

FinalRevised Attachment_13_ Environmental Assessment_PAAFCS_2013-05-28

FDA (Food and Drug Administration)

1. May 28, 2013 (revised Aug 16, 2013)

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4. Description of Proposed Action

The action requested in this notification is the establishment of a clearance to permit the use of a food contact substance (FCS) described as a mixture containing peroxyacetic acid (PAA), hydrogen peroxide, glycerol, water, and optionally acetic acid or sulfuric acid.

The antimicrobial agent is intended for use in fish and seafood processing plants and processed and pre-formed meat and poultry processing plants throughout the United States, and may also be used aboard fishing vessels during the initial evisceration and cleaning of fresh-caught seafood. The FCS is also intended to control microbial growth in wash water that contacts fruits and vegetables that are not raw agricultural commodities.

The FCS is intended to be produced on-site and diluted to maximum PAA concentrations of 1000 ppm for poultry, 400 ppm for meat, 190 ppm for fish and seafood and 80 ppm for fruits and vegetables, with other associated components in proportional concentrations. The maximum peroxygen actives concentrations for the intended applications are as follows:

Component	Application			
	Meat (ppm)	Poultry (ppm)	Fish & Seafood (ppm)	Fruits & Vegetables (ppm)
Peroxyacetic acid	400	1000	190	80
Hydrogen Peroxide	280	700	140	60

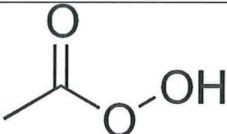

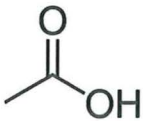
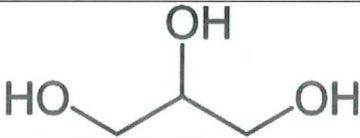
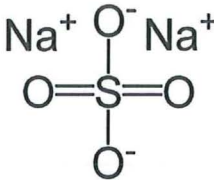
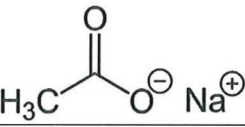

The hydrogen peroxide concentration shown in the Table above and its proportion with respect to PAA concentration is controlled via the exact manufacturing configuration. The concentration shown in this Table represents a *maximum concentration*, independent of the manufacturing configuration.

The intended technical effect of the FCS is to inhibit the growth of undesirable or pathogenic microorganisms from the process water used to prepare fish and seafood and in the process water or ice used to wash, rinse, store, or cool processed and preformed meat and poultry products, and to retard the spoilage of the contacted food, ultimately providing safer products for consumers.

5. Identification of Substance

The FCS is a mixture of peroxyacetic acid, hydrogen peroxide, glycerol, water and optionally acetic acid or sulfuric acid. Depending upon the manufacturing configuration the acetic acid or sulfuric acid will be present in the final formulation as sodium acetate or sodium sulfate, respectively.

FCS Components:

Name	Chemical Formula	Chemical Structure	CAS Reg. No.
Peroxyacetic Acid	C ₂ H ₄ O ₃		79-21-0
Hydrogen Peroxide	H ₂ O ₂		7722-84-1
Acetic Acid	C ₂ H ₄ O ₂		64-19-7
Glycerol	C ₃ H ₈ O ₃		56-81-5
Sodium Sulfate	Na ₂ SO ₄		7757-82-6
or Sodium Acetate	NaC ₂ H ₃ O ₂		127-09-3
Water	H ₂ O		7732-18-5

6. Introduction of Substance into the Environment:

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

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicating any adverse environmental impact as a result of the manufacture of the antimicrobial agent. The FCS

is produced on-site and on-demand. The feedstocks for the manufacturing process are hydrogen peroxide, sodium hydroxide, triacetin, water, and optionally acetic acid or sulfuric acid. There is no intended transportation of the FCS to the end-use facility. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here. No extraordinary circumstances would apply to the on-going manufacture of the FCS.

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

The FCS is proposed for use in water as an antimicrobial during the processing of meats, poultry, seafood, and fruits and vegetables. Introduction of dilute solutions of the antimicrobial agent into the environment will take place primarily via release in wastewater treatment systems, but may also take place from on-board processing of fish and seafood on fishing vessels.

