

more than 0.005% phosphate (≤ 50 ppm) and not more than 10 mg tin/kg hydrogen peroxide (≤ 10 ppm; ≤ 14 ppm as stannate (SnO_3^{2-})).

The FCS will have no ongoing effect in or on the food products due to its decomposition into molecular oxygen and water during the subsequent pasteurization process. The proposed use of the FCS therefore will result in no introductions of the FCS into the environment. The only environmental introductions anticipated are relatively minor amounts of phosphate and stannate stabilizers present in the FCS solution that will remain in the food through ingestion by consumers.³

B. Need for Action

This FCS is intended for use as a processing aid in the production of frozen dessert mixes and ready-to-drink beverages containing whey protein. The heat of pasteurization can induce aggregation of β -lactoglobulin in the presence of milk salts. Treatment of frozen dessert mixes and ready-to-drink beverages with hydrogen peroxide just prior to pasteurization provides significant improvement in heat stability, and decreased whey protein denaturation and aggregation.

C. Locations of Use/Disposal

Hydrogen peroxide will be added directly to ingredient mixtures of frozen dessert mixes and ready-to-drink beverages containing whey protein, prior to pasteurization, in processing facilities throughout the United States. Although the hydrogen peroxide is transformed into water and molecular oxygen by the pasteurization process, the phosphate and stannate stabilizers will remain intact in the foods that are shipped from the processing facilities using the FCS. No environmental introductions are anticipated at the locations of use. The only environmental introductions will be due to residential disposal of human waste products containing trace amounts of these phosphate and stannate stabilizers. Wastewater containing the FCS will be diluted and treated at a Publicly Owned Treatment Works (POTW) prior to being combined with surface waters.

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

Chemical Identity

The FCS that is the subject of this FCN is hydrogen peroxide (CASRN 7722-84-1) complying with the Food Chemicals Codex (FCC) specification for food grade hydrogen peroxide, that will usually have a concentration between 30% and 50% prior to being diluted to the at-use concentration. The FCS concentrate is stabilized with not more than 0.005% phosphate (≤ 50 ppm) and not more than 10 mg tin/kg hydrogen peroxide (≤ 14 ppm SnO_3^{2-}) in accordance with the FCC specifications. The FCS will be used at levels not to exceed 0.005% of the pre-pasteurized ingredient mixture. The corresponding stabilizer concentrations in the frozen

³ Phosphate and stannate stabilizers provide stability to hydrogen peroxide solutions during shipment and storage prior to its application to the food ingredients. Their purpose is to improve the shelf life of the hydrogen peroxide solution prior to use. These stabilizers serve no technical purpose and exert no technical effect once the FCS is used.

dessert mixes and ready-to-drink beverages containing whey protein therefore will not exceed 8.3 ppb phosphate and 2.3 ppb stannate in the dessert or beverage.⁴

6. Introduction of Substances into the Environment

A. Introductions as a Result of Manufacture

An environmental assessment focuses on relevant environmental issues relating to the use and disposal from use rather than the production of FDA-regulated articles [Title 21 C.F.R. § 25.40(a)]. The Notifier is aware of no information suggesting the existence of extraordinary circumstances that would indicate a potential for adverse environmental impacts resulting from the manufacture of the FCN. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided.

B. Introductions as a Result of Use and Disposal

Additives necessary for a functional shelf life of hydrogen peroxide ultimately will be ingested by consumers as components of foods containing these substances, and then excreted intact. Environmental introductions of these stabilizers are limited to those resulting from the treatment and disposal of human waste products containing the stabilizers. The stabilizer concentrations in human excreta would not significantly exceed the concentrations in the daily diet which is estimated as follows:

1. Dietary Concentration of Stannate from Frozen Desserts Containing Whey Protein

Smiciklas-Wright *et al.* report that of 1543 males surveyed between the ages of 23 and 39 years, 23 reported eating an average of 398 g of ice cream or ice milk⁵ on both days of the two-day dietary survey (90th percentile, highest consumption age group).^{6,7} Modeling these men

