REVISED ATTACHMENT 7

ENVIRONMENTAL ASSESSMENT
PEROXYCHEM, LLC
FOOD-CONTACT NOTIFICATION

1.	**Date:**	August 31, 2017
2.	**Name of Applicant:**	PeroxyChem, LLC
3.	**Address:**	

All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. Description of Proposed Action

a) Requested Approval

The action identified in this Notification is to provide for the use of an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1) and acetic acid (CAS Reg. No. 64-19-7) stabilized with maleic acid (CAS Reg. No. 110-16-7) and/or oxalic acid (CAS Reg. No. 144-62-7) as an antimicrobial additive that may be used alone or in combination with other processes for the commercial sterilization of aseptic filling equipment and packaging prior to filling, except the FCS is not intended for use on food packaging materials and/or aseptic food packaging equipment used to hold infant formula or breast milk.

The two stabilizers used in the production of the FCS, maleic acid and oxalic acid, may be used alternately or in combination. When used either alone in combination, the total stabilizer content (sum of both) in the FCS will not exceed a maximum level of 1.0 wt-% of the FCS solution. In the following assessment, the term stabilizer is used to refer to either stabilizer, (maleic acid, or oxalic acid). The estimated environmental concentrations derived below therefore represent the maximum for each stabilizer when used at the maximum level of 1% alone in the FCS. When used in combination such that each is less than 1%, but the total does not exceed 1%, the environmental concentrations of each stabilizer will necessarily be less.

The nominal concentration of the PAA in the stabilized PAA solutions (i.e., the FCS) supplied to PeroxyChem's customers is 15.0% (by weight). The maximum concentration of the stabilizer in these solutions, as supplied, is 1.0% (by weight). The maximum concentration of PAA in the treatment solution as applied to packaging is 4000 parts per million (ppm), a 37.5-fold dilution of the concentrate. The stabilizer concentration corresponding to this dilution is therefore 267 ppm (1% ÷ 37.5).

When the FCS is applied to food containers, the containers are filled with the treatment solution containing the FCS, drained and then rinsed with sterile water. The drained treatment solution is recycled to the treatment solution reservoir for reuse. The rinse water generated in the rinse step is routed to the main wastewater header of the food processing plant where it merges with wastewater from other operations in the plant prior to treatment in wastewater treatment facilities. Furthermore, the 900-gallon treatment solution reservoir is drained approximately once every 48-hours. This spent treatment solution is also routed to the main wastewater header of the food processing plant.

In addition, the interior of the cabinet may be sterilized prior to a production run by spraying the machine surfaces with the FCS solution prior to introducing the packaging films or bottles into the aseptic filling machine. During a filling operation, food is introduced directly into the sterilized package through a valved pipe or tube. Neither the packaging nor the FCS can access the interior of the pipe carrying the food thus, none of the machine surfaces accessible to the FCS are food-contact surfaces.

The FCS is intended as an alternative to other aqueous peroxyacetic acid-based sterilizing solutions used in aseptic processing applications involving polymeric food packaging materials. The FCS is expected to be applied in a similar manner as currently approved alternative products, which generally would involve spraying the FCS on food-contact materials, or immersing packaging material in the FCS. Furthermore, this FCS is not expected to expand the types of food products packaged in aseptic packaging, nor is it expected to expand the types of packaging material on which sterilizing treatments may be used.

b) Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food-contact surfaces of containers and closures used to package food. The requested action is needed to address current and future needs of food processors to improve food safety. Use of the FCS provides another option for antimicrobial interventions. The FCS is intended for use as an antimicrobial solution for sanitizing food-contact surfaces of aseptically filled packaging materials and the non-food-contact surfaces of the filling equipment.

c) Locations of Use/Disposal

The antimicrobial agent is intended for use in food processing facilities engaged in aseptic packaging of food throughout the United States. Disposal of the FCS is expected to occur nationwide within the United States. "Unused" quantities of the FCS (*i.e.*, solution remaining in reservoirs at the end of production runs, as well as solution that is drained or otherwise removed from packaging material and aseptic processing equipment) are expected to be deposited to the food processing facilities' wastewater discharge streams.

Waste process water containing the FCS is expected to be disposed of through the 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). In addition, when sewage sludge from POTW is treated and processed, the resulting biosolids can be safely recycled and applied as fertilizer to sustainably improve and maintain productive soils and stimulate growth.[1] In consideration of the potential land application of such biosolids, we have also estimated maximum potential concentrations in soil from this route of disposal.

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

The food contact substance (FCS) that is the subject of this FCN contains peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), and water (CAS Reg. No. 7732-18-5) and is stabilized with maleic acid (CAS Reg. No. 110-16-7) and/or oxalic acid (CAS Reg. No. 144-62-7).

The FCS is therefore characterized as follows:

Substance	Nominal Amount (%)	Maximum Amount (%)
Peroxyacetic Acid	15.0	17.0
Hydrogen Peroxide	10.0	12.0
Acetic Acid	35.0	38.0
Water	38.0	43.0
Maleic acid and/or Oxalic acid	1.0	1.0

The FCS is intended to be diluted a minimum of 37.5-fold to yield peroxyacetic acid at-use concentrations not exceeding 4000 ppm.

