

ATTACHMENT 8

PART IV – ENVIRONMENTAL INFORMATION

B - ENVIRONMENTAL ASSESSMENT

1. **Date:** January 20, 2020
2. **Applicant:** Solvay Chemicals Inc.
3. **Address:** 3737 Buffalo Speedway, Suite 800
Houston, TX 77098

Lewis & Harrison LLC (Agent)
2461 South Clark Street, Suite 710
Arlington, VA 22202

4. **Description of Proposed Action:**

a. Description of the Requested Action:

The action identified in this FCN is to provide for the use of the food-contact substance (FCS), an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), (optionally) dipicolinic acid (DPA), and (optionally) sodium hydroxide as an antimicrobial agent at levels of 600 ppm PAA, 1112 ppm HP, 34 ppm HEDP, and 0.68 ppm DPA in water and ice used for washing or chilling fruits and vegetables in a food processing facility.

b. The Need for Action:

The higher proposed maximum FCS concentrations of 600 ppm PAA, 1112 ppm HP, 934 ppm AA, 34 ppm HEDP, and (optionally) 0.68 DPA reduces or inhibits the growth of pathogenic and non-pathogenic microorganisms that may be present on and in food to provide safer foods for consumers.. Fruit and vegetable processors face greater challenges to reduce pathogens in response to faster processing speeds and shorter contact times. Solvay is therefore proposing to increase the FCS concentration limit for fruit and vegetable processing in an effort to improve food safety.

This FCS is intended for use as an antimicrobial agent in food processing water and ice and used for washing or chilling fruits and vegetables at food processing facilities.

The FCS identified herein therefore will compete for a share of the market already occupied by these other products rather than introduce a new product or create a new market when this notification becomes effective. Consequently, all potential environmental introductions will

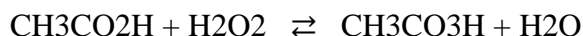
be substitutional for previously authorized products. No new environmental introductions are anticipated.

c. Discussion of the Use and Disposal of the FCS:

The FCS is intended for use in processing plants throughout the United States as an antimicrobial agent for fruits and vegetables. After use, the diluted FCS solution 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 directly discharged to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS-containing wastewater will undergo pretreatment on-site and travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments. For the purposes of this EA, we assume that wastewater is treated on site before direct discharge to surface waters, in accordance with the plant's NPDES permit.

5. Identification of Substance:

The subject of this notification is an aqueous mixture of 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), and (optionally) dipicolinic acid ("DPA," CAS Reg. No. 499-83-2). PAA formation is the result of an equilibrium reaction between acetic acid and hydrogen peroxide.



6. Introduction of Substances into the Environment:

a. Introduction of substances into the environment as a result of manufacture:

The FCS is manufactured in plants that meet all applicable federal, state and local environmental regulations. Solvay asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS.

Under 21 Code of Federal Regulations (CFR) § 25.40(a), an EA should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles.

b. As a Result of Use and Disposal:

Process water containing the FCS will be treated at an on-site wastewater treatment facility and/or at a POTW. HEDP, the only stable component of the FCS, will partition between the treated process water and the treated sludge, as described more fully below. Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment due to the landfill disposal of sludge containing HEDP in light of the EPA regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill

units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

It is assumed, for the purposes of this Environmental Assessment, that treated wastewater will be discharged directly to surface waters in accordance with a National Pollutant Discharge Elimination System (NPDES) permit. This assumption may be considered a worst-case scenario since it assumes no further treatment at a Publicly Owned Treatment Works (POTW).

Treatment of the process water at an on-site wastewater treatment facility and/or at a POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid.¹ Specifically the peroxyacetic acid will break down into oxygen and acetic acid, while hydrogen peroxide will break down into oxygen and water. In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.² Therefore, these substances are not expected to be introduced into the environment to any significant extent when the FCS is used as intended.