⁴
$$\frac{\text{Phosphate in Dessert of Beverage}}{(0.3 \text{ g HP/g HP Concentrate}) \times (50 \times 10^{-6} \text{ g Hydrogen Peroxide/Dessert or Beverage})} = 0.0083 \text{ } \mu\text{g Phosphate/g Dessert or Beverage} = 8.3 \text{ ppb phosphate in the Dessert of Beverage.}$$

$$\frac{\text{Stannate in Dessert of Beverage}}{(0.3 \text{ g HP/g HP Concentrate}) \times (50 \times 10^{-6} \text{ g HP/Dessert or Beverage})} = 0.002 \text{ } \mu\text{g Stannate/g Dessert or Beverage} = 2.3 \text{ ppb Stannate in the Dessert of Beverage.}$$

⁵ FDA revoked the standard of identity for “ice milk” in 1994, and instead allowed products formerly labeled as “ice milk” to be labeled as “reduced fat ice cream” or “low fat ice cream.” See 59 Fed. Reg. 47063, at 47072 (Sep. 14, 1994).

⁶ Smiciklas-Wright, H., D.C. Mitchell, S.J. Mickle, A.J. Cook, and J.D. Goldman. 2002. Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1994-1996. U.S. Department of Agriculture NFS Report No. 96-5, pre-publication version, 252 pp. Available online <https://www.ars.usda.gov/ARUserFiles/80400530/pdf/portion.pdf>

⁷ Smiciklas-Wright *et al.* report that the “Ice Cream and Ice Milk” category of their report excludes sherbet, frozen yogurt, and all novelties such as popsicles and cones. Nevertheless,

as 60 kg persons, this corresponds to 6.63 g Dessert/kg·bw/day. Stannate exposure resulting from application of FCC grade hydrogen peroxide to the frozen dessert mixes may be estimated using these data in the following exposure model:

- The FCC limits tin in a 30% HP Solution to 10 ppm (14 ppm SnO₃⁻²);
- There are 50 ppm of hydrogen peroxide in the frozen dessert mix (0.005%);
- The 90th percentile consumption of the frozen dessert is 398 g/person·day (6.63 g/kg·bw/day); and,
- The general population is modeled as a 60 kg person that consumes 3 kg Food per day.

$$\text{Exposure (SnO}_3^{-2}) = (14 \mu\text{g SnO}_3^{-2}/\text{g HP Concentrate}) \div (0.3 \text{ g HP/g HP Concentrate}) \times (50 \times 10^{-6} \text{ g HP/g Dessert}) \times (6.63 \text{ g Dessert/kg}\cdot\text{bw/day}) = 0.015 \mu\text{g SnO}_3^{-2}/\text{kg}\cdot\text{bw/day}$$

$$\text{Intake (SnO}_3^{-2}) = (\text{Exposure}) \times (60 \text{ kg}\cdot\text{bw/person}) = (0.015 \mu\text{g SnO}_3^{-2}/\text{kg}\cdot\text{bw/day}) \times (60 \text{ kg}\cdot\text{bw/person}) = 0.9 \mu\text{g SnO}_3^{-2}/\text{person}\cdot\text{day}$$

$$\text{DC} = (0.015 \mu\text{g SnO}_3^{-2}/\text{kg}\cdot\text{bw/day}) \times (60 \text{ kg}\cdot\text{bw/person}) \div (3 \text{ kg Food/person}\cdot\text{day}) = 0.3 \mu\text{g SnO}_3^{-2}/\text{kg Food in the diet} = 0.3 \text{ ppb SnO}_3^{-2} \text{ in the diet}$$

Thus, the concentration of stannate in human excreta due to the use of food grade hydrogen peroxide in frozen desserts containing whey protein is unlikely to significantly exceed 0.3 μg SnO₃⁻²/kg Excreta.

2. Dietary Concentration of Stannate from Ready-to-Drink Beverages Containing Whey Protein

Non-animal whey protein from fermentation is also used to formulate beverages that are used as alternatives to cow's milk. These types of beverages are prepared in a manner that is analogous to the process described for preparing frozen desserts. FCC grade hydrogen peroxide is intended to be used in the production of these beverages in the same manner, and for the same technical purpose, as described for the frozen desserts.

