PART IV ENVIRONMENTAL INFORMATION

SECTION B - ENVIRONMENTAL ASSESSMENT

1. **Date:** February 1, 2024

2. **Notifier:** Clean Chemistry Inc.

3. **Address:**

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4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as an aqueous mixture of peracetic acid (PAA), hydrogen peroxide (HP), sodium acetate, and glycerin (or glycerol), in the production and preparation of: whole or cut meat and poultry; processed and pre-formed poultry and meat; fruits and vegetables; fish and seafood; grains of wheat, corn and rice; shell and hardboiled peeled eggs, whey protein concentrate, lactose, brines, sauces, and marinades; and, aseptic filling and packaging systems.

When used as intended, the components of the FCS mixture will not exceed:

1) As an antimicrobial agent in in spray, wash, rinse, dip, chill, and scald process water, ice, or brine used in the production, processing, and preparation of whole or cut meat carcasses, parts, trim, and organs at a maximum use level of 2000 ppm peracetic acid and 44.4 ppm hydrogen peroxide;

2) As an antimicrobial agent in spray, wash, rinse, dip, chill, and scald process water, ice, or brine used in the production, processing, and preparation of whole or cut poultry carcasses, parts, trim, and organs at a maximum use level of 2000 ppm peracetic acid and 44.4 ppm hydrogen peroxide;

3) As an antimicrobial agent in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat at a maximum use level of 495 ppm peracetic acid and 11 ppm hydrogen peroxide;

4) As an antimicrobial agent in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed poultry at a maximum use level of 495 ppm peracetic acid and 11 ppm hydrogen peroxide;

5) As an antimicrobial agent in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities at a maximum use level of 600 ppm peracetic acid and 13.3 ppm hydrogen peroxide;

6) As an antimicrobial agent in process water and ice used to commercially prepare fish and seafood at a maximum use level of 230 ppm peracetic acid and 5.1 ppm hydrogen peroxide;

7) As an antimicrobial agent in applied during the tempering and before milling of grains of wheat, corn, and rice applied at a level not to exceed 3% by weight of the grain at a maximum use level of 6000 ppm peracetic acid and 133.3 ppm hydrogen peroxide;

8) As an antimicrobial agent in water for washing shell eggs at a maximum use level of 2000 ppm peracetic acid and 44.4 ppm hydrogen peroxide;

9) As an antimicrobial agent in spray, wash, dip, rinse, mist, or chiller water for hard boiled, peeled eggs at a maximum use level of 2000 ppm peracetic acid and 44.4 ppm hydrogen peroxide;

10) As an antimicrobial additive to liquid, pasteurized whey used in the production of whey protein concentrate at a maximum use level of 15 ppm peracetic acid and 0.33 ppm hydrogen peroxide;

11) As an antimicrobial to control microorganisms in wash water used to manufacture lactose at a maximum use level of 30 ppm peracetic acid and 0.67 ppm hydrogen peroxide;

12) As an antimicrobial agent used in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces at a maximum use level of 50 ppm peracetic acid and 1.1 ppm hydrogen peroxide;

13) As an antimicrobial agent used in surface sauces and in marinades applied on processed and preformed meat and poultry products at a maximum use level of 50 ppm peracetic acid and 1.1 ppm hydrogen peroxide; and,

14) As an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging, at 4500 ppm peracetic acid and 100 ppm hydrogen peroxide.

The FCS is not for use in contact with infant formula and human milk. The FCS is also not for use on food packaging used in contact with infant formula and human milk or on aseptic filling equipment used to fill such packaging. Such uses were not included as part of the intended use of the substance in the FCN.

b. Need for Action

The FCS reduces and/or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food during production.

The purpose of this FCN is to propose uses for the FCS in order to address current and future needs of food processors and government agencies for improving food safety. Using the FCS provides more options for antimicrobial interventions, allowing the food industry to improve processing techniques and provide greater flexibility in terms of time, concentration, application method (e.g., spray vs. immersion) to improve the control of food pathogens.

c. Locations of Use/Disposal

The FCS is intended for use in meat and poultry, fruit and vegetable, fish and seafood, grain, egg, cheese, and lactose processing plants and filling and packaging facilities throughout the United States. It is expected that on-site wastewater treatment facilities will discharge to publically owned treatment works (POTW). During the onsite treatment process, very minor quantities of the solution are lost to evaporation. When used aboard fishing vessels, the water containing the FCS is expected to be disposed back into the open waters in compliance with local fishing discharge regulations.