Any toxicity from NaOH results from possible pH changes related to OH- discharges, as the toxicity of the Na+ ion is expected to be insignificant compared to the (potential) pH effect.³ As the final, treated effluent is expected to be near neutral, pursuant to NPDES requirements, we do not expect any significant effects to the aquatic environment from the requested use of NaOH.

The remainder of the environmental assessment will therefore consider only the environmental introduction, fate, and potential effects of the stabilizers, HEDP and DPA.

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

Application	Use	HEDP (ppm)	DPA (ppm)
Fruits and Vegetables	Water and ice used for washing or chilling fruits and vegetables in a food processing facility	34	0.68

¹ Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p.18. http://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_G-67_1-Dec-93.pdf

² U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001. Page 1 of Appendix 1. http://iaspub.epa.gov/opthpv/document_api.download?FILE=c13102tp.pdf#_ga=1.33870884.425726753.1445002626

³ Institute of Health and Consumer Protection (IHCP), European Union Risk Assessment Report - SODIUM HYDROXIDE, CAS No: 1310-73-2, EINECS No: 215-185-5: TARGETED RISK ASSESSMENT <http://echa.europa.eu/documents/10162/0ded9c53-4082-405b-b09a-e16e57e158af>

We will use the Environmental introduction concentration (EIC) of 34 ppm for HEDP and 0.68 ppm for DPA as the worst-case concentration for all processing facilities using the FCS in the intended applications. Therefore, the discussion of impacts in Items 7 and 8 will focus on fruit and vegetable processing facilities, namely the use on fruits and vegetables, as the use with the highest concentration of HEDP and DPA.

Introduction of the components of the FCS into the environment will result from use of the FCS as an antimicrobial agent in process water and ice used to spray, wash, rinse, or dip fruit and vegetables. The subsequent disposal of such water into the processing plant wastewater treatment facility. When the FCS is used at the maximum level under the proposed action, HEDP and DPA would be present in water at a maximum level of 34 and 0.68 parts per million (ppm), respectively. Assuming, in the very worst-case, that all the water used in a fruit and vegetable processing plant is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the environmental introduction concentration (EIC), would not exceed 34 ppm and 0.68 ppm, respectively.

HEDP is expected to partition between water and sludge so the EIC for HEDP needs to be refined. Based on information from a report issued by the Human and Environmental Risk Assessment (HERA)⁴ project, we expect HEDP will significantly partition to sewage sludge. According to the HERA report, the treatment steps at an onsite treatment facility will remove or decompose at least a portion of any HEDP that remains. The HERA report cites 80% adsorption of HEDP to sewage treatment sludge. Therefore, the EIC for HEDP has been adjusted by applying the 20:80 (water: sludge) partition factor from the HERA report to estimate the concentrations in water and sewage sludge, as shown in the table below.

No refinement is necessary for DPA since, as discussed below, this substance is anticipated to remain solely with water and not partition into sludge

As previously mentioned, PAA, HP, and AA are not expected to survive treatment at the primary wastewater treatment facilities; therefore, Expected Environmental Concentrations (EECs) have not been calculated for these substances.

The EECs for HEDP and DPA in surface water has been calculated by applying a 10-fold dilution factor to the estimated EIC.⁵ This dilution factor accounts for the expected dilution in surface waters of effluent from an onsite treatment facility as supported by data reported by Rapaport. Finally, we note that the EEC 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.

The estimated environmental concentrations for HEDP and DPA, calculated as described above, are provided in the tables below.

⁴ HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. <https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

⁵ Rapaport, Robert A., 1988 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. <http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract>

HEDP EIC and EEC for Fruits and Vegetables

HEDP EIC _(max)	HEDP EIC _{water}	HEDP EIC _{sludge}	HEDP EEC _{sludge}	HEDP EEC _{water}
34 ppm	6.8 ppm	27.2 ppm	27.2 ppm	0.68 ppm

