Environmental Assessment

1. Date October 12, 2022

2. Name of Applicant Omya International AG and its Affiliates

3. Address Communications to be sent care of:

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4. Description of Proposed Action

The action requested in this Food Contact Notification (FCN) is to permit the use of the substance 2-Propenoic acid, polymer with 2,5-furandione, sodium salt (CAS # 52255-49-9) (hereinafter MAPA, the food contact substance, or FCS) as a component of fillers or mineral coatings for food-contact paper and paperboard. When the paper and paperboard is used in contact with food, the FCS may be used at a maximum rate of 0.07 weight-percent in the finished paper under the 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") as described in FDA's Tables 1 and 2. [1]

The FCS is intended for use as dispersion agent for calcium carbonate that, in turn, is used as a filler and coating during the paper manufacturing process. The processing benefits provided by the FCS result in increased brightness, opacity, and cost-efficiency.

Omya does not manufacture the paper pulp or paper and paperboard that could contain the FCS. Instead, Omya plans to market the FCS-containing calcium carbonate to paper and paperboard mills in the United States. Finished articles containing the FCS are expected to be utilized in patterns corresponding to the national population density and widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide. According to the U.S. Environmental Protection Agency's (EPA) 2018 update regarding municipal solid waste in the United States, which is the most recent data available, 68.2% of paper and paperboard materials in MSW were recycled, leaving 25.6% of paper MSW for disposal in landfills or elsewhere and 6.2% for combustion. [2] More detailed data are provided by EPA on the recycling, combustion, and landfilling specifically of containers and packaging. [3]

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[1] U.S. Food and Drug Administration, Food Types & Conditions of Use for Food Contact Substances, *available at:* https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

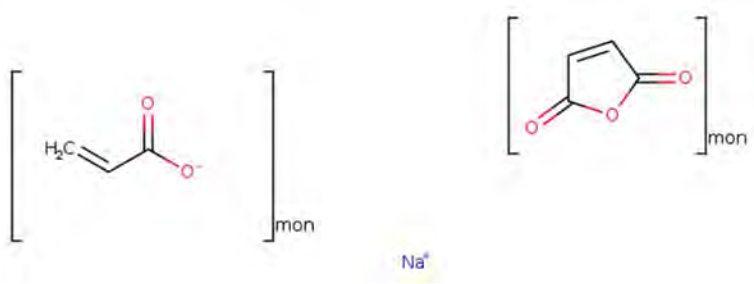
[2] *See* U.S. Environmental Protection Agency (EPA), "Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States" (EPA530-F-20-009) December 2020, Table 1, *available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

[3] *Id.*

These data indicate that 20.8% are recycled and of the remaining generated waste, 15.5% (1,340 of 8,640 thousand tons generated) was combusted and 63.7% (5,500 of 8,640 thousand tons generated) was landfilled. [4]

5. Identification of Substances that are Subject of the Proposed Action

The FCS is 2-Propenoic acid, polymer with 2,5-furandione, sodium salt (CAS # 52255-49-9):



The FCS is intended for use as dispersion agent for calcium carbonate that, in turn, is used as a filler and coating during the paper manufacturing process. The typical physical and environmental properties for MAPA are as follows:

Table 1: Physical and Environmental Properties of MAPA

Property	Value [5]
Appearance	Yellowish, amber viscous liquid
pH (at 20°C)	7.5 ± 1 (measured)
Specific gravity	1.27 ± 0.02 (measured)
Melting point	> 150°C (decomp)[a]
Boiling Point	Not applicable[a]
Vapor pressure	Not applicable[a]
Water Solubility	> 40% (> 400g/L)[a]

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

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. The FCS may be manufactured in plants both inside and outside of the United States. When manufactured in the U.S., the plants meet all applicable federal, state and local environmental

[4] Advancing Sustainable Materials Management: 2018 Tables and Figures Assessing Trends in Materials Generation and Management in the United States, December 2020, Table 5, *available at:* https://www.epa.gov/sites/production/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf.