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[1] https://www.epa.gov/biosolids/basic-information-about-biosolids

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment resulting from 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 substances. Moreover, information available to the Notifier suggests no extraordinary circumstances indicative of any adverse environmental impact resulting from the manufacture of solutions containing the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment resulting from use/disposal

Treatment of process water at on-site wastewater treatment facilities and/or at Publicly Owned Treatment Works (POTW) is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid.[2] Specifically, the peroxyacetic acid will break down into oxygen and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water.[3] Therefore, these substances are not expected to be introduced into the environment to any significant extent due to the proposed use of the FCS. The remainder of the environmental assessment will therefore consider only the environmental introduction, fate and potential effects of the stabilizers.

The Notifier supplies the FCS to customers as concentrated aqueous solutions with instructions for dilution to end-use concentrations prior to application to packaging. The FCS is intended for use in two container and closure treatment applications: (1) A no-rinse application for treating containers and closures with a vapor or fine mist; and, (2) An application where containers and closures are filled with treatment solution, then emptied and rinsed.

The waste generated from the *no-rinse* application for treating containers and closures with a vapor or fine mist would be virtually nil for the following reasons:

1) The amount of treatment solution applied to each container and closure pair is only enough to coat the packaging surface, therefore, no ‘‘run off” is expected to be present;

2) Because this system does not recycle the treatment solution, it is unnecessary to regularly recharge the treatment solution reservoir as required for the filled container-with-rinse application. It is therefore unnecessary to drain treatment solution reservoirs to the wastewater system. Further, because there is no rinse step, there is no rinse water waste stream containing the FCS.

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[2] Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18.

[3] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category; American Chemistry Council, June 28, 2001.

3) Thus, there is no identifiable waste stream containing the FCS components for the no-rinse application for treating containers and closures with a vapor or fine mist.

The second application identified in this FCN involves the use of the FCS in treatment solutions applied to containers and closures by filling the containers and closures. This application would generate three primary waste streams. The first waste stream is generated as result of rinsing the excess treatment solution from the containers and closures after draining the treatment solution. This waste stream would be continuous and dilute in the FCS component concentrations. The second waste stream would be generated as result of periodic draining of the treatment solution reservoir. This waste stream would be intermittent, and relatively concentrated compared to the rinse water waste stream. The third waste stream would be generated as result of overfilling the containers and closures. This waste stream would be more concentrated than the rinse water stream, and more continuous than waste water stream generated from periodic draining of the treatment solution reservoirs.

An additional intermittent waste stream of intermediate concentration results from the application of the FCS to the interior of the equipment cabinet prior to introducing the packaging films or bottles into the aseptic filling machine. As discussed more fully below, the potential environmental introductions of the stabilizers due to the application of the sterilant to the filling equipment at the commencement of a filling operation is fully encompassed by the calculations provided for the container rinsing and reservoir draining operations.

Thus, the worst-case instantaneous and long term average environmental release calculations can be determined by considering only the first and second waste streams (*i.e.*, the method used to estimate environmental concentrations attributable to the first and second waste streams fully encompasses the release attributable to the other waste streams).

All waste water streams from packaging operations (including those containing the FCS) will enter the main wastewater header of the food processing facility and undergo treatment with other wastewater generated at the food processing facility. Many food-processing plants operate on-site wastewater treatment plants (WWTPs) to treat their wastewater. Some WWTPs discharge their effluent to publicly owned treatment works (POTWs) for additional treatment prior to discharge to receiving waters, while others are permitted to discharge their effluent directly into surface waters or over land. Other food processing plants send their wastewater directly to POTWs without pretreatment at an on-site WWTP. Sludge removed from WWTPs or POTWs may be disposed of in one of two ways (e g., land spreading or incineration).

For the purposes of this Environmental Assessment, we have considered a food processing plant using only one water treatment operation (*i.e.*, either WWTP or a POTW, but not both) followed by final wastewater discharge to receiving waters or discharge over land. We have considered land spreading as the worst-case sludge disposal scenario.

For the reasons discussed in Section 7 below, only the stabilizers used in the FCS are expected to be present upon discharge to the environment through aquatic or terrestrial routes. Thus, the primary focus of this assessment is the potential introduction into the environment of the stabilizers resulting from the use of this FCS in aqueous mixtures.

Containers treated with the FCS solution are first filled to overflow with the solution, followed by an appropriate holding period. Containers are then inverted to allow the solution to drain. The overflow and the drained solution are returned to a reservoir for reuse (*i.e.*, recycled). Excess solution remaining in the package is then rinsed from the containers using sterile water.