Calculations:

$$\text{HEDP-EIC}_{\text{water}} = \text{max use} \times \text{water partition} = 34 \text{ ppm} \times 20\% = 6.8 \text{ ppm}$$

$$\text{HEDP-EIC}_{\text{sludge}} = \text{max use} \times \text{sludge partition} = 34 \text{ ppm} \times 80\% = 27.2 \text{ ppm}$$

$$\text{HEDP-EEC}_{\text{sludge}} = 27.2 \text{ ppm} \text{ (assume that the } \text{EIC}_{\text{sludge}} = \text{EEC}_{\text{sludge}} \text{ since there is no dilution)}$$

$$\text{HEDP-EEC}_{\text{water}} = \text{EIC}_{\text{water}} \div \text{dilution in aqueous receiving body} = 6.8 \text{ ppm} \div 10 = 0.68 \text{ ppm}$$

DPA EIC and EEC for Fruits and Vegetables

DPA EIC	DPA-EIC _{water}	DPA-EEC _{water}
0.68 ppm	0.68 ppm	0.068

Calculations:

$$\text{DPA-EEC}_{\text{water}} = \text{EIC}_{\text{water}} \div \text{dilution in aqueous receiving body} = 0.68 \text{ ppm} \div 10 = 0.068 \text{ ppm}$$

7. Fate of Emitted Substances in the Environment:

a. HEDP Fate in Terrestrial Environment

HEDP is expected to partition between water and sludge during wastewater treatment. Sludge resulting from wastewater treatment may end up landfilled or land applied. If applied to land, HEDP shows degradation in soil; as such, disposal on land should ensure mineralization and removal from the environment.⁶ HEDP's half-life in soil is estimated to be 373 days, extrapolated from observed degradation of 20% after 120 days.⁷ Phosphonates are also sensitive to radical-mediated degradation, which may operate in the soil environment and serve as a method for the removal of phosphonate pollution.⁸

If HEDP-containing sludge is disposed of in a landfill, HEDP would be expected to be controlled by the relevant EPA regulations and state or local guidelines, as described in Item 6.b.

b. HEDP Fate in Aquatic Environment

Wastewater from food processing facilities that contain the diluted FCS mixture is expected to be disposed of through the processing plant wastewater treatment facility or through a local POTW. Once HEDP enters the aquatic environment, it is quite stable, though hydrolysis and degradation are enhanced in the presence of metal ions, aerobic conditions, and sunlight.¹⁰ Photolysis can serve as an important route for the removal of phosphonates

⁶ Page 18 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. <https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

⁷ Ibid.

⁸ Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijt, T. Environmental risk assessment of phosphonates, used in domestic laundry and cleaning agents in the Netherlands. *Chemosphere* 2002, 47, 655-665. <https://www.ncbi.nlm.nih.gov/pubmed/12047077>

¹⁰ Page 16 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products:

like HEDP from the environment, with photodegradation half-lives varying from hours to days depending on the presence of cofactors such as oxygen, peroxides, and complexing metals like iron, copper, or manganese. For example, in the presence of iron, 40-90% degradation occurs within 17 days.¹¹

In sediment/river water systems, the ultimate biodegradation of HEDP is estimated as 10% in 60 days, with a corresponding half-life of 395 days.¹² In such systems, phosphonates like HEDP can become tightly adsorbed onto the sediment, indicating that the major part of biodegradation may occur in the sediment, where a half-life of 471 days was observed for HEDP.¹³ While hydrolysis half-lives are comparatively long (50-200 days) when compared with photodegradation, hydrolysis may serve as a significant route of removal in soil and sediment environments.¹⁴

c. Environmental Fate of DPA

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 0.11 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:

a. Terrestrial Toxicity for HEDP

Phosphonates. 06/09/2004. <https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

¹¹ Page 19 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products:

Phosphonates. 06/09/2004. <https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

¹² Page 16 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products:

Phosphonates. 06/09/2004. <https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

¹³ Page 18 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products:

Phosphonates. 06/09/2004. <https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

¹⁴ 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. *Chemosphere* 2002, 47, 655-665.