Cow-free beverages containing non-animal whey protein from fermentation are intended to be used as a replacement for beverages containing whey protein derived from cow's milk. Such beverages are therefore anticipated to be consumed in the same manner as cow's milk. Smiciklas-Wright *et al.* report that of 696 males surveyed between the ages of 12 and 19 years, 625 reported consuming an average of 998 g of total milk on both days of the two-day dietary survey (90th percentile, highest consumption age group). Modeling this subpopulation as 60 kg

consumption of sherbet, frozen yogurt and other dairy-like frozen desserts would follow patterns similar to that of ice cream. It is expected, for example, that the possible consumption of both ice cream and frozen yogurt on the same day by the same person would be so rare as to have no impact on the overall 90th percentile intake of the highest consumption age group due to the similarity of these products and how they are used by consumers.

persons, this corresponds to 16.6 g Total Milk/kg·bw/day. Stannate exposure resulting from application of FCC grade hydrogen peroxide to cow-free beverages may be estimated using these data in the following exposure model:

- The FCC limits tin in a 30% HP Solution to 10 ppm (14 ppm SnO₃⁻²);
- There are 50 ppm of hydrogen peroxide in the beverages containing non-cow whey protein (0.005%);
- The 90th percentile consumption of the beverages containing non-cow whey protein is 998 g/person·day (16.6 g/kg·bw/day); and,
- The general population is modeled as a 60 kg person that consumes 3 kg Food per day.

$$\text{Exposure (SnO}_3^{-2}) = (14 \mu\text{g SnO}_3^{-2}/\text{g HP Concentrate}) \div (0.3 \text{ g HP/g HP Concentrate}) \times (50 \times 10^{-6} \text{ g HP/g Dessert}) \times (16.6 \text{ g Beverage/kg}\cdot\text{bw/day}) = 0.039 \mu\text{g SnO}_3^{-2}/\text{kg}\cdot\text{bw/day}$$

$$\text{Intake (SnO}_3^{-2}) = (\text{Exposure}) \times (60 \text{ kg}\cdot\text{bw/person}) = (0.039 \mu\text{g SnO}_3^{-2}/\text{kg}\cdot\text{bw/day}) \times (60 \text{ kg}\cdot\text{bw/person}) = 2.34 \mu\text{g SnO}_3^{-2}/\text{person}\cdot\text{day}$$

$$\text{DC} = (0.039 \mu\text{g SnO}_3^{-2}/\text{kg}\cdot\text{bw/day}) \times (60 \text{ kg}\cdot\text{bw/person}) \div (3 \text{ kg Food/person}\cdot\text{day}) = 0.78 \mu\text{g SnO}_3^{-2}/\text{kg Food in the diet} = 0.78 \text{ ppb SnO}_3^{-2} \text{ in the diet}$$

Thus, the concentration of stannate in human excreta due to the use of food grade hydrogen peroxide in ready-to-drink beverages containing whey protein is unlikely to significantly exceed 0.78 μg SnO₃⁻²/kg Excreta.

3. Total Stannate Dietary Concentration

Modeling the high consumer as persons who consume both frozen dairy desserts and milk each day at the 90th percentile, the stannate dietary concentration is represented here by the sum of the stannate contribution from frozen desserts and ready-to-drink beverages containing whey protein:⁸

$$\text{Total Stannate Dietary Concentration} = (\text{Total Exposure}) \times (60 \text{ kg}\cdot\text{bw/person}) \div (3 \text{ kg Food/person}\cdot\text{day}) = (0.054 \mu\text{g SnO}_3^{-2}/\text{kg}\cdot\text{bw/day}) \times (60 \text{ kg}\cdot\text{bw/person}) \div (3 \text{ kg Food/person}\cdot\text{day}) = 1.08 \mu\text{g SnO}_3^{-2}/\text{kg Food in the diet} = 1.08 \text{ ppb SnO}_3^{-2} \text{ in the diet.}$$