It is difficult to determine the amount of the antimicrobial agent that could be released into the environment as a result of the intended uses, as amounts used in processing will depend on the location and equipment used and the amount of fish and seafood, and meat, poultry, and fruits and vegetable processed. However, this FCS only contains components that are non-toxic and readily biodegradable at intended use concentrations. The peroxygen compounds, PAA and hydrogen peroxide, are highly reactive and short-lived due to the inherent instability of the peroxide bond, and are expected to degrade rapidly into their breakdown products carbon dioxide, water, oxygen, and acetic acid. As will be discussed in Section 7 below, neither the peroxygen compounds, nor the other components of the FCS are expected to be present in environmentally significant concentrations upon discharge to the environment through aquatic or terrestrial routes.

Estimates for Uses

The maximum proposed use concentration of PAA for any of the intended uses listed in this application is 1000 ppm. The limitations for all proposed uses are set at concentrations consistent with other PAA mixtures that have already received FDA approval as a food contact substance for identical applications. Undoubtedly the FCS may be used at somewhat lower concentrations in certain areas/processes, but the focus for this environmental assessment shall be at the highest limits requested in this application.

Meat processing facilities

This product will be applied to the surface of freshly killed beef or swine carcasses following removal of the hide, head and hooves. This is accomplished by spraying the carcasses on a moving conveyor line or on a rail system. The carcasses are suspended from a hook attached to the conveyor, which carries the carcass into a spray cabinet. Spray nozzles are distributed within the cabinet in such a manner that ensures even application of the dilute solution on the surface of the beef carcass. The carcass exits the other side of the spray cabinet and continues on the processing line. After the diluted product is sprayed onto the carcass, the majority of the product drains off of the meat and ultimately runs into drains and enters the meat processing plant water treatment facility prior to it being sent to a wastewater treatment plant (WWTP) or publicly operated

treatment works (POTW). Very minor quantities are lost to evaporation. Estimates of water usage in meat processing applications vary widely. In one report, it is estimated that water used, primarily from meat carcass washing and process clean-up during meat processing, is in the range of 150-450 gal/ animal processed.¹ Another source reported the estimated water used at a meat processing facility was 300 gal/ head, and for an “Efficient Water Use” plant the amount was 150 gal/ head.²

We estimate the following facility operations utilize spray washings and consume water at the following average rate: hide-on washers 300 gpm, hide off carcass washers 170 gpm, head washers 50 gpm, PECS (pre-evisceration cabinets) 70 gpm, hot washers 70 gpm. Therefore, the total wash water listed = 660 gpm. Assuming that a large plant processes about 5,000 head/day, which equals about 5.2 head/minute (960 minutes/day), the average process water used per head = 660 gal/min ÷ 5.2 head/min. = 126.9 gal/head. This calculation will be rounded to 150 gal/head for convenience. Using an estimated total cumulative wastewater discharge at the meat processing facility to be 450 gal/head, a conservative dilution factor (DF) of 3 (450 gal/ head total discharge water ÷ 150 gal/ head of process water) can be used to determine the estimated concentrations of the components prior to treatment at a POTW. As discussed in section 7 below, none of the components FCS are expected to be present in environmentally significant concentrations upon discharge to the environment after treatment.

Component	At-use concentration (ppm)	Discharge Concentration (ppm)
		DF=3
Peroxyacetic acid	400	134*
Hydrogen Peroxide	280	94*
Acetic acid	2500	834
Glycerol	360	120
Sodium Sulfate, or Sodium Acetate	1300	434

*The peroxygen components of the FCS would be expected to have a very short half-life and are expected to be largely degraded in the food plant wastewater discharge system, prior to treatment in the POTW.

Poultry processing facilities

Spray application of the diluted product will usually take place prior to chilling by submersion. A de-feathered, eviscerated carcass hung on a shackle is carried into a spray cabinet by a moving line. Spray nozzles inside the cabinet apply the diluted product to the carcass. The carcass then exits the spray cabinet for further processing. Application of the diluted product by submersion of multiple carcasses into a chiller bath will occur usually following the spray application step. Carcasses are moved through the chiller bath by a paddle or auger-type conveyor, then exit the chiller bath for further processing. Carcass parts or organs may also be chilled by submersion in water containing the product. Additional applications of the diluted product include submersion of multiple carcasses into an after-chiller processing bath containing diluted product or spray of carcasses on conveyor belts or in an after-chiller spray cabinet. After the diluted product is sprayed onto the poultry carcasses, the bulk of the solution drains off of the poultry

carcass. The waste solution ultimately run into drains and enters the poultry processing plant water treatment facility. The diluted product in chiller water / after-chiller bath will also be disposed of by pouring it down drains that lead to the poultry processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to a POTW. Very minor quantities are lost to evaporation into the air.