1) Whole or Cut Meat and Poultry Processing

EPA requires meat and poultry processors to meet specific effluent pre-treatment standards.[1] Therefore, the waste process water containing the FCS is expected to be released to the processing plant’s wastewater treatment facility before being discharged either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to POTW.

In poultry processing facilities the diluted FCS is applied to poultry carcasses, organs, parts, or trim by an immersion dip or in a spray cabinet. Carcasses are carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the FCS. Chiller baths typically include a “main chiller” bath and a “finishing chiller” bath, which both contain the FCS. After the diluted FCS is sprayed onto the carcasses, or the carcasses are removed from an immersion dip, most of it drains off of the poultry. The waste solution runs into drains and enters the poultry processing plant water treatment facility. All water is collected and treated by the water treatment facility before being sent to a POTW. Very small quantities of this water would be lost to evaporation.

In meat processing facilities the diluted FCS is applied to meat carcasses or parts by spraying carcasses suspended on a moving conveyor line or rail system. The carcasses are carried into a spray cabinet where the dilute FCS solution is evenly applied onto the surface of the meat. The carcasses exit the spray cabinet and continue through the processing line. In some instances, meat parts are placed in a dip tank containing the diluted FCS in order to ensure full contact with the intervention treatment. After the diluted FCS is applied to the carcass, most of it drains off of the meat. This water ultimately runs into drains and enters the meat processing plant water treatment facility before being sent to a POTW. Very small quantities of water would be lost to evaporation.

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[1] US EPA Meat and Poultry Products Effluent Guidelines, 40 CFR Part 432 https://www.epa.gov/eg/meat-and-poultry-products-effluent-guidelines.

2) Processed and Preformed Meat and Poultry

The FCS is used as a treatment for washing, rinsing, and cooling water applied to processed and pre-formed meat and poultry products. Most of the solution drains off the product.

3) Fruit and Vegetable Processing Facilities

Produce may be washed by submersion, spray, or both.[2] The FCS components that would enter environment will result from its use in the fruit and vegetable processing water and the subsequent disposal of such water draining into the processing plant wastewater treatment facility. There may also be direct discharge to surface waters from use of the PAA product in fruit and vegetable processing facilities.

4) Fish and Seafood Processing Facilities

Land Based Seafood Processing Facilities: Seafood products are caught in open waters or grown in seafood farms. Caught seafood products are sorted and separated into parts. Parts of seafood products are then flash frozen and packaged. The diluted FCS is sprayed directly onto the raw or processed seafood products before flash-freezing. The bulk of the solution drains off of the seafood products. The waste solution ultimately runs into drains and enters the seafood processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to a POTW or discharged directly to surface water in accordance with the plants' NPDES permit. Direct discharge to surface water is considered the worst-case scenario as it does not take into account any further treatment that may occur at a POTW. Very small quantities would be lost to evaporation into the air.

The diluted FCS may also be frozen into ice and then packaged with the frozen seafood product. The dilute frozen product will eventually thaw and drain off the seafood products at downstream facilities in the supply chain (e.g. grocery stores). This waste solution ultimately runs into drains and is sent to a POTW.

On-Board Seafood Processing: The proposed use in seafood and fish processing also includes use aboard fishing vessels during the initial evisceration and cleaning of freshly caught seafood. It is expected that wastewater will be discharged into the ocean where the peroxygen components in the FCS would have a very short half-life. In this discharge case, the component dilution residuals into the ocean would be impossible to calculate, and the resultant concentration of the components in the ocean would be negligible. Direct discharge of wastewater is an accepted practice within the fishing industry.

5) Grain Milling

The FCS is proposed for use as an antimicrobial agent for process water applied during the tempering and before milling of grains of wheat, corn, and rice. The primary pathway for the FCS to reach the environment is by the use and disposal of the FCS.