Thus, the total concentration of stannate in the diet, and by extension human excreta, that may result from the proposed use of hydrogen peroxide in frozen dessert mixes and ready-to-drink beverages containing whey protein is estimated to be 1.08 ppb. The concentration of

⁸ It is not typically meaningful to simply sum two such distinct exposure estimates because these two different types of foods are not usually consumed by the same persons on the same days. Exposure is usually based on the intersection of these two consumption data sets. Nevertheless, because milk is consumed with very high frequency in all age groups, the intersection of these consumption data will not differ significantly from the simple sum. Further, because the simple sum implies that both foods are consumed by the same person each day the simple sum will always be greater than the intersection.

phosphate in human excreta that would result from the proposed use of hydrogen peroxide in frozen dessert mixes and ready-to-drink beverages containing whey protein is 3.86 ppb using the same model.

The concentrations of stannate and phosphate in human excreta will be further diluted when the human excreta containing the stannate and phosphate mixes with water used in the domestic residence. The US Geologic Survey reports that the national average per capita water use was 82 gallons per capita per day (GPCD) for public-supplied domestic water use in 2015.⁹ This value fluctuates yearly and usually ranges higher than the deliveries reported in 2015.¹⁰ Thus, 82 GPCD represents a conservative estimate for a dilution factor.

Domestic water use includes indoor and outdoor uses at residences. Common indoor water uses are drinking, food preparation, washing clothes and dishes, bathing, and flushing toilets. Common outdoor uses are watering lawns and gardens or maintaining pools, ponds, or other landscape features in a domestic environment. The US Environmental Protection Agency (EPA) reports that approximately 70 percent of all domestic water consumption occurs indoors, with the bathroom being the largest component.¹¹ Thus, the concentrations of phosphate and stannate in human excreta will be diluted into 70% of 82 GPCD or 57.4 gallons (corresponding to 217.3 kg water) prior to being introduced into the receiving water of the POTW.

Approximating the individual daily mass of human excreta produced as substantially similar to the total mass of food consumed per day (3 kg), the concentration of stannate in the receiving waters of the POTW resulting from the proposed use of hydrogen peroxide in frozen dessert mixes and ready-to-drink beverages containing whey protein is unlikely to exceed 0.015 ppb.¹² The concentration of phosphate resulting from the proposed use of hydrogen peroxide is estimated similarly to be 0.053 ppb in the receiving waters of the POTW.

Phosphate and stannate will partition between the treated wastewater and the treated sludge, as described more fully below. Only extremely small amounts, if any, of these additives

⁹ Dieter, C.A., Maupin, M.A., Caldwell, R.R., Harris, M.A., Ivahnenko, T.I., Lovelace, J.K., Barber, N.L., and Linsey, K.S., 2018, *Estimated use of water in the United States in 2015*: U.S. Geological Survey Circular 1441, 65 p., <https://doi.org/10.3133/cir1441>. [Supersedes USGS Open-File Report 2017-1131.]

¹⁰ This per capita usage is less than the rate of 101 GPCD observed in 1995, 100 GPCD in 2005, and 88 GPCD in 2010. Domestic deliveries from public supply were not compiled nationally in 2000. *Ibid.*

¹¹ *Indoor Water Use in the United States*, WaterSense, U.S. Environmental Protection Agency, Office of Wastewater Management (4204M), 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460
<https://19january2017snapshot.epa.gov/www3/watersense/pubs/indoor.html>

¹² Stannate in POTW Receiving Waters = $(1.08 \mu\text{g SnO}_3^{-2}/\text{kg Excreta}) \times (3 \text{ kg Excreta}/\text{person}\cdot\text{day}) \div (217.3 \text{ kg Domestic Water}/\text{person}\cdot\text{day}) = 0.015 \mu\text{g SnO}_3^{-2}/\text{kg Water} = 0.015 \text{ ppb}$ in the receiving water of the POTW.

are expected to enter the environment due to the landfill disposal of sludge containing minute amounts of the additives 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).

