

Environmental Assessment

1. **Date** August 19, 2022 *
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4. **Description of Proposed Action**

a. **Requested Action**

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as an aqueous mixture of peroxydic acid (PCA), hydrogen peroxide (HP), citric acid, lactic acid, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and optionally sulfuric acid. The FCS is intended for use as an antimicrobial agent used in process water, ice or brine used in the production, processing and preparation of meat, poultry, processed and preformed meat and poultry, fruits, vegetables, fish and seafood. The FCS solution is sold as a concentrate that is diluted by the user as described on the label instructions. The concentrated FCS solution will be stored for no more than six months before use.

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

- [1] 2000 ppm PCA, 2480 ppm HP, and 136 ppm HEDP in process water, ice, or brine applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut poultry, including carcasses, parts, trim, and organs; and
- [2] 495 ppm PCA, 1180 ppm HP, and 29 ppm HEDP in process water, ice, or brine for, rinsing, or cooling processed and pre-formed poultry; and
- [3] 2000 ppm PCA, 2480 ppm HP, and 121.5 ppm HEDP in process water, ice, or brine applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut meat, including carcasses, parts, trim, and organs; and
- [4] 495 ppm PCA, 1180 ppm HP, and 33.5 ppm HEDP in process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed meat; and
- [5] 600 ppm PCA, 1112 ppm HP, and 34 ppm HEDP in process water or ice used for washing, rinsing, chilling, or processing fruits and vegetables in food processing facilities; and
- [6] 230 ppm PCA, 280 ppm HP, and 15 ppm HEDP in process water, ice, or brine used during commercial preparation of fish and seafood in food processing facilities.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature and to reformat for conformance with assistive technologies.

b. Need for Action

The antimicrobial agent inhibits the growth of undesirable or pathogenic microorganisms in the process water and/or the surface of the products.

c. Locations of Use / Disposal

The antimicrobial agent is intended for use in food processing facilities throughout the United States, and applied to meat, poultry, fish and seafood, and fruits and vegetables. After use, the FCS will be disposed of with processing plant wastewater. For processing plants that hold a National Pollutant Discharge Elimination System (NPDES) permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS-containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments. As a conservative approach, it can be assumed that wastewater will be treated onsite before discharge to surface water pursuant to a NPDES permit.

It is expected that process water not containing the FCS will be used in plants for activities such as cleaning and sanitation, resulting in significant dilution of HEDP into the total water effluent. Wastewater from fishing vessels is expected to be disposed in the ocean. We have also estimated maximum potential concentrations in soil from application of sludge from wastewater treatment facilities to soil.

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

The raw materials used in this product are hydrogen peroxide, citric acid, lactic acid, acetic acid, HEDP and optionally sulfuric acid and water. The chemical identities of these substances are presented in Table 1 (on next page). Peroxycitric acid formation is the result of an equilibrium reaction between hydrogen peroxide and citric acid. The FCS is supplied in concentrated form and is diluted at the processing plant for use to achieve the desired level of peroxyacid that is needed to address the microbial load.

The chemical equation for production of the FCS is:



Table 1: Chemical Identity of Substances of the Proposed Action

Component	CAS Reg. No.	Molecular Weight	Structural Formula	Molecular Formula
Hydrogen peroxide	7722-84-1	34.01	HO – OH	H ₂ O ₂
Peroxydictric acid	127542-89-6	208.12		C ₆ H ₈ O ₈
Citric acid	77-92-9	192.12		C ₆ H ₈ O ₇
Lactic acid	50-21-5	90.08		C ₃ H ₆ O ₃
Acetic acid	64-19-7	60.05		C ₂ H ₄ O ₂
1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)	2809-21-14	206.3		C ₂ H ₈ O ₇ P ₂
Sulfuric acid	7664-93-9	98.08		H ₂ SO ₄
Water	7732-18-5	18.01		H ₂ O

6. Introduction of Substances 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. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. The Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements; or 3) production associated with the proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

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

The antimicrobial agent is intended for use in food processing facilities throughout the United States. The FCS may be applied to poultry, meat, fish and seafood, and fruit and vegetables. The FCS will be supplied concentrated to be diluted at food processing facilities. Once diluted, the FCS is designed to be applied via immersion/dip or through various spraying techniques (including electrostatic), mist or fog application. Introduction of diluted solutions of the FCS into the environment will take place primarily via release from wastewater treatment systems. Introduction of the components of the FCS into the environment will result from use of the FCS as an antimicrobial agent in processing water and spray applications onto food. Following use, the disposal of such water and spray drainage will be into on-site treatment plants and/or POTWs. The total amount of product used at a typical facility will vary significantly, depending on the equipment used and the amount of food processed.

