Environmental Assessment

1. Date	June 15, 2016
2. Name of Applicant	Ecolab, Inc.
3. Address	Agent for Notifier: Mitchell Cheeseman, Ph.D. Steptoe & Johnson LLP 1330 Connecticut Avenue, NW Washington, DC 20036

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 2-pyridinethiol-1-oxide, sodium salt (CAS No. 15922-78-8; 3811-73-2) as a preservative for rinse aids used in commercial dishwashing machines used to clean food preparation, storage, and eating utensils in facilities such as restaurants, delis, cafeterias, bars, residential dining facilities, and medical institutions. The FCS will be present at a maximum concentration of 3 parts per million (ppm) in the final rise water at the completion of the dishwashing process and will be allowed to drain from washed food contact materials.

b. Need for Action

The FCS will be used as a preservative for a rinse aid concentrate. Rinse-aids reduce the surface tension of water causing the use-solution to spread out on the surface of the articles being washed. A faster drainage of water prevents water solids from spotting/filming and aids in the drying process.

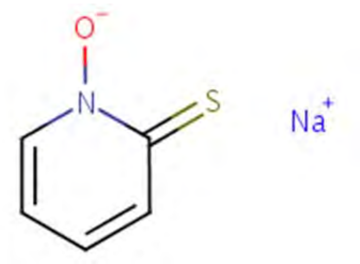
The rinse aid is diluted in the dishwasher sump to the appropriate solution that results in a maximum concentration of the FCS in the solution of 3 ppm. The FCS preserves the in-sump solution, which may remain in the dishwasher for an extended period. As the sump is a warm and wet environment, the FCS is needed to prevent growth in the solution of undesirable microorganisms that would then be incorporated into the wash water and could be transferred to the food contact materials. The FCS only serves a preservative effect in the in-sump solution and serves no technical effect on the food contact surfaces.

c. Locations of Use/Disposal

The rinse aid will be used on food preparation surfaces, storage, and eating utensils in commercial facilities such as restaurants, delis, cafeterias, bars, residential dining facilities, and medical institutions. Application will be by machine ware washing, i.e., sprayed onto plates, cups, silverware, pots, and pans as a last step in the washing process, no water rinse afterwards. Therefore, it is expected that the vast majority of the FCS will be discharged with the facility's waste water and sent to a publicly owned treatment works (POTW). Use of the FCS will be in accord with current population distribution throughout the U.S.

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

The food contact substance is 2-pyridinethiol-1-oxide, sodium salt (CAS No. 15922-78-8; 3811-73-2). The molecular formula of the FCS is C_5H_4NNaOS. The FCS has a molecular weight of 149.149. The structure of the FCS can be depicted as follows:



6. Introduction of Substances into the Environment

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

Ecolab does not manufacture the FCS but purchases the product from a supplier identified in the confidential attachment to the EA. 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. It is Ecolab's expectation that the FCS is manufactured in plants which meet all applicable federal, state, and local environmental regulations. The FCS is added to rinse aid products at various Ecolab manufacturing facilities. All of Ecolab's manufacturing facilities meet all applicable federal, state and local environmental regulations. On these bases, 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 (40 C.F.R. § 1508.27(b)(10)); 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

Introduction of dilute solutions of the FCS into the environment will take place primarily through release in wastewater treatment systems. Introduction of the components of the product into the environment will result from use of rinse aid products in dishwashing machines in commercial food handling facilities such as restaurants, delis, cafeterias, bars, residential dining facilities and medical institutions. Application will be by machine ware washing - i.e., sprayed onto plates, cups, silverware, pots, pans as a last step in the washing process with no water rinse. The FCS will be present in the final rinse water at concentrations less than or equal to 3 ppm. All water from the dishwashing process is expected to be disposed of via local POTWs. The treated water from the POTW will be discharged into local waters, and the environmental introduction concentration into the aquatic environment is discussed below. We have also estimated maximum potential concentrations in soil from application of sludge from wastewater treatment facilities to soil. No direct disposal to land is expected.