Aquatic Introductions

Another significant dilution of the wastewater carrying human excreta occurs upon mixing with other wastewater from additional public water uses at the Publicly Owned Treatment Works (POTW). Nevertheless, we consider the simple case where all the water entering the POTW contains the full 0.053 ppb phosphate and 0.015 ppb stannate. We anticipate an additional 10-fold dilution upon discharge of POTW to receiving water (which is the expected scenario for these kinds of facilities). The expected environmental concentrations (EEC) of phosphate and stannate in aquatic environmental compartments therefore would not exceed 0.0053 ppb and 0.0015 ppb, respectively, due to the proposed use of the FCS.

Terrestrial Introductions

It is assumed here that the additives treated in the POTW partition into the solids in the sedimentation tank with no specific affinity for the solid phase (sludge). Sludge is typically dewatered prior to land application. The solids content of mechanically dewatered sludge typically ranges from 20 to 45 percent solids by weight; most processes produce concentrations of solids at the lower end of that range.¹³ Thus, assuming sludge is an average of 67% water and the concentration of phosphate and stannate in that water is 0.053 ppb and 0.015 ppb, respectively, the concentration of phosphate and stannate in the sludge that may be land applied is 0.036 ppb and 0.01 ppb, respectively.¹⁴ It is reasonable to assume that components of sludge will be diluted to a concentration of 2.5% of their concentration in sludge upon incorporation of

¹³ Use of Reclaimed Water and Sludge in Food Crop Production, Committee on the Use of Treated Municipal Wastewater Effluents and Sludge in the Production of Crops for Human Consumption, Water Science and Technology Board, Commission on Geosciences, Environment, and Resources, National Research Council, National Academy Press, Washington, D.C., 1996, Chapter 3, page 52.

¹⁴ Phosphate = 0.053 ppb × 67% = 0.036 ppb; Stannate = 0.015 ppb × 67% = 0.01 ppb.

sludge into soil,¹⁵ which is equivalent to a concentration of phosphate and stannate in the soil of 0.0009 ppb and 0.00025 ppb, respectively.¹⁶

Atmospheric Introductions

Examination of the structure of the additives indicates that volatilization from an aqueous solution is not an available fate process for these additives. The introduction of these additives into the atmosphere therefore would be virtually nil.

The environmental introduction concentrations (EIC) and the expected environmental concentrations (EEC) of phosphate and stannate resulting from the use of the FCS proposed herein are summarized in the following table.

Additive	EIC	EEC_{sludge}	EEC_{water}
Phosphate	0.053 ppb	0.0009 ppb	0.0053 ppb
Stannate	0.015 ppb	0.00025 ppb	0.0015 ppb

The estimated concentrations of the additives in POTW effluent and sludge are below levels of concern for *toxicity* of these materials in the environment (*see* Item 8, below). Nevertheless, even low concentrations of phosphate may raise concerns for excessive eutrophication of the receiving waters. The actual environmental concentrations of phosphate, however, will be controlled by the Clean Water Act (CWA) through the establishment of receiving water quality standards, and, when indicated, through establishment of permit limits for phosphate during the NPDES permitting process.

7. Fate of Emitted Substances in the Environment

Hydrogen peroxide is not expected to survive the pasteurization of these food products. Hydrogen peroxide rapidly decomposes into water and molecular oxygen when the foods are pasteurized. The phosphate and stannate stabilizers, however, remain intact and may be emitted to the environment as described above.

Phosphorus is indispensable to life on Earth, as it is involved in the passage of genetic information, energy transfer, and the construction of plant cells. Despite this, the amount of phosphorus available for biological uptake is relatively small, so productivity in many terrestrial

¹⁵ See Harrass, M.C., Erickson, C.E. III, Nowell, L. H., "Role of Plant Bioassays in FDA Review: Scenarios for Terrestrial Exposure," *Plants for Toxicity Assessment: Second Volume, ASTM STP 11115*, J. W. Gorsuch, W.R. Lower, W. Wang, and M. A. Lewis, Eds., American Society for Testing and Materials, Philadelphia, 1991, pp 12-28.