[5] The values marked with "a" are sourced from Human and Environmental Risk Assessment (HERA) on Ingredients of European Household Cleaning Products, Polycarboxylates used in detergents (Part II) Polyacrylic/maleic acid copolymers and their sodium salts (CAS 52255-49-9), 2014, *available at:* https://www.heraproject.com/files/HERA_P-AAMA_final_v3_03032014.pdf.

regulations.

Notifier asserts that there are no extraordinary circumstances that would indicate the potential for significant 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 significantly 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.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

The FCS is intended for use as dispersion agent for calcium carbonate that, in turn, is used as a filler and coating during the paper manufacturing process. Omya plans to market the FCS- containing calcium carbonate to paper and paperboard mills in the U.S. Potential environmental exposure would occur during paper processing and when the paper and paperboard products, themselves (as packaging), are disposed by the user.

Waste Water:

We will assume that all of the FCS used in the filler application will enter the facility waste water processing system. Paper processors are among those industries required by EPA to meet industry specific effluent pretreatment standards. [6] Effluent from the pulp and paper processing is expected to be disposed of through the processing plant's onsite wastewater treatment facility before discharge either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to a publicly-owned treatment works (POTW). [7] The intended technical effect of MAPA is to increase dispersion of the calcium carbonate filler added to food contact paper in order to increase brightness and opacity. A major application is in the production of bleached paper products. [8] Bryant, *et al*. have analyzed water use in paper and paperboard production based on process and product type. [9] Although this reference does not

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[6] https://www.epa.gov/npdes/pubs/pretreatment_program_intro_2011.pdf and see table of regulated industries at http://www.epa.gov/eg/industrial-effluent guidelines.

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

[8] Grönfirs, J., Use of Fillers in Paper and Paperboard Grades, Final Thesis, Tampere University of Applied Sciences (May 2010), pp. 23-25, *at:* https://theseus.fi/bitstream/handle/10024/16226/Gronfors_Jarkko.pdf?sequence=1, which discusses the types of cartonboard typically used in food contact applications and identifies them primarily as using bleached chemical pulp.

[9] Pulp and Paper, 2001 pg 36 and EPA Office of Compliance Sector Notebook Project Profile of the Pulp and Paper Industry 2nd Edition, November 2002.

specifically address the production of food contact paper, it does report information on the water use in various types of mills, including integrated pulp and paper mills, bleached kraft market pulp mills, and paper mills producing more and less than 100 tons paper/day. [10] The reported median water use levels for these types of facility (in thousands of gallons per short ton) are 22.9, 23.0, 3.6 and 12.0, respectively. [11] The report notes that specialty grade mills may have very high water use relative to other mills in their category, [12] which would include some mills producing food contact papers. In describing the water consumption rate data for paper mills producing greater than 100 air-dried short tons (ADST) per day, Bryant, *et al.* states, "[of] the 11 categories analyzed, mills producing paper and board with production rates greater than 100 tons/day had the lowest median water use at 3,600 gallons/ton." The histogram for this mill category (Fig. 3) shows that 14% of mills in this category (218 × 14% = 31 mills) use less than or equal to 1,000 gal/ton and 54% of these mills (218 × 45% = 118 mills) use less than or equal to 4,000 gal/ton per day. As summarized above, a reasonable conservative water consumption rate would be 1,000 gal/ton/day.

Assuming 1,000 gal/ton, the calculated daily water use would be:

1,000 gal/short ton paper x 3.785 L/gal x 1 kg water/L water = 3,785 kg water

The presence of MAPA in the wastewater is anticipated only as a result of the filling application. The coating is applied during the dry-end of production (*i.e.,* to the dried sheet) using a blade coating system. In Omya's experience, the only loss of water-containing MAPA from the coating application would be minor losses to evaporation, while excess coating is returned to the system for reuse. The use level requested for the MAPA in the filler application is 0.07% by weight relative to the weight of the finished paper. This equates to 700 g of MAPA being used per metric ton of paper produced, equivalent to 636 g/short ton. [13] The level of MAPA in the water is therefore calculated as:

