

1. **Date:** June 1, 2016
2. **Name of Applicant:** Evonik Corporation
3. **Address:**
All communications on this matter are to be sent in care of:
Evonik Corporation
ATTN: Tiana M. Rosamilia, Manager -ESHQ Services North America
299 Jefferson Rd, Parsippany NJ, 07054
4. **Description of the Proposed Action**

A. Requested Action

The action identified in this Notification is to provide for the use of the food-contact substance (FCS), an equilibrium mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, l-hydroxyethylidene-1,1-diphosphonic acid (HEDP), dipicolinic acid, and sulfuric acid as an antimicrobial agent in process water applied as a 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, and trim.

The components of the FCS mixture will not exceed: 2000 parts per million (ppm) peroxyacetic acid (PAA), 403 ppm hydrogen peroxide (HP), 5 ppm HEDP, and 0.88 ppm dipicolinic acid in 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, and trim.

Mixtures containing these substances have previously been cleared by other Notifiers for the same uses. However, this formulation at use has lower amounts of hydrogen peroxide, HEDP, and dipicolinic acid (DPA), which results in lower releases to the environment.

B. Need for Action

The antimicrobial effect of peroxyacetic acid reduces or eliminates populations of pathogenic and nonpathogenic microorganisms that may be present on the food. In poultry processing, particularly, industry has now added “finishing chillers” in order to treat the pathogen *Campylobacter* more effectively. The use of the proposed product will also reduce the amount of HEDP that will be released into the environment compared to other formulations that are currently on the market.

C. Locations of Use/Disposal

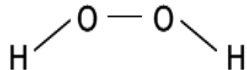
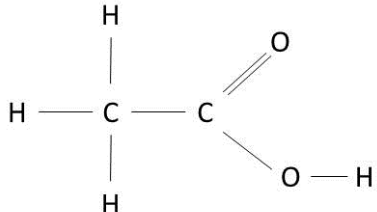
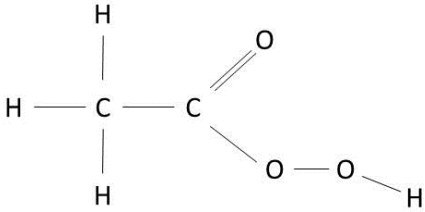
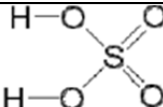
The FCS is intended for use in poultry processing plants throughout the United States. All waste process water containing the FCS at these plants is expected to enter the wastewater treatment unit at the plants. For the purposes of this Environmental Assessment, it is assumed that treated wastewater will be discharged directly to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit. This assumption can be considered a "worst- case" scenario since it does not take into account any further treatment that may occur at a Publically Owned Treatment Works (POTW). It is further assumed that very minor or negligible quantities of the FCS are lost via evaporation.

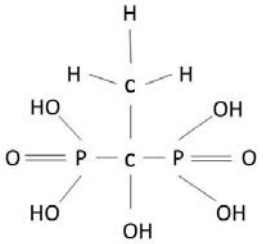
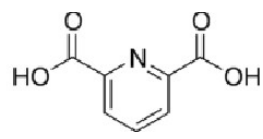
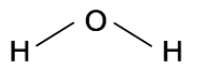
5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Identity

The subject of this notification is a clear liquid solution containing peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), sulfuric acid (CAS Reg. No. 7664-93-9), dipicolinic acid (DPA) (CAS REG. No. 499-83-2) and water (CAS Reg. No. 7732-18-5). A detailed confidential manufacturing process is cited in the Form 3480 of this Notification. PAA formation is the result of an equilibrium reaction between acetic acid and hydrogen peroxide.