In the case of poultry operations, the FCS is used as an antimicrobial treatment in sprays and chiller/finishing chiller applications. For our calculations, we assume an estimated 0.25 gal FCS will be sprayed per carcass treated in poultry processing applications. On January 27, 2012, the USDA Food Safety Inspection Service (FSIS) published a proposed rule entitled “Modernization of Poultry Slaughter Inspection”³ that provides a new inspection system for poultry slaughter facilities that allows for higher line speeds and more birds processed per minute. The increased throughput will allow up to 175 bpm (birds per minute) to be processed at a typical facility.⁴

In consideration of the new inspection rules, the calculations for estimated total use are as follows:

Spray Application:

175 bpm = 252,000 carcasses per 24 h day
252,000 carcasses x 0.25 gal of spray/ carcass= 63,000 gallons

Chiller Bath:

25,000 estimated initial gallons, with make up water at a rate of 0.25 gallons/carcass, assuming 252,000 carcasses processed per day. Thus, 63,000 gallons of water are added to the bath per day, bringing the total chiller water consumption to 88,000 gallons for a 252,000 birds per day processing plant.

This applicant will use the figures of 151,000 gal per day water used (63,000 gallons for spray applications and 88,000 gal per day for chiller applications) for general processing in an average 252,000 bird per day processing plant. Water is used in a poultry plant for other non-processing purposes including cleaning, spraying, lubricating, bathroom uses and boiler operations, for example. It is estimated that the average poultry plant consumes a total of 26 L/bird.⁵ Therefore the total consumption is estimated to be $26L/3.784$ (no. of L per gal) x 252,000 birds/day = 1,731,500 gal/day. The DF for the average poultry plant is therefore, $1,731,500 \text{ gal/day} \div 151,000 = 11.47$. Assuming no loss of the actives during processing, and rounding the dilution factor down to a slightly more conservative DF of 10, would result in the following concentrations of the components of the FCS reaching the POTW. As discussed in section 7 below, none of the components FCS are expected to be present in environmentally significant concentrations upon discharge to the environment after treatment.

Component	Maximum Use Concentration (ppm)	Maximum Concentration in POTW (ppm)
		DF=10
Peroxyacetic acid	1000	100*
Hydrogen Peroxide	700	70*
Acetic Acid (including breakdown of PAA to AA)	7000	700
Glycerol	900	90
Sodium sulfate, or Sodium Acetate	1300	130

*The peroxygen components of the FCS would be expected to have a very short half-life and are expected to be largely degraded in the food plant wastewater discharge system, prior to treatment in the POTW.

Fish and Seafood Processing

Ship-Board Fish and Seafood Processing

The FCS is proposed for use aboard fishing vessels as an antimicrobial agent during the commercial processing and storage of fish and seafood. The FCS may be used during the initial evisceration and cleaning of fresh-caught seafood. Wastewater from this process would likely be discharged into the ocean. In this situation, the peroxygen activities of the FCS would have a very short half-life of less than 20 min.⁶ The dilution of glycerol and acetic acid into the ocean waters would be impossible to calculate, but are not expected to persist in concentrations having any negative effect in the environment.

Land-Based Fish and Seafood Processing Facility

The FCS is also intended for use in land-based fish and seafood processing facilities. Seafood products are sorted and separated into parts. Parts of seafood products are then flash frozen and packaged. The diluted product is sprayed directly onto the raw or processed seafood products before flash frozen procedures, the bulk of the solution drains off of the seafood products. The diluted product is also flash frozen into ice particles with an ice machine and then packaged with the frozen seafood product. The dilute frozen product will eventually thaw and drain off the seafood products. There is additional process water used in many stages of fish and seafood processing, including water used for transporting fish and offal around the plant in flume systems, for cleaning plant and equipment, for washing raw materials and product, and for de-icing and thawing.⁷ The FCS is unlikely to be used in all of these applications, thus any FCS-containing wastewater will be diluted by other process wastewater.