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[2] U.S. Food and Drug Administration (February 2008) *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, Section VIII.C.2.b, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables

Following appropriate use, waste process water containing the diluted FCS solution will be disposed of at industrial wastewater treatment facilities established at processing plant use sites, in combination with publicly owned treatment works (POTWs), or privately owned treatment plants. For processing plants with active National Pollutant Discharge Elimination System (NPDES) permits (i.e., direct dischargers), FCS-containing wastewater will be treated on-site before discharge to surface waters or reuse. For processing plants without NPDES permits (i.e., indirect dischargers), wastewater that contains diluted FCS material is collected and treated by the facility. Wastewater treated at processing facilities is then directed through sanitary sewer systems into POTWs for standard wastewater treatment before movement into aquatic environments (i.e., surface water).

6) Egg Processing Facilities

The FCS is intended for use as an antimicrobial agent in processing water or ice used for washing, rinsing, storing, cooling and otherwise processing of peeled, hard-boiled eggs and shell eggs in food processing facilities throughout the United States.

Following appropriate use, waste process water containing the diluted FCS solution will be disposed of at industrial wastewater treatment facilities established at processing plant use sites, in combination with publicly owned treatment works (POTWs), or privately owned treatment plants. For processing plants with active National Pollutant Discharge Elimination System (NPDES) permits (i.e., direct dischargers), FCS-containing wastewater will be treated on-site before discharge to surface waters or reuse. For processing plants without NPDES permits (i.e., indirect dischargers), wastewater that contains diluted FCS material is collected and treated by the facility. Wastewater treated at processing facilities is then directed through sanitary sewer systems into POTWs for standard wastewater treatment before movement into aquatic environments (i.e., surface water).

7) Whey Pasteurization Facilities

The FCS is added directly to ingredient mixtures of frozen dessert mixes and ready-to-drink beverages containing whey protein, prior to pasteurization, in processing facilities throughout the United States. No environmental introductions are anticipated at the locations of use. The only environmental introductions will be due to residential disposal of human waste products. Wastewater containing the FCS will be diluted and treated at a Publicly Owned Treatment Works (POTW) prior to being combined with surface waters.

8) Lactose Production Facilities

FCS is used at the end of the lactose production by injecting FCS using flow-proportional dispensing equipment in the final stage "refining process", just prior to the TEMA separator (which is the stage that separates the liquid from the crystal lactose just prior to drying).

During the subsequent dehydration process the lactose, and a small amount of the FCS that remains, is subjected to drying temperatures of 195-210°F. Peroxy compounds cannot exist in a dehydrated form, and thus decompose to their degradation products carbon dioxide, oxygen and water. Small amounts of the degradation byproducts may remain as a result of the dehydration process.

The FCS substance, if accidentally discharged or released as over-flow from the process area, would be directed to the food plant wastewater discharge system, industrial wastewater treatment facilities established at processing plant use sites, in combination with publicly owned treatment works (POTWs), or privately owned treatment plants. For processing plants with active National Pollutant Discharge Elimination System (NPDES) permits (i.e., direct dischargers), FCS-containing wastewater will be treated on-site before discharge to surface waters or reuse. For processing plants without NPDES permits (i.e., indirect dischargers), wastewater that contains diluted FCS material is collected and treated by the facility. Wastewater treated at processing facilities is then directed through sanitary sewer systems into POTWs for standard wastewater treatment before movement into aquatic environments (i.e., surface water).

9) Brines, Sauces, Marinades for Meat and Poultry

In a typical marinade operation, a fresh marinade batch containing the FCS may be made prior to each 4-hour interval of an 8 hour shift, and then disposed after 4 hours of use. The marinade batches are commonly blended in 50-200 gallon tanks. Following each 4-hour interval, the remainder of the marinade batch, typically up to 30-40 percent, is treated at the meat or poultry processor’s on-site pretreatment facilities before discharge to a POTW or surface waters, depending upon whether the facility has an individual NPDES permit. Therefore, meat and poultry processors discharge their wastewater first to onsite treatment facilities and subsequently to POTWs or discharged directly to surface waters if the facility has an individual NPDES permit. Direct discharge to surface water is considered the worst-case scenario as it does not take into account any further treatment that may occur at a POTW.