The chemical structures are shown here:

Complete Name	CAS #	Molecular Weight	Molecular Formula	Structural Formula
Hydrogen Peroxide	7722-84-1	34.01 g/mol	H ₂ O ₂	
Acetic Acid	64-19-7	60.05 g/mol	C ₂ H ₄ O ₂	
Peracetic Acid	79-21-0	76.05 g/mol	C ₂ H ₄ O ₃	
Sulfuric Acid	7664-93-9	98.1 g/mol	H ₂ SO ₄	

Hydroxyethylidene Diphosphoric Acid (HEDP)	2809-21-4	206.03 g/mol	$C_2H_8O_7P_2$	
Dipicolinic Acid (DPA)	499-83-2	167.12 g/mol	$C_7H_6NO_4$	
Water	7732-18-5	18.01 g/mol	H_2O	

6. Introduction of Substances into the Environment

a. 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. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. As a Result of Use and Disposal

Sulfuric acid is listed as an optional ingredient in the FCS formulation. It is also affirmed as generally recognized as safe (GRAS) for use directly in or on food under Title 21 C.F.R. § 184.1095. Sulfuric acid is used to catalyze the reaction between acetic acid and hydrogen peroxide, more rapidly producing a stable PAA solution, and to modify the pH of the FCS.

Sulfuric acid is not a toxicological or environmental concern at the proposed use levels. While the environmental effects of aerosols of 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.¹ These references also provide the following

¹ See HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Sodium Sulfate. Section 4 (Environment), January 2006, available at http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf.

See also Sulfuric Acid. The Organization for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals. 2001, available at <http://www.inchem.org/documents/sids/sids/7664939.pdf>

analyses relating to sodium sulfate: 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 a 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 a 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 uses of sodium sulfate does not present a major hazard to the environment.

The FCS mixture is provided as a concentrate that is diluted on site. When diluted for use, the resulting concentration of PAA, hydrogen peroxide, HEDP, and DPA will be as follows:

Use	PAA	H2O2	HEDP	DPA
Whole or cut poultry, carcasses, parts, and trim	2000 ppm	403 ppm	5 ppm	0.88 ppm

Treatment of the process water at an on-site waste water treatment facility and/or at a POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid. Specifically, the peroxyacetic acid will breakdown into oxygen and acetic acid, while hydrogen peroxide will breakdown into oxygen and water.² Furthermore, acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water.³ Therefore, these substances are not expected to be introduced into the environment to any significant extent as a result of the proposed use

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

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

of the FCS. The remainder of this section will therefore consider only the environmental introduction of HEDP and DPA.

Poultry Processing Facilities

In poultry processing facilities, the defeathered, eviscerated carcasses are generally sprayed before being chilled via submersion in baths.⁴ The carcass is carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be passed through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the antimicrobial agent. Chiller baths typically include a “main chiller” bath, as well as a “finishing chiller” bath, both containing the FCS. Again, the majority of the solution containing the antimicrobial agent drains from the poultry carcasses and enters the plant’s wastewater processing treatment facilities.

The poultry industry added “finishing chillers” in response to the U.S. Department of Agriculture Food Safety and Inspection Service’s (FSIS) new performance standards for *Campylobacter* and *Salmonella*.⁵ The finishing chiller combines a high-dose treatment with shorter dip times to treat *Campylobacter*, as required by its dose- response characteristics. In contrast, the main chiller targets primarily *Salmonella*, which is a time-responsive bacteria that requires a longer residence time in the chiller bath, but does not require the high antimicrobial concentration. We understand that as permitted by 9 CFR 416.2(g)(3), the finishing chiller water is recycled into the main chiller system. The finishing chiller bath will typically contain the maximum concentration of the FCS, but contains a much lower volume of water. The contents of the finishing chiller feed the main chiller as a water source. Since much greater amounts of water are present in the main chiller (roughly 10 times that of the finishing chiller), the FCS is significantly diluted in the main chiller. With respect to environmental impact, it is the contents of the main chiller that pass into the wastewater treatment system and are ultimately released to the environment.

Assuming, in the very worst-case, that all of the water used in a processing plant is treated with the FCS, the HEDP and DPA environmental introduction concentrations (EICs) would be 5 ppm and 0.88 ppm, respectively.