The maximum at-use concentration of PCA, hydrogen peroxide, and HEDP for each application is presented in Table 2.

Table 2: Summary of Intended Uses

Use	PCA (ppm)	H ₂ O ₂ (ppm)	HEDP (ppm)
Water or ice applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut poultry, including carcasses, parts, trim, and organs	2000	2480	136
In in process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed poultry	495	1180	29
Water or ice applied as a wash, spray, dip, rinse, chiller water, or scald water for whole or cut meat, including carcasses, parts, trim, and organs	2000	2480	121.5
In process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed meat	495	1180	33.5
In process water, or ice, for washing or chilling fruits and vegetables in food processing facilities	600	1112	34
In process water, ice, or brine used during commercial preparation of fish and seafood in food processing facilities	230	280	15

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in complete degradation of PCA, hydrogen peroxide, lactic acid and acetic acid. Specifically, the PCA will breakdown into oxygen, water and citric acid. The half-life of PCA in buffered solutions was 4.08 days.¹

All four resulting compounds, hydrogen peroxide, citric acid, lactic acid and acetic acid are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight.

Hydrogen peroxide is a weak acid with strong oxidizing properties. In the environment, hydrogen peroxide is unstable and normally short-lived as it rapidly decomposes to water and oxygen² in the presence of dissolved transition metals (e.g., copper, iron, and manganese), organic material, and exposure to sunlight.³ Although a stabilizer is present to slow the decomposition, hydrogen peroxide will begin to break down readily once exposed to large quantities of organic material (e.g., raw produce). If hydrogen peroxide persists through disposal,

¹ Calculated using EPA's OPERA Model, available at https://comptox.epa.gov/dashboard/calculation-details?model_id=17&search=431965.

² U.S. Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18, available at https://archive.epa.gov/pesticides/reregistration/web/pdf/peroxy_compounds.pdf.

³ ECETOC, JACC No. 22, *Hydrogen Peroxide*, January, 1993, Table 6, p. 23, "Degradation in the River Saône of Hydrogen Peroxide," available at <https://www.ecetoc.org/wp-content/uploads/2021/10/JACC-022.pdf>.

it will not be present for long when treated by a POTW. In an environmental risk assessment for hydrogen peroxide, the European Commission Joint Research Centre (European Commission 2003) presents a half-life for hydrogen peroxide of 2 minutes in sewage treatment plants. Treatment of the process water by the food processing plant's wastewater treatment facility and/or a POTW is expected to result in complete degradation of the hydrogen peroxide.

Thus, use of the FCS is not expected to increase concentrations of hydrogen peroxide in the environment. ⁴

Citric acid is a solid and highly soluble weak organic acid. Due to its physio-chemical characteristics, citric acid will partition almost entirely (>99.9%) to the aquatic compartment when introduced to the environment. ⁵

The OECD has conducted investigations on high volume chemicals including citric acid (HERA 2005). ⁶ Its Screening Information Dataset (SIDS) Initial Assessment Report (SIAR), published by the United Nations Environmental Program (UNEP), indicates that a large body of environmental data exists for citric acid, although much is old and located only in standard reference works and reviews. Based on this information, it concludes that citric acid degrades rapidly in POTWs and surface water (OECD 2001). Based on these and other available data, OECD judged that citric acid presents no hazard to the environment and required no further investigation.

USEPA's EPI Suite (EPIWIN), using BIOWIN output, estimates 92% total biodegradation of citric acid in a sewage treatment plant (STP). Hoyt and Gewanter (1992) ⁷ determined citrate removal rates to be 80% to >99% by POTWs. At these removal rates, citric acid may be completely degraded prior to release by the POTW.

Lactic acid is a naturally occurring, biologically important, and water-soluble organic acid. Based on a Level III fugacity model that assumes equal emissions to air, water, and soil, lactic acid is expected to partition primarily to water (46.3%) and soil (50.5%) (USEPA 2008). USEPA's EPI Suite (EPIWIN), using BIOWIN output, estimates 92% total biodegradation of lactic acid in a STP. At these high removal rates, very little lactic acid is expected to be released to the environment.

