

Environmental Assessment

1. **Date** November 8, 2019
2. **Name of Applicant/Notifier** BASF Corporation
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4. Description of the Proposed Action

The action requested in this Notification is the establishment of a clearance to permit the use of *bis* (hydrogenated palm-oil alkyl) hydroxyamines (CAS Reg. No. 1374859-51-4) for use as an antioxidant and/or stabilizer in olefin polymers complying with 21 CFR 177.1520(c); intended for single and repeat food contact use. Use of this FCS is needed to minimize changes to the melt flow rate of olefin polymers and copolymers following multiple extrusions.

1. At levels not to exceed 0.1 percent by weight of polypropylene polymers complying with 21 CFR 177.1520(c), item 1.1, 1.2, 1.3, 3.1a (with density of 0.85-0.91 gram per cubic centimeter), 3.2b, 3.4 and 3.5. The finished polymers may be used in contact with: (a) food types I, II, IV-B, VII-B and VIII described in Table 1, under Condition of Use A through H described in Table 2; (b) food types VI-A and VI-B described in Table 1, under Conditions of Use A through C described in Table 2; and food types III, IV-A, V, VI-C, VII-A, and IX described in Table 1, under Conditions of Use B through H described in Table 2.
2. At levels not to exceed 0.1 percent by weight of high density polyethylene polymers and copolymers complying with 21 CFR 177.1520(c), item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.6 (with a density not less than 0.94 gram per cubic centimeter) and 5. The finished polymers may be used in contact with food types I, II, IV-B, VI-A, VI-B, VII-B and VIII under Conditions of Use A through H as described in Tables 1 and 2, and with food types III, IV-A, V, VI-C, VII-A and IX under Conditions of Use B through H as described in Tables 1 and 2.

3. At levels not to exceed 0.1 percent by weight of polyethylene polymers and copolymers complying with 21 CFR 177.1520(c), item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.4, 3.5, and 3.6 (with a density less than 0.94 gram per cubic centimeter). The finished polymers may be used under Conditions of Use B through H described in Table 2.

The FCS is not for use in contact with infant formula and human milk, as these uses were not specifically addressed in the FCN.

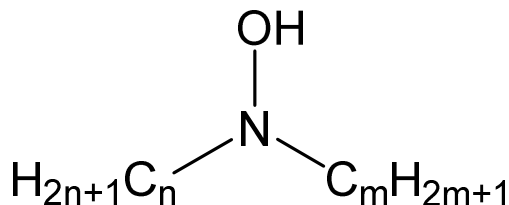
The Notifier does not intend to produce finished food packaging, as the FCS is an additive that is used in the manufacture of articles for food-contact applications. The FCS will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the FCS will 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 resins containing the FCS will occur nationwide. It is estimated that, of the 14,680,000 tons of plastic containers and packaging present in municipal solid waste (MSW) generated in 2015, approximately 68.6% generally was land disposed, 16.8% was combusted, and 14.6% was recovered for recycling.¹

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

Chemical Name: *bis* (hydrogenated palm-oil alkyl) hydroxyamines

CAS Registry Number: 1374859-51-4

Chemical Formula: $C_{36}H_{75}NO$ as di- C_{18} compound



Chemical Structure:

Where:

- a. n is primarily 18, but may also be 20, 16 or 14
- b. m is primarily 18, but may also be 20, 16 or 14
- c. n may or may not be equal to m

¹ United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2015 Tables and Figures, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, July 2018 (Page 9, Table 8). Available at the following website: https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf.

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

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

The Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 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 (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action 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.

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

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Air: (Combustion)

The subject FCS consists of the elements carbon, hydrogen, oxygen, and nitrogen. Thus, carbon dioxide and nitrous oxide are expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide and nitrous oxide from the FCS have been calculated in a confidential appendix to the Environmental Assessment and an assessment of these worst-case releases is also included in the same confidential appendix. To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide and that available nitrogen will be converted to nitrous oxide, and assumed that 16.8% of the market volume will be combusted.

The greenhouse gas (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 EPA under 40 C.F.R. Part 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 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 confidential market volume data, the expected carbon dioxide equivalent (CO₂-e) emissions 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.

Soil and Water:

No significant environmental 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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of food-contact materials manufactured with the FCS. Therefore, the fate of the FCS in the aqueous environment does not need to be addressed.

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. Therefore, the fate of the FCS in terrestrial environments does not need to be addressed.

Landfill:

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 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate. Even if a very small amount of substances leach from the landfilled food-packaging material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

7. Fate of Emitted Substances in the Environment

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. Therefore, an evaluation of the environmental effects of the proposed use of the FCS is not required. In addition, the use and disposal of finished articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors or and Part 258 that pertain to landfills.

8. Environmental Effects of Released Substances

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified under Item 6. Consequently, evaluation of the environmental effects of the proposed use of the FCS is not required.

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 such as petroleum products, coal, and the like. 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 is intended to be used in food-contact resins in place of similar, phenol-free hydroxylamine-based, stabilizers now on the market for use in food-contact applications.

The replacement of other antioxidants and/or stabilizers by the subject FCS in food-contact resins is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, its use in resins, and the final conversion to finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of the stabilizer. Packaging materials produced from resins containing the FCS are expected to be disposed of according to the same patterns when used in place of current materials. Thus, 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 food-contact materials fabricated from the use of 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 which would necessitate alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the currently marked materials; such action would have no significant environmental impact.

12. List of Preparers

Devon Wm. Hill, J.D. and Masters in Chemistry, 20 years of experience related to all aspects of preparing Food Additive Petitions and Food Contact Notifications, Partner at Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

Michael A. Hubbard, Ph.D. in Chemistry, 1 year of experience related to all aspects of preparing Food Contact Notifications, 28 years of total experience in FDA regulated industries. 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: November 8, 2019


Devon Wm. Hill, Partner
Counsel for BASF Corporation

14. List of References

1. United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2015 Tables and Figures, Assessing Trends in Material Generation, Recycling, Combustion with Energy Recovery and Landfilling in the United States*, July 2018 (Page 9, Table 8). Available at the following website:
https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf.

15. List of Attachments

1. Confidential Environmental Assessment.