Due to inherent instability of the FCS active ingredients and the recycle of the PAA solution, it may be necessary to periodically replenish the reservoir with fresh, concentrated PAA solution to maintain desired levels of the active ingredients. Because the additives used in the PAA solution, are substantially more stable than the active components of the PAA solution, and because they do not evaporate from the sterilant reservoirs, the additive concentration in treatment solution reservoirs is expected to increase as concentrated PAA solution is added. The rate of concentration is determined by the ratio of additive to PAA in the PAA solution, the rate of addition to the reservoir and the reservoir volume. The effect of this recycle on the concentration of the additive in the reservoir is anticipated in the calculation of environmental exposure to the additive provided below.

If treatment solution losses from overfilling are significant, regularly scheduled refilling of the reservoir to make up solution volume loss may occur before there is any need to add concentrated PAA solution to supplement active ingredient strength. In this case, the increase in additive concentration in the reservoir is insignificant.

The various waste streams from the packaging treatment process (*i.e.*, rinse water waste, spent treatment solution from reservoirs, and treatment solution overfill and leakage waste) are all routed to the main wastewater header of the food processing plant. Wastewater streams from various additional operations conducted in the food processing plant (including wastewater streams unrelated to packaging treatment operations) merge in the main wastewater header prior to being sent to wastewater treatment facilities. The environmental release calculations provided below account for the worst-case instantaneous additive concentrations in effluent streams (*i.e.*, WWTP effluent released to receiving water or spread over land) that may result during draining full reservoir volumes over short durations, in which the additive content of the treatment solution has increased to its maximum level due to the processes described above. Moreover, the additive content of sludge generated in WWTPs accounts for the periodic tank draining based on the typical production schedules.

As indicated above, certain types of packaging equipment generate substantial waste volumes due to overfilling of containers, leakage, and other loss of treatment solution from the system other than through rinse water, reservoir draining, or on food packaging. The method used to estimate environmental release quantities set forth below does not specifically address waste flow rates and concentrations associated with these overfilling and leakage sources of waste. Nevertheless, the method employed fully encompasses these sources based on the following explanation.

The losses due to overfilling and leakage of treatment solutions are not made up to the treatment solution reservoir continuously, but rather, the treatment solution losses are made up only after the treatment solution reservoir has lost most of its volume. The notifier informed us that a 600-gallon reservoir may lose as much as 400 gallons over an 8-hour period due to overfilling and leakage. This is equivalent to a waste flow rate of 50 gallons per hour (400 gallons in ≈ 8 hours). The lost solution is made up at the end of the 8-hour cycle. After approximately 6 cycles of this solution refilling process (*i.e.*, 48 hours), when the treatment solution reservoir would otherwise be refilled on the 8-hour schedule, the treatment solution reservoir is entirely drained and refilled with fresh treatment solution. In calculating the worst case instantaneous environmental release concentrations of the additives, we assumed that the entire treatment solution reservoir volume, which is 900 gallons (accounting for the 600 gallon treatment solution reservoir used for container treatment operations and the 300 gallon treatment solution reservoir for cap treatment operations) would be drained to the main wastewater header over a period of 2 hours.

Moreover, we assumed as a worst case that the additive concentration in the solution would have increased 5-fold over this period (thus, the additive concentration would be 5-fold higher than its starting level). The instantaneous waste volume flowrate based on this method is 450 gallons per hour (900 gallons over 2 hours), which is substantially higher than the waste flow rate predicted based on solution loss due to leakage and overfilling (50 gallons per hour) or equipment application.

Furthermore, the 5-fold increase in stabilizer concentration is thought to be a highly exaggerative given that most of the treatment solution would be entirely replaced every 8-hours. Therefore, the model parameters on which the environmental release of additives are based are highly exaggerative as compared to actual use scenarios, and we submit that it is not necessary to further evaluate specific release quantities associated with treatment solution losses due to overfilling and leakage.

Direct discharge from the WWTP would result in higher concentrations of FCS in the environment than the indirect discharge from the POTW. Thus, we have assumed in determining the worst-case environmental concentrations of the FCS components that food processing facilities would treat their wastewater only in an on-site WWTP and then discharge the WWTP effluent directly to receiving waters or to land application. We have also addressed disposal of sludge removed from the WWTP by assuming it is mixed with surface soil. These assumptions ensure that we are considering the worst-case potential environmental exposure to the additives. Detailed calculations of the environmental introduction concentrations and expected environmental concentrations of the stabilizers are provided below.

The calculations below include dilution of wastewater from container treatment operations in the on-site WWTP upon mixing with wastewater from other operations in the food-processing plant, such as wash down of process vessels, tanks, floors, and pipes. In one case study of a bottling facility, container washing operations accounted for 62% of daily water used.[4] Thus, we have used a WWTP dilution factor of 0.38 in our calculations. In addition, as the wastewater is

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[4] Ait Hsine, E.; Benhammou, A.; Pons, M.-N. Industrial water demand management and cleaner production potential: a case of beverage industry in Marrakech – Morocco. *Afrique Science* **2005,** *1*, 95-108.

treated in the WWTP, the stabilizers may be expected to partition in the solids in the sedimentation tank with no specific affinity for the solid phase (sludge).

