

3rdRevisedAttachment_13_ Environmental Assessment_PAAFCS_2017-02-17

FDA (Food and Drug Administration)

1. February 17, 2017 (revised May 30, 2017)

2. Eltron Research and Development, Inc.

3. 4600 Nautilus Ct. South, Boulder, CO, 80301

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, acetic acid, glycerol, water and optionally sodium sulfate.

The antimicrobial agent is intended for use in fish and seafood processing plants and 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 and H₂O₂ actives concentrations, as shown in the table below. Maximum concentrations of inert components for the intended applications are in the Appendix I for confidential information:

Component	Application			
	Processed Meat (ppm)	Processed Poultry (ppm)	Fish & Seafood (ppm)	Fruits & Vegetables (ppm)
Peroxyacetic acid	1800	2000	230	350
Hydrogen Peroxide	1215	1474	165	525

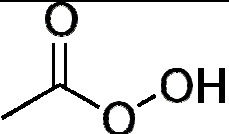
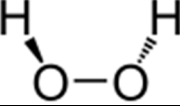
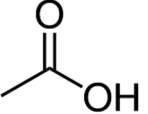
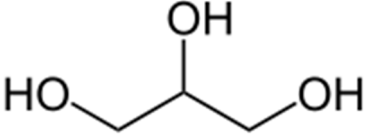
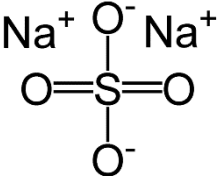
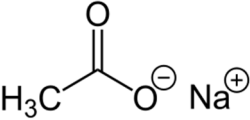
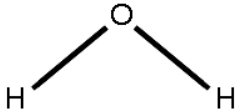
** The PAA concentration, and proportion with respect to all other components is controlled via the manufacturing process. The concentration shown in this table represents a maximum concentration, independent of the manufacturing configuration.*

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, or cool meat and poultry products thereby providing safer products for consumers.

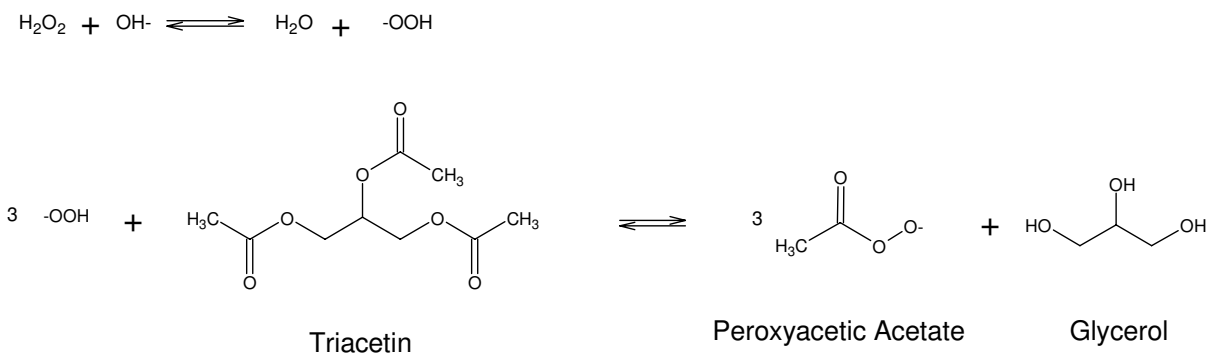
5. Identification of Substance

The FCS is a mixture of peroxyacetic acid, hydrogen peroxide, acetic acid/ sodium acetate, glycerol and water. It is made by blending alkaline aqueous hydrogen peroxide with triacetin followed by optional acidification with acetic acid or sulfuric acid, resulting in either sodium acetate or sodium sulfate, depending on the exact manufacturing configuration.