The confidential attachment to this EA includes modeling of environmental introductions based on Ecolab's estimated production volume, using the U.S. Environmental Protection Agency's (EPA) Exposure and Fate Assessment Screening Tool (E-FAST). E-FAST is a screening-level computer tool that allows users to estimate chemical concentrations in water to which aquatic life may be exposed, as well as generate human inhalation, drinking water ingestion, and fish ingestion exposures resulting from chemical releases to air, water, and land. Ecolab used the E-FAST Down-the-Drain module, with the following physical-chemical properties: chemical identification, a bioconcentration factor (BCF), and wastewater treatment (WWT) removal.[1] Additional required properties are production volume (kg/year) and the exposure duration (years of use).[2]

Chemical identification refers to the chemical identity of the FCS (described above), while the BCF and WWT removal values were generated from the EPI (Estimation Programs Interface) Suite™, a modeling program developed by EPA and Syracuse Research Corporation (SRC). The BCF is determined using BCFBAF™, a program that estimates fish bioconcentration factor and its logarithm using two different methods: (1) the traditional regression based on log K_{OW} plus any applicable correction factors; and (2) the Arnot-Gobas method, which calculates BCF from mechanistic first principles. BCFBAF™ also incorporates prediction of apparent metabolism half-life in fish, and estimates BCF and BAF for three trophic levels. For the WWT removal factor, EPA recommends using the BIOWIN™/EPA draft method because it accounts for biodegradation.[3] BIOWIN™ estimates aerobic and anaerobic biodegradability of organic chemicals using seven different models, and the most current model estimates anaerobic biodegradation potential. As the FCS was found to be readily biodegradable, this method was considered appropriate in this case.[4]

The parameters for the exposure duration are 57 years, which is the default assumption in the model, and the number of release days per year is assumed to be 365 days, representing continuous release. As the EPI Suite is considered to be protective of the environment,[5] and the

[1] Versar, Inc., for US EPA, *Exposure and Fate Assessment Screening Tool (E-FAST) Version 2.0 Documentation Manual* (October 2007), Table 2-1, available at https://www.epa.gov/sites/production/files/2015-04/documents/efast2man.pdf.
[2] Id., at p. 3-57.
[3] US EPA Office of Chemical Safety and Pollution Prevention, *Sustainable Futures / P2 Framework Manual*, EPA-748-B12-001 (2012), p. 5-19, available at https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual. The default method used by EPI Suite™ is the Sewage Treatment Plant Chemical Fate Estimation Program (STPWIN) which assumes negligible biodegradation and will greatly underestimate removal. Ecolab also conducted E-FAST modeling using this method. However, because US EPA recommends using the BIOWIN™/EPA draft method and because testing demonstrated that the FCS is readily biodegradable, Ecolab is relying on the results of the testing using the BIOWIN™/EPA draft method-developed WWT removal factor in the E-FAST model.
[4] Arch Chemicals, *Sodium Pyrithion: Assessment of ready biodegradability – Modified Sturm Test FINAL REPORT* (December 8, 1998).
[5] See US EPA Science Advisory Board (SAB), *Review of the Estimation Programs Interface Suite (EPI Suite™)* (Sept. 7, 2007), p. 16, available at https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/CCF982BA9F9CFCFA8525735200739805/$File/sab-07-011.pdf.

exposure duration and production volume are expected to be highly conservative estimates, this modeling represents a conservative model of release of the FCS into the environment. Based on this model, the worst-case EIC based on the 1Q10 receiving stream flow (i.e., low flow) is conservatively calculated to be 0.19 µg/L (ppb).

