Environmental Assessment

1.	**Date:**	February 13, 2024 *
2.	**Name of Applicant/Petitioner:**	Polysecure GmbH
3.	**Address:**	All communications on this matter are to be sent to: Angelique Downey Knoell USA, LLC Address: 2 Christy Dr | Suite 102 | Chadds Ford, PA 19317 | USA Telephone: 919-432-3236 Email: adowney@knoellusa.com

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), identified as diyttrium dioxide sulfide (CAS Reg. No.: 12340-04-4)- doped with lanthanide ions, when used in food-contact materials (FCM).

The FCS is intended for use at levels not to exceed 0.02 % by weight of polymers with the function as a marker-additive for single- or repeat-use food contact articles. The food contact articles containing the FCS may contact all food types under FDA's Conditions of Use B through H [1], as described in Tables 1 and 2. The food contact articles containing the FCS are not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCS.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food contact articles.

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[1] FDA's Food Types and Conditions of Use are defined in Tables 1 and 2 at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature and to reformat for conformance with Section 508 assistive technologies.

B. Need for Action

The FCS is an additive intended to be used as a tracer in all food contact polymers. The food-contact articles include all food packaging and repeat-use articles, as well as disposable food contact materials such as utensils and serving ware, except articles in contact with infant formula and human milk.

C. Location of Use/Disposal

The Notifier does not intend to produce food contact materials or articles from the subject substance. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food contact materials and articles. The FCS is implemented in food contact materials by the customers. Finished food-contact articles 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 food-contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste (MSW) generally. Consequently, there are no special circumstances regarding the release to environment surrounding either the use or disposal of food-contact materials containing the FCS other than the release of SO_2 during incineration in low concentrations.

According to U.S. Environmental Protection Agency (EPA) Advancing Sustainable Materials Management: 2018 Tables and Figures updated in December 2020 [2], in 2018 in the United States, approximately 292,360,000 tons municipal solid waste (MSW) were generated, in which approx. 146,120,000 tons (50.0%) were landfilled; approx. 69,090,000 tons (23.6%) were recycled; approx. 34,550,000 tons (11.8%) were combusted; 24,890,000 tons (8.5%) were composted and approx. 17,710,000 tons (6.1%) were managed by other food management pathways.

As the food-contact materials and articles containing the FCS is expected to be primarily disposed of through combustion, land-filling and recycling (i.e. not composted, or handled through other food management pathways), we have taken the US EPA data as reference and recalculate the possible disposal pattern of food-contact materials and articles containing FCS based on the quantities of MSW that are land disposed, combusted and recycled annually as follows [3]:

a) Combusted: 13.8%,
b) Recycled: 27.7%,
c) Landfilled: 58.5%.

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[2] Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Land and Emergency Management, November 2020, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf

[3] Example of calculation (Combusted): 11.8% Combusted ÷ (11.8 % combusted + 50% land disposed + 23.6% recycled) = 13.8% combusted.

With reference to Table 1 of U.S. Environmental Protection Agency (EPA) Advancing Sustainable Materials Management (2020), 12.2% of total quantity of MSW was plastics, in which 26,970,000 tons of plastic waste was landfilled (Tabel 4, corresponding to 75.5%, 5,620,000 tons were combusted (Tabel 3, corresponding to 15.8%) and 3,090,000 tons recycled (Tabel 2, corresponding to 8.7%). The use of the FCS in food-contact polymers can have a positive impact on the disposal pattern of plastics, accordingly, saving of resources and energy. More details are included in the Confidential Appendix of this environmental assessment report.

5. Identification of the Subject of the Proposed Action

The subject of this notification is diyttrium dioxide sulfide doped with lanthanide ions, as a marker-additive family.

Chemical name: diyttrium dioxide sulfide
CAS Reg. No.: 12340-04-4
Chemical formular: Y_2O_2S

This base substance is doped with doping-elements (dopants), which substitute yttrium (Y) at the yttrium crystal lattice site.

6. Introduction of Substances into the Environment

A. Resulting from the manufacture of the FCS

The FCS is manufactured outside the US. Thus, no manufacturing byproducts will get introduced into the United States 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 materials. Current information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact since the manufacture of FCS will not take place in the United States. Hence, information on the manufacturing site and compliance with relevant emission requirements is not provided in this Notification.