⁴ ECJRC European Commission. 2003. Hydrogen Peroxide. CAS No: 7722-84-1. EINECS No: 231-765-0. Summary Risk Assessment Report. European Commission Joint Research Centre. Special Publication I.03.148 *available at* <https://echa.europa.eu/documents/10162/590965ca-33e7-43a0-a109->

⁵ Organisation for Economic Co-operation and Development (OECD). 2001. Citric Acid. CAS No: 77-92-9. OECD Screening Information Dataset (SIDS); *available at* <https://hpcvchemicals.oecd.org/ui/handler.axd?id=ff78c453-36c1-430d-9034->

⁶ Human & Environmental Risk Assessment (HERA). 2005. Substance: Citric Acid and Salts. (CAS#77-92-9; 5949-29-1; 6132-04-3). HERA on ingredients of household cleaning products Edition 1.0 April. *Available at* https://www.heraproject.com/files/37-f-05-hera_citricacid_version1_april05.pdf

⁷ Hoyt, H.L and H.L. Gewanter. 1992. Citrate. In *The Handbook of Environmental Chemistry*. Volume 3 Part F, Anthropogenic compounds, Detergents (O. Hutzinger, ed.). Springer Verlag: Berlin. Pp. 229–242.

In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.⁸ Acetic acid is not expected to concentrate in the wastewater discharged to the treatment facility/POTW.

Sulfuric acid is listed as an optional ingredient in the FCS formulation. Sulfuric acid may be added to the reactants to increase the rate at which the solution reaches equilibrium.

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 significant environmental effects.⁹ 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. 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.

Therefore, these substances are not expected to be introduced into the environment to any significant extent as result of the proposed use of the FCS. As a result, the remainder of this section, Section 7, and Section 8 will consider only the environmental introduction of HEDP.

Because it is difficult to establish water usage levels, we assume, in the very worst-case, that all of the water used in a plant is treated with the FCS, and we will use the maximum level of HEDP to calculate the environmental introduction concentration (EIC) of HEDP would be 136 ppm.

7. Fate of Emitted Substances in the Environment

Prior to wastewater discharge by the POTW, hydrogen peroxide is expected to degrade completely to water and oxygen. Likewise, peracids should degrade completely to oxygen, carbon dioxide, water, or the parent acids (i.e., citric acid). As such, hydrogen peroxide and peracids, as components of the FCS, are not expected to be introduced to the environment following use by food processing plants.

⁸ American Chemistry Council, Acetic Acid and Salts Panel, U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category, June 28, 2001, Appendix 1, p. 1; available at https://iaspub.epa.gov/opthpv/document_api.download?FILE=c13102tp.pdf.

⁹ See Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006; see also The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001; available at <https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb>.

The fate of the remaining FCN components in the environment is analogous to that described above in relation to their fate during wastewater treatment (see Section 6). Citric acid, acetic acid and lactic acid may be completely degraded prior to release by the POTW, and any remaining citric acid, acetic acid or lactic acid that makes its way through the POTW is expected to degrade rapidly in the environment.

HEDP will mineralize to soil particles and organic matter and utilization of the phosphonate moiety by microorganisms as a phosphorus source.¹⁰ Phosphate anions are strongly bound to organic matter and soil particles,¹¹ and phosphate is a required macronutrient of plants. However, given the maximum level estimated to be released, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in soil or water receiving treated effluent. Decomposition of HEDP occurs at a moderately slow pace; a Dissolved Organic Carbon removal of 23-33% after 28 days was observed in an inherent biodegradability test (Zahn-Wellens test).¹² Therefore, increases in phosphate in soils amended with wastewater sludge, or in water receiving treated effluent are not expected.

The Human and Environmental Risk Assessment Project (HERA) report on phosphonates indicates that the treatment steps at an onsite wastewater treatment facility or POTW will remove at least a portion of any HEDP in the process water.¹³ The HERA report cites 80% adsorption of HEDP to sewage treatment sludge.