<https://www.ncbi.nlm.nih.gov/pubmed/12047077>

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

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC184408/pdf/aem00086-0158.pdf>

¹⁶ Seyfried, B. and Schnink, B. "Fermentive degradation of dipicolinic acid (Pyridine-2,6- dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria," *Biodegradation*, 1990, 1(1), 1-7. <https://link.springer.com/article/10.1007/BF00117046>

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

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC239453/pdf/600483.pdf>

HEDP present in the surface water or on land applied sludge is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. 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 >284 mg/kg body weight.¹⁸ These values are all well above the EECs estimated in Item 6, above.

Additionally, as noted above, the maximum estimated concentration of HEDP in sludge is 27.2 ppm. HEDP shows no toxicity to terrestrial organisms at levels of up to 1,000 mg/kg in soil.¹⁹ Thus, the very conservatively estimated *maximum* concentration in sludge is only 2.72% of the NOEC. The maximum concentration in soil will be lower due to dilution by the soil when the sludge is used as a soil amendment resulting in an even larger margin of safety with respect to this NOEC level. As such, the FCS is not expected to present any terrestrial environmental toxicity concerns.

b. Aquatic Toxicity for HEDP

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

Species	Endpoint	(mg/l)=ppm
Short Term		
<i>Lepomis macrochirus</i> ^A	96h LC50	868
<i>Oncorhynchus mykiss</i> ^A	96h LC50	360
<i>Cyprinodon variegatus</i> ^A	96h LC50	2180
<i>Ictalurus punctatus</i> ^A	96h LC50	695
<i>Leuciscus idus melonatus</i> ^A	48h LC50	207-350
<i>Daphnia magna</i> ^A	24 - 48h EC50	165-500
<i>Palaemonetes pugio</i> ^A	96 h EC50	1770
<i>Crassostrea virginica</i> ^A	96h EC50	89
<i>Selenastrum capricornutum</i> ^B	96h LC50	3
<i>Selenastrum capricornutum</i> ^B	96h NOEC	1.3
Algae ^B	96h NOEC	0.74
<i>Chiarella vulgaris</i> ^A	48h NOEC	>100
<i>Pseudomonas putida</i> ^A	30 minute NOEC	1000
Long Term		
<i>Oncorhynchus mykiss</i> ^A	14 d NOEC	60-180
<i>Daphnia magna</i> ^A	28 d NOEC	10 - <12.5
Algae ^B	14 day NOEC	13

¹⁸ Table 13 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. <https://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. *Chemosphere* 2002, 47, 655-665. <https://www.ncbi.nlm.nih.gov/pubmed/12047077>

Jaworska *et al.* showed that acute toxicity endpoints for HEDP ranged from 0.74 to 2,180 mg/L, while chronic NOECs were 60 to 180 mg/L for the 14 day NOEC for *Oncorhynchus mykiss* and the 28 day NOEC for the *Daphnia magna* ranged from 10 mg/l to <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.²⁰

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 (NOEC_i) and a NOEC that accounts for chelating effects (NOEC_c) 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.²¹

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.²² As such, these levels are not relevant in situations such as food processing plants, where excess nutrients are present. The HERA report on phosphonates includes a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms.²³ 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. Jaworska *et al.* reports the lowest relevant endpoint for aquatic toxicity to be the 28 day NOEC for *Daphnia magna* (10 mg/L),²⁴ which is well above the highest conservatively estimated EEC_{water} of 1.1 ppm for the fruit and vegetable processing waters application c. Ecotoxicology for DPA

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.²⁵ 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

²⁰ 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. *Chemosphere* 2002, 47, 655-665. <https://www.ncbi.nlm.nih.gov/pubmed/12047077>

²¹ US EPA Office of Water, Fact Sheet EPA-822-F-01-010; Ecoregional Nutrient Criteria, Dec 2001, available at <https://nepis.epa.gov/Exe/ZyPDF.cgi/P1009KCN.PDF?Dockkey=P1009KCN.PDF>.

²² 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. *Chemosphere* 2002, 47, 655-665. <https://www.ncbi.nlm.nih.gov/pubmed/12047077>

²³ Page 25 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. <https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

²⁴ 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. *Chemosphere* 2002, 47, 655-665.