636 g MAPA/short ton paper ÷ 3,785 kg water/short ton paper/day =
0.168 g MAPA/kg water/day = 168 ppm

The polycarboxylate copolymer of acrylic acid and maleic acid (P-AA/MA) chemical class has been shown to be eliminated from sewage treatment plants through precipitation and adsorption processes at 90% worst case assumption (HERA, 2014). Therefore, for the purposes of this Environmental Assessment (EA), it will be assumed that this worst-case elimination process will occur, in which 90% of the FCS will distribute primarily to the pulp material with a smaller fraction as a component of solid wastes, or sludge, produced by the waste water treatment process. Therefore, the expected introductory concentration (EIC) of the FCS in the effluent/waste water is estimated to be 10% of the 168 ppm, or 16.8 ppm. These water effluent concentrations are conservative as they do not take into account water recycling, reclamation during on-

[10] *Id.*, Table 2.

[11] *Id.*

[12] *Id.*, p. 2.

[13] 700 g ÷ 1.1 short ton/metric ton = 636 g.

site chemical recovery processes, sorption onto white and waste water sludge produced on-site, or during waste water processing treatment through publicly owned water treatment facilities. A ten-fold dilution factor is applied to discharge to surface waters. [14] Additionally, in the aquatic environment, the FCS would partition predominantly to solids (approximately 90%) with only a fraction (10%) remaining in the surface water (*see section 7 for further discussion*). Therefore, for purposes of this EA, a worst-case maximum expected environmental concentration (MEEC) of the FCS into the environment via surface water is the EIC for the FCS in white water effluents from pulp manufacturing (16.8 ppm) divided by a 10-fold dilution factor via water treatment facilities multiplied by the removal factor (1-0.9 = 0.1), which is equivalent to 0.168 ppm.

Air (Combustion):

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

The FCS consists of carbon, hydrogen, oxygen, and sodium, elements commonly found in municipal solid waste. 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 assumed that 15.5% of the market volume 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. The GHG emissions resulting from the use and disposal of the FCS relate to 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 "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 CO_2-e emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we 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 attachment to the EA, are below 25,000 metric tons on an annual basis. Because 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.

Landfill:

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of finished articles containing the FCS. 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

[14] Rapaport, R.A., 1099. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7:107-115.

Table 2: Acute Aquatic Ecotoxicity of P-AA/MA

Mean MW [g/mol]	**Test Species**	**Method**	**LC/EC$_{50}$** [mg/L] **(Exposure Time)**	**Reliability**	**Reference**
Acute Toxicity to Fish					
12,000	*Brachydanio rerio*	OECD 203 (range finding)	> 200 (96 hr)	1	Procter & Gamble, 1982 [a]
50,000	*Leuciscus idus*	DIN 38412 part L15	> 500 (96 hr)	2	BASF AG, 1987 [c]
70,000	*Brachydanio rerio*	OECD 203 (range finding)	> 100 (96 hr)	1	Procter & Gamble, 1982 [b]
100,000	*Brachydanio rerio*	OECD 203	> 100 (96 hr)	1	BASF AG, 2002 [a]
Acute Toxicity to Aquatic Invertebrates					
12,000	*Daphnia magna*	OECD 202 (range finding)	> 200 (48 hr)	1	Procter & Gamble, 1984 [f]
70,000	*Daphnia magna*	OECD 202 (range finding)	> 100 (48 hr)	1	Procter & Gamble, 1982 [b]
70,000	*Daphnia magna*	OECD 202	> 500 (48 hr)	1	BASF AG, 1985
100,000	*Daphnia magna*	OECD 202	> 100 (48 hr)	1	BASF AG, 2002 [b]
Acute Toxicity to Algae					
70,000	Scenedesmus subspicatus	OECD 201	> 500 (96 hr)	1	BASF AG, 1985 [c]
70,000	Chlorella vulgaris	OECD 201	> 500 (96 hr)	1	BASF AG, 1987 [g]
100,000	Scenedesmus subspicatus	OECD 201	> 100 (72 hr)	1	BASF AG, 2002 [c]

Reliability criteria of IUCLID according to Klimisch et al. (1997) are used:
1 = valid without restriction; 2 = valid with restriction; 3 = not valid; 4 = validity is not assignable.

Table 3: Chronic Aquatic Ecotoxicity of P-AA/MA

Mean MW [g/mol]	Test Species	Method	LC/EC$_{50}$ [mg/L] (Exposure Time)	Reliability	Reference
Chronic Toxicity to Fish					
70,000	*Brachydanio rerio*	OECD 204	100 (14 days)	2	BASF AG, 1986 [a]
70,000	*Brachydanio rerio*	OECD 210	100 (42 days)	1	BASF AG, 1986 [b]
Chronic Toxicity to Aquatic Invertebrates					
70,000	*Daphnia magna*	OECD 202	350 (21 days)	1	Procter & Gamble, 1986 [b]
70,000	*Daphnia magna*	OECD 202	6.2 (21 days)	1	BASF AG, 1986 [n]
70,000	*Daphnia magna*	OECD 202	7.5 (21 days)	1	BASF AG, 1985 [c]
70,000	*Daphnia magna*	OECD 202	3.75 (21 days)	1	BASF AG, 1985 [f]
Chronic Toxicity to Algae					
70,000	Scenedesmus subspicatus	OECD 201	EC$_{10}$ = 32 (96 hr)	4	Schumann, 1990
100,000	Scenedesmus subspicatus	OECD 201	37.2 (72 hr)	1	BASF AG, 2002 [c]

Reliability criteria of IUCLID according to Klimisch et al. (1997) are used:
1 = valid without restriction; 2 = valid with restriction; 3 = not valid; 4 = validity is not assignable.

Per HERA (2014), the copolymers of acrylic/maleic acid have a favorable ecotoxicological profile; however, it is important to note the limitations of the available data. For the acute data noted in Table 2, all of these values are not exact. Notably, for all of the available ecotoxicity studies on fish, *Daphnia*, and algae, the L(E)C50 could not be determined because the effect values were above the highest tested concentration.

Acute toxicity to aerobic bacteria, and soil and terrestrial organisms is low for MAPA, [16] in general, but the aquatic data are insufficient for deriving a reliable risk quotient (RQ). [17] First, these data are "unbounded" (not true values as explained above) and highly variable for all organisms tested (in contrast, the chronic data do not display the same variability, are more robust, and are more useful for deriving a RQ for the most sensitive aquatic species, i.e., *Daphnia*). Second, the solubility of MAPA in the environment (i.e., not in the distilled water that can be used in lab studies) is extremely low at the anticipated environmental concentration calculated above (i.e., 0.168 ppm). At water concentrations below 25 ppm, MAPA is predominantly present in insoluble precipitate form, due to the co-polymers precipitating out of solution as a calcium salt. [18] Furthermore, at MAPA water concentrations of < 10 ppm, the gastroenteric tract of *Daphnia*.

[16] Human and Environmental Risk Assessment (HERA) on Ingredients of European Household Cleaning Products, Polycarboxylates used in detergents (Part II) Polyacrylic/maleic acid copolymers and their sodium salts (CAS 52255-49-9), 2014, available at: https://www.heraproject.com/files/HERA_P-AAMA_final_v3_03032014.pdf.

[17] See, e.g., De Leo, *et al* (2020). Environmental risk assessment of polycarboxylate polymers used in cleaning products in the United States. Chemosphere 258: 127242. See also, HERA (2014). Both used chronic data in lieu of acute data to derive risk quotients for aquatic invertebrates.

[18] ECETOC Joint Assessment of Commodity Chemicals (JACC) No. 23 (November 1993). Polycarboxylate polymers as used in detergents. ISSN-0773-6339-23. See also BASF SE (2013). Unpublished data on ecotoxicology of AA-MA copolymer, BASF SE 13G0326/11G182 [as cited in HERA (2014)].

from entering ground and surface water, and to have groundwater monitoring systems. (40 C.F.R. Part 258).

7. Fate of Emitted Substances in the Environment

a. Air

As described above, no significant quantities of any substances will be released to the atmosphere upon the use and disposal of finished articles manufactured with the FCS. Therefore, an assessment of the environmental fate of these substances is not required.

b. Water

The P-AA/MA chemical class are characterized with high water solubility, non-volatility, and moderate to high sorption coefficients under biodegradation studies with sewage sludge (HERA, 2014). Therefore, they are expected to partition predominantly to solids (approximately 90%), followed by water (10%) and negligible distribution to atmosphere. Biodegradation is considered negligible under both environmental (aerobic and anaerobic) and waste treatment plant processes (HERA 2014, page 12).

The additional means by which the FCS is expected to be released into the environment is as a component of effluents from waste water treatment facilities. As discussed earlier, the MEEC for surface water environments is estimated to be 0.168 µg FCS / mL water (0.168 ppm). This MEEC value is extremely low and does not raise a significant concern. However, the publicly available aquatic toxicity data are presented below to support a conclusion of no significant impact.

The potential release of the FCS is not expected to result in any significant environmental effects. This expectation is based on the low levels at which the product will be released into the environment and on available data regarding the potential toxicity of 2-propenoic acid, polymer with 2,5-furandione, sodium salt.

The FCS is a maleic-acrylic acid copolymer. The following tables summarize the available data on the environmental effects of copolymers of acrylic/maleic acid. The tables are excerpted from an extensive review of the environmental impact of polycarboxylates used in detergents by HERA (2014) and the data are reported as mg/L active. All of the studies tabulated, with one exception, have a Klimisch score of either 1 (reliable without restriction) or 2 (reliable with restriction). [15]

[15] The Klimisch score is a method of assessing the reliability of toxicological studies, and is utilized mainly for regulatory purposes. Klimisch, H.J.; Andreae, M.; Tillmann, U. (1997). "A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data". Regulatory Toxicology and Pharmacology. 25: 1–5.

was observed to turn from its normal green color (indicating normal algal consumption) to a gray color (indicating ingestion of polymeric particles). At higher concentrations of synthetic water (or in distilled water) used for aquatic studies (> 500 ppm), MAPA is completely soluble and the toxicity to Daphnia is much lower. [19] Thus any mortality noted in the available acute studies is secondary from ingestion of polymeric particles that are in the same size class as the *Daphnia*'s normal algal food. Finally, due to the insoluble (particulate) nature of low-level MAPA in water, these secondary effects would not be anticipated given the very high removal done by wastewater treatment plants (*e.g.*, as high as 90%).

For the purposes of deriving a RQ, the acute data are not reliable and thus, this EA relies instead on chronic data for deriving a Tier B RQ. [20] With regard to the available chronic data, the available No Observable Effect Concentrations (NOECs) for *Daphnia* are in good agreement with very low variability, with the exception of the Procter & Gamble study which was performed with soluble MAPA (as opposed to all the others, which used insoluble MAPA). The remaining studies cited above derive NOECs from 3.75 to 7.5 ppm using 21-day testing.

For the Tier B assessment, the FDA Guidance specifies the use of NOEC values and specific Assessment Factor (AF). For the Tier B assessment, the selected chronic toxicity data from Table 8 (Hera, 2014), the appropriate AF, and the resulting Predicted No Effect Concentrations (PNECs) are tabulated below. The ratio of the MEEC to the PNEC, the RQ, is also presented. The Tier B assessment demonstrates that all RQ are well below 1 for chronic toxicity exposures.

Table 4: PNECs and RQs at Tier B (chronic)

Species	NOEC, mg/L [a]	AF [b]	PNEC, mg/L	RQ [c]
Fish, *Brachydanio rerio*	100	10	10	0.0168
Invertebrates, *Daphnia magna*	3.75	10	0.375	0.448
Algae, *Scenedesmus subspicatus*	37.2	10	3.72	0.045

[a] Taken from Table 8, HERA, 2014

[b] AF from FDA Guidance for Industry #166 for Tier B [21]

[c] RQ = MEEC of 0.168 µg/mL = 0.168 mg/L ÷ PNEC

Based on the modeled MEEC and the available toxicity data, all RQs are well below 1 and we conclude that there will be no significant adverse effects to ecological receptors from the potential release of the acrylic/maleic acid copolymer to the environment.

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[19] BASF AG (1985). Unpublished data on the ecotoxicology of AA-MA copolymer. BASF AG 188-A 1/15 20.12.1985 [as cited by HERA (2014)].

[20] The main criteria for advancing to Tier B is when the RQ is ≥1 or in the case of soil microorganisms an effect > 25%. *See* https://www.fda.gov/media/69927/download

[21] *Id.*

c. Land

Considering the factors discussed above, no significant effects on the concentrations of land exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. As discussed above, EPA's regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate.

On these bases, 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 production of food contact paper and paperboard.

8. Environmental Effects of Released Substances

No significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified above. Therefore, an evaluation of the environmental effects of the proposed use of the FCS is not required. In addition, the use and disposal of finished articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors or and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food contact substances, the production, use, and disposal of the FCS involves the use of natural resources such as petroleum products and coal. The use of the FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, because the FCS is intended to be used in packaging which will be used in place of similar paper and paperboard materials now on the market for use in food packaging applications. The partial replacement of these types of materials by products containing the FCS is not expected to have any adverse impact on the use of energy and resources.

The FCS also is not expected to have a significant effect on paper recycling programs. Due to its affinity for water, MAPA used in the filler application is expected to almost entirely remain with the whitewater in the processing plant. MAPA used in the coating application may be present in paper that is recycled.
When the paper for recycling is re-pulped, the MAPA would be expected dissolve into the pulp slurry and will be treated with other chemicals from the recycling process. For this reason, the intended use of MAPA will have no effect on the recyclability of paper.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS when present in waste water or in finished paper and paperboard. Therefore, the FCS is not reasonably expected to result in any new environmental issues that require mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this FCN. If the proposed action is not approved, the result would be the continued use of the currently marketed materials that the subject FCS would replace. Such action would have no environmental impact.

12. List of Preparers

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Ave., NW, Washington, D.C. 20036 with 30 years of experience with Food Additive Petitions, FCN submissions, and environmental assessments.

Patricia Kinne, Environmental Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, D.C. 20036 has over 10 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Erik R. Janus, Regulatory Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, D.C. 20036 has 20 years of experience in the environmental health sciences, including human health, toxicology and ecological risk assessment.

13. Certification

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

Date: October 12, 2022

Joan Sylvain Baughan, Partner

14. References

Grönfirs, J., *Use of Fillers in Paper and Paperboard Grades*, Final Thesis, Tampere University of Applied Sciences (May 2010).

Human and Environmental Risk Assessment (HERA). 2014. *Human and Environmental Risk Assessment on ingredients of European household cleaning products: Polycarboxylates used in detergents (Part II Polyacrylic/maleic acid copolymers and their sodium salts* (CAS 52255-49-9). Version 3.0.

Klimisch, H.J.; Andreae, M.; Tillmann, U. (1997). "*A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data*". Regulatory Toxicology and Pharmacology. 25: 1–5.

Pulp and Paper, 2001 and EPA Office of Compliance Sector Notebook Project Profile of the Pulp and Paper Industry 2nd Edition, November 2002.

Rapaport, R.A., 1099. *Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution*. Environmental Toxicology and Chemistry 7:107-115.

U.S. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States* (EPA530-F-20-009) December 2020

U.S. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures Assessing Trends in Materials Generation and Management in the United States*, December 2020

U.S. Food and Drug Administration, *Food Types & Conditions of Use for Food Contact Substances*.

15. Attachments

Confidential Attachment to the Environmental Assessment.