polyamide food-contact films complying with applicable authorizations, except for use in contact with infant formula and breast milk.

The Food Contact Substance (FCS) is intended for use at levels up to 0.5% in polyamide food-contact films not exceeding 100 µm thick. Films containing the FCS are intended for use under Conditions of Use A ("High temperature heat-sterilized (e.g., over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at the time of use").

The subject FCS is a multifunctional additive that provides improvements in melt processing operations for polyamides. For example, the FCS helps improve the stability of melt pressure that leads to smoother and more consistent processing of polymer films. In addition, the additive, being a hindered amine light stabilizer, can significantly boost UV protection of the polymer, especially in polyamides.

Films containing the FCS will be used to package food that will be distributed in patterns corresponding to the national population density. It is therefore expected that the FCS will be widely distributed across the country upon use. Therefore, it is anticipated that disposal will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.[1]

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[1] U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Facts Sheet -- Assessing Trends*

(footnote continued)

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

The food-contact substance that is the subject of this Notification is 1,3-benzenedicarboxamide, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)- (CAS Reg. No. 42774-15-2).

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

No environmental release is expected upon the use of the subject FCS to fabricate packaging materials. In these applications, the FCS will be entirely incorporated into the finished food-contact films. Any waste materials generated in this process (*e.g.*, plant scraps) are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced using the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The FCS is composed of carbon, hydrogen, nitrogen and oxygen; elements that are commonly found in municipal solid waste. We compared the projected fifth year market volume for the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual municipal solid waste (MSW) production (254.1 million tons MSW in 2014), and to the portion of that total that is landfilled, and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled. Therefore, we expect no extraordinary circumstances that would suggest a significant environmental impact resulting from post-consumer disposal of films that contain the FCS. Further, the proposed use

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in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01 (November 2016), *available at* https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf. According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, approximately 52.6% generally was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting). If we assume that food-contact articles containing the FCS are expected to be disposed of by land-filling or combustion (*i.e.*, not recovered for recycling), we 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 food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows: 12.8% combusted ÷ (12.8% combusted + 52.6% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

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 12.9% of the 254.1 million tons total waste generated, or 32.8 million tons, as of 2014.[2] 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 films 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).

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_2 equivalents (CO_2-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 (CO_2-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 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.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the Environmental Assessment, 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.

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 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

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2 *See* Footnote 1.

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.

The only potential source of environmental introductions of the FCS therefore will be due to the consumption and subsequent elimination of the minute amounts of the FCS that may migrate to food and subsequently be consumed by the consumer. The concentration of the FCS in the diet resulting from this FCN becoming effective is estimated in **Attachment 5** of the FCN to be 182 ppb. Assuming in the worst-case that that FCS is eliminated unchanged, this concentration will be diluted significantly when 1) combined with other waters used in the household and then 2) again when these household waters are disposed of by sanitary sewer and subsequently combined with other municipal waters received at the POTW, and 3) again when the POTW discharges to surface waters. Nevertheless, further refinement of this value is unnecessary because, as discussed more fully below, a sufficient margin of safety already exists between the undiluted dietary concentration and the lowest ecotoxicity value of 1 mg/l (1000 ppb) corresponding to the no observed effect concentration (NOEC) for algae.

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 does not readily volatize as evidenced by the evaluation set forth in the **Attachment 12**, the confidential environmental assessment.

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. 60-compliant operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

(b) Water

The FCS, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)-1,3-benzenedicarboxamide is not readily biodegradable.[3] Nevertheless, 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. The very conservatively estimated undiluted dietary concentration of the FCS identified in Item 6, 182 ppb, is well below the lowest ecotoxicity value identified for the FCS. Bioaccumulation occurs when the rate of intake of a substance exceeds the rate of metabolism and/or excretion. For organic compounds, lipophilicity is generally the

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[3] *See* Annex 1 to this Attachment, "Ecotoxicity Studies"; Final Report, Biodegradation study of SEED by microorganisms, Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan, January 17, 2001.

most important property responsible for potential bioaccumulation. Because the FCS has high water solubility, and the estimated environmental concentration is extremely low, bioaccumulation is not expected to occur under the intended conditions of use.[4]

(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, virtually no leaching of FCS under normal environmental conditions is expected when finished films are landfill 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 in the manufacture of films intended for use in contact with food.