There is the potential for the FCS to enter the terrestrial environment when sewage sludge from a POTW is applied to land. FDA guidance indicates that substances with an adsorption coefficient (Koc) > 1000 might adsorb significantly to sewage sludge.[6] As discussed below, soil sorption data on the FCS indicates that sorption behavior is dependent on the pH of the soils, and leaching potential is low. Testing data on zinc pyrithione indicates that the K_{OC} values similarly range considerably depending on the type of material, with 2,347 for Marblehead salt soil, 784 for Portland fresh soil, 10,633 for Marblehead salt sediment, and 3,597 for Portland fresh sediment.[7] Given this range, we have calculated an EIC for the terrestrial environment based on the following assumptions from FDA's EA Guidance: (1) Even distribution of the food substance throughout the U.S. per day; (2) total consumption of the food substance; and (3) all of the substance adsorbs to sewage sludge. FDA's EA Guidance includes an assumption regarding no biodegradation, however, as discussed above, biodegradation has been estimated using the BIOWIN™/EPA draft method, and this factor has been incorporated in the calculation. Other factors in the calculation from the EA Guidance are as follows: (1) Estimated production volume; (2) 6.4 x 10^9 kg sewage sludge/year; (3) 55.5% of POTW biosolids is land-applied or composted. As outlined in the Confidential Attachment, the EIC is calculated to be 0.71 mg/kg (ppm).[8]

7. Fate of Emitted Substances in the Environment

The intended use of the FCS as a rinse aid is a "down-the-drain" (DTD) use, meaning that there is no onsite water treatment; rather, the wastewater goes to a POTW. Some information on the environmental fate of the FCS is described in an EPA scoping document prepared as part of the reregistration process for the FCS under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[9] EPA noted a hydrolysis study, in which measurements at each combination of concentration (10 mg/l or 100 mg/l), temperature (5 °C or 40 °C), and pH (4, 7, or 10), indicate that a half-life of 23 days was obtained at 40°C, pH 10, and 10 mg/l concentration.[10] At other levels of concentration, temperature, and pH, the FCS

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[6] US FDA, *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition - Appendix A (Guidance for Preparing an Environmental Assessment for Substances that are Macronutirient Replacements)* (May 2006), available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm081049.htm ("EA Guidance").

[7] Arch Chemicals, *Adsorption and Desorption of [pyridine-2 ,6-^{14}C] Zinc OMADINE* in Two Sediments and Two Terrestrial Soils* (April 30, 1996).

[8] We note that the EPI Suite modeling, using the BIOWIN™/EPA draft method, indicates that 0.62% of the FCS will adsorb to sludge during wastewater treatment. We have not relied on this very small adsorption factor in our calculations, but note that it is evidence of the conservatism of this calculated EIC and the likelihood of an even greater margin of safety.

[9] US EPA, *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document in Support of Registration Review of Sodium Omadine* (December 21, 2011) (hereinafter "EPA Scoping Document"), available at http://www.regulations.gov, docket number EPA-HQ-OPP-2011-0611.

[10] Id., p. 10.

hydrolyzed more slowly, or was stable to hydrolysis.[11] Hydrolytic products were more readily formed at an alkaline pH than at neutral and acidic pH.[12] EPA also noted that photolysis is probably a more important route of dissipation than hydrolysis, based on a study in photolytic half-lives of 40-126 minutes at a concentration of 100 mg/l and irradiation by natural sunlight, although EPA also noted limitations in the methodology of this study.[13]

EPA states that the FCS will dissociate in the environment into sodium and pyrithione ions, and that the pyrithione ions would be expected to possible form metal complexes like zinc and copper pyrithione. Identified degradates are those common to zinc and copper pyrithione: pyrithione disulfide; pyrithione sulfinic acid; pyrithione sulfonic acid; pyrithione thiosulfonic acid; pyridine disulfide; pyridine sulfinic acid; pyridine sulfonic acid; 2-mercaptopyridine/2-mercaptopyrine-N-oxide (mixed disulfides).[14]

A ready biodegradability test, using the Modified Sturm test, was conducted on the FCS.[15,16] Mean cumulative CO_2 production by mixtures containing the FCS at 10 mgC/l was equivalent to 2% after eight days of incubation and 60% after 18 days. 70% degradation was achieved after 43 days. Under the parameters of the test, the FCS is considered to be readily degradable.