The calculations below also include a 10-fold receiving water dilution factor to account for dilution expected to occur upon discharge of the treated wastewater to surface waters. Some vegetable processors are permitted by state agencies to discharge their wastewater to land application systems, where organic matter becomes nutrients for plants.[5] The current FCN covers the use of the FCS to sterilize food packaging for processed foods, not for produce. Moreover, the food processing facilities that would use the FCS for applications covered by the current FCN operate throughout the year, including winter months when absorption of pollutants by growing plants would not be a suitable means of environmental remediation. Although, land application systems are not an expected disposal route for the FCS under the current applications of interest, we have nevertheless, addressed this possibility.

Environmental concentration of stabilizers present in sludge removed from on-site WWTPs has been estimated using the methodology described by Harrass *et. al,* 1991.[6]

i. pH Control

Although use of the FCS solution may have a slight impact on the pH of the water at a food processing facility, all of wastewater will be treated either at a WWTP or a POTW prior to release to the environment. WWTPs and POTWs routinely adjust the pH of wastewater prior to discharge to receiving waters. Local, state, and federal law impose limits on the pH of wastewater discharged to the environment. For example, 40 CFR Part 403.5 requires that wastewater discharged by POTWs may not be less than a pH of 5. In addition to pH requirements for discharge to POTWs, any effluent discharged to natural waters and POTWs will require a National Pollutant Discharge Elimination System (NPDES) permit and will have restrictions on the pH of the effluent. We do not think the intended use of FCS solution covered in this Notification would unduly burden a WWTP's or POTW's ability to comply with the laws and regulations governing pH control of wastewater discharged to the environment.

ii. Stabilizers

The concentrations of stabilizers in a food packaging facility's wastewater are determined by dilution level of the treatment solution, dilution level from water used to rinse the containers, wastewater from other plant processes, and other factors that we have addressed in the calculations provided below.

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[5] *Land Application of Food Processing By-Products Solids Fact Sheet,* Wisconsin Department of Natural Resources: May 2012, available at: http://dnr.wi.gov/topic/wastewater/documents/57665_fs.pdf (accessed August 30, 2017

[6] Harrass, M.C., Erickson, C.E. III, Nowell, L. H., “Role of Plant Bioassays in FDA Review: Scenarios for Terrestrial Exposure,” *Plants for Toxicity Assessment: Second Volume, ASTM STP 11115,* J. W. Gorsuch, W.R. Lower, W. Wang, and M. A. Lewis, Eds., American Society for Testing and Materials, Philadelphia, 1991, pp 12-28.

The stabilizers are the only components likely to be present in measurable quantities in wastewater or sludge discharged to the environment. In the remainder of this Environmental Assessment we will focus on the potential environmental discharge of the stabilizers to receiving waters and in sludge mixed with surface soil.

Due to need to periodically replenish the reservoir with fresh, concentrated PAA solution to maintain required levels of the active ingredients, the stabilizer concentration in the treatment solution reservoir may be expected to increase somewhat over time. The spent solution will be emptied periodically and drained to the main wastewater header of the food processing plant. The combined total volume of typical recycle holding tanks is 900 gallons. The detailed calculations included below account for the increase in stabilizer concentration during the time in which a particular batch of solution is used, and the concentration of stabilizer in the spent sterilant sent to the wastewater header reflects its maximum concentration. We have not accounted for reduction in stabilizer concentrations in WWTP effluent attributable to decomposition because the WWTP effluent concentrations were well below acceptable limits without this additional reduction factor.

Aquatic Introductions

The average concentration of stabilizer contained in the wastewater generated from container rinsing, for 8-oz containers, can be determined based on the following model parameters:

(1) 8-oz container throughput = 39,600 containers/hr (as indicated by PeroxyChem);

(2) Rinse water use rate = 18,625 liters per hour (L/h) (as indicated by PeroxyChem);

(3) Initial stabilizer concentration in treatment solution = 267 ppm;

(4) As a conservatism, the concentration of stabilizer in treatment solution over 48 hour timeframe could increase to as much as five times the initial concentration. Therefore, the final stabilizer concentration in the treatment solution reservoir just before it is drained and recharged would be 1335 ppm, and the average concentration in the treatment solution over a 48-hour operational cycle would be 801 ppm (267 ppm + (1335 ppm – 267 ppm) ÷ 2 = 801 ppm);[7]

(5) The surface area of an 8-oz container is approximated as 42.4 in^2; [8]

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[7] For reasons described in the EA, any actual increase in stabilizer concentration from this application is expected to be much lower.

[8] The interior surface area of an 8-oz container may be estimated by approximating the container shape as a cylinder with a height (h) of 6.0-inches corresponding to the height of the container "body" (*i.e.*, the 7-inch total container height minus the l-inch "neck"), and a container radius (r) (measured at bottom) of 0.94 in. The surface area is obtained by application of the equation for the surface area of a cylinder ($2\pi \cdot r^2 + 2\pi \cdot r \cdot h$).