The marinade may be treated with the FCS after the batch is initially made and again treated with the FCS after each hour of use in the marinade operation to maintain the target PAA concentration. For each 4-hour interval, the total amount of marinade that may be typically disposed of in an on-site pretreatment facility or wastewater discharge system is 80 gallons based on a 200 gallon marinade batch. For an 8-hour shift, the total amount of marinade containing the FCS that may be disposed of into an on-site pretreatment facility or wastewater discharge system is 160 gallons. For two 8-hour shifts, the total amount of marinade containing the FCS that may be disposed of into an on-site pretreatment facility or wastewater discharge system is 320 gallons. Within a meat or poultry processor’s on-site wastewater discharge system, the FCS components would be diluted in a similar manner to other liquid products, then subsequently diluted further upon entry into the POTW and surface waters.

10) Aseptic Packaging

The FCS may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. In a typical food processing facility, a fresh batch containing the FCS may be initially made prior to an eight (8) hour shift, and then completely disposed of after approximately 6 cycles of 8 hours each (48 hours total time) of use. Due to use of the FCS and loss of the FCS during treatment of the glass and plastic food packaging and their enclosures, it is often necessary to replenish the FCS containing reservoirs during the 6 cycles of use. The FCS used for replenishment is typically made at the beginning of an 8-hour shift during the 6 cycles of use. The reservoirs are then filled and re- filled as needed.

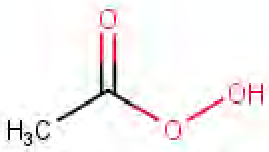
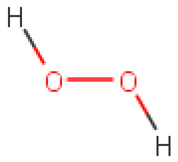
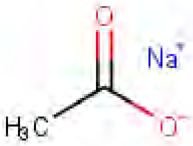
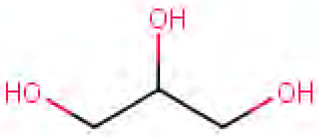
The batches containing the FCS are commonly blended in tanks filled to approximately 900 gallons. Typically, about 600 gallons of the FCS in a reservoir is intended for use in glass and plastic food packaging treatment operations and approximately 300 gallons of the FCS in a reservoir is used in enclosure treatment operations. During each 8-hour shift, the loss of the FCS solution due to its use, may be up to 50 percent or 450 gallons of the FCS. The FCS solution that is lost during use is diluted with other liquid waste products at the processing plant. The diluted FCS solution will be disposed of with processing plant wastewater according to NPDES regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS- containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS containing wastewater would travel through the sanitary sewer system into POTWs for standard wastewater treatment processes before movement into aquatic environments.

The FCS is initially made up at the target PAA concentration. For each 8-hour shift the total amount of FCS that may be typically disposed of in an on-site pretreatment facility or wastewater discharge system is 450 gallons based on a total of 900 gallons of FCS. For two 8-hour shifts consisting of a typical day, the total amount of the FCS that may be disposed is 900 gallons. The FCS solution will be disposed of with processing plant wastewater according to NPDES regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS containing wastewater would travel through the sanitary sewer system into POTWs for standard wastewater treatment processes before movement into aquatic environments.

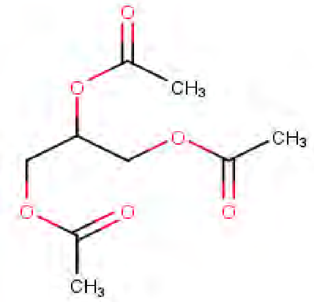
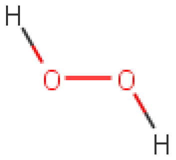
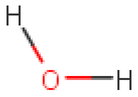
5. Identification of Substances that are Subject of the Proposed Action

This food contact substance is a mixture of peracetic acid, sodium acetate, and glycerin (or glycerol). The FCS is intended to be generated on-site then diluted to achieve the desired active concentration, detailed in Part 4, above.

