Environmental Assessment

1 Date

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4 Description of the proposed action

4-1 Requested action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as N,N'-dioleoylethylenediamine (CAS Reg. No. 110-31-6).

The FCS is intended for use as a release agent in copolymers of ethylene and methyl acrylate, complying with 21 CFR, §177.1340 'Ethylene-Methyl acrylate copolymer resins' except for use in contact with infant formula and human milk (see Limitations / Specifications).

Limitations/Specifications For use at a level not to exceed 1,500 ppm in authorized copolymers. Treated copolymers may be used in —— (1) impact-modifier resins, where the treated copolymer comprises up to 20% of the resin in contact with all types of food, for single or repeated use under Conditions of Use (COU) A through H (A-H) as described in Table 2, or (2) multilayer laminated structures, where the treated copolymer comprises up to 1.2 mil (30 µm) of single-use, laminated food-contact articles for all types of food except type V (i.e., low moisture fats and oils) under COU D through H.

4-2 Need for action

The FCS is used as a component of finished food contact articles. The FCS is used as a release agent. The food contact articles include food packaging for both uses (impact modifier resins and multilayer laminated structures) and repeat-use articles such as kitchenware (spatulas, spoons ladles, etc) for only the impact modifier uses.

4-3 Location of Use/Disposal

The Notifier does not intend to produce finished food packaging materials from the FCS.

The notifier manufactures the copolymers of ethylene and butyl, methyl, or ethyl acrylate with or without maleic anhydride or glycidyl methacrylate, that incorporate the FCS. These copolymers are intended to be produced in Europe by SK Functional Polymer SAS.

These copolymers will be then converted into the finished food contact articles by convertors.

Both polymer pellets and finished food contact articles are exported to the US.

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 will occur nationwide.

According to the U.S. Environmental Protection Agency's 2020 update regarding MSW in the United States, of the total 292.4 million tons of MSW generated in 2018, 50.0% was land disposed, 11.8% was combusted with energy recovery , and 32.1% was recovered (a combination of waste recovered for recycling (23.6%) and for composting (8.5%). The remaining 6.1% consists of food that was processed through other food management pathways. **[1]**

As the FCS is used in a resin that is expected to be disposed primarily 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 19.1 % [1] of food-contact materials containing the FCS will be combusted annually.

5 Identification of Substances that are Subject of the Proposed Action

The FCS is a release agent, is already authorized by the FDA for many food contact applications, such as :

§175.300 Resinous and polymeric coatings
§175.320 Resinous and polymeric coatings for polyolefins
§176.170 Components of paper and paperboards in contact with aqueous food
§177.1200 Cellophane
§178.3860 Release agents for use only in polyvinyl chloride films

N,N'-dioleoylethylenediamine is also authorized by FCN 1059 for use at levels not to exceed 0.14 percent by weight in LLDPE with a maximum thickness of 120 µm, which may contact all food types under Conditions of Use A through H, as described in Table 2 of 21CFR §176.170 5(c) (effective date April, 19, 2011) **[2]**

6 Introduction of Substances into the Environment

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. The Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as:

1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment;

2) the action threatening a violation of Federal, State or local environmental laws or requirements,

[1] As the FCS is expected to be disposed primarily 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 19.6% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: 11.8% combusted x 100% / (11.8% combusted + 50.0 % landfilled) = 19.1%

3) production associated with the 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 adverse environmental release is expected upon the use of the subject FCS in food-contact materials. In these applications, the FCS 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 material manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The FCS is composed of carbon, oxygen, nitrogen, and hydrogen, elements that are commonly found in municipal solid waste. Because of EPA's regulations governing landfills (40 C.F.R. Part 258), and the marginal amount of the FCS that would be landfilled only very small amounts of the FCS is expected to be introduced to land, and to an even lesser extent water.

Similarly, because of the composition of the FCS and the low market volume of the FCS, it is not anticipated that combustion of the FCS would threaten a violation of EPA regulations governing MSW combustion facilities (40 C.F.R. Part 60).

As secondary support that disposal of the FCS will not significantly impact the environment, we compared the market volume information for the FCS, contained in the confidential attachment to this Environmental Assessment, to the annual municipal solid waste (MSW) production (292.4 million tons MSW in 2018), and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there is a significant environmental impact resulting from post-consumer disposal of the FCS.

Further, the proposed use of the FCS and corresponding market volume (available in the Confidential Attachment) shows that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which EPA has indicated to be 34.55 million tons, as of 2018 **[1].**

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 (40 C.F.R. Part 60 and/or relevant state and local laws).

As noted above, the 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 as 'non-significant' in a confidential attachment.

The greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of packaging 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 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 equivalents (CO2-e) emission threshold for required reporting.

GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis and is calculated in the **Confidential Attachment** to this EA. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

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 groundwater monitoring systems. 40 C.F.R. Part 258.

Even if a small amount of substances leach from the landfilled food-contact 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

7-1 Air

The FCS, characterized by a high molecular weight (i.e. 588.89 g/mole) is a solid at ambient temperature (Melting point (slip point) = 121-124 °C ([2])). It is not likely to volatilize, due to its high molecular weight (i.e. ca 589 g/mole) and its high expected boiling point **[3].**

Only 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 Municipal Solid Waste) combustion facilities shall be considered**.**

7-2 Water

No significant effects on the concentrations of the FCS and on exposures to the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS as demonstrated in reference **[3]** solubility QSPR studies.

No significant quantities of the FCS will be added to these water systems upon the disposal in landfills of the FCS due to the extremely low levels of aqueous migration of its insoluble components.

No significant quantities of any substances will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills.

7-3 Land

Similarly, no significant effects on the concentration 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 extremely low levels of maximum migration of components of the FCS, demonstrated by its insolubility, indicate that virtually no leaching of the components may be expected to occur under normal environmental conditions when finished food-contact materials are disposed.

Further, the low production volume of food-contact articles containing the FCS precludes any substantial release of its components to the environment (as supported in the confidential attachment). The regulations at 40 C.F.R. 258 prevents MSW components from leaching from landfills.

[2] According to Reach Notifiers : Determination of slip point is a popular method used for waxy solids. This measurement was carried out following the company's own guidelines.

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.

Conclusion: 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 subject FCS in the manufacture of food-contact articles and packaging intended for use in contact with food.

8 Environmental Effects of Released Substances

As discussed previously, we do not expect the FCS to be released to the environment. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS.

9 Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar substances already on the market. In particular, the FCS already is permitted for the same uses as those proposed in this Notification, most notably, effective FCN 1059. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Thus, the energy used for the production of the FCS is not significant.

10 Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of finished 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 significant 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 significant impact.

12 Certification

The undersigned certifies that the information presented is true, accurate and complete to the best of his knowledge

Stéphane PIERRE , PhD

13 List of References

[1] Advancing Sustainable Materials Management: 2018 Tables and Figures, U.S. Environmental Protection Agency, December 2020, Table 1 (Total MSW, 2018), page 4, accessed December 2021, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

[2] Inventory of effective food contact substance (FCS) Notifications Inventory of Effective Food Contact Substance (FCS) Notifications (fda.gov)

[3] ECHA Website N,N'-ethane-1,2-diylbisoleamide - Registration Dossier - ECHA (europa.eu)

14 List of Attachments

Confidential attachment