As indicated by the Human & Environmental Risk Assessment Project (HERA)⁶,

4 See DRAFT FSIS Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Raw Poultry December 2015 available at <http://www.fsis.usda.gov/wps/wcm/connect/6732c082-af40-415e-9b57-90533ea4c252/Controlling-Salmonella-Campylobacter-Poultry-2015.pdf?MOD=AJPERES>

5 See USDA-FSIS Press Release, “USDA Proposes New Measures to Reduce *Salmonella* and *Campylobacter* in Poultry Products”, dated January 21, 2015, available at: <http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2015/01/0013.xml&printable=true>, as well as Notice and Request for Comments, Docket No. FSIS-2014-0023, available at: <http://www.fsis.usda.gov/wps/wcm/connect/03910f0e-48f8-4111-ba52-490b07c25c24/2014-0023.htm?MOD=AJPERES>.

6 HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Sodium Sulfate. Section 4 (Environment), January 2006, available at http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf

the treatment of wastewater at an onsite treatment facility or POTW will result in the absorption of approximately 80% of HEDP into sewage treatment sludge. By applying this 80% factor, we are able to estimate the potential environmental introduction of HEDP to water and sewage sludge, respectively. To calculate the expected environmental concentrations (EECs), we have incorporated a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW,⁷ as indicated below.

$$\begin{aligned}\text{HEDP EEC}_{\text{sludge}} &= 5 \text{ ppm} \times 0.8 = 4.00 \text{ ppm HEDP} \\ \text{HEDP EEC}_{\text{aqueous}} &= 5 \text{ ppm} \times 0.2/10 = 0.10 \text{ ppm HEDP} \\ \text{DPA}_{\text{aqueous}} &= 0.88 \text{ ppm}/10 = 0.088 \text{ ppm DPA}\end{aligned}$$

Even if a POTW receives and mixes water from two different facilities employing the FCS, the maximum EEC will never be greater than the highest single use concentration, *i.e.*, 0.10 ppm HEDP and 0.088 ppm DPA.

There already exist authorizations for the FCS for the same use proposed here, which permit higher concentrations of HEDP in the process water.

7. Fate of Emitted Substances in the Environment

As noted and referenced above, treatment of the process water at an on-site waste water treatment facility or at a POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, acetic acid, and sulfuric acid. The U.S. High Production Volume (HPV) Chemical Challenge Program determined that 99% of acetic acid degraded in 7 days under anaerobic conditions, and therefore, the FCS is not expected to concentrate in the waste water that is discharged to municipal treatment plants.⁸ Upon contact with organic materials, transition metals, and exposure to sunlight, peroxyacetic acid and hydrogen peroxide will rapidly degrade. According to the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), the half-life for PAA in buffered solutions was 64 hours (pH = 7) for a 748 ppm solution and 48 hours (pH = 7) for a 95 ppm solution while the half-life for hydrogen peroxide varies based on the surface water.⁹

Sulfuric acid degrades into sulfate (SO₄), which is not a toxicological or environmental concern at the proposed use levels.¹⁰ Specifically, as indicated by the

7 Rapaport, Robert A., 1988 Prediction of consumer product chemical concentrations as a function of publically owned treatment works, treatment type, and riverine dilution. *Environmental Toxicology and Chemistry* 7(2), 107-115.

8 See U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council, Appendix I. June 28, 2001.

9 ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals. JACC No.40, "Peracetic Acid and its Equilibrium Solutions", January 2001 and JACC No. 22, "Hydrogen Peroxide", January 1993.

10 Sulfuric Acid. The organization for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals. 2001, *available at*

Human Environmental Risk Assessment Project (HERA), dispersive uses of sulfate do not present major hazards to the environment.¹¹

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.¹²

As noted in the HERA:

“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.”¹³

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 unadapted flora and fauna.¹⁴

<http://www.inchem.org/documents/sids/sids/7664939.pdf>

11 HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Sodium Sulfate. Section 4 (Environment), January 2006, *available at* http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf

12 See *supra* note 10.

13 See *supra* note 11

14 See *supra* note 11

It has been shown that DPA, a polysubstituted pyridine derivative readily biodegrades under both aerobic and anaerobic conditions^{15,16, 17}. In presenting a review on the microbial metabolism of pyridines, including DPA, Kaiser, *et al.* describe aerobic metabolism of DPA to carbon dioxide, ammonium, and water, and anaerobic metabolism to dihydroxypyridine which is then rapidly photodegraded to organic acids (i.e., propionic acid, acetic acid), carbon dioxide, and ammonium.