The chemicals in the proposed FCS include:

Name	Chemical Formula	Chemical Structure	CAS Reg. No.
Peracetic Acid	C2H4O3	 Peroxyacetic Acid	79-21-0
Hydrogen Peroxide	H2O2		7722-84-1
Sodium Acetate	NaC2H3O2	 Sodium Acetate	127-09-3
Glycerin (or Glycerol)	C3H8O3	 Glycerol	56-81-5

Clean Chemistry, Inc. supplies the raw materials and hardware used in the on-site generation of the FCS. This includes a source for the chemical feedstocks as well as the generator responsible for the mixing of these raw materials and output of the FCS. This on-demand patented process uses the following chemical feedstocks:

Name	Chemical Formula	Chemical Structure	CAS Reg. No.
Triacetin	C9H1406		102-76-1
Hydrogen Peroxide	H2O2		7722-84-1
Sodium Hydroxide	NaOH	$Na^+ \ OH^-$	1310-73-2
Water	H2O		7732-18-5

On-demand generation of the FCS eliminates the need to incorporate a stabilizer such as 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP) in the formulation. As described below, the FCS is prepared in a non-equilibrium process that produces PAA that is immediately applied in the desired concentration. No stabilizers are contained in this FCS since it is produced and used on-demand.

Ingredients are combined in a controlled process as follows:

a. Process Step 1: Preparation of the alkaline substrate

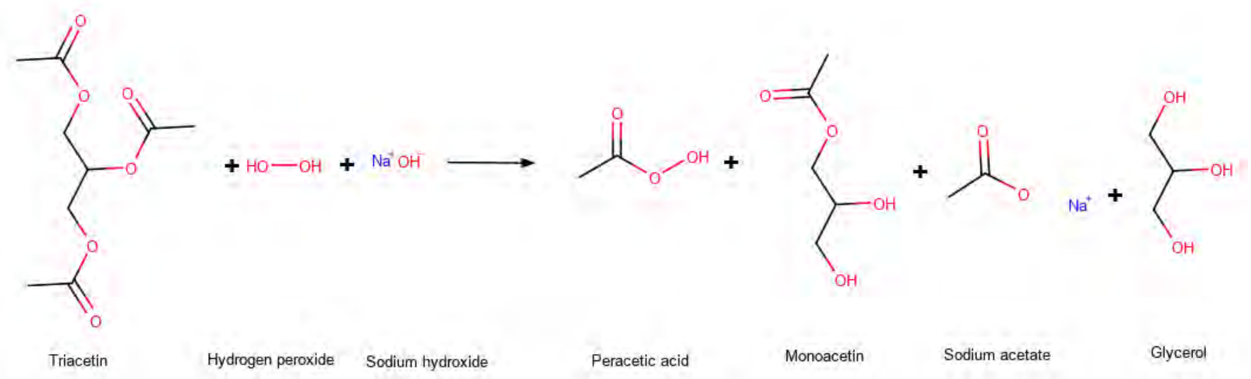
Water is fed into the generator/mixer followed by concentrated sodium hydroxide providing the alkaline environment needed for the next steps.

b. Process Step 2: Addition of hydrogen peroxide

$$2NaOH + H2O2 \rightarrow Na2O2 + 2H2O$$

Next, hydrogen peroxide is blended into the mixer's alkaline solution and forms an alkaline peroxide solution.

c. Process Step 3: Addition of triacetin



In the next step, under continuous agitation, triacetin is added to the process. Triacetin rapidly reacts with the alkaline peroxide to form an aqueous mixture of PAA. Alkaline pH (pH>10) is used to accelerate the reaction since the hydrogen peroxide anion is a much better nucleophile than hydrogen peroxide. Both the hydrogen peroxide anion, O_2^{2-} and HO^- compete in the reaction with triacetin's acetyl groups, the former producing a PAA and the latter producing acetate. The reaction takes place at ambient temperature and pressure.

The reaction medium that is formed in this step almost instantaneously forms a non-equilibrium solution of PAA. The hydrogen peroxide reacts with triacetin, the acetyl precursor, to form peracetic acid.

d. Process Step 4: Collection of PeroxyMAX

Once generated, PeroxyMAX is collected in a small buffer tank from which it is drawn and conveyed by a chemical feed pump to its point of use immediately after preparation.