An activated sludge respiration inhibition test was performed to estimate possible effects of the FCS on aerobic microbial sewage treatment plants, using concentrations of the test substance of 0.67, 1.67, 4.18, 10.44, and 26.10 mg/L with positive and negative controls.[17] The test determined EC 20, 50, and 80 values of 0.48, 1.81, and 6.84 mg/L, respectively.

A soil sorption and desorption study was conducted on five soils (silty loam, clay loam, loam, clay, and sand).[18] Very high sorption data was obtained for the acidic soils, high sorption for the neutral soils, and moderate sorption for the basic soil. The leaching potential of the test substance was considered to be low in the soils used in the study. The observed sorption behavior suggests that sorption and desorption is more related to the pH of the soils than to the texture and organic carbon content.

As discussed in the confidential attachment to the EA, available information and data on zinc and copper pyrithiones may be used to bridge the gaps in existing data for sodium pyrithione. Some environmental fate data are summarized in an EPA Reregistration Eligibility Document for zinc pyrithione, as follows:[19]

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[11] Id.
[12] Id.
[13] Id.
[14] Id.
[15] Arch Chemicals, *Sodium Pyrithion: Assessment of ready biodegradability – Modified Sturm Test FINAL REPORT* (December 8, 1998).
[16] The environmental fate studies summarized in this section are proprietary to Arch Chemicals and study summary reports have been provided to FDA. The studies were conducted according to OECD recognized methods, but have not been published in the peer-reviewed literature.
[17] Arch Chemicals, *"Natrium Pyrion": Activated Sludge Respiration Inhibition Test* (August 7, 2002).
[18] Arch Chemicals, *"Natrium Pyrion": Soil Sorption and desorption* (March 25, 2002).
[19] US EPA, *Environmental Fate Science Chapter on Zinc Pyrithione (Zinc Omadine®) For Reregistration Eligibility Document (RED)* (April 14, 2004).

Zinc Pyrithione … appears hydrolytically stable in abiotic, buffered and simulated water systems with an extrapolated half life between 99, 120 and 123 days in buffered medium and 96 days (extrapolated) in simulated sea water. Photolytically, however, it rapidly degrades with a half life of 13 minutes in buffered aqueous medium and 17 minutes in simulated sea water. It may not pose a concern for surface water run-off.

There are multiple degradation pathways for zinc pyrithione. Under aerobic conditions, zinc pyrithione degradation half life is 0.6 hours in aqueous system and 0.89 days in sediment. Similarly zinc pyrithione shows a tendency of degrading anaerobically in water within 0.5 hours and in about 19 hours in sediments. It may not be a concern for ground water contamination.

Zinc pyrithione shows a moderately strong tendency to bind with soils and sediments: With salt water soil and sediment its K_ds are 50 and 99 respectively. Tendency to bind with freshwater soils and sediments are less strong and observed K_ds are 11 and 48 respectively. There may be a short-lived water/sediment partitioning issue. There could be an acute adverse impact on benthic aquatic organisms.[20] However, since it degrades fairly quickly in freshwater and saltwater soils and sediments (half lives 0.89 days to 19 hours), the acute adverse impact may be very short-lived. It is not likely to persist in water and microbial soils and sediments.

Reported Octanol/Water Partition coefficient K_{OW} is < 1000, and therefore zinc pyrithione is not likely to bioaccumulate in aquatic organisms (fish etc.).[21]

8. Environmental Effects of Released Substances

a. Terrestrial Toxicity

EPA noted that the FCS is moderately toxic to avian species on an acute oral basis (test in Bobwhite quail determined LD50 of 441 mg/kg bw, 185 mg/kg active) and slightly toxic to avian species on subacute dietary basis (tests in Bobwhite quail and Mallard ducks determined LC_{50}s of 1300 and 3650 mg active/L, respectively).[22]

