Environmental Assessment

1.	**Date**	March 9, 2021
2.	**Name of Applicant/Petitioner**	Sasol Limited
3.	**Address**	All communications on this matter are to be sent in care of Counsel for Notifier: Cynthia B. Lieberman, Partner Keller and Heckman LLP 1001 G Street, N.W., Suite 500 West Washington, DC 20001 Telephone: 202-434-4114 E-mail: lieberman@khlaw.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), "paraffin waxes and hydrocarbon waxes, oxidized" (CAS Reg. No. 68153-22-0) when used in food-contact materials.

The FCS is intended for use as a component of the following finished food-contact materials:

1. Resinous and polymeric coatings complying with 21 CFR § 175.300;
2. Resinous and polymeric coatings on polyolefin films complying with 21 CFR § 175.320;
3. Coatings for paper and paperboard complying with 21 CFR §§ 176.170 and 21 CFR 176.180;
4. Defoaming agents used in the manufacture of paper and paperboard complying with 21 CFR § 176.210;
5. Cellophane complying with 21 CFR § 177.1200.

Food contact materials containing the FCS may 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: Ready prepared foods intended to be reheated in container at time of use").[1] The finished food-contact materials containing the FCS are not for use in contact with

[1] *See* 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.

infant formula and human milk, as these uses were not included as part of the intended use of the FCS.

B. Need for Action

The FCS is intended to be used as a defoamer in the manufacture of food-contact paper and paperboard and as an additive to food-contact coatings and cellophane. Regarding the defoamer application, the FCS is a wax additive that, based on its chemical composition, exhibits surfactant properties in water, thereby facilitating the destruction and coalescence of foam produced in the wet-end of papermaking operations. Foam control is necessary to avoid drainage problems, paper-formation problems, and to decrease production costs (*i.e.*, deposits, decrease production rate, etc.), for example. Regarding uses of the FCS in food-contact coatings, the FCS provides desirable properties to the finished coatings, which include for example rheology modification, lubricity, gloss, dispersibility, surface refinement, and hardness.

C. Location of Use/Disposal

Finished food-contact materials containing the FCS will be utilized in patterns corresponding to the population density, and they will be widely distributed across the country. Thus, it is anticipated that disposal will occur nationwide. According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solids waste is currently deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting), and 6.1% was directed to other food management pathways.[2] The low use level of the FCS in the production of paper and paperboard will not significantly impact the disposal patterns of the articles on which the FCS is used. In some of the applications, articles containing the FCS may be collected for recycling (*e.g.*, coatings for cans). In most of the above applications, the food-contact materials containing the FCS are not expected to be collected for recycling to a significant extent, except potentially as a part of a mixed plastics recycling stream (*e.g.*, coated polyolefin film).

5. Identification of the Subject of the Proposed Action

The subject of this notification is "paraffin waxes and hydrocarbon waxes, oxidized" (CAS Reg. No. 68153-22-0). The FCS is variable mixtures of long-chain oxygenated hydrocarbons prepared via oxidation of Fischer-Tropsch (FT) waxes and is comprised of the elements carbon, hydrogen, and oxygen. The FCS can be generally described as a mix of long-chain, predominantly normal paraffin hydrocarbons to which oxygenates (*e.g.*, acids, alcohols, ketones, etc.) have been introduced. Total oxygen content of the FCS ranges from 5.1 – 7.7%. Carbon chain lengths of the FCS range from C20 to C105, with a majority of the distributions

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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*: Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov).

> C30. The FCS is chemically analogous to oxidized polyethylene (CAS Reg. No. 68441-17-8), which is a polar reaction product of the mild air oxidation of polyethylene.

6. Introduction of Substances into the 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. The Notifier is not aware of any information to 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 subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

A. As a Result of Use

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

When the FCS is intended for use as a defoamer in the manufacture of food-contact paper and paperboard, potential environmental exposure to the FCS would occur during the papermaking process and from the disposal of the finished paper and paperboard packaging by the end-user. When used as a defoamer, a portion of the FCS will enter the facility wastewater processing system. Effluent from the pulp and paper processing will be treated via wastewater treatment facilities before release into the environment.[3] In determining the environmental impact, we assume that all of the FCS enters the wastewater.

The intended technical effect of the FCS is to control foam produced during the wet-end of the papermaking process. During the wet-end phase of papermaking, the aqueous concentration of solids (fibers and fillers) typically varies between 0.5% and 1% by weight.[4] We consider a solids concentration of 1% in this assessment.

The use level of a typical defoamer in the wet-end may vary from 10 ppm – 0.2% concentration relative to fiber, depending on the needs of the process. The FCS is not likely to

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[3] Water-discharging facilities producing pulp, paper, and paperboard are subject to the U.S. Environmental Protection Agency's effluent guidelines and standards under the Clean Water Act, at 40 C.F.R. Part 430.

[4] Orlando J. Rojas and Martin A. Hubbe, The Dispersion Science of Papermaking, JOURNAL OF DISPERSION SCIENCE AND TECHNOLOGY, Vol. 25, No. 6, pp. 713-732, 2004.

constitute the full defoamer formulation, but we consider as a worst-case here that the FCS compromises 100% of the defoamer. Thus, the aqueous concentration of the FCS in a papermaking facility is anticipated to be no greater than 0.002%, or 20 mg/L.[5] This value represents an overestimate of the environmental introduction concentration (EIC) due to the poor water solubility of oxidized waxes.

In lieu of specific data on the FCS with respect to removal efficiency in conventional wastewater treatment, we consider that the EIC may be fully distributed (*i.e.* 20 mg/mL) in either sludge or in the treated wastewater as a worst-case. If we consider a 10-fold dilution factor for discharge to surface waters,[6] the estimated environmental concentration (EEC) in sludge and treated waters are 20 mg/L and 2 mg/L, respectively.

Sludge resulting from wastewater treatment may end up landfilled or land applied.

B. As a Result of Disposal

Disposal by the ultimate consumer of the finished food-contact materials will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, incineration, or to a minor extent, recovery for recycling.

a. Air

Solid wastes, including disposal by users of food-contact coating and paper products generated with the FCS, are expected to be disposed of by either landfill or incineration.

The FCS consists of carbon, hydrogen, and oxygen, elements commonly found in MSW. 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 11.8% of the food-contact materials manufactured with the FCS will be combusted.

There is the potential for greenhouse gas (GHG) emissions to result from the use and disposal of the FCS during 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 "established 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) described the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO2-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

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[5] (0.01 g-solids/g-water) x (0.002 g-defoamer/g-solids) = 2.0 x 10^{-5} g/g = 20 mg/L.

[6] Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution.* Environmental Toxicology and Chemistry, 7(2), 107-115.

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 estimated market volume of the FCS used in the requested applications, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, 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. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors, as the FCS contains carbon, oxygen, and hydrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

b. Landfill

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 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 ground-water monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active MSW 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.

We compared the confidential market volume information for the FCS, contained in a confidential attachment to this Notification, to the annual municipal solid waste production (292.4 million tons MSW in 2018), 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.

7. Introduction of Substances into 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. As noted in the Confidential Attachment, the molecular weight of the FCS supports that it is negligibly volatile. Paraffin waxes and the like have low vapor pressures. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact paper manufactured with the FCS.

The FCS will make up a very small portion of the total MSW currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating MSW combustors, and incineration of the FCS will not cause MSW combustors to

threaten a violation of applicable emissions laws and regulations. *See* Confidential Attachment for additional details.

B. Water

As noted in Item 6.A., release of the subject substance to water environments based on its use in paper manufacturing facilities is continuous, and therefore, both acute and chronic exposure to aquatic organisms is possible.

No aquatic toxicity test data are available for the subject FCS. However, based on its chemical composition, no significant toxicity is expected for aquatic organisms. The waxes are composed primarily of linear and methyl-branched paraffins to which oxygenate groups (*e.g.*, acids, alcohols, ketones) have been added at low levels (*i.e.*, oxygen content below 7.7%). Carbon chains lengths of the FCS range from C20 to C105, with a majority of the distributions > C30. Therefore, their toxicological properties are comparable to those of common paraffin waxes. Available summary reports on related wax materials report no acute effects at saturation for 1-tetradecene (as a surrogate for paraffin and hydrocarbon waxes, of which are higher molecular weights) for fish (96-h LC50) and invertebrates (48-h EC50) and no chronic toxicity effects at saturation to invertebrates.[7] Therefore, no acute or chronic aquatic toxicity effects are expected due to the proposed use of the FCS when used as a defoamer in the manufacture of food-contact paper and paperboard.