6. Introduction of Substances into the Environment

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

Per 21 CFR Section 25.40(a), the environmental assessment for the FCS should focus on environmental issues only relating to the use and disposal from use of FDA-regulated articles. The FCS is produced on-site and on-demand at the point of use. The FCS is not manufactured in a separate facility and transported to the end-use site, therefore, information on the manufacturing site is not provided here. The end-use site will be the site of manufacture and therefore emissions requirements are addressed in section 6.b. The Notifier confirms that there are no extraordinary circumstances pertaining to the continuous, on-site manufacture of the FCS such as:

1) unique emissions that are not already addressed by general or specific emission requirements (including occupational) established by Federal, State or local environmental agencies and that may harm the environment; or,

2) an action in violation of Federal, State or local environmental laws or requirements; or,

3) production associated with the proposed action that may adversely affect a species or the habitat of a species as 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 Federal law.

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

Any release of dilute solutions of the FCS into the environment will primarily occur via wastewater treatment systems. Release of the FCS components into the environment will result from its use as spray applications onto food and in processing water. The subsequent disposal of processing water and spray drainage will be to on-site treatment plants and/or POTWs. The total amount of FCS used at a facility will vary depending on the equipment used and the amount of food processed. The maximum use concentration of PAA and HP for each application is as follows:

Summary of Intended Uses

Use	PAA (ppm)	HP (ppm)
Process water or ice used for washing, rinsing, or cooling whole or cut meat, including carcasses, parts, trim, and organs	2000	44.4
Spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40°F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs	2000	44.4
Water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed meat as defined in 21 CFR 170.3(n)(29)	495	11
Water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed poultry as defined in 21 CFR 170.3(n)(34)	495	11
Water for washing or chilling fruits and vegetables in food processing facilities	600	13.3
Water and ice used to commercially prepare fish and seafood	230	5.1
Tempering and before milling of grains of wheat, corn, and rice	6000	133.3
Water for washing shell eggs	2000	44.4
Spray, wash, dip, rinse, mist, or chiller water for hard boiled, peeled eggs	2000	44.4
Additive for liquid, pasteurized whey used in the production of whey protein concentrate	15	0.33
Wash water used to manufacture lactose	30	0.67
Brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts and pieces	50	1.1
Surface sauces and in marinades applied on processed and preformed meat and poultry products	50	1.1
Commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging	4500	100

Treatment of process water at an on-site wastewater treatment plant or POTW is expected to result in complete degradation of PAA. PAA will break down into oxygen, water, and acetic acid. Any residual hydrogen peroxide remaining in the FCS as an impurity of less than 0.1% will break down into oxygen and water.[3] PAA, acetic acid, and hydrogen peroxide are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. The half-life of PAA in buffered solutions was 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[4] The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to 15.2 days and 20.1 days when the concentration decreased to 250 ppm and 100 ppm, respectively.[5] In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.[6] acetic acid is not expected to concentrate in the wastewater discharged to the wastewater treatment plant or POTW. Therefore, peracetic acid, hydrogen peroxide, and acetic acid are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS.

In the current reaction scheme associated with this FCS, a mixture of hydrogen peroxide is blended with sodium hydroxide and dilution water. Triacetin is then added to this diluted mixture. The resulting reaction converts the three available acetyl groups on triacetin into PAA with a resulting aqueous solution having a PAA purity of greater than 94 percent. The remaining acetyl groups from triacetin would be in the form of monoacetin. None would be in the form of unreacted triacetin or diacetin because the first two acetyl groups are more easily reacted from triacetin than the final acetyl group. Due to excess alkalinity, the 'first-formed' PAA hydrolyzes residual monoacetin to sodium acetate and glycerin (or glycerol). To further emphasize that release of monoacetin residuals is not anticipated, and if they were, no significant environmental impacts would result we note that a2012 U.S. Army Public Health Command study of wildlife toxicity of triacetin[7] contains the following discussion on page 2:

"When triacetin is released into the environment, it is believed to degrade rapidly. Due to its low vapor pressure of 0.0033 hPa at 25°C, triacetin most likely exists entirely in the vapor phase in the ambient atmosphere (OECD 2002) where it is degraded photochemically to hydroxyl radicals. An estimated Koc of 10.5 suggests that the compound should readily leach from soil to surface water or groundwater. When in water, degradation is expected to occur rapidly and near completely by hydrolysis, producing glycerol and acetic acid, which are further broken down to carbon dioxide. Because of its high solubility and low vapor pressure in a water medium, 99% of the initial parent compound is believed to remain until hydrolysis is complete."