In a 28 day reproduction test on Collembola (*Folsomia candida*), the FCS (40%) caused no statistically significant effects on mortality up to and including to the concentration of 500 mg/kg soil dry weight.[23,24] The NOEC for mortality was determined to be 500 mg/kg soil dry weight. The LC50 was determined to be 822 mg/kg soil dry weight. The reproduction

[20] As summarized below, ZnPT toxicity to benthic organisms is usually measured in the parts per million. The bioavailability of pyrithiones are greatly reduced due to binding to the sediment.
[21] We note that the K_{ow}seems high, as the Log P for ZnPT is 0.97. In addition, in a bioaccumulation study in oysters ZnPT demonstrated a 30-day bioconcentration factor of 8.6-11.0.
[22] EPA Scoping Document, p. 11.
[23] Arch Chemicals, *Sodium-Pyrion 40% on Reproduction of the Collembola Folsomia candida in Artificial Soil* (2009).
[24] The environmental effect studies summarized in this section are proprietary to Arch Chemicals and study summary reports have been provided to FDA. The studies were conducted according to OECD- or EPA-recognized methods, but have not been published in the peer-reviewed literature.

values were not statistically different compared to the control at 250 mg/kg soil dry weight, which was therefore determined to be the NOEC for reproduction and to be the overall NOEC. The EC50 for reproduction was determined to be 670 mg/kg soil dry weight.

An acute toxicity test on the FCS in the Earthworm (*Eisenia fetisa*) found no mortality up to and including 1000 mg/kg, while 100% mortality was found at ≥10,000 mg/kg.[25] The body weights of the surviving worms ranged from +2.8% to -15.7% compared to a weight loss of -3.4% in the control.

EPA indicates that zinc pyrithione is moderately toxic to birds via acute oral exposure, and slightly toxic to practically non-toxic to birds via dietary exposure.[26]

Based on these data, the FCS is of a low order of toxicity to terrestrial organisms. The EIC is calculated to be 0.71 mg/kg, which is orders of magnitude lower than the lowest NOEC of 250 mg/kg. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable,[27] the wide margin of safety is more sufficient to conclude there will be no significant impact from the potential application of biosolids containing the FCS to land.

b. Aquatic Toxicity

EPA considers the FCS to be very highly toxic to rainbow trout, bluegill sunfish, and daphnia, noting that from the information available, coldwater rainbow trout are more acutely sensitive to the FCS than bluegill sunfish and daphnia.[28] EPA noted that a study it reviewed did not provide a definitive LC_{50} value for the rainbow trout (i.e, 96-h LC50 < 7.3 ppb FCS), but a second study in rainbow trout determined a NOEC of 13 µg/L (ppb).[29]

A toxicity study of the FCS in green alga *Selenastrum capricornutum* determined a NOEC of 0.08 mg/L, and an EC_{50} of 0.46 mg/L.[30]

EPA states that zinc pyrithione is very highly toxic on an acute basis to freshwater and marine fish and invertebrates, as well as to aquatic plant species,[31] and that it also causes adverse impacts on freshwater and marine invertebrate reproduction and growth at very low levels.[32] Two major degradants of zinc pyrithione, pyridine sulfonic acid and pyrithione sulfonic acid, are

[25] Arch Chemicals, *Acute Toxicity of Sodium-Pyrion 40% to the Earthworm Eisenia fetida (14 days Exposure in Artificial Soil)* (2007).
[26] EPA, *Zinc Pyrithione Ecological Hazard and Environmental Risk Characterization Chapter for the Reregistration Eligibility Decision (RED) Document*, p. 2 (September 20, 2004) (hereinafter "ZnPT EHERC").
[27] 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 EC_{50} 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.
[28] EPA Scoping Document, p. 12.
[29] Arch Chemicals, *Sodium Pyrion: Acute toxicity to rainbow trout Oncorhynchus mykiss* (December 1995).
[30] Arch Chemicals, *Sodium Pyrion: Toxicity to the green alga Selenastrum capricornutum* (March 10, 1994).
[31] ZnPT EHERC, p. 2.
[32] Id. These reproductive effects were seen at or near lethal concentrations.

