Environmental Assessment

1. **Date:** December 31, 2007

2. **Name of Applicant/Petitioner:** FMC Corporation, Peroxygens Division

3. **Address:** All communications on this matter are to be sent in care of Counsel for Notifier, John B. Dubeck, Keller and Heckman LLP, 1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
Telephone. 202-434-4125

4. **Description of Proposed Action:**

The proposed action is a clearance in the form of an effective Food Contact Notification (FCN) to permit the use of peroxyacetic acid (PAA) solutions stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (hereinafter referred to as "HEDP-stabilized PAA solutions" or "PAA solutions") to treat plastic containers and their closures (e.g., caps or lids), prior to filling with food, to reduce or eliminate pathogenic and non-pathogenic microorganisms that may be present on the container/closure surface. This Notification is intended to cover use of the FCS in food processing plants throughout the United States.

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

The food contact substance (FCS) that is the subject of this FCN is described as peroxyacetic acid (PAA) solution stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP). The CAS Reg. No. for PAA is 79-21-0; the CAS Reg. No. for HEDP is 2809-21-4. The maximum concentrations of the components in the PAA solution are described in the Confidential Supplement to this Environmental Assessment.

6. **Introduction of Substances into the Environment:**

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

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of solutions containing the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use/disposal:

FMC supplies its HEDP-stabilized PAA solutions to it customers as concentrated aqueous solutions, and instructs its customers to dilute these solutions with water, to appropriate concentrations, prior to application to food packaging. The FCS is intended for use in two container/closure treatment applications: (1) A *no rinse* application for treating containers/closures with a fine mist; and (2) An application where containers/closures are filled with treatment solution (including FMC's sodium salicylate-based adjuvant solutions), then emptied and rinsed

The waste generated from the *no rinse* application for treating containers/closures with a fine mist would be virtually nil for the following reasons:

(1) The amount of treatment solution applied to each container/closure is only enough to coat the packaging surface, therefore, no "run off" is expected to be present;

(2) Because this is a "one pass" system that does not recycle the treatment solution, it will not be necessary to recharge the treatment solution reservoir on a regular basis, as discussed below for the filled-container *with rinse* application; therefore, it is not necessary to drain treatment solution reservoirs to the wastewater system; and

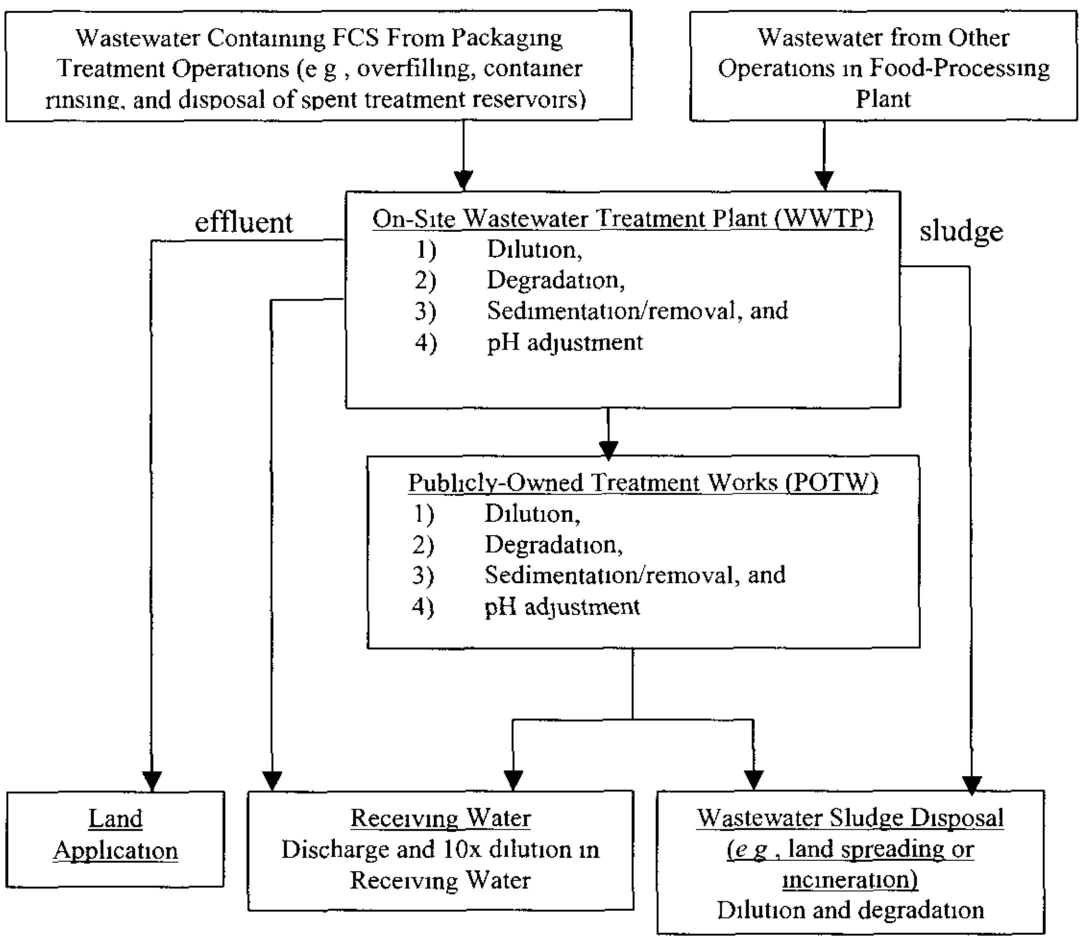
(3) Because there is no rinse step, there is no rinse water waste stream containing the FCS

Thus, there is no identifiable waste stream containing the FCS components for the *no rinse* application for treating container/closures with a fine mist.

The second application covered by this FCN involving the use of the FCS in treatment solutions applied to containers/closures by filling the containers/closures, would generate three primary waste streams. The first waste stream is generated as result of rinsing the excess treatment solution from the containers/closures after draining the treatment solution. This waste stream would be continuous and dilute in the FCS component concentrations. The second waste stream would be generated as result of periodic draining of the treatment solution reservoir. This waste stream would be intermittent, and relatively concentrated compared to the rinse water waste stream. The third waste stream would be generated as result of overfilling the containers/closures. This waste stream would be more concentrated than the rinse water stream, and more continuous than waste water generated as result of treatment solution reservoirs. Nevertheless, as described below, and in the confidential supplement to this environmental assessment, the worst-case instantaneous and long term average environmental release calculations can be determined by considering only the first and second waste streams (*i.e.*, the method used to estimate environmental concentrations attributable to the first and second waste streams fully encompasses the release attributable to the third waste stream).

All of the waste water streams from packaging operations (including those containing the FCS) will enter the main wastewater header of the food processing facility and undergo treatment with other wastewater generated at the food processing facility.

Many food-processing plants operate on-site wastewater treatment plants (WWTPs) to treat their wastewater. Some WWTPs discharge their effluent to publicly owned treatment works (POTWs) for additional treatment prior to discharge to receiving waters, while others are permitted to discharge their effluent directly into surface waters or over land.[1] Other food processing plants send their wastewater directly to POTWs without pretreatment at an on-site WWTP.[2] Sludge removed from WWTPs or POTWs may be disposed of in one of several ways (*e g.*, land spreading or incineration). The following diagram illustrates the possible wastewater treatment steps for a typical food processