Environmental Assessment

1. Date May 2, 2024 *

2. Name of Applicant/Notifier Valtris Specialty Chemicals

3. Address All communications on this matter are to be sent in care of Agent for Notifier: Mark McDaniel, AlterEcho, 112 N. Rubey Dr. Suite 200 Golden, CO 80401 Telephone: (303) 589-9766 Email: Mark.McDaniel@AlterEcho.com

4. Description of the Proposed Action

A. Requested Action

The action requested in this Notification is to permit the use of the Notifier's food-contact substance (FCS), Valtris Santicizer® Platinum INT-7000, a plasticizer for polyvinyl chloride (PVC), which is composed of 2-ethylhexyl epoxy soyate (EHES; CAS Reg. No. 68082-34-8). The FCS will be used at levels up to 20 percent by weight in polyvinyl chloride food contact articles with a thickness of 0.5 mil to 2 mil (0.0005 inch to 0.02 inch). The finished product containing the FCS will contact food under Conditions of Use C ("Hot filled or pasteurized above 150°F") through G ("Frozen storage (no thermal treatment in the container)")[1] The finished plasticizer containing the FCS is not for use in contact with infant formula and human milk, as these uses are not addressed in the FCN.

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 food-contact article manufacturers. Note that Section 409 of the Federal Food, Drug and Cosmetic Act defines an FCS as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. As such, Santicizer® Platinum INT-7000 is an FCS, not a food additive.

[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 corrections of an editorial nature and to harmonize the EA to the final FCN regulatory language.

B. Need for Action

The FCS is intended to be used as a plasticizer for PVC products that contact food. The FCS functions to intercalate the rigid polymer structure of PVC for easy movement and flexibility. The food-contact articles may include food packaging and repeat-use articles, as well as disposable food-contact materials such as utensils and serving ware.

C. Location of Use/Disposal

Finished 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. Thus, it is anticipated that disposal will occur nationwide. It is estimated that, of the 14,530,000 tons of plastic packaging present in municipal solid waste (MSW) generated in 2018, approximately 69.5% generally was land disposed, 17.0% was combusted, and 13.6% was recovered for recycling[2] The use of the FCS in food-contact materials will not significantly impact the disposal patterns of the articles in which they are used.

The types of environments present at and adjacent to these disposal locations are the same as that for the disposal of any other food-contact material in current use. Thus, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the subject FCS.

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

The FCS that is the subject of this Notification, Valtris Santicizer® Platinum INT-7000, is 2-ethylhexyl epoxy soyate (EHES; CAS Reg. No. 68082-34-8). It is variously referred to as fatty acids, soya, epoxidized, 2-ethylhexyl esters or as epoxidized 2-ethylhexyl soyate. It is a synthetic epoxidized soya fatty acid monoester derived from vegetable oils. Soya fatty acids (SOFA) are commonly comprised of the following fatty acids in the following approximate amounts: palmitic (12%), stearic (6%), oleic (27%), linoleic (51%), and linolenic (4%). The specific chemical formulas and molecular weights of the fatty acid are described in Form 3480, Section 2A. The distribution of fatty acid-based epoxidized esters will be the same in the FCS, and the representative fatty acids in SOFA are listed in Table 1 below.

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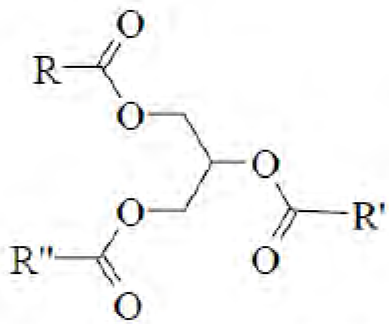
[2] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Land and Emergency Management, November 2020,* available at: https://www.epa.gov/sites/production/files/2020-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

Figure 1 Epoxidized soybean oil Representative Structure:



Where R, R' and R'' = an epoxidized hydrocarbon chain

Table 1 Representative Fatty Acids in Soya Fatty Acids (SOFA)

Fatty Acid	Name	Structure	Designation
Palmitic	Hexadecanoic acid	$CH_3(CH_2)_{14}CO_2H$	16:0
Stearic	Octadecanoic acid	$CH_3(CH_2)_{16}CO_2H$	18:0
Oleic	Cis-9-Octadecenoic acid	$CH_3(CH_2)_7C=C(CH_2)_7CO_2HCH_3(CH_2)_7CO_2H$	18:1
Linoleic	Cis, cis-9,12-Octadecadienoic acid	$CH_3(CH_2)_4C=C-C=C(CH_2)_7CO_2H$	18:2
Linolenic	Cis-9,12,15-octadecatrienoic acid	$CH_3CH_2C=CCH_2C=CCH_2C=C-(CH_2)_7CO_2H$	18:3

The preparation of INT-7000 (2-ethylhexyl epoxy soyate CAS# 68082-34-8) is as follows:

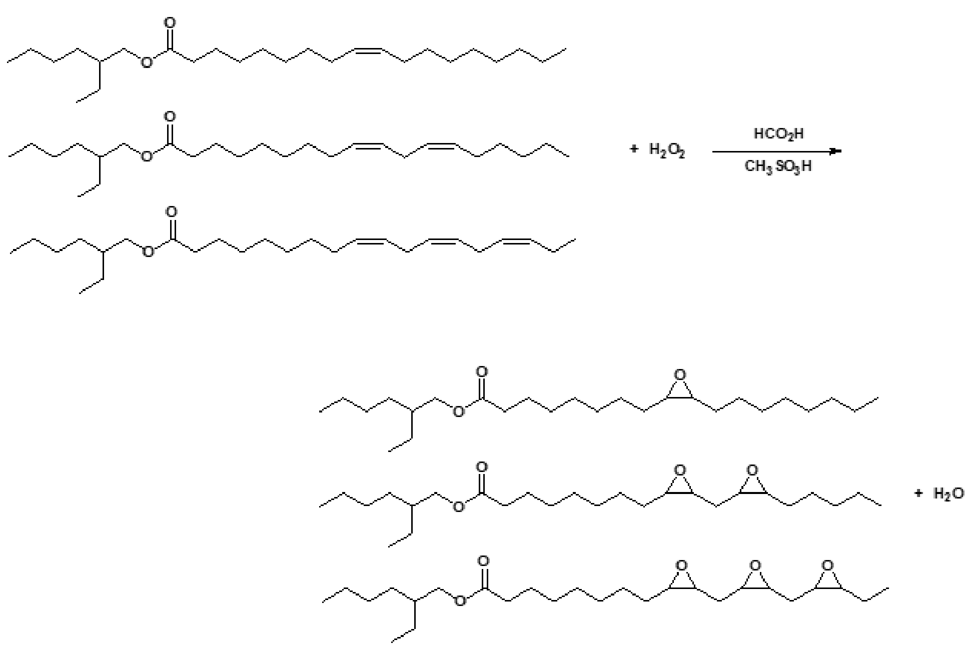


Table 2. Stoichiometry and Batch Charges

Raw Material	Mol Wt.	Equivalent	Kmol	Weight (lb.)
2-Ethylhexyl soyate (V-1000)	390.00	1.000	43.21	37152
H_2O_2, 70%	34.01	1.824	78.82	8442
HCO_2H, 65%	46.03	0.144	6.22	971
Methanesulfonic acid, 70%	99.11	0.004	0.17	54

Reaction Conditions

1) **Pre-treatment**: 2-Ethylhexyl soyate (37152 lb.) is treated with a mother liquor (mother liquor consists of leftover reactants from the previous batch. Typical concentration is 15-25% Hydrogen peroxide, 5-10% Formic acid and 65-80% water) After settling, layers were separated. The aqueous layer is disposed to the waste plant and the oil layer is transferred to another vessel for the main reaction.

2) **Main Reaction**: To the above pretreated 2-Ethylhexyl soyate, are simultaneously charged 65%formic acid (971 lb., pre-mixed with 54 lb. of 70% methanesulfonic acid) and 70% hydrogen peroxide (8456 lb.). The mixture was agitated at 65°C for a total of 10 hours.

Purification

The reaction mixture is settled, and phases are separated. The aqueous player is charged to the next batch for pretreatment to reduce the hydrogen peroxide level prior to disposal to the waste plant. The oil layer is washed with water (including a dilute caustic soda wash (NaOH)) to remove the residual fatty acids. The washed oil is steam distilled under reduced pressure to further reduce residual 2-hexylhexanol which has been carried over from soya fatty acid. The oil is polish filtered to furnish epoxidized 2-Ethylhexyl soyate.

6. Introduction of Substance Into the Environment

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, according to 21 CFR § 25.40(a). 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; or 3) production associated with a 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 environmental release is expected upon the use of the FCS to fabricate food packaging materials, as it will be incorporated into the finished food-contact article and is expected to remain in that article through use and disposal. Any waste materials produced in this process are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal of the food packaging materials containing the FCS by the ultimate consumer will be by conventional garbage disposal and, thus, primarily by sanitary landfill or incineration. The subject FCS contains carbon, hydrogen, and oxygen, which are elements commonly found in municipal solid waste. The proposed use of the FCS and market volume data show that (1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 46.2 million tons, or 15.8% of 292.4 million tons in 2018, as noted in Footnote [2]); (2) the FCS will not substantially alter the emissions from properly operating municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 CFR §60 and/or relevant state and local laws).

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 ("EPA") under 40 CFR 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 CFR § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalents (CO_{2Eq}) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment. The expected $CO2_{Eq}$ 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 adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

For calculation purposes, we assume that the FCS is used in all possible PVC resin used in Containers and Packaging as described in Table 8 of Advancing Sustainable Materials Management: 2018 Tables and Figures - Assessing Trends in Materials

Generation and Management in the United States. December 2020 (see https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf) and that combustion it is spread among 77 U.S. MSW incinerators (see Energy Recovery Council 2016 report http://energyrecoverycouncil.org/wp-content/uploads/2016/06/ERC-2016-directory.pdf). Because the rates of recycling combustion and landfilling for containers and packaging made from PVC resins are not provided, we assume that PVC items containing the FCS will be disposed at proportions similar to those of overall plastic containers and packaging. The calculation is as follows:

Total Plastics in Containers & Packaging (all resins) recycled is (2460 / 14,530) thousand tons × 100 = 17 %

Total PVC used in plastic containers and packaging is 390,000 tons

Amount Combusted: 17% × 390,000 = 66,300 tons

FCS will comprise up to 20% of PVC = 20% × 66300 = 13260 tons of FCS combusted

Percentage of Carbon in FCS (assuming it is mostly linoleic acid) 77 %

Total C combusted is 77% × 13260 tons = 10210 tons x (0.907 mT/ton) = 9261 mT

Total possible GHG emissions [i] (Total CO2-e) = approx. 33957 metric tons / 77 combustors = 441 mT/y.

This expected GHG emission is below the 25,000 metric ton threshold for mandatory reporting under EPA's GHG reporting program.

Only extremely small amounts of the polymer constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles in accordance with the EPA's regulations governing municipal solid waste landfills. EPA requires 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 groundwater and surface water, as well as for them to have groundwater monitoring systems in accordance with 40 CFR § 258.

7. Fate of Emitted Substances in the Environment

a. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere is anticipated due to the proposed use of the subject FCS. The FCS does not volatilize. Therefore, no significant quantities of any substances will be released upon the use and disposal of food-contact articles with this polymer.

Also, as indicated in Section 6 above, the FCS will make up a very miniscule portion of the total municipal solid waste currently combusted, will not substantially alter the emissions from properly operating municipal solid waste combustors, and will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations when it is incinerated.

b. Water

No significant introductions of substances into the environment were identified in Section 6. Therefore, no substantial effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are expected due to the proposed use of the subject FCS. As such, is it not necessary to discuss the impacts or fate of the FCS in the aqueous environment. However, for comparative purposes, the following discussion relates to the biodegradation of ESBO and 2-ethylhexyl epoxy soyate (EHES) in the aquatic environment.

OECD (2006) reports on the biodegradation of both epoxidized tall oil (ETO) and ESBO in standardized biodegradation tests. ETO is used for this read-across to EHES as they are structurally similar (i.e., both epoxidized ethyl hexyl molecules esterified to a C-18 fatty acid chain). As with ESBO and EHES, ETO has a variable structure, however, more than half of the fatty acid portion is oleic (single unsaturation at C9-10), leading to a single epoxide.

ETO biodegradation was measured in a stirred, manometric biodegradation test following OECD guideline 301F. Due to the low solubility of ETO, silica gel was used to increase the surface area of ETP in the test, resulting in 70% degradation in 28 days (OECD, 2006). In a second study conducted using the older American Public Health Association (APHA) closed bottle procedure (non-stirred), 21% degradation of ETO occurred after 20 days. OECD indicated that the lack of stirring and low biomass in the APHA method lead to low biodegradation of ETO and they concluded that ETO is likely readily degradable.

Conversely, testing with ESBO found it to be readily biodegradable (79% after 28 days; OECD 301B (stirred respirometry test) in a standard CO2 evolution test (OECD, 2006). In a second study using methods from APHA and an acclimated inoculum, ESBO was not readily biodegradable, yielding 24% biodegradation in 20 days. No degradation was observed with an unacclimated inoculum (OECD, 2006). Given questions about the biomass used in the second study, and ready degradation in the first, OECD concluded that all chemicals in the epoxidized oil category should be assumed to be readily biodegradable; discrepancy in results among these biodegradation studies can be attributed to differences in inoculum density, and more importantly, the degree to which the insoluble test substance is dispersed in the aqueous test mixtures. In a report to the Danish EPA, available environmental data on ESBO were reviewed and the authors concluded that ESBO is readily biodegradable (Stuer-Lauridsen et al. 2001).

In conclusion, testing of ESBO and EHES finds that both are readily biodegradable using modern testing methods. It is likely that the rate and extent of solubilization and/or formation of low mass microemulsions are important determinants of the rate of biodegradation in these tests and in the environment. It appears that low level releases of ESBO and EHES into acclimated environments will lead to rapid biodegradation. However, releases of large quantities of either oil into unacclimated environments will lead to slow biodegradation and will depend on solublization rates and rates of formation of microemulsions.

c. Land

Considering the factors discussed in the above sections, no substantial effects on the concentrations of and exposures to any substance in terrestrial ecosystems are expected as a result of the proposed use of the subject FCS. Specifically, given the nature of the food-contact substance, it is expected that there will be essentially no leaching of the components or biodegradation products of the FCS under normal environmental conditions when finished food-contact materials are disposed. Moreover, the very low production of the FCS for use in food-contact applications precludes any significant release to the environment of its components. Therefore, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Furthermore, considering the above sections, 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 articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed earlier, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the FCS consist of significantly small quantities of combustion products and extractables, if any at all. Therefore, no adverse effects on organisms in the environment is expected as a result of use and/or disposal of the FCS because, as discussed under Section 6, only extremely small quantities, if any at all, of substances will be introduced into the environment as a result of the use and/or disposal of the FCS. Thus, the use and disposal of the FCS are not anticipated to threaten a violation of applicable laws and regulations, for example, EPA’s regulations in 40CFR § 60 and 258.

9. Use of Resources and Energy

The production, use, and disposal of the subject FCS involves the use of natural resources such as petroleum products, coal, and the like, similar to other food packaging materials. However, the use of the subject FCS in the fabrication of food-contact materials is not anticipated to result in a net increase in the use of energy and resources, as the FCS is intended to be used in place of similar plasticizers now on the market for use in food packaging applications. The manufacture of the FCS and its further conversion to finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of the plasticizers the FCS would replace.

In addition, the use of the FCS is not expected to have any impact on current or future recycling efforts. EPA resin-specific data for plastic materials used in containers and packaging show that recycling of PVC food-contact articles is negligible [Advancing Sustainable Materials Management: 2018 Tables and Figures, Table 8. Available at https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf] so impacts to recycling of packaging materials are not anticipated. However, if recycled, we assert that PVC containing the FCS would be as recyclable as unmodified PVC and PVC containing other approved plasticizers. Therefore, the proposed use of the polymer is expected to have no adverse impact on current or future recycling programs for packaging materials.

10. Mitigation Measures

As discussed above, no substantial adverse environmental impacts are anticipated to result from the intended use and disposal of food-contact materials fabricated from the subject FCS. The only potential adverse environmental impacts would be those resulting from the use and disposal of articles containing the subject FCS. Also as discussed above, no substantial effects on the environment are expected, primarily due to the low levels of migration of FCS constituents, as well as the similarity between this FCS and other currently cleared plasticizers with which it is intended to compete. Therefore, the use of the FCS as proposed is not reasonable anticipated to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

Because there are no significant adverse environmental effects identified herein, no alternative actions to the proposed notification need be necessitated. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject FCS would otherwise replace; such impact would have no environmental effect.

12. List of Preparers

Mark McDaniel, AlterEcho

Ann Schnitz, Ph.D., AlterEcho

13. Certification

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

Date: May 2, 2024

Mark McDaniel
Alter Echo Project Manager for
Valtris Specialty Chemicals

14. List of References

The following footnotes are found within the Environmental Assessment Document:

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: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf

Other References

Organisation for Economic Co-operation and Development (OECD). 2006. Epoxidized Oils and Derivatives. SIDS Initial Assessment Report for SIAM 22, Paris, France, 18-21 April 2006, 173p.

Stuer-Lauridsen, F, S Mikkelsen, S Havelund, M Birkved, LP Hansen. 2001. Environmental and Health Assesment of Alternatives to Phthalates and to flexible PVC. Environmental Project No. 590, Miljøprojekt, pp. 107-111.

[i] Greenhouse gas emissions based on calculations at EPA Greenhouse Gas Equivalencies Calculator. https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator#results