ENVIRONMENTAL ASSESSMENT

FOOD CONTACT NOTIFICATION

Emery Oleochemicals GmbH

1. Date: **May 25, 2020**

2. Name of Applicant/Notifier

Emery Oleochemicals GmbH

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All communications on this matter are to be sent to:
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3. Description of the Proposed Action

The action identified in this food-contact notification (FCN) is to provide for the use of the food-contact substance (FCS), Ethylene glycol dipalmitate (CAS Reg. No. 624- 03-3), for use as a processing aid for various types of thermoplastics to facilitates mold filling and mold release in injection molding at levels up to 0.4% in the manufacture of plastics made from PVC, and up to 0.2% in the manufacture of plastics made from PC and PLA food-contact articles.

Articles made from PVC and PC will contact all food types under FDA's Conditions of Use A ("High temperature heat-sterilized (*e.g.*, over 212°F)") through H ("Frozen or refrigerated storage")

Articles made from PLA will contact food types under FDA's Conditions of Use D (Hot filled or pasteurized below 66 ºC (150 ºF) through H (Frozen or refrigerated storage; ready prepared foods intended to be reheated in container at time of use.)

The FCS is not for use in contact with infant formula and breast milk because such

uses were not included as part of the intended use of the substance in the FCN.

The FCS is meant to act as a mold release agent for the resins to which it is added. The Notifier does not intend to produce finished food packaging, as the FCS is an additive that is used in the manufacture of resins used for food-contact applications. Resins containing the FCS will then be sold to manufacturers engaged in the production of food- contact articles. Food- contact articles produced with resins 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 of resins containing the FCS will occur nationwide. It is estimated that, of the plastic containers and packaging present in municipal solid waste (MSW) generated in 2017, approximately 69.9% generally was land disposed, 17.0% was combusted, and 13.0% was recovered for recycling.[1]

4. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this notification is ethylene glycol dipalmitate (CAS No. 624-03-3). The product is marketed under the trade name Loxiol® G59.

5. 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, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any significant 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 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 non-hazardous solid waste in accordance with established procedures.

[1] Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, November 2019. U.S. Environmental Protection Agency Report # EPA 530-F-19-007.
See https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf. According to Table 4 of this report, of plastic containers and packaging comprising MSW in 2017, approximately 69.9% was land disposed, 17.0% was combusted, and 13.0% was recovered for recycling.

The subject FCS consists of the elements carbon, hydrogen, and oxygen. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS has 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 "Annex to EA: Estimation of annual GHG."

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 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Section 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.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations in 40 C.F.R. § 1508.27, which define 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. Moreover, 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 appendix 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 constituents are 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 groundwater monitoring systems.[2] 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.

[2] 40 C.F.R. Part 258

6. Fate of Emitted Substances in the Environment

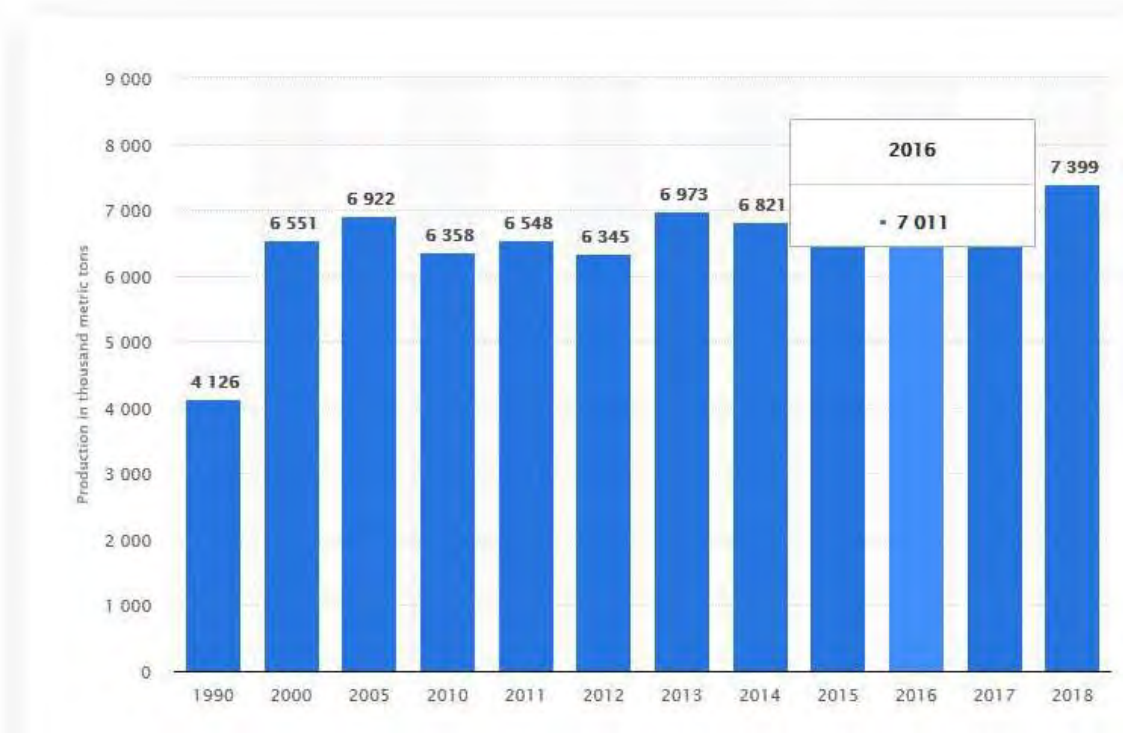
No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject FCS as a result of the use of the FCS as a mould release agent. The FCS is a fatty acid glycol ester and does not readily volatilize during use of the FCS (bp < 500°C), and the analysis discussed above in Item number 5 demonstrates that no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this FCS.