The waste solution ultimately run 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. Very minor quantities are lost to evaporation into the air.

Wastewater containing the FCS would be discharged to an on-site pretreatment facility or POTW. As discussed will be discussed below, the PAA, hydrogen peroxide, and acetic acid/sodium acetate, and glycerol are expected to degrade rapidly to their degradation products, carbon dioxide, water, and oxygen. None of the components of the FCS are expected to remain in the wastewater after treatment, excluding the sodium cation, which isn't technically biodegraded.

Dilution factors (DF) have been determined at poultry processing plants and it was found that 71% of facilities had DF's >100, and 96% had a DF of 20 or greater.”⁸ Therefore, a DF of 10 is assumed by this applicant to be a conservative DF for the majority of food processing facilities. In wastewater treatment band-based applications, assuming no decomposition of the active or inactive components, the concentrations of the components in the process water would be; 190 ppm PAA, 140 ppm hydrogen peroxide, 1200 ppm acetic acid, 180 ppm glycerol, 610 ppm sodium (as either sodium acetate or sodium sulfate). Assuming continuous spray-bar application to the fish processing line is the method used, a spray bar would typically consist of 3 nozzles at 1 gpm. Assuming there will be 3 spray bars, the total water utilized would be 9 gpm. This would equate to 12,960 gallons over a continuous 24 hr. period. A conservative DF of 10 would yield a residual composition of 19 ppm PAA, 14 ppm hydrogen peroxide, 120 ppm acetic acid, 18 ppm glycerol and 61 ppm sodium (as either sodium sulfate or sodium acetate) to be treated at the wastewater treatment facility.

Component	Maximum Use Concentration (ppm)	Maximum Concentration in POTW (ppm)
		DF=10
Peroxyacetic acid*	190	19*
Hydrogen Peroxide*	140	14*
Acetic Acid (including breakdown of PAA to AA)	1200	120
Glycerol	180	18
Sodium sulfate, or Sodium Acetate	610	61

*The peroxygen components of the FCS would be expected to have a very short half-life and are expected to be largely degraded in the seafood plant wastewater discharge system, prior to treatment in the POTW.

Fruits and Vegetables that are not Raw Agricultural Commodities

The FCS can also be used as a sanitizer in the wash and rinse water during the processing of fruits and vegetables that are not raw agricultural commodities. It is difficult for this Applicant to estimate a DF for a typical fruits and vegetable processing

facility. Information from the Food Processing Environmental Assistance Center (FPEAC) estimates that approximately 50% of water used in fruit and vegetable processing is for washing and rinsing operations.⁹ For the purpose of this application we will estimate that all of the water used for washing and rinsing processes contain the FCS at the highest intended use concentration. Since 50% of discharge is estimated to be from washing and rinsing (DF=2) the following concentrations can be calculated prior to treatment at a POTW. As discussed in section 7 below, none of the components FCS are expected to be present in environmentally significant concentrations upon discharge to the environment after treatment.

Component	Maximum Use Concentration (ppm)	Maximum Concentration in POTW (ppm)
		DF=2
Peroxyacetic acid*	80	40*
Hydrogen Peroxide*	60	30*
Acetic Acid (including breakdown of PAA to AA)	500	250
Glycerol	80	40
Sodium sulfate, or Sodium Acetate	260	130

*The peroxygen components of the FCS would be expected to have a very short half-life and are expected to be largely degraded in the food processing plant wastewater discharge system, prior to treatment in the POTW.

7. Fate of the Substance in the environment:

Peroxyacetic Acid and Hydrogen Peroxide

It is well documented in accepted in the scientific community that PAA and HP are short lived in the environment, do not bioaccumulate, have innocuous degradation byproducts, and are of no toxicological or ecotoxicological concern.¹⁰⁻¹² The acetic acid degrades to acetate due to increased pH effects. Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment in the primary wastewater treatment facility due to their reactivity and pH sensitivity.¹⁰