As indicated above, the highest amount of DPA that may be released into the environment during use of the FCS would be a maximum of 0.088 ppm. Extrapolation of the data trend discussed in the study referenced above (which showed complete degradation of 20 ppm levels in 8 days) results in anticipated degradation in approximately one hour (20 ppm/192 hours = 0.1 ppm/hr).

8. Environmental Effects of Released Substances

Terrestrial Toxicity

HEDP present in the land-applied surface water is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds, which are several orders of magnitude above the 0.10 ppm aqueous EEC for HEDP. Specifically, the No Observed Effect Concentration (NOEC) for soil dwelling organisms was >1,000 mg/kg soil dry weight for earthworms in soil, while the 14-day LC50 for birds was >248 mg/kg body weight.¹⁸

Additionally, as noted above, the maximum concentration of HEDP in sludge is 3.5 ppm. A report by Jaworska *et al.*¹⁹ indicates that HEDP shows no toxicity to terrestrial organisms at levels of up to 1,000 mg/kg in soil NOEC. Therefore, the maximum concentration in sludge is less than 1% of the NOEC and the maximum concentration in soil, when used as a soil amendment, should have an even larger margin of safety with respect to the NOEC level. As such, the FCS is not expected to present any terrestrial environmental toxicity concerns.

15 J.A. Amador and B.P. Tatlor, "Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid" *Applied and Environmental Microbiology* **1990**, 56(5), 1352-1356.

16 B. Seyfried and B. Schnink, "Fermentive degradation of dipicolinic acid (Pyridine-2,6- dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria," *Biodegradation*, **1990**, 1(1), 1-7.

17 J.P. Kaiser, Y. Feng, and J.M. Bollag, "Microbial metabolism of pyridine, quinolone, acridine, and their derivatives under aerobic and anaerobic conditions," *Microbiological Reviews*, **1996**, 60(3), 483-498.

18 Human & Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004), Table 13, available at <http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

19 Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijtel, T. Environmental risk assessment of phosphonates, used in domestic laundry and cleaning agents in the Netherlands, Table 4. *Chemosphere* **2002**, 47, 655-665.

Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized, and is shown in the following table:

Environmental Toxicity Data for HEDP		
Species	Endpoint	mg/L
Short Term		
<i>Lepomis macrochirus</i> ^a	96 hr LC50	868
<i>Oncorhynchus mykiss</i> ^a	96 hr LC50	360
<i>Cyprinodon variegatus</i> ^a	96 hr LC50	2180
<i>Ictalurus punctatus</i> ^a	96 hr LC50	695
<i>Leuciscus idus melonatus</i> ^a	48 hr LC50	207 – 350
<i>Daphnia magna</i> ^a	24 – 48 hr EC50	165 – 500
<i>Palaemonetes pugio</i> ^a	96 hr EC50	1770
<i>Crassostrea virginica</i> ^a	96 hr EC50	89
<i>Selenastrum capricornutum</i> ^b	96 hr EC50	3
<i>Selenastrum capricornutum</i> ^a	96 hr NOEC	1.3
<i>Algae</i> ^b	90 hr NOEC	0.74
<i>Chlorella vulgaris</i> ^a	48 hr NOEC	≥100
<i>Pseudomonas putida</i> ^a	30 minute NOEC	1000
Long Term		
<i>Oncorhynchus mykiss</i> ^a	14 day NOEC	60 – 80
<i>Daphnia magna</i> ^a	28 day NOEC	10 - <12.5
<i>Algae</i> ^b	14 day NOEC	13

^a Jaworska, et al. (2002)²⁰

^b HERA_Phosphonates (2004)²¹

20 See supra note 19

21 See supra note 18

These data show that acute toxicity endpoints for HEDP ranged from 0.74 – 2,180 mg/L, while chronic NOECs were 60 – 180 mg/L for the 14 day NOEC for *Oncorhynchus mykiss* and the 28 day NOEC for the *Daphnia magna* was 10-<12.5 mg/L. Although a chronic NOEC of 0.1 mg/L for reproductive effects in *Daphnia magna* was reported, it is inconsistent with other toxicity data and Jaworska *et al.* suggest that it is due to the depletion of micronutrients by HEDP instead of the intrinsic toxicity of HEDP.²²