(6) The amount of sanitizer remaining on the food-contact surface after draining is 1 milligram per square centimeter (mg/cm^2), a value that FDA has historically used to estimate residues of sanitizers on food-contact surfaces after draining;

(7) The wastewater flow rate from container rinsing operations is equal to the rinse water use rate, *i.e.*, the amount of liquid residue in the container after draining the treatment solution and before injecting rinse water would be the same as the amount of liquid residue in the container after injecting the rinse water and draining the rinse water to the wastewater header (this is based on the "drained film" weight of 1 mg/cm^2 described in (6), above).

We may estimate the stabilizer concentration in the wastewater stream from container rinsing based on these model parameters as follows:

(1) The total treatment solution present in an 8-oz container after draining, and before rinse, would be the drained film weight multiplied by the interior container surface area (1 mg sterilant/cm^2 × 6.45 cm^2/in^2 × 42.4 in^2/container = 273 mg treatment solution/container);

(2) The average amount of stabilizer present in an 8-oz container after draining, and before rinse, is the total treatment solution contained in the container multiplied by the average stabilizer concentration of the treatment solution (273 mg treatment solution/container × 801 mg stabilizer/1,000,000 mg treatment solution = 0.21 mg stabilizer/container);

(3) The amount of rinse water used per container is 470,000 mg (18,625 L/h ÷ 39,600 containers/h = 0.47 L/container = 470 mL/container = 470,000 mg/container);

(4) The concentration of stabilizer in the rinse water applied to the 8-oz container after all the rinse water is injected is calculated as the amount of stabilizer in the container (0.21 mg) divided by the combined weight of the rinse water per container (470,000 mg/container) and the pre-rinse treatment solution film (273 mg), calculated as:

Stabilizer concentration in rinse water = (0.21 mg stabilizer/container) ÷ ((470,000 mg rinse water + 273 mg Sanitizer)/container) = 0.45×10^{-6} mg stabilizer/mg rinse water = 0.45 mg Stabilizer/L rinse water (0.45 ppm).

Thus, the estimated flow rate of wastewater from rinsing 8-oz containers is 18,625 L/hr (which is equivalent to the rinse water use rate), and the estimated stabilizer concentration in this wastewater stream is 0.45 mg stabilizer/L. This is equivalent to a stabilizer flow rate of approximately 8381 mg Stabilizer/hr (or 8.38 g stabilizer/hr).

As described in Attachment 7, container washing operations can be estimated to account for 62% of daily water usage at a bottling facility. Thus, assuming 18,625 L/h represents 62% of total water usage at the bottling facility, the total water usage can be estimated as 30,040 L/h (18,625 L/h ÷ 0.62). The concentration of the stabilizer in the wastewater at the header during times when the reservoirs are not being drained is therefore 0.28 mg stabilizer/kg wastewater, or 0.28 ppm stabilizer in the wastewater (8381 mg stabilizer/hr ÷ 30,040 L wastewater/hr).

Approximating the total water usage at a bottling facility as essentially constant over time, we may also account for the additional stabilizer contribution due to draining of a treatment solution reservoir (900 gallons) to the wastewater header, which is conducted approximately once every 48 hours.

The total stabilizer content of a 900 gallon treatment solution reservoir, assuming the stabilizer concentration just before draining is 1335 ppm, is approximately 4.55 kg (1335 mg stabilizer/1,000,000 mg treatment solution × 900 gal treatment solution × 3.79 L/gal × 1000 mL/L × 1,000 mg/mL ≈ 4,550,000 mg stabilizer = 4.55 kg stabilizer). Because the 900 gallon treatment solution reservoir is drained over a 2-hour period into the wastewater header, the total amount of solution entering the header during the draining period, assuming a constant wastewater flowrate from all operations at the bottling facility of 30,040 L/h, is somewhat less than 63,500 L ((2 h × 30,040 L/h) + (900 gal × 3.79 L/gal)). The total stabilizer content flowing into the header during this 2-hour period, calculated as the contribution from the treatment solution draining plus the contribution from package rinsing, as follows: (4.55 kg Stabilizer + (2 hr × 8381 mg stabilizer/hr × 1 kg/1,000,000 mg) = 4.57 kg Stabilizer). Thus, the concentration of stabilizer in the wastewater at the header during a treatment solution reservoir draining is estimated as: 4.57 kg stabilizer/63,500 L wastewater = 7.2×10^{-5} kg stabilizer/L wastewater = 72 mg stabilizer/L wastewater or 72 ppm stabilizer in the wastewater during the reservoir draining operation.