¹⁶ Phosphate = 0.053 ppb × 67% × 2.5% = 0.00025 ppb; Stannate = 0.015 ppb × 67% × 2.5% = 0.00025 ppb.

and aquatic ecosystems is often limited by phosphorus availability.¹⁷ Phosphorus usually exists as fully oxidized phosphate in the natural environment. The phosphorus cycling comprises a geological (long-term) cycle and a biological (short-term) cycle, the latter with both terrestrial and aquatic components. Phosphate introduced into the environment will participate in both cycles. On a geologic scale, phosphate cycles from phosphate rock to soil by weathering then to water and is ultimately deposited in ocean sediment wherein it can be re-transformed into phosphate rock. In the biological cycle, phosphate is absorbed by plants from water or soil and incorporated into plant tissues which are consumed by animals and ultimately returned to the soil.¹⁸ Because P is almost always limiting and ecosystems have evolved to deal with low levels of P, the addition of P even in relatively low concentrations into water-bodies can cause adverse effects such as eutrophication. The potential of the treated wastewater from the food-processing plants using the FCS contributing to nutrient pollution and eutrophication of the water-bodies receiving treated wastewater (TWW) will be addressed during the NPDES permitting for facilities treating wastewater containing the additives.

Land applications related to the proposed use will result in phosphorus concentrations in soil that are an insignificant fraction of total phosphorus concentrations introduced into the environment as fertilizers. USDA reported, in 2019, that over 7.79 million tons of phosphate fertilizers were consumed in the U.S in 2015, the most recent year for which data are available.¹⁹ Annual production and use of the FCS itself is negligible when compared with this figure, and the annual land application of any phosphate-containing sludge or treated effluent that could be expected from the proposed use represents an even more insignificant portion of land-applied phosphorus.

Tin compounds are generally only sparingly soluble in water and are likely to partition to soils and sediments though stannate (SnO_3^{2-}) is soluble in water. In water, inorganic tin exists as either divalent (Sn^{2+}) or tetravalent (Sn^{4+}) cations under environmental conditions.²⁰ Cations such as Sn^{2+} and Sn^{4+} generally will be adsorbed by soils, which reduces their mobility. Tin(II) dominates in reduced (oxygen-poor) water and will readily precipitate as tin(II) sulfide or as tin(II) hydroxide in alkaline water. Tin(IV) readily hydrolyses and can precipitate as tin(IV) hydroxide. The solubility product of tin(IV) hydroxide has been measured at approximately 10–

¹⁷ Turner BL, Raboy V. 2019. Phosphorus cycle. In: AccessScience. McGraw-Hill Education. doi:10.1036/1097-8542.508930 (last accessed 2021 Jun 1), available at: <https://www.accessscience.com/content/phosphorus-cycle/508930>.

¹⁸ V. Smil, *Phosphorus in the Environment: Natural Flows and Human Interferences*, Annual Review of Energy and the Environment, Vol. 25:53-88 (November 2000).

¹⁹ USDA. (2019). Fertilizer Use and Price: Table 5 – U.S. consumption of selected phosphate and potash fertilizers, 1960-2015. Accessed July 26, 2021, available at: <http://www.ers.usda.gov/data-products/fertilizer-use-and-price.aspx>.

²⁰ International Programme on Chemical Safety, (2005), Concise International Chemical Assessment Document 65, Tin and Inorganic Tin Compounds, Geneva, World Health Organization, available at: <https://apps.who.int/iris/handle/10665/43223>.

56 g/litre at 25°C. In general, tin(IV) would be expected to be the only stable ionic species in the weathering cycle.²¹ On release into estuaries, inorganic tin is principally converted to the insoluble hydroxide and rapidly scavenged by particles, which are the largest sink. Thus, tin is generally regarded as being relatively immobile in the environment.²²

8. Environmental Effects of Released Substances

The results of the ecotoxicity tests of tricalcium phosphate and calcium hydrogen orthophosphate are summarized as follows:²³ in an acute toxicity test with *Oryzias latipes*, 96 hr 50% lethal concentration (LC₅₀) was > 100 (measured: > 2.14) mg/L and > 100 (measured: > 13.5) mg/L, respectively. In the *Daphnia* test, 48 hr 50% effective concentration (EC₅₀) was > 100 (measured: > 5.35) mg/L and > 100 (measured: > 2.9) mg/L, respectively. In a growth inhibition test with *Pseudokirchneriella subcapitata*, 72 hr EC₅₀ was > 100 (measured: > 1.56) mg/L and > 100 (measured: > 4.4) mg/L, respectively.