The half-life of PAA in buffered solution solutions was 63 hrs at pH 7 for a 748 ppm solution, and 48 hrs for a 95 ppm solution, also at pH 7.¹¹ The half-life of hydrogen peroxide is concentration dependant, and is reported to range from 2.5 days in natural river water when initial concentrations of 10,000 ppm were introduced, and increased to 15.2 days when the concentration decreased to 250 ppm.¹² In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions, and it is not expected to concentrate in the wastewater discharge.¹¹

Glycerol

Glycerol is a liquid with a calculated vapor pressure of 0.000106 hPa (at 25°C), is fully miscible with water and has a Log K_{ow} of -1.76 (measured). It has a calculated half-life for photo-oxidation of ~7 hours and is not susceptible to hydrolysis. The experimental data indicate that glycerol is readily biodegradable under aerobic conditions. Fugacity modeling (Mackay Level III) predicts that glycerol will partition to the aquatic compartment (100%). Based on the low Log K_{ow} , it has a low potential for sorption to soil and is not expected to bioaccumulate.¹³ The distribution in a sewage treatment plant has been estimated using the SimpleTreat model to be 87% degraded, 13% to water, based on ready biodegradability, log K_{ow} = -1.76, water solubility = 1×10^5 mg/L and vapor pressure = 0.000106 hPa.¹³ A number of biodegradation assays have been carried out with glycerol. In a Closed Bottle test (performed according to OECD 301) 92% biodegradation was reported after 30 days. More than 60% biodegradation measured as ThOD was reached within the 10-day window.¹⁴ Glycerol is considered to be readily biodegradable. In addition, the relationship between BOD₅, COD and ThOD was determined. The standard dilution method for a period of 5 days (BOD₅) and the standard potassium dichromate method (COD) were used for the determinations. Both tests were performed according to APHA and ASTM guidelines, respectively. BOD₅ was 82% of ThOD and 86% of COD. It can be concluded that glycerol has the potential to be rapidly biodegraded in a wastewater treatment plant.¹⁵ The BOD₅/COD ratio is 0.86 and the fact that it is >0.5 further supports the ready biodegradability of glycerol. Several other studies using adapted activated sludge or effluent from a sewage treatment plant demonstrates rapid biodegradation of glycerol.¹⁶⁻¹⁹ Under anaerobic conditions, using microorganisms adapted to acetate, glycerol was biodegradable.²⁰

Acetic Acid and Sodium Acetate

Summary ecotoxicity data from the High Production Volume (HPV) Assessment Plan for Acetic Acid and Salts²¹ indicate that acetic acid is not highly toxic to aquatic plant and animal species. In water, acetic acid dissociates into the acetate anion and the hydrogen proton. The anion is readily biodegradable, with 99% degraded after 7 days (anaerobic conditions, in the presence of activated sludge).

Reliable data for environmental fate and transport behavior are available for acetic acid and its salts (see Appendix 1 in Reference 21). Biodegradation appears to be the most significant removal mechanism. Acetic acid is readily biodegradable: 99% after 7 days under anaerobic conditions using activated sludge. Sodium acetate readily dissociates into their 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.

Data also indicate that acetic acid and sodium acetate (acetic acid, sodium salt) photodegrade, although the rate is substantially slower than that of biodegradation. Acetic acid photodegrades 5.1×10^{-13} cm³/molecule·sec exhibiting 50% degradation after 21 days while studies of sodium acetate indicate 6.6% photomineralization after 17 h UV irradiation (> 290 nm). Level I fugacity modeling predicts that about 73% of any acetic acid released to the environment would partition to water, with the remainder partitioning into the air. These data demonstrate that acetic acid and its salts are not persistent in the environment.

Sodium Sulfate and Sulfuric Acid

Sulfuric acid is a strong mineral acid that dissociates readily in water to sulfate ions and hydrated protons, and is totally miscible with water. Its pKa is 1.92 at 25 °C. At pH 3.92, for example, the dissociation is 99%, and sulfate ion concentration is 1.2×10^{-4} moles = 11.5 mg/l. So at environmentally relevant concentrations, sulfuric acid is practically totally dissociated, sulfate is at natural concentrations and any possible effects are due to acidification. This total ionization will imply also that sulfuric acid, itself, will not adsorb on particulate matters or surfaces and will not accumulate in living tissues.²²

Sodium sulfate is not biodegradable in the legal sense of the word, but it takes part in the sulfur cycle, in which sulfate is either incorporated into living organisms or reduced to sulfides by anaerobic bacteria, deposited as sulfur, or re-oxidised in the atmosphere and oceans to sulfur dioxide and sulfate. It has been estimated that the amount of sulfur globally contributed to the atmosphere from all natural and man-made sources is about 100 to 200 million tons. If all sulfur from above mentioned sodium sulfate production were to go into the atmosphere, it would contribute less than 0.25% to the world's total.²³

Sodium sulfate/ sulfuric acid are substances with favorable ecological profiles. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment although locally, peak concentrations may be damaging to un-adapted flora and fauna.