Biological organisms within any wastewater treatment system necessarily require sufficient contact time with the organic material in the wastewater to produce effluent of acceptable quality. The contact time, daily flow rate, influent parameters, and effluent parameters determine the size of the aeration tank where air is used to mix wastewater to supply oxygen to promote biological growth. The hydraulic retention time for typical extended aeration package plants is approximately 18-24 hours.[9] Because of this requirement for an adequate hydraulic retention time, the wastewater sent to the header during the 2 hours when the sanitizer reservoirs are drained necessarily mixes with other waters previously sent to the treatment facility as well as waters sent after the reservoir drain when it reaches the treatment plant. The stabilizer concentration *in the wastewater plant* therefore will be a time average of the concentration at the header during the 2 hour drain time and the concentration at the header during the 16-22 hours of required hydraulic residence time when the reservoirs are not being drained. The concentration of the stabilizer in the wastewater treatment plant is therefore calculated as a time average, conservatively using the shortest residence time for typical plants and would not exceed 8.2 ppm ([72 ppm × 2 hr + 0.28 ppm × 16 hr] ÷ 18 hr). Because the hydraulic residence time in the treatment plant is 18 hours but the sanitizer reservoirs are emptied only every 48 hours, the concentration of the stabilizer in the wastewater at the treatment plant will slowly fluctuate in time between levels bounded by a maximum of 8.2 ppm and a minimum of 0.28 ppm due to the mixing that occurs at the plant and the intermittent nature

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[9] *Wastewater Technology Fact Sheet Package Plants*, United States Environmental Protection Agency, Office of Water, Washington, D.C. EPA 832-F-00-016, September 2000.

of the reservoir drain operation. We will use the maximum instantaneous value of 8.2 ppm in the calculations that follow.

Application of the FCS to sanitize the filling equipment prior to the introduction of packaging to the machine will not affect the maximum instantaneous estimated concentration in the wastewater at the treatment plant in any significant way for several reasons. First, because the application occurs only once at the beginning of the production run, the concentration of the stabilizer in the sterilant solution is not concentrated by recharging the sterilant reservoir. This accounts for a 5-fold lower stabilizer concentration in the solution applied to the equipment. Second, the application of the sterilant to the equipment is followed by a sterile water rinse that provides an additional 2-fold reduction of stabilizer concentration at the wastewater header. Third, the volume of sterilant applied to the equipment, and the time required to apply the sterilant to the equipment are far less than the volume of the reservoir tank and the time required to drain the reservoir tank. Thus, the environmental introductions due to the application of the FCS to aseptic packaging equipment is fully encompassed by the use the maximum instantaneous value of 8.2 ppm estimated in the calculations above .

If the WWTP/POTW effluent were discharged directly to land, the maximum stabilizer concentration in the discharge would be 8.2 mg stabilizer/L of effluent, as demonstrated above.[10] We can anticipate an additional 10-fold dilution upon discharge to receiving water when the WWTP/POTW were discharged to receiving waters (which is the expected scenario for the kinds of facilities that would operate under the FCN). Thus, the concentration of stabilizer in receiving waters can be estimated as 0.82 mg/L receiving water.

Terrestrial Introductions

With respect to the stabilizer content in sludge removed from WWTPs/POTWs, the concentration of stabilizer in sludge can be estimated by assuming a sludge production rate based on the effluent flow rate. *Solids Inventory Control for Wastewater Treatment Plant Optimization* provides a theoretical dry solids production rate of 150 kilograms dry solids per 1,000 cubic meters of effluent with the addition of water treatment chemicals.[11] The average flow to the WWTPs modeled here is estimated as 720,960 liters per day (30,040 L/h × 24 h/d). If the facility runs 24 hours a day, 7 days a week, the total flow would be 263,150,400 liters per year, or 263,150 cubic meters per year (1 cubic meter = 1000 liters). The sludge generated from this yearly flow can be estimated as approximately 39,500 kilograms of sludge per year (with chemical addition).

The total amount of stabilizer generated *on an annual basis* can be estimated based on the stabilizer content of spent treatment solution, which is drained approximately once every 2 days

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[10] This level would obtain only in the very unlikely event that no biodegradation occurs in the wastewater treatment plant.

[11] *Solids Inventory Control for Wastewater Treatment Plant Optimization*, Issue No. 1.0, March 2004, Federation of Canadian Municipalities and National Research Council, ISBN 1–897094–60–4, available at: https://www.grandriver.ca/en/our-watershed/resources/Documents/Water_Wastewater_Optimization_InfraguideSolids.pdf

(183 times per year), and the steady stabilizer flow from container rinsing. The stabilizer content of a treatment solution reservoir, as estimated above, is approximately 4.55 kg. Multiplying 4.55 kg by 183, we can estimate a total annual contribution from spent treatment solution draining of 833 kg stabilizer/yr. Based on the flowrate of 8.38 g stabilizer/hr from container rinsing operations, we can estimate an annual stabilizer contribution from container rinsing of 73,408 g Stabilizer/yr, or 73.4 kg stabilizer/yr. Adding these two contributions together, a total stabilizer flow to wastewater treatment systems (i.e., WWTP or POTW or both) is estimated as 833 kg/yr + 73.4 kg stabilizer/yr = 906 kg Stabilizer/yr.