Because HEDP is a strong chelating agent, which can result in negative environmental effects such as, the complexing of essential nutrients, both an intrinsic NOEC (NOECi) and a NOEC, which accounts for chelating effects (NOECc) are determined. As noted, it is probable that there will be excess nutrients present in industrial wastewater because eutrophication occurs widely in industrial wastewater coming from food processing facilities.²³

We note that the 96 hour NOEC, 24-48 hour EC50, and 96 hour EC50 values reported by Jarworska *et al.* for *Selenastrum capricornutum*, *Daphnia magna*, and *Crassostrea virginica*, respectively, were all likely due to chelation effects rather than intrinsic toxicity.²⁴ As such, these levels are not relevant in such situations as food processing plants, where excess nutrients are present. The HERA report on phosphonates included a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities.²⁵ Jaworska *et al.* reports the lowest relevant endpoint for this use pattern to be 10 mg/L.²⁶ The worst-case EECaq for HEDP is below this value and is, thus, not expected to result in any adverse environmental effects.

There is little available ecotoxicology data for DPA. The Material Safety Data Sheet (MSDS) from one supplier states that the freshwater fish 96 hour LC50 is 322 mg/L for fathead minnow.²⁷ The Ecological Structure Activity Relationships (ECOSAR) Class Program is a computerized predictive system maintained and developed by the U.S. EPA that estimates aquatic toxicity. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by using computerized Structure Activity

²² See *supra* note 19

²³ See US EPA Office of Water, Fact Sheet EPA-822-F-01-010; Ecoregional Nutrient Criteria, Dec 2001 http://www.epa.gov/sites/production/files/documents/ecoregions_9docfs.pdf

²⁴ See *supra* note 19

²⁵ See *supra* note 18

²⁶ See *supra* note 19

²⁷ See representative MSDS for DPA available at http://www.apolloscientific.co.uk/downloads/msds/OR5062_msds.pdf.

Relationships (SARs).²⁸ This program is a sub-routine of the Estimation Program Interface (EPI) Suite – a structure-function predictive modeling suite also developed and maintained by the U.S. EPA.²⁹ The ECOSAR results for DPA predict the following acute and chronic toxicity endpoints tabulated below.³⁰ The complete ECOSAR report for this analysis is attached to this EA (see Attachment A).

ECOSAR Class	Organism	Endpoint	mg/L
Pyridine-alpha-acid	Fish	96 hr LC50	324
	Fish	ChV	29 ³¹
Neutral Organic SAR	Fish	96 hr LC50	2657
	Daphnid	48 hr LC50	1322
	Green Algae	96 hr EC50	570
	Fish	ChV	222
	Daphnid	ChV	89
	Green Algae	ChV	111

These values are all much higher than the “worst-case” scenario of an EECaq of 0.088 ppm, which is over 300 times lower than the lowest chronic toxicity endpoint for the most sensitive species. Thus, the use of DPA at such a minimal level is not expected to result in any adverse environmental effects.

28 Information on ECOSAR can be found at <https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>.

29 EPI Suite predicts various physical-chemical properties and environmental fate endpoints and also include models for environmental transport. Running the tool will give the user an indication of the transport and persistence of a chemical. Information on EPI Suite is available at <https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>.

30 See EPI Suite – ECOSAR Program Results for CAS 499-83-2; Attachment A

31 Chronic toxicity was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

9. Use of Resources and Energy

The notified use of the FCS mixture will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar HEDP/DPA stabilized peroxy antimicrobial agents already on the market. The manufacture of the antimicrobial agent will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the mixture are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes.

10. Mitigation Measures

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

11. Alternatives to the Proposed Action

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

12. List of Preparers

Tiana M. Rosamilia, MPH, 15 years experience as a toxicologist, experience in conducting product risk assessments.

Devon Wm. Hill, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. J.D. and Masters in Chemistry with 20 years of experience with Food-Contact Notification submissions and environmental assessments.