Based on these results, it is concluded that phosphate, with nominal concentrations above 100 mg/L, possessed no toxicity in aquatic organisms. Thus, the expected aquatic environmental concentration of 0.0053 ppb resulting from the proposed use of the FCS presents no environmental toxicity concerns.

Extensive data on toxicity of inorganic tin to aquatic organisms has been summarized in a chemical assessment of tin and organic tin compounds conducted by the World Health Organization.²⁴ This summary is as follows:

“The most sensitive microalgae are the marine diatoms *Skeletonema costatum* and *Thalassiosira guillardii*, with 72-h EC₅₀s of tin(II), based on growth inhibition, of around 0.2 mg/litre. Acute LC/EC₅₀s of tin(II) for aquatic invertebrates range from 3.6 to 140 mg/litre, with a 21-day EC₅₀, based on reproductive success in daphnids, of 1.5 mg/litre. The fish toxicity tests clearly show that tin(IV) chloride is less toxic than the more soluble tin(II) chloride. Ninety-six-hour LC₅₀s for fish range from 35 mg/litre for tin(II) to > 1000 mg/litre for tin(IV). Embryo-larval test results (7- to 28-day LC₅₀s) for fish and amphibians range from 0.1 to 2.1 mg/litre for tin(II).”

²¹ IPCS (1980) Tin and organotin compounds: a preliminary review. Geneva, World Health Organization, International Programme on Chemical Safety (Environmental Health Criteria 15).

²² Gerritse R.G., Vriesema R., Daleberg J.W. (1982) Effect of sewage sludge on trace element mobility in soils. *Journal of Environmental Quality*, 11:359–364.

²³ E. Kim, S. Yoo, H-Y. Ro, H-J. Han, Y-W. Baek, I-C. Eom, H-M. Kim, P. Kim, and K. Choi, Aquatic Toxicity Assessment of Phosphate Compounds, *Environ Health Toxicol.* 2013; 28, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3577115/>.

²⁴ See *supra* Footnote 20, at 34.

Adverse effects on the yield of spring wheat (expressed as dry weight) at soil inorganic tin(II) concentrations of 125 mg/kg were completely eliminated after the addition of sludge due to an increase in soil nutrient content and a decrease in soil acidity.²⁵ *Sinapis alba* seeds showed low sensitivity to inorganic tin, with 72-h EC₅₀s, based on root growth inhibition, of 281 mg/litre for tin(II) (as tin(II) chloride) and 417 mg/litre for tin(IV) (as sodium stannate).²⁶ Thus, the expected terrestrial environmental concentration of 0.000025 ppb resulting from the proposed use of the FCS presents no environmental toxicity concerns.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to be treated in existing wastewater treatment plants. The manufacture of the FCS will consume comparable amounts of energy and resources as the same products used in different applications, 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

No significant adverse environmental impacts are expected to result from the use and disposal of the dilute FCS solution. Therefore, the solution 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 that would necessitate alternative actions to that proposed in this Notification.

12. List of Preparers

Devon Wm. Hill, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Mr. Hill has a J.D., with many years of experience drafting food additive petitions and FCN submissions and environmental assessments.

Mark Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Hepp has a Ph.D. in Chemistry with many years of experience with FCN submissions and environmental assessments.

²⁵ Kick H., Nosbers R., Warnusz J. (1971) The availability of Cr, Ni, Zn, Cd, Sn and Pb for plants. In: Proceedings of the international symposium on soil fertility evaluation, New Delhi. New Delhi, Indian Society of Soil Science, pp. 1039–1045.

²⁶ Fargasova A. (1994) *A comparative study of the toxicity and inhibitory effects of inorganic tin compounds on various biological subjects*, *Biologia*, 49(3):307–311.

13. Certification

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

Date: August 11, 2022



Devon Wm. Hill
Counsel for Notifier