Wastewater Volume

The change in the wastewater volume due to the use of the FCS should be negligible in processes that already use food disinfectants to treat beef, poultry, fish, and fruits and vegetables. The FCS can be a replacement for other PAA disinfectant products on the market based upon the economics of the FCS. The FCS and the other PAA products will be diluted to the same concentration and therefore have the same volume of wastewater produced.

8. Environmental Effects of Released Substances:

As noted above, wastewater from the use scenarios described above as well as wastewater from other plant operations will be directed to an on-site WWTP or a POTW, or both. It is expected that all of the components in the FCS will decompose in the WWTP or POTW prior to water being discharged to the environment. Below is a summary of the decomposition reaction and, if applicable, environmental persistence and ecotoxicity of each component in the FCS.

Peroxyacetic acid

Decomposes rapidly to acetic acid and hydrogen peroxide (which decomposes into water and oxygen) when exposed to transition metals (such as Fe, or Mn) and organic material. The fate of acetic acid is discussed below. However, lifetime of PAA is so short in both the process water and also in the wastewater stream at the wastewater treatment facility that the environmental release is anticipated to be well below concentrations found to have a negative impact on aquatic organisms. The 48-hour EC₅₀ for *Daphnia magna* ranges from 0.50 to 1.1 mg/L; the 96-hour EC₅₀ for *Oncorhynchus*

mykiss and *Lepomis macrochirus* ranges from 0.91 to 2.0 mg/L and 1.1 to 3.3 mg/L, respectively.¹¹

Hydrogen peroxide:

Decomposes rapidly to water and oxygen when exposed to transition metals (such as Fe, or Mn) and organic material. Like peroxyacetic acid, it is not expected to enter the environment after wastewater treatment. The 96-hour LC₅₀ is 16.4 Φg/L and 37.4 Φg/L for *Pimephales promelas* and *Ictalurus punctatus*, respectively. The 24-hour EC₅₀ for *Daphnia magna* is 7.7 mg/L. Several algae species are reported to have less than 5% of the original chlorophyll content when exposed to hydrogen peroxide concentrations ranging from 1.7 to 17 mg/L for 24-48 hours.¹²

Acetic acid and Sodium Acetate:

In water, acetic acid dissociates into the acetate anion and hydrogen proton. Acetic acid is readily biodegradable: 99% after 7 days under anaerobic conditions using activated sludge. Sodium acetate readily dissociates into their sodium cation and the acetate anion. Sodium acetate is also inherently biodegradable: 100% after 5 days @ 160 mg/L under aerobic conditions using activated sludge. 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.

Summary ecotoxicity data from the High Production Volume (HPV) Assessment Plan for Acetic Acid and Salts²¹ indicate that acetic acid is not highly toxic to aquatic plant and animal species. The LC₅₀ for fathead minnow is 106-122 ppm (24-hour), 92-106 ppm (48-hour), and 79-88 ppm (96-hour). The 48-hour LC₅₀ for rainbow trout is 105 ppm and the 48-hour EC₅₀ for *Daphnia* is 65 ppm. Toxicity thresholds were reported for green algae (*Scenedesmus quadricauda*; 4000 ppm), blue-green algae (*Anacystis aeruginosa*; 90ppm), and euglenoid (*Entosiphon sulcatum*; 78 ppm).

The available data indicate that acetic acid and its salts have generally low acute mammalian toxicity (see Appendix 1 Ref 21). Acute oral toxicity data for mammals are available acetic acid and sodium acetate. Acute inhalation data are available for acetic acid and the sodium salt, however, inhalation is not expected to be a primary route of exposure given that acetic acid and its salts have generally low volatility and are highly soluble. Dermal toxicity data are available only for acetic acid, but the level of toxicity is low and the salts are expected to exhibit a comparable dermal safety profile. Several studies indicate that the acute toxicity via other routes of exposure (i.e., intravenous, subcutaneous, intraperitoneal, etc.) is also low.