B. Resulting from the use of the FCS

No environmental release is expected when the subject FCS is used in the manufacture of food-contact materials. The FCS is expected to be entirely incorporated into finished food-contact polymers, and essentially all of it is expected to remain completely within these materials throughout the use/disposal of the finished materials and articles by the consumer. Any waste material generated during the manufacture of the finished materials and articles, *e.g.*, production waste, is expected to be recycled by the manufacturer or disposed as part of the manufacturer's overall solid waste in accordance with established procedures.

C. Resulting from the disposal of the FCS

As noted in the Item 4 (c) above, disposal by the ultimate consumer of the finished food-contact materials containing the FCS will be by conventional rubbish disposal and, hence, by sanitary landfill, incineration, or recycling.

The FCS is an inorganic compound consisting of lanthanide ions, oxygen, and sulfur. Upon combustion of the FCS, the lanthanide ion reacts with oxygen forming the relevant inert rare-earth oxides that deposit in slag of incineration followed by landfilling, while sulfur reacts with oxygen forming sulfur dioxide. Based on the elemental composition of the FCS, the worst-case release of sulfur dioxide has been calculated in the confidential appendix to this Environmental Assessment.

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 materials and articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the 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 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. Further, when materials containing the FCS are combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60 and 62, as it is inorganic that does not contain carbon, and release of other GHSs is not expected. The estimated sulfide oxide emission released into the environment is expected to be extremely low (see confidential appendix) and though incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. As such, no significant environmental impacts are anticipated resulting from combustion of materials and articles containing 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 landfilling of food-contact articles, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW 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). 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 actions 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 FCS. The FCS is not expected to readily volatilize. As indicated above in Item 6, even if the FCS were to combust, no significant adverse environmental impacts are anticipated resulting from incineration of the FCS in MSW combustion facilities. The contribution of SO_2 emission though incineration of the FCS will make up an extremely small portion of the total municipal solid waste currently combusted (see confidential appendix). Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

B. Water

The FCS is practically water insoluble and it´s completely incorporated into the plastics. 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 FCS. No significant quantity of the FCS expected to be release to these water systems upon the proper incineration of food-contact materials containing the FCS, nor upon its disposal in landfilling. The fate of the FCS in 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 exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the insolubility of the FCS and its complete incorporation into plastics are expected to result in no meaningful introductions of the landfill leachate under normal environmental conditions when these food contact materials are proper disposed.

Considering the foregoing, the environmental fate 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 was identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed under Item 6 above, 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 only extremely 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.

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 as a marker-additive for food-contact materials and articles is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used as a component of food-contact materials. Usage of the FCS is performed in the same way as with other additives like colorants or pigments or other marking additives for polymers. Accordingly, consumption of energy and resources is similar as with other marketed products. In contrast, the FCS can improve the recycling of food-contacted materials and articles, thereby saving of resources and energy, accordingly (see confidential appendix).

For all of the foregoing reasons, the use of the FCS as described in this Notification will not have a negative impact on energy and resources.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of materials and articles fabricated with the subject FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

No significant adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. We are not aware of a comparable FCS enable to track food-contact materials that is cleared via Food Contact Notification. Therefore, no alternatives to the proposed action can be proposed. If the proposed action is not approved, alternative additive use of other additives may need to be developed. Such action would have no significant environmental impact.

12. List of Preparers

Dr. Xiaohua He, Senior Expert of Ecotoxicology, knoell Germany GmbH, Konrad-Zuse-Ring 25, 68163 Mannheim, Germany, Dr. He has over 15 years of experience in in chemical regulatory consulting and environmental assessments.

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13. Certification

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

Date: 14-Feb-2024

14. List of References

The following footnotes are found within the Environmental Assessment document:

Food and Drug Administration, "Food Types & Conditions of Use for Food Contact Substances," available at: https://www.fda.gov/food/packaging-foodcontact-substances-fcs/food-types-conditions-use-food-contact-substances

Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Land and Emergency Management, November 2020, *available at*: https://www.epa.gov/sites/production/files/202011/documents/2018_ff_fact_sheet.pdf

15. Confidential Appendix