We assert that monoacetin would behave similarly due to its structural similarity to triacetin. Therefore, release of monoacetin to the environment is not anticipated. As a result, the

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[3] U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993), p. 18 https://archive.epa.gov/pesticides/reregistration/web/pdf/peroxy_compounds.pdf.

[4] European Centre for Toxicology and Toxicology of Chemicals, *Joint Assessment of Commodity Chemicals No. 40 Peracetic Acid and its Equilibrium Solutions*, January 2001, p.29, Table 11 http://www.ecetoc.org/publication/jacc-report-40-peracetic-acid-and-its-equilibrium-solutions/

[5] European Centre for Toxicology and Toxicology of Chemicals, *Joint Assessment of Commodity Chemicals No. 22, Hydrogen Peroxide,* January, 1993 p 23, Table 6 www.ecetoc.org/publication/jacc-report-22-hydrogen-peroxide/

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

[7] U.S. Army Public Health Command "Public Health Notice: Wildlife Toxicity Assessment for Triacetin" (May 2012) https://phc.amedd.army.mil/PHC%20Resource%20Library/WTA_%20Triacetin.pdf

remainder of this EA analysis will consider only the environmental introduction, fate, and impacts of glycerin (or glycerol) and sodium acetate.

7. Fate of Emitted Substances in the Environment

As previously mentioned, PAA, acetic acid, and hydrogen peroxide are not expected to survive treatment at the primary wastewater treatment facilities. Further, no significant amounts of the process residual monoacetin are expected to be released. Therefore, Expected Environmental Concentrations (EECs) have not been calculated for these substances. With respect to the process residuals glycerin (or glycerol) and sodium acetate we provide the subsequent analysis.

The OECD-SIDS document[8] for glycerol states that 100% of glycerol (or glycerin) will end up in the water phase, and negligible amounts will be distributed towards soil, air and sediment. In addition, it was concluded that glycerol is considered to be readily biodegradable. The OECD-SIDS document also reports that glycerol is 92% biodegradable in 30 days, and more than 60% in 10 days.[9]

Neither the FCS, nor the components used in its generation, are expected to be present in environmentally significant concentrations at discharge or during disposal. Similarly, the already environmentally benign glycerin (or glycerol) and acetic acid byproducts present post-use and at disposal will further degrade into carbon dioxide. Glycerin (or glycerol), acetic acid, and sodium acetate are all readily biodegradable as demonstrated in studies utilizing activated sludge under aerobic conditions. The same studies indicate the estimated concentrations of glycerin (or glycerol), acetic acid, and sodium acetate capable of reaching a wastewater treatment plant to be well below concentrations capable of negative environmental impact. Glycerin (or glycerol) exists almost entirely in the water phase and only negligible amounts would be distributed into soil, air, or sediment.

a. Glycerin (or Glycerol)

Fate in Terrestrial Environment

If released to soil, glycerin (or glycerol) is expected to have very high mobility based upon an estimated Koc of 1. Volatilization from moist soil surfaces is not expected to be an important fate process based upon a Henry's Law constant of 1.73x10-8 atm-cu m/mole.[10] Glycerin (or glycerol) may not volatilize from dry soil surfaces based upon its vapor pressure. A 63% of theoretical BOD using activated sludge in the Japanese MITI test suggests that biodegradation is an important environmental fate process in soil and water.

Fate in Aquatic Environment

If released into water, glycerin (or glycerol) is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. An

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[8] OECD-SIDS (March 2002) “Glycerol: SIDS Initial Assessment Report” pages 8-9 https://hpvchemicals.oecd.org/ui/handler.axd?id=4b0a2d87-3183-40d4-84f5-0e118c647b19

[9] Ibid.

[10] Ibid.

estimated BCF (bioconcentration factor) of 3 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.

Fate in Air

If released to air, a vapor pressure of 1.68x10-4 mm Hg at 25°C indicates glycerin (or glycerol) will exist in both the vapor and particulate phases in the atmosphere. Vapor-phase glycerin (or glycerol) will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 7 hours. Particulate-phase glycerin will be removed from the atmosphere by wet or dry deposition. Glycerin (or glycerol) does not contain chromophores that absorb at wavelengths >290 nm, and therefore is not expected to be susceptible to direct photolysis by sunlight.[11, 12]

Sodium Acetate

Sodium acetate readily dissociates into sodium cation and the acetate anion; whereby the anion is subsequently biodegraded. Sodium acetate is also inherently biodegradable: 100% after 5 days @ 160 mg/L under aerobic conditions using activated sludge.[13] Because it is readily biodegradable, it is expected that the environmental concentrations will be well below concentrations found to have any negative impact on the environment after discharge from the wastewater treatment plant.