There are repeated dose, genetic, and developmental/teratogenic toxicity test endpoints for acetic acid. An essentially complete set of data for the sodium salt of acetic acid also is available. In addition, acetic acid is naturally occurring as the acid in apple cider vinegar and other fruit derived products. It and several of its salts are commonly used as food additives (e.g., as flavor enhancers) and are listed as Generally Recognized as Safe (GRAS) by the USFDA.

Glycerol

Glycerol is considered to be readily biodegradable (92% biodegradation was reported after 30 days. More than 60% biodegradation measured as ThOD was reached within the 10-day window.¹⁴) Glycerol is also photodegradable. The calculated half-life for the photo-oxidation (reaction with hydroxyl radicals) of glycerol in air is 6.8 hours¹³ The estimated concentrations of glycerol reaching the WWTP as well as the concentration upon discharge from the WWTP are estimated to be well below the concentrations that can negatively impact the environment.

The evidence indicates that glycerol is of low toxicity to aquatic organisms. The lowest LC₅₀ for fish is a 24-h LC₅₀ of >5000 mg/l for *Carassius auratus* (Goldfish) and for aquatic invertebrates, a 24h EC₅₀ of >10000 mg/l for *Daphnia magna* is the lowest EC₅₀. Several tests on algae are available, which suggest very low toxicity to a range of species. A QSAR prediction for the 96h EC₅₀ to algae was 78,000 mg/l. No toxicity towards the microorganism *Pseudomonas putida* was observed at 10000 mg/l after exposure for 16 hours.¹³

Sulfuric Acid and Sodium Sulfate

An optional ingredient, sulfuric acid, is used modify the pH of the FCS. As such, the sulfuric acid added to the FCS stream is consumed in reaction forming sodium sulfate (Na₂SO₄²⁻). Sulfuric acid is not a toxicological or environmental concern at the proposed use levels. While the environmental effects of aerosols sulfuric acid and sulfates on the atmosphere and rain are well known, small quantities of water or terrestrial discharges are not expected to have environmental effects.²¹⁻²³

Sulfate is a ubiquitous environmental anion and low concentrations are well tolerated in aquatic and terrestrial ecosystems. Sodium sulfate is a solid inorganic salt well soluble in water (161-190 g/l at 20 °C) with a melting point of 884 °C and density of 2.7 g/cm³.

In water sodium sulfate completely dissociates into sodium and sulfate ions. The ions cannot hydrolyse. In anaerobic environments sulfate is biologically reduced to (hydrogen) sulfide by sulfate reducing bacteria, or incorporated into living organisms as source of sulfur, and thereby included in the sulfur cycle. Sodium sulfate is not reactive in aqueous solution at room temperature. Sodium sulfate will completely dissolve, ionize and distribute across the entire planetary "aquasphere". Some sulfates may eventually be deposited, but the majority of sulfates participate in the sulfur cycle in which natural and industrial sodium sulfate is not distinguishable.

Sodium sulfate is widely distributed in nature; it occurs as mineral salts (e.g. thenardite, mirabilite), it is present in almost all fresh and salt waters and sulfate as such is normally present in almost all natural foodstuffs. Both sodium and sulfate ions are among the most common ions found in all living organisms. In mammals, sulfate is a normal metabolite of sulfur-containing amino-acids, it is normally incorporated in a variety of body compounds and it plays an important role in detoxification/ excretion processes due to sulfoconjugation. Sodium sulfate is a substance with a favorable ecological profile. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment.

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 production processes. Energy used specifically for the production of the FCS 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 FCS mixture. Thus, 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 Proposed Action:

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of alternative methods of ensuring the sterility of food surfaces including alternative PAA sanitizer mixtures already approved for similar uses. These alternatives consist of a stabilizer component (hydroxyethylidene 1,1-diphosphonic acid- HEDP) that is more toxic and less environmentally friendly than the components of this FCS.

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13. Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Eltron Research & Development, Inc.

Date: 5/28/2013 (Revised 08/16/2013)

Signature: 

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