only slightly toxic to practically non-toxic to freshwater and marine/estuarine fish and invertebrates and aquatic plants.[33]

Aquatic toxicity of sodium, zinc and copper pyrithione has been summarized in the following table:

Table 1: Summary of Aquatic Toxicity Data for Sodium, Zinc and Copper Pyrithione

Substance (Purity)	Aquatic Organism	Toxicity Endpoint	NOEC	Source
NaPT (40%)	Rainbow trout	LC_{50} 1300 µg/L	13 µg/L	Arch Chemicals
NaPT (41.9%)	Rainbow trout	LC_{50} 7.3 µg/L	Not recorded	EPA Scoping Document
ZnPT (97.8%)	Rainbow Trout	LC_{50} 3.6 ppb	1.6 ppb	Zn EHERC
NaPT (41.9%)	Bluegill sunfish	LC_{50} 8100 µg/L	0.89 mg/L	EPA Scoping Document
ZnPT (97.8%)	Fathead minnow	LC_{50} 2.68 ppb	1.1 ppb	Zn EHERC
CuPT (94.7%)	Fathead minnow	96 hr. LC_{50} 4.3 µg/L	Not provided	EPA Scoping Document
ZnPT (98.2%)	Fathead minnow	Early Life Stage	1.22 ppb	Zn EHERC
NaPT (40%)	*Daphnia magna*	EC_{50} 9.2 µg/L	11 ppb	EPA Scoping Document
NaPT	*Daphnia magna*	48 hr. EC_{50} 0.15 mg/L	0.02 mg/L	Arch Chemicals
ZnPT (97.8%)	*Daphnia magna*	LC_{50} or EC_{50} 8.25 ppb	1.1 ppb	Zn EHERC
CuPT (94.7%)	*Daphnia magna*	96 hr. LC_{50} 10.1 µg/L	Not provided	EPA Scoping Document
ZnPT (98.2%)	*Daphnia magna*	Reproduction length	2.7 ppb	Zn EHERC
ZnPT (97.8%)	Sheepshead minnow	LC_{50} 400 ppb	200 ppb	Zn EHERC
ZnPT (97.8%)	Eastern oyster (shell deposition)	96 hr. EC_{50}/ LC_{50} 22 ppb	7.1 ppb	Zn EHERC
CuPT (94.7%)	Eastern oyster (shell deposition)	96 hr. LC_{50} 9.2 µg/L	Not provided	EPA Scoping Document
ZnPT (97.8%)	Mysid	96 hr. LC_{50} 4.7 ppb	1.6 ppb	Zn EHERC
ZnPT (97.8)	Mysid	Reproduction LOEC 9.16 ppb Growth LOEC 4.2 ppb	Reproduction 4.2 ppb Growth 2.28 ppb	Zn EHERC

[33] Id.

ZnPT (98.2%)	*Hyalella azteca*	LC_{50} or EC_{50} 136 ppb		Zn EHERC
ZnPT (98.2%)	*Hyalella azteca*	EC_{50} 18 mg/kg	10 mg/kg	European Chemicals Agency (ECHA)[34] (2004)
ZnPT	*Arbacia punctulata*	Fertilization LOEC 1.7 µg/L Embryo LOEC 60 µg/L Adult 30-day LOEC 99 µg/L	Fertilization 1 µg/L Embryo 29 µg/L Adult 30-day 45 µg/L	ECHA (2004)[35]
ZnPT (98.2%)	*Leptocheirus plumulosus*	EC_{50} 26 mg/kg	12 mg/kg	ECHA (2004)[36]
ZnPT	*Ciona intestinalis*	Test 1: Effect of ZPT on unfertilised eggs in embryonic development. Test 2: Effect of ZPT on fertilised eggs on embryonic development. Test 3: Effect of ZPT throughout embryonic development. Test 4: Effect of ZPT on larval settlement. Test 5: Delayed effect of ZPT on larval settlement. Test 6: Effects of natural sunlight and lab UV light exposed ZPT throughout embryonic development.	The most sensitive response was larval settlement, which was approximately 10 times more sensitive than embryonic development, with an EC50 of 108 nM.	ECHA (2005)[37]
NaPT (40%)	*Selanastrum capriconutum*	EC_{50} 0.23 mg/L biomass 0.46 mg/L growth	0.08 mg/L	Arch Chemicals
ZnPT (97.8%)	*Selanastrum capriconutum*	96 hr. EC_{50}/ LC_{50} 28 ppb	7.8 ppb	Zn EHERC
ZnPT (98.3%)	*Anabaena flos-aquaea*	96 hr. EC_{50}/ LC_{50} 7.1 ppb	3.8 ppb	Zn EHERC
ZnPT (98.3%)	*Navicula pelliculosa*	96 hr. EC_{50}/ LC_{50} 2.6 ppb	2.4 ppb	Zn EHERC
ZnPT (98.2%)	*Lemna gibba G3*	96 hr. EC_{50}/ LC_{50} 8.87 ppb	4.0 ppb	Zn EHERC