Peter N. Coneski, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Ph.D. in Chemistry with 3 years of experience with Food-Contact Notification submissions and environmental assessments.

13. Certification

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

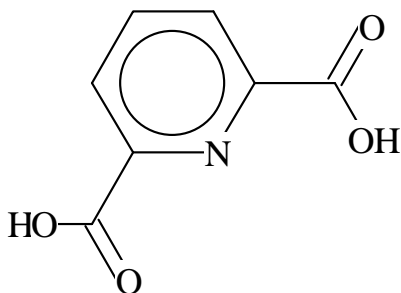
A solid gray rectangular box used to redact the signature of the undersigned.

Tiana M. Rosamilia

Attachment A: EPI Suite – ECOSAR Program Results for DPA, Date of Analysis: 04-15-2016

The Ecological Structure Activity Relationships (ECOSAR) Class Program is a computerized predictive system maintained and developed by the U.S. EPA that estimates aquatic toxicity. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by using computerized Structure Activity Relationships (SARs). Information on ECOSAR can be found at: <https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>.

EPI Suite – ECOSAR Program Results For CAS 499-83-2



SMILES : O=C(O)c(nc(cc1)C(=O)O)c1
CHEM : 2,6-Pyridinedicarboxylic acid
MOL FOR: C7 H5 N1 O4
MOL WT : 167.12

----- EPI SUMMARY (v4.11) -----

Physical Property Inputs:
Log Kow (octanol-water): -----
Boiling Point (deg C) : -----
Melting Point (deg C) : -----
Vapor Pressure (mm Hg) : -----
Water Solubility (mg/L): -----
Henry LC (atm-m3/mole) : -----

ECOSAR Program (v1.11) Results:

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ECOSAR Version 1.11 Results Page

SMILES : O=C(O)c(nc(cc1)C(=O)O)c1
CHEM : 2,6-Pyridinedicarboxylic acid
CAS Num:
ChemID1:
MOL FOR: C7 H5 N1 O4
MOL WT : 167.12

Log Kow: 0.567 (EPI Suite Kowwin v1.68 Estimate)
Log Kow: (User Entered)
Log Kow: (PhysProp DB exp value - for comparison only)
Melt Pt: (User Entered for Wat Sol estimate)

Melt Pt: 249.00 (deg C, PhysProp DB exp value for Wat Sol est, 249 dec)
 Wat Sol: 4829 (mg/L, EPISuite WSKowwin v1.43 Estimate)
 Wat Sol: (User Entered)
 Wat Sol: 5000 (mg/L, PhysProp DB exp value)

Values used to Generate ECOSAR Profile

Log Kow: 0.567 (EPISuite Kowwin v1.68 Estimate)
 Wat Sol: 5000 (mg/L, PhysProp DB exp value)

ECOSAR v1.11 Class-specific Estimations

Pyridine-alpha-Acid

Predicted

ECOSAR Class	Organism	Duration	End Pt	mg/L (ppm)
Pyridine-alpha-Acid:	Fish	96-hr	LC50	323.608
Pyridine-alpha-Acid:	Fish		ChV	29.342 !
Neutral Organic SAR:	Fish	96-hr	LC50	2656.694
(Baseline Toxicity):	Daphnid	48-hr	LC50	1321.570
:	Green Algae	96-hr	EC50	569.703
:	Fish		ChV	222.165
:	Daphnid		ChV	89.187
:	Green Algae		ChV	111.124

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported.

NOTE: ! = exclamation designates: The toxicity value was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

Class Specific LogKow Cut-Offs

If the log Kow of the chemical is greater than the endpoint specific cut-offs presented below, then no effects at saturation are expected for those endpoints.

Pyridine-alpha-Acid :

Maximum LogKow: 5.0 (LC50)
 Maximum LogKow: 6.4 (EC50)
 Maximum LogKow: 8.0 (ChV)

Baseline Toxicity SAR Limitations:

Maximum LogKow: 5.0 (Fish 96-hr LC50; Daphnid LC50)
 Maximum LogKow: 6.4 (Green Algae EC50)
 Maximum LogKow: 8.0 (ChV)