FCS Components:

Name	Chemical Formula	Chemical Structure	CAS Reg. No.
Peroxyacetic Acid	$C_2H_4O_3$		79-21-0
Hydrogen Peroxide	H_2O_2		7722-84-1
Acetic Acid	$C_2H_4O_2$		64-19-7
Glycerol	$C_3H_8O_3$		56-81-5
Sodium Sulfate	Na_2SO_4		7757-82-6
or Sodium Acetate	$NaC_2H_3O_2$		127-09-3
Water	H_2O		7732-18-5

The reactions to produce the above FCS can best be represented by the following:



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, on-demand. There is no transportation of the FCS to the end-use facility. The feedstocks for the manufacturing process are hydrogen peroxide, sodium hydroxide, triacetin, water, and acetic acid. No extraordinary circumstances would apply to the ongoing manufacture of 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 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. However, as shown in Item 7 in this EA, the 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.

The maximum proposed use concentration of PAA for any of the intended uses listed in this application is 2000 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. 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. Wastewater containing the diluted FCS solution is expected to be disposed of through the processing plant wastewater treatment facility or through a local POTW. Treatment of the process

water at a waste water treatment facility is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, acetic acid and glycerol. All four compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern at the proposed use levels. Therefore, peroxyacetic acid, hydrogen peroxide, acetic acid, glycerol and sulfuric acid are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS

As the fate of the FCS components in wastewater treatment would be the same regardless of the type of processing facility, the analysis of environmental effects will rely on the fate of the FCS in wastewater. As provided in Item 7, all FCS components degrade in wastewater, therefore EEC calculations are not necessary for determining environmental impact and are not provided.

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.¹⁻³ The acetic acid degrades to acetate due to increased pH effects.⁴ Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment in the primary wastewater treatment facility due to their reactivity and pH sensitivity.¹

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 7.² The half-life of hydrogen peroxide is concentration dependent, 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.³ 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.⁴

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.⁵ 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 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. 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.⁵ 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. Under anaerobic conditions, using microorganisms adapted to acetate, glycerol was biodegradable.⁵

Acetic Acid and Sodium Acetate

Summary ecotoxicity data from the High Production Volume (HPV) Assessment Plan for Acetic Acid and Salts⁴ 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 4). 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.⁶

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-oxidized 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.⁷

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 processing 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. Having demonstrated in Item 7 above that the FCS is unlikely to have a significant adverse effect, because the components readily degrade, additional analysis in the EA is not necessary. However, included 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.²

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.³

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.⁴ 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 Salts⁴ 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 4). 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.⁵) Glycerol is also photodegradable. The calculated half-life for the photo-oxidation (reaction with hydroxyl radicals) of glycerol in air is 6.8 hours⁵ 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.⁵

Sulfuric Acid and Sodium Sulfate

An optional ingredient, sulfuric acid, is used to modify the pH of the FCS. As such, the sulfuric acid added to the FCS stream is consumed in reaction forming sodium sulfate ($\text{Na}_2\text{SO}_4^{2-}$). 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.⁶⁻⁷

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 hydrolyze. 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, identification of mitigation measures is not necessary.

11. Alternatives to Proposed Action:

No significant 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 PAA sanitizer mixtures already approved for similar uses. Such action would have no significant environmental impact.

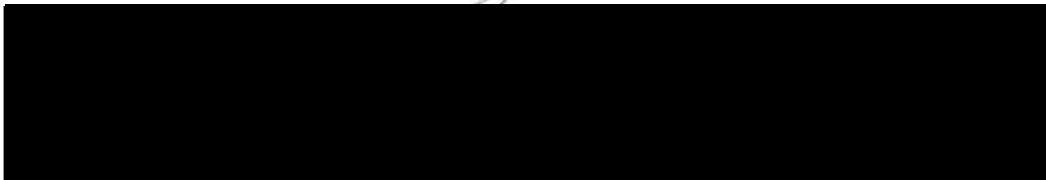
12. List of Preparers:

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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: 5/30/2017



Name and Title:

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Bibliography and Literature Citations

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