Data also indicate that sodium acetate (acetic acid, sodium salt) photodegrades, although the rate is substantially slower than that of biodegradation. Studies of sodium acetate indicate 6.6% photomineralization after 17 h UV irradiation (> 290 nm).[14]

8. Environmental Effects of Released Substances

a. Glycerin (or Glycerol)

Terrestrial Toxicity

If released to soil, glycerin (or glycerol) is expected to undergo rapid biodegradation under aerobic conditions. It is expected to display very high mobility in soil and it is not expected to significantly volatilize to the atmosphere.

Aquatic Toxicity

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[11] U.S. Army Public Health Command "Public Health Notice: Wildlife Toxicity Assessment for Triacetin" (May 2012) https://phc.amedd.army.mil/PHC%20Resource%20Library/WTA_%20Triacetin.pdf

[12] OECD-SIDS (March 2002) "Glycerol: SIDS Initial Assessment Report" pages 8-9 https://hpvchemicals.oecd.org/ui/handler.axd?id=4b0a2d87-3183-40d4-84f5-0e118c647b19

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

[14] Ibid.

Studies indicate glycerin (or glycerol) is of low toxicity to aquatic organisms[15]. The lowest reported LC50 for fish is a 24-hour LC50 of >5000 mg/L for Goldfish (Carassius auratus). The lowest EC50 for aquatic invertebrates is >10000 mg/L for Daphnia magna. Based on this and related data, the Organization for Economic Cooperation and Development (OECD) Screening Information Dataset (SIDS) reports a predicted no-effect concentration (PNEC) of 780 mg/L. We note that the most conservative EEC possible for glycerin (or glycerol), that of a very small fraction of the 6000 ppm PAA solution used for tempering and before milling of grains of wheat, corn, and rice would be orders of magnitude lower than these ecotoxicity endpoints. Thus, significant environmental impacts from residual glycerin (or glycerol) are not anticipated.

Study	Value	Species	Duration
Acute aquatic, fish	> 5,000 mg/L	*Carassius auratus* (Goldfish)	24 h
Acute aquatic, algae	2,900 mg/L	*Microcystis aeruginosa*	24 h
Acute aquatic, Daphnia	10,000 mg/L	*Daphnia magna*	24 h

b. Sodium Acetate

Ecotoxicity data from the High Production Volume Assessment Plan for Acetic Acid and Salts[16] describe these substances as not highly toxic to mammalian or aquatic plant and animal species. Reported 48-hour LC50 values for fathead minnow, rainbow trout, and Daphnia are 92-106 ppm, 105 ppm, and 65 ppm, respectively. Toxicity thresholds for Scenedesmus quadricauda (4000 ppm), Anacystis aeruginosa (90 ppm) and Entosiphon sulcatum (78 ppm) are also given. We note again, as with glycerin (or glycerol), amounts of this residual released to the environment are expected to be much lower than these ecotoxicity endpoints and, as such, no significant environmental impacts are expected.

9. Use of Resources and Energy

The use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials that are used in 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 the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilutions of antimicrobial product. Therefore, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

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[15] OECD-SIDS (March 2002) “Glycerol: SIDS Initial Assessment Report” pages 23-24 https://hpvchemicals.oecd.org/ui/handler.axd?id=4b0a2d87-3183-40d4-84f5-0e118c647b19

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

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact 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 processers is not expected to increase the use of PAA antimicrobial products.

12. List of Preparers

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b. Conor Pierce, Ph.D., Clean Chemistry, Inc.

c. Wendy A. McCombie B.Sc., TSG Consulting

13. Certification

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

Name: Wendy A. McCombie, TSG Consulting

Title: Agent for Clean Chemistry Inc.

Signature: [redacted]

Date: February 1, 2024

14. References

American Chemistry Council, Acetic Acid and Salts Panel, *U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category*, June 28, 2001

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