We have estimated the potential environmental introduction concentrations (EICs) of HEDP in water and sewage sludge based upon the information above. We have considered the poultry application as the worst-case scenario because it has the highest use level for HEDP. To calculate the EICs for HEDP in water and sewer sludge we have applied the 20:80 partition factor from the above HERA report ($EIC_{\text{sludge}} = 136 \times 80\% = 108.8$ ppm; $EIC_{\text{water}} = 136 \times 20\% = 27.2$ ppm). (See Table 3, below).

When the water from the facility or POTW is discharged to surface waters, HEDP will be diluted a further 10-fold, resulting in an estimated environmental concentration (EEC) of 2.72 ppm.¹⁴

¹⁰ Nowack, B., *Environmental chemistry of phosphonates*, Water Research 37(11): 253-2546, June 2003

¹¹ HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates* (CAS 6419-19-8; 2809-21-4; 15827-60-8), Draft 06/09/2004, p. 11, available at <http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf>.

¹² HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates* (CAS 6419-19-8; 2809-21-4; 15827-60-8), Draft 06/09/2004, Table 7, p. 16, available at <http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf>.

¹³ *Ibid.*, at Table 12, p. 22.

¹⁴ Rapaport, R.A., Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution, *Environmental Toxicology and Chemistry* 7(2), 107-115 (1988). Available at <https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.5620070204>

Table 3: Worst-case EICs for HEDP Using Poultry Processing as the Worst Case for HEDP

Use	EIC Total	EEC _{sludge}	EEC _{water}
Poultry – HEDP	136 ppm	108.8 ppm ¹⁵	2.72 ppm ¹⁶

Finally, we note that the HEDP EIC for sludge is a maximum for terrestrial impacts, as any sludge used as a soil amendment will likely be significantly diluted by soil or sludge from other sources.

8. Environmental Effects of Released Substances

a) Terrestrial Toxicity

The above HERA report discusses biodegradation of HEDP and estimates a half-life in soil of 373 days. Therefore, HEDP is expected to degrade, albeit slowly, in soil. HEDP shows no toxicity to terrestrial organisms at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC). ¹⁷ Our maximum estimated concentration in sludge (108.8 ppm) is well below the NOEC, and, due to dilution, the maximum concentration in soil when used as a soil amendment should have an even larger margin of safety with respect to the NOEC. Therefore, the FCS is not expected to have any terrestrial environmental toxicity concerns at levels at which it is expected to be present in sludge or soil. Moreover, the much smaller level of HEDP present in the surface water is not expected to have any adverse environmental impact with respect to sedimentation based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. ¹⁸

¹⁵ Example Calculation $136 \text{ ppm} \times 80\% = 108.8 \text{ ppm}$

¹⁶ Example Calculation $136 \text{ ppm} \times 20\% / 10 = 2.72 \text{ ppm}$

¹⁷ Jaworska, J., et al, Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands, *Chemosphere* 2002, 47(6), 655-665, May 2002. Available at <https://pubmed.ncbi.nlm.nih.gov/12047077/>

¹⁸ *Ibid.*

b) Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized and is shown in Table 4.

Table 4: Summary of Environmental Toxicity Data for HEDP ¹⁹

Exposure Duration	Species	Endpoint	mg/L
Short Term	<i>Lepomis macrochirus</i>	96-hr LC50	868
	<i>Oncorhynchus mykiss</i>	96-hr LC50	360
	<i>Cyprinodon variegatus</i>	96-hr LC50	2180
	<i>Ictalurus punctatus</i>	96-hr LC50	695
	<i>Leuciscus idus melonatus</i>	48-hr LC50	207 – 350
	<i>Daphnia magna</i>	24 – 48-hr EC50	165 – 500
	<i>Palaemonetes pugio</i>	96-hr EC50	1770
	<i>Crassostrea virginica</i>	96-hr EC50	89
	<i>Selenastrum capricornutum</i>	96-hr EC50	3
	<i>Selenastrum capricornutum</i>	96-hr NOEC	1.3
	Algae	96-hr NOEC	0.74
	<i>Chlorella vulgaris</i>	48-hr NOEC	≥ 100
	<i>Pseudomonas putida</i>	30-minute NOEC	1000
Long Term	<i>Oncorhynchus mykiss</i>	14-day NOEC	60 – 180
	<i>Daphnia magna</i>	28-day NOEC	10 – < 12.5
	Algae	14-day NOEC	13

¹⁹ Short term values for *Lepomis macrochirus*, *Oncorhynchus mykiss*, *Cyprinodon variegatus*, *Ictalurus punctatus*, *Leuciscus idus melonatus*, *Daphnia magna*, *Palaemonetes pugio*, *Crassostrea virginica*, *Chlorella vulgaris*, *Pseudomonas putida*, and long term values for *Oncorhynchus mykiss*, *Daphnia Magna* found in Jaworska, et al, p. 662 (2002). Short term values for *Selenastrum capricornutum*, and short and long term values for algae found in HERA (2004) (Tables 13 and 14, p. 29-31).