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

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.

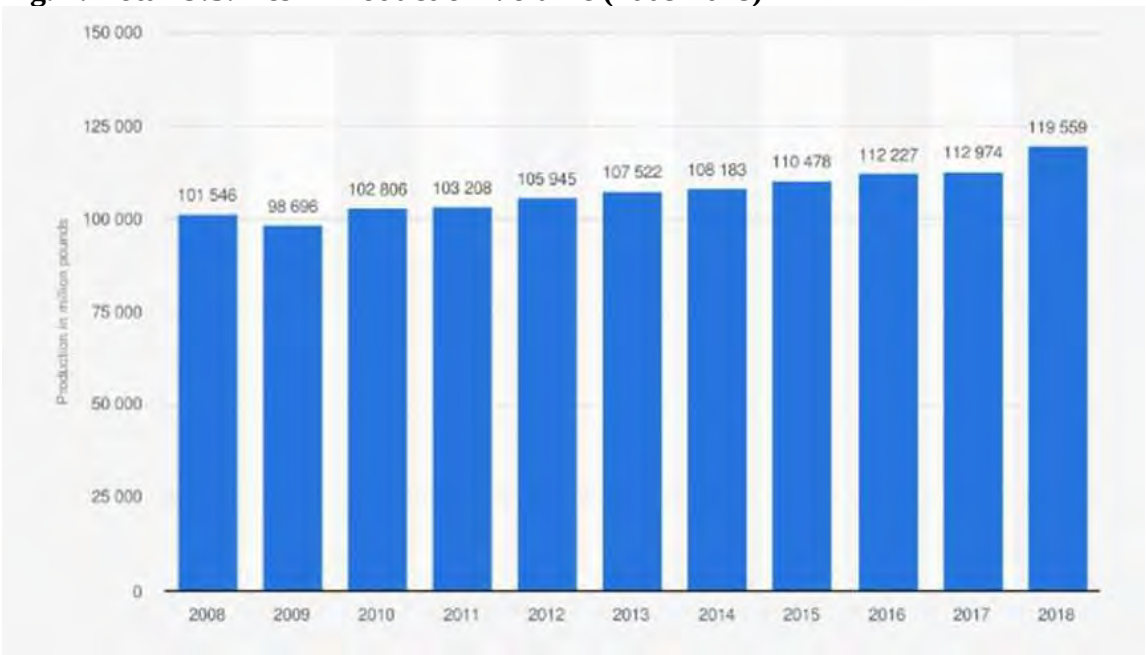
Statistics tell that production levels is more or less constant over the last years (Figs 1 and 2, below). Consequently, new additives entering the market will replace existing products supporting new converter technologies. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Fig. 1: U.S. Polyvinyl Chloride Production Volume (1990-2018)



(in 1,000 metric tons)
Source: www.statista.com/statistics/975603/us-polyvinyl-chloride-production-volume/

Fig. 2: Total U.S. Resin Production Volume (2008-2018)



(in million pounds)
Source: https://www.statista.com/statistics/203398/total-us-resin-production-from-2008/

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 articles intended for use in contact with food.

7. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, 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.

8. 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 natural fats and oils, petroleum and the like.

However, the use of the subject FCS in the fabrication of food-contact materials is not expected to result in a significant increase in the use of energy and resources because growth rates of the plastic market is limited

9. 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 resins 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.

10. Alternatives to the Proposed Action

No 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

environmental impact and because the FCS is expected to compete with, and to some degree replace polymer additives already on the market for use as mold release agents.

11. List of Preparers

Jessica Sieberger, Manager Product Safety & Regulations Emery Oleochemicals GmbH

Ms. Sieberger has a degree in economic chemistry. For the past 10 years she has been working in Product Safety and Regulation for Emery Oleochemicals GmbH where she writes environmental assessments as part of her responsibilities when submitting EU REACH dossiers and EU FOOD CONTACT applications.

12. Certification

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

Manager	Jessica Sieberger
	[redacted]
	Manager Product Safety & Regulations Oleochemicals GmbH
Date	May 25, 2020

13. References

1. Advancing Sustainable Materials Management Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, November 2019. U.S. Environmental Protection Agency Report # EPA 530-F-19-007. Table 4. https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

2. 40 C.F.R. Part 258

3. US PVC production volumes; https://www.statista.com/statistics/975603/us-polyvinyl-chloride-production-volume/

4. Total US resin production volumes; https://www.statista.com/statistics/203398/total-us-resin-production-from-2008/

14. Appendices

Appendix 1: Confidential Environmental Information (CONFIDENTIAL)