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject FCS when used as a component of food-contact coatings and articles.

C. Land

Sludge containing adsorbed FCS may be landfilled or used as agricultural fertilizer. In the latter case, the concentration of the FCS in sludge is calculated to be no greater than 20 mg/kg. Accounting for dilution with base soils (and the fact that the FCS will not make up the entirety of typical defoamer formulations), the environmental concentration of the FCS is expected to be significantly lower than 20 mg/kg. Data available in summary reports for related wax materials report no effects at saturation for 1-tetradecene for aquatic plants (72/96-h EC50).[8] Due to the comparable chemical composition and higher molecular weight of the FCS to paraffin waxes, no effects are expected due to the proposed use of the FCS.

With regard to environmental introductions as a result of landfilling of sludge and disposal of food-contact materials containing the FCS, the molecular weight of the FCS is

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[7] *See* Screening-Level Hazard Characterization, Waxes and Related Materials Category, *available at:* https://www.petroleumhpv.org/~/media/PetroleumHPV/Documents/Category_Waxes%20and%20Related%20Materials_September_2011.pdf.

[8] *Id.*

expected to result in virtually no leaching of FCS components under normal environmental conditions when the FCS is landfilled. 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.

Based on 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 food-contact paper, coatings, and articles. Therefore, the environmental fate of substances does not need to be addressed because no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, only low levels of the FCS are expected to be released into the environment upon the use and disposal of the FCS. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the use and disposal of the FCS and food-contact materials containing the FCS. In addition, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.,* the EPA's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to MSW combustors and Part 258 that pertain to landfills.

9. Uses 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 and coal. The manufacturer of the FCS will consume comparable amounts of energy and resources as similar hydrocarbon-based defoamers and paraffin or oxidized waxes already being marketed, as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this alternative product will have no significant impact on the use of resources and energy.

Paper products containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used paper products. Because the FCS is used at an exceedingly low level in the manufacture of paper products, and is not expected to remain in the finished paper, there will be no significant 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 the FCS when present in wastewater or in finished paper and paperboard. Further, no significant environmental impacts are expected to result from the use of the FCS in food-contact coatings and articles. Therefore, the FCS is not reasonably expected to result in any significant adverse environmental impacts that require mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified in this assessment that would necessitate alternative actions to those proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would otherwise replace (*i.e.*, oxidized polyethylene and similar defoamers cleared under 21 C.F.R. 176.210 ("Defoaming agents used in the manufacture of paper and paperboard") and similar products cleared *via* Food Contact Notifications; oxidized polyethylene cleared under 21 C.F.R. 177.1620 ("Polyethylene, oxidized")). Such action would have no significant environmental impact.

12. List of Preparers

1. Cynthia B. Lieberman, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Lieberman has over 13 years of experience counseling and representing corporate entities on Food Contact Notifications, including their Environmental Assessments.

2. Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Manning has over 4.5 years of experience preparing Food Contact Notifications, including Environmental Assessments.

13. Certification

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

Date: March 9, 2021

Cynthia B. Lieberman
Counsel for Sasol Limited

14. List of References

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.

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*: Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov).

3. Orlando J. Rojas and Martin A. Hubbe, The Dispersion Science of Papermaking, JOURNAL OF DISPERSION SCIENCE AND TECHNOLOGY, Vol. 25, No. 6, pp. 713-732, 2004.

4. Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution.* Environmental Toxicology and Chemistry, 7(2), 107-115.

5. Screening-Level Hazard Characterization, Waxes and Related Materials Category, *available at*: https://www.petroleumhpv.org/~/media/PetroleumHPV/Documents/Category_Waxes%20and%20Related%20Materials_September_2011.pdf.

15. Attachments

1. Confidential Attachment