According to Jaworska et al,²⁰ the primary adverse effects of HEDP result from chelation of nutrients rather than direct toxicity of HEDP. 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. The lowest short-term EC50 values published for *Selenastrum capricornutum* (3 ppm), *Daphnia magna* (165 ppm), and *Crassostrea virginica* (89 ppm) are acute toxicity endpoints considered to result from this chelation effect. These values are not relevant when excess nutrients are present as expected in food processing wastewaters. The lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable,²¹ based on the available environmental toxicology data, reliance upon the NOEC for *Daphnia magna* is appropriate.²² The conservatively estimated EEC of 2.7 ppm is lower than the 10 ppm chronic NOEC for *Daphnia magna*, and the FCS is not expected to have any aquatic toxicity.

9. Use of Resources and Energy

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

10. Mitigation Measures

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

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. If the proposed action is

²⁰ Jaworska, et al (2002).

²¹ Blok J. and Balk F., *Environmental regulation in the European Community*, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995, chapter 27 (“NOEC determinations are likely more statistically variant (uncertain) than EC50 determinations”); also see Organisation for Economic Co-operation and Development (OECD), *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 54, Environment Directorate, Paris, 2006 (recommending that that NOECs be abandoned), available at [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2006\)18&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&doclanguage=en)

²² Jaworska, et al (2002).

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 peroxyacid antimicrobial products.

12. List of Preparers

Ms. Patricia Kinne, Environmental Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue, N.W., Washington, D.C. 20036 with over 10 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Ave., N.W., Washington, D.C. 20036 with 30 years of experience with Food Additive Petitions, FCN submissions, and environmental assessments.

13. Certification

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

Date: August 19, 2022



Joan Sylvain Baughan, Partner

14. References

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

Blok J. and Balk F., Environmental regulation in the European Community, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995.

European Centre for Ecotoxicology of Chemicals (ECETOC). 1993. Joint Assessment of Commodity Chemicals (JACC) No. 22. Hydrogen Peroxide (CAS No. 7722-84-1). ECETOC. ISSN-0733-6339-40. Brussels, Belgium. January.

European Commission. 2003. Hydrogen Peroxide. CAS No: 7722-84-1. EINECS No: 231-765-0. Summary Risk Assessment Report. European Commission Joint Research Centre. Special Publication I.03.148

Human & Environmental Risk Assessment (HERA). 2005. Substance: Citric Acid and Salts. (CAS#77-92-9; 5949-29-1; 6132-04-3). HERA on ingredients of household cleaning products Edition 1.0 April.

HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8), Draft 06/09/2004

HERA, Human and Environmental Risk Assessment on ingredients of Household Cleaning Products: Sodium Sulfate (January 2006).

Hoyt, H.L and H.L. Gewanter. 1992. Citrate. In *The Handbook of Environmental Chemistry. Volume 3 Part F, Anthropogenic compounds, Detergents* (O. Hutzinger, ed.). Springer Verlag: Berlin. Pp. 229–242.

Jaworska, J., et al, Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands, *Chemosphere* 2002, 47(6), 655-665, May 2002.

Nowack, B., Environmental chemistry of phosphonates, *Water Research* 37(11): 253-2546, June 2003

Organisation for Economic Co-operation and Development (OECD). 2001. Citric Acid. CAS No: 77-92-9. OECD Screening Information Dataset (SIDS). United Nations Environmental Programme (UNEP) Publications.

Organisation for Economic Co-operation and Development (OECD), *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 54, Environment Directorate, Paris, 2006

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

United States Environmental Protection Agency (USEPA). 1993. EPA R.E.D. Facts. Peroxy Compounds. USEPA Prevention, Pesticides and Toxic Substances. EPA-738-F-93-026.