Using an estimation method based on molecular connectivity indices, the K_{oc} of maleic acid may be estimated to be 5, the estimated K_{oc} of oxalic acid is 7.[12] These values indicate high soil mobility and no specific affinity for adsorption to sludge for both substances. Further, both stabilizers exist almost entirely in anion form in the environment which also indicates that they would not be expected to adsorb preferentially to organic matter in or on soil or sludge. We can therefore estimate the concentration of the stabilizers in sludge by assuming they each partition between the water and the sludge with approximately equal concentrations in each phase. Because the sludge comprises 0.015% of the total effluent (39,500 kg sludge ÷ (263,150 m^3 effluent × 1000 kg effluent/m^3 effluent) × 100%), it will also contain 0.015% of the stabilizer or 0.14 kg stabilizer (906 kg Stabilizer × 0.015%). Thus, the concentration of the stabilizer in the sludge is 3.5 ppm (0.14 kg stabilizer ÷ 39,500 kg dry matter × 10^6).[13]

It is reasonable to assume that components of sludge will be diluted to a concentration of 2.5% of their concentration in sludge upon incorporation of sludge into soil.[14] Thus, the concentration of stabilizer in soil after incorporation is estimated to be 0.09 mg stabilizer/kg soil.

As discussed in Attachment 7, the estimated concentrations of stabilizer in effluent and sludge are far below any level of concern for these materials in the environment. Also, additional degradation would be expected to occur after land application of either effluent or sludge.

Atmospheric Introductions

The Henry's Law constant for maleic acid is estimated as 1.4×10^{-12} atm-cu m/mole using a fragment constant estimation method.[15] This Henry's Law constant indicates that maleic acid is

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[12] US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.11. Nov, 2012, estimates Koc of 5 for oxalic acid and 7 for maleic acid.

[13] Because sludge is harvested on a longer time scale than effluent discharges occur, this average concentration in the sludge correctly corresponds closely to the midpoint between the instantaneous concentration limits (maximum of 8.2 ppm and a minimum of 0.28 ppm) of the stabilizer in the treatment plant due to the mixing that occurs at the plant and the intermittent nature of the reservoir drain operation, as discussed above.

[14] *See* Harrass, M.C., Erickson, C.E. III, Nowell, L. H., "Role of Plant Bioassays in FDA Review: Scenarios for Terrestrial Exposure," *Plants for Toxicity Assessment: Second Volume, ASTM STP 11115,* J. W. Gorsuch, W.R. Lower, W. Wang, and M. A. Lewis, Eds., American Society for Testing and Materials, Philadelphia, 1991, pp 12-28.

expected to be essentially nonvolatile from water surfaces. In addition, the pKa values of maleic acid are 1.94 and 6.22,[16] indicating that this compound will exist almost entirely in anion form in the environment and that volatilization is not an important fate process. Maleic acid is not expected to volatilize from dry soil surfaces based upon a vapor pressure of 1.34×10^{-5} mm Hg.[17]

The Henry's Law constant for oxalic acid was measured to be 1.4×10^{-10} atm-cu m/mole indicating that it is essentially nonvolatile from water surfaces.[18] In addition, the pKa values of oxalic acid are 1.25 and 4.28,[19] indicating that this compound will exist almost entirely in anion form in the environment and that volatilization is not an important fate process. Oxalic acid is not expected to volatilize from dry soil surfaces based upon a vapor pressure of 2.34×10^{-4} mm Hg.[20]

We may therefore conclude that introduction of these stabilizers into the atmosphere would be virtually nil.

Summary of Environmental Introductions

Aquatic Introductions

EIC = 8.2 mg stabilizer/L of effluent,
EEC = 0.82 mg/L receiving water

Terrestrial Introductions

EIC = 3.5 mg stabilizer/kg sludge
EEC = 0.09 mg Stabilizer/kg soil

Atmospheric Introductions

EIC = Virtually nil
EEC = Virtually nil

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[15] US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.11. Nov, 2012.

[16] ECHA; Maleic Acid (CAS 110-16-7) Registered Substances Dossier. European Chemical Agency, available in the database entry for maleic acid from: http://echa.europa.eu/ by selecting the Tab for Physical & Chemical properties, and selecting the sub-tab labeled Dissociation constant. The pKa values (negative logarithms of the Ka values) are labeled in the database as pH.

[17] *Ibid.*

[18] Atkinson R; Environ Toxicol Chem 7, 435-42 (1988).

[19] Buxton GV et al; J Phys Chem Ref Data 17(2): 517-882 (1988).

[20] Bernales CA *et al*; Kirk-Othmer Encycl Chem Tech., 3rd Ed., Wiley **16**, 618-36 (1981).

7. Fate of Emitted Components in the Environment

Peroxyacetic acid, hydrogen peroxide and acetic acid are not expected to survive treatment at the wastewater treatment facilities at food packaging plants. Specifically, the peroxyacetic acid will breakdown into oxygen and acetic acid, while hydrogen peroxide will breakdown into oxygen and water.[21] Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water.[22]

The maximum instantaneous concentration of stabilizer in waters receiving the WWTP effluent (EEC) is estimated above as 0.82 mg/L from the combined bath disposal and bottle washing operations, modeling the reservoir disposal as occurring over a two-hour period. The maximum concentration of stabilizer in soils receiving applications of sludge is estimated to be 0.09 mg stabilizer/kg soil. The stabilizers are not expected to enter the air at any meaningful level.