[34] http://echa.europa.eu/registration-dossier/-/registered-dossier/14333/6/2/5/?documentUUID=c9fd45c3-e5d8-4703-b42e-ed1f13efea12.
[35] http://echa.europa.eu/registration-dossier/-/registered-dossier/14333/6/2/5/?documentUUID=8e9b6221-52a6-42da-b03b-6b96963cf5c0.
[36] http://echa.europa.eu/registration-dossier/-/registered-dossier/14333/6/2/5/?documentUUID=4388fdde-82a6-4d90-b672-1afdd9ea3370.
[37] http://echa.europa.eu/registration-dossier/-/registered-dossier/14333/6/2/5/?documentUUID=764e1b2f-c633-4979-8f3f-94e0a2fd8e59.

ZnPT (98.2%)	*Skeletonema costatum*	120 hour EC_{50} 1.3 µg/L	0.46 µg/L	Arch Chemicals[38]
ZnPT (98.4%)	*Skeletonema costatum*	72 hour EC_{50} 3.06 µg/L	0.31 µg/L	Arch Chemicals[39]

The acute toxicity of two pyrithione degradants to fish and aquatic invertebrates exposed in the water column is summarized in the ZN EHERC, and demonstrates that the degradants are only slightly toxic to practically nontoxic.[40] Consequently, we focus on the parent compound as the compound that is ecotoxicologically significant.

Based on the available ecotoxicity data, pyrithione salts are very highly toxic on an acute basis to freshwater and marine fish and invertebrates, as well as to aquatic plant species. Coldwater rainbow trout appear to be more acutely sensitive to the FCS than bluegill sunfish and Daphnia magna, while *Skeletonema costatum* appears to be the most sensitive species, with a NOEC of 0.31 µg/L, or 0.31 ppb, and an EC_{50} of 3.06 µg/L. The calculated EIC of 0.19 ppb is below the most stringent of these thresholds, which permits the conclusion that there will be no significant impact from discharge of POTW waters into aquatic environments. Moreover, the calculated EIC is very conservatively calculated.

9. Use of Resources and Energy

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 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 FCS to the options available for commercial rinse aids is not expected to increase the use of such products.

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[38] Arch Chemicals, *Zinc Pyrithione: Influence on Growth and Growth Rate of the Marine Diatom, Skeletonema costatum* (April 13, 2004).
[39] Arch Chemicals, *Zinc Pyrithione: Static Growth Inhibition Test with the Marine Diatom, Skeletonema costatum* (amended report, June 6, 2012).
[40] EPA Scoping Document, p. 14.

12. List of Preparers

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Attwood has seven years of experience preparing environmental submissions to FDA.

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011 including oversight of FDA's initial NEPA review for the regulations implementing the Food Safety Modernization Act.

13. Certification

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

Date: June 15, 2016

Mitchell Cheeseman, PhD

14. References

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15. Attachments