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 FCS 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 films 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 films containing the FCS. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, *e.g.,* the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

As noted under Item 6, using very conservative estimation methods, a minute amount of the additive is expected to migrate to food and become a component of the diet as a result of the intended use of the FCS (182 ppb). The only potential source of environmental introductions of the FCS will be due to the consumption and subsequent elimination and disposal via sanitary sewers of these minute amounts of the FCS that may migrate to food.

The results of certain ecotoxicity investigations conducted on the notified chemical are summarized in the following table.[5]

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[4] *See* Annex 1 to this Attachment, "Ecotoxicity Studies"; Final Report, Bioconcentration test of SEED in carp, Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan, September 17, 2001.

Test	Endpoint	Result
Fish Toxicity	48 h & 96 h LC_{50}	> 110 mg/l (both)
Daphnia Toxicity	48 hour EC_{50}	15 mg/l
Algal Toxicity[6]	72 hour E_rC_{50} NOEC	27 mg/l 1.0 mg/l

These results support a conclusion that the notified substance is not harmful to aquatic organisms, and that the undiluted dietary concentration provided in item 6, above, is indeed insignificant.

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 films is not expected to result in a significant net increase in the use of energy and resources mainly because the projected market for the additive is insignificant and is offset by the benefits derived from its use. Specifically, improved stability of melt pressure provided by the FCS allows for more consistent machine currents in film production. Further, the consumption of minute amounts of the FCS that may migrate to food and subsequently be disposed by sanitary sewer is not expected to result in any increase in the use of energy and resources, because the amounts so disposed are insignificant.

Manufacture of the FCS, and its conversion to use in a finished film, will consume energy and resources in amounts comparable to the manufacture and use of other, similar food-contact materials. Furthermore, the finished films in which the FCS is used are not currently recovered for recycling. 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 current materials. Thus, there will be no impact on current or future 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 from the subject FCS, or from the minute amounts of the FCS that may migrate to food, be consumed and subsequently disposed

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[5] *See* Annex 1 to this Attachment, "Ecotoxicity Studies"; 1) Final Report, 96-Hour acute toxicity study of SEED in Medaka, Chemicals Evaluation and Research Institute, Japan, February, 2010; 2) Final Report, A 48-hour acute immobilization study of SEED in *Daphnia magna*, Chemicals Evaluation and Research Institute, Japan, February, 2010; and, 3) Final Report, Algal Growth Inhibition Study of SEED in *Pseudokirchneriella subcapitata*, Chemicals Evaluation and Research Institute, Japan, February, 2010.

[6] Reported results were shown to be due to a combination of the pH of the test solution and the test substance. When the pH was adjusted to the pH of the test medium, the 72 hour E_rC_{50} and the NOEC were 52 and 3.2 mg/l, respectively.

by sanitary sewer. This is primarily due to the minute levels of leaching of potential migrants from the finished article and the insignificant impact on environmental concentrations of combustion products containing 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 that 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 significant environmental impact.

12. List of Preparers

1) George G. Misko, Partner, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, D.C. 20001. Juris Doctorate; Twenty-six years of experience in preparing Environmental Assessments related to Food Additive Petitions and Food Contact Notifications.

2) Mark A. Hepp, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Ph.D. (Chemistry); Fifteen years as a Consumer Safety Officer for the U.S. Food and Drug Administration, Office of Food Additive Safety, and an additional six years of experience preparing Environmental Assessments related to Food Contact Notifications while with Keller and Heckman.

13. Certification

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

[redacted]

Date: February 9, 2018

14. List of References

1. Advancing Sustainable Materials Management: Facts and Figures, Materials and Waste Management in the Unites States Key Facts and Figures (internet summary), U.S. Environmental Protection Agency, November 2016, *available at* https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures.

2. Advancing Sustainable Materials Management: Facts and Figures 2014. Assessing Trends in Materials Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), November 2016, *available at:* https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

3. Ecotoxicity Studies to this environmental assessment; 1) Final Report, 96-Hour acute toxicity study of SEED in Medaka, Chemicals Evaluation and Research Institute, Japan, February, 2010; 2) Final Report, A 48-hour acute immobilization study of SEED in *Daphnia magna*, Chemicals Evaluation and Research Institute, Japan, February, 2010; and, 3) Final Report, Algal Growth Inhibition Study of SEED in *Pseudokirchneriella subcapitata*, Chemicals Evaluation and Research Institute, Japan, February, 2010.

15. List of Attachments

1. Annex 1: Ecotoxicity Studies

2. Confidential Attachment