²⁵ See representative MSDS for DPA available at http://www.apolloscientific.co.uk/downloads/msds/OR5062_msds.pdf

(long-term or delayed) toxicity to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by using computerized Structure Activity Relationships (SARs).²⁶ 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.²⁷ The ECOSAR results for DPA predict the following acute and chronic toxicity endpoints tabulated below.²⁸ The complete ECOSAR report for this analysis is attached to this EA (see Attachment).

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

These values are all much higher than the “worst-case” scenario of an EEC_{water} of 0.068 ppm, which is at least 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.

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 stabilized peroxyacetic acid 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

²⁶ Information on ECOSAR can be found at <https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>.

²⁷ EPISuite 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-screeningtools/epi-suite-estimation-program-interface>.

²⁸ See EPI Suite – ECOSAR Program Results for CAS 499-83-2; Attachment A

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 significant environmental impact.

12. List of Preparers:

This Environmental Assessment was prepared on behalf of Solvay Chemicals Inc., by Wendy A. McCombie of Lewis & Harrison, LLC. Ms. McCombie has a B.S. in Biology with 25 years of experience providing consulting services for chemical regulations.

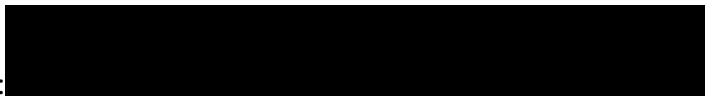
13. Certification:

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

Name: Wendy A. McCombie, Lewis & Harrison LLC

Title: Agent for Solvay Chemicals Inc.

Signature:



Date: January 20, 2020

14. List of References:

Amador, J.A. and Taylor, B.P. "Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid" Applied and Environmental Microbiology 1990, 56(5), 1352-1356. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC184408/pdf/aem00086-0158.pdf>

Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p.18. http://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_G-67_1-Dec-93.pdf

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Institute of Health and Consumer Protection (IHCP), European Union Risk Assessment Report - SODIUM HYDROXIDE, CAS No: 1310-73-2, EINECS No: 215-185-5: TARGETED RISK ASSESSMENT <http://echa.europa.eu/documents/10162/0ded9c53-4082-405b-b09a-e16e57e158af>

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. *Chemosphere* 2002, 47, 655-665.

<https://www.ncbi.nlm.nih.gov/pubmed/12047077>

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14. Attachments

Ecological Structure Activity Relationships (ECOSAR) for DPA

ATTACHMENT

Ecological Structure Activity Relationships (ECOSAR) for DPA

SMILES : O=C(O)c(nc(cc1)C(=O)O)c1
 CHEM : 2,6-Pyridinedicarboxylic acid
 CAS Num: 000499-83-2
 ChemID1:
 MOL FOR: C7 H5 N1 O4
 MOL WT : 167.12
 Log Kow: 0.567 (EPISuite Kowwin v1.68 Estimate)
 Log Kow: 0.570 (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: 4800 (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: 0.570 (User Entered)
 Wat Sol: 5000 (mg/L, PhysProp DB exp value)

 Available Measured Data from ECOSAR Training Set

CAS No	Organism	Duration	End Pt	Measured mg/L (ppm)	Ecosar Class	Reference
000499-83-2	Fish	96-hr	LC50	322	Pyridine alpha-acid	DUL

 ECOSAR v1.1 Class-specific Estimations

Pyridine-alpha-Acid

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Pyridine-alpha-Acid	: Fish	96-hr	LC50	322.219
Pyridine-alpha-Acid	: Fish		ChV	29.208 !
Neutral Organic SAR (Baseline Toxicity)	: Fish	96-hr	LC50	2641.902
	: Daphnid	48-hr	LC50	1314.539
	: Green Algae	96-hr	EC50	567.257
	: Fish		ChV	220.993
	: Daphnid		ChV	88.774
	: Green Algae		ChV	110.708

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)