Maleic Acid

The UV spectrum of maleic acid in water indicates that the compound does not absorb at wavelengths >290 nm and, therefore, is not expected to be susceptible to direct photolysis by sunlight.[23] Nevertheless, results of several screening tests indicate that maleic acid is readily biodegradable, and therefore, biodegradation is expected to be an important fate process in soil and aquatic compartments.[24]

Oxalic Acid

Photolysis is expected to be an important fate process for oxalic acid. The daytime persistence of oxalic acid on soil surfaces is not expected to exceed a few hours.[25] The predominant aquatic fate process for oxalic acid are expected to be photolysis in surface waters and aerobic and anaerobic biodegradation. Oxalic acid is expected to be removed rapidly from

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[21] Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 16.

[22] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category; American Chemistry Council, June 28, 2001.

[23] Clark BJ et al, ed; UV Spectroscopy: Techniques, Instrumentation and Data Handling. New York, NY: Chapman & Hall Inc., p. 49 (1993).

[24] ECHA; Maleic Acid (CAS 110-16-7) Registered Substances Dossier. European Chemical Agency. Available in the database entry for maleic acid from http://echa.europa.eu/ by selecting the tab labeled *Environmental fate & pathways*, and then selecting the sub-tab labeled *Biodegradation* and then selecting the sub-sub-tab labeled *Biodegradation in water: screening tests*.

[25] Grosjean D et al; Measurements of Organic Acids in the South Coast Air Basin ARB-R-88/375 PB89-145441) Gov Rep Announce Index (U.S.) 89(9) Abstr No. 921,946 (1989), as summarized in the National Library of Medicine’s Hazardous Substance Database.

surface water by direct photolysis; the daytime persistence of oxalic acid is not expected to exceed a few hours.[26]

8. Environmental Effects of Released Substances

The stabilizers used in the FCS have been evaluated. Maleic acid is readily biodegradable in both the terrestrial and aquatic compartments where environmental introductions may occur. Further, the available environmental toxicity data indicate that the estimated EEC for the stabilizer is far below the available benchmarks of toxicity to aquatic organisms. Specifically, in a short-term toxicity to aquatic invertebrates (EU Method C.2 (Acute Toxicity for Daphnia)) the 24 hour EC_{50} value was determined to be 200 mg/L, far above the aquatic EEC estimated above.[27] Further, toxicity to aquatic algae and cyanobacteria was measured by OECD Guideline 201 (Alga, Growth Inhibition Test) and a 72 hour NOEC was determined to be 130 mg/L,[28] again far above the aquatic EEC estimated above.

The environmental persistence of the oxalic acid is not expected to exceed a few hours. Further, this compound is ubiquitous in the environment (and in the human diet) at levels far above the EEC estimated to occur from the proposed use of the FCS and therefore, this action would not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. Specifically, oxalic acid occurs in many commonly consumed plant foods such as spinach, sweet potatoes, broccoli, brussel sprouts, grapefruit, chives, beans and rhubarb, among many others, at levels between 0.01% and 1.7%.[29] It also occurs, at significant levels in many non-food plants such as water lilies and duckweed.[30] (Consider, for example, the many species of flowering and non-flowering plants in the genus *Oxalis*, named for the presence of oxalic acid.)

9. Use of Resources and Energy

The use of the FCS mixture will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials used in the production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for production of the FCS mixture components is not significant.

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[26] *Ibid.*

[27] K. Verschueren, Handbook of Environmental Data on Organic Chemicals, New York, Chichester, Weinheim, John Wiley & Sons, Inc., Vol. 2, 4th ed., p. 1397, 2001.

[28] SIDS Initial Assessment Profile "Maleic Anhydride - Maleic Acid" SIDS Initial Assessment Meeting, 2004, ICCA - SIAR Publication, Washington, Brussels.

[29] USDA, *Oxalic Acid Content of Selected Vegetables*, Agriculture Handbook No. 8-11, Vegetables and Vegetable Products, 1984. See also USDA ARS Nutrient data Laboratory available at: https://www.ars.usda.gov/northeast-area/beltsville-md/beltsville-human-nutrition-research-center/nutrient-data-laboratory/docs/oxalic-acid-content-of-selected-vegetables/

[30] Smith RL, Oremland RS; Appl Environ Microbiol 46: 106-13 (1983).

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilute FCS mixture. Therefore, the use of the subject mixture is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no environmental impact. The addition of the antimicrobial agent to the options available to food processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Mark A. Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Dr. Hepp has a Ph.D. in chemistry with 21 years of experience in reviewing and preparing food-contact notifications, environmental assessments and findings of no significant impact for both the federal government and the private sector.

Devon Wm. Hill, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. J.D. with 21 years of experience with FCN submissions and environmental assessments.

13. Certification

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

[redacted]

Devon Wm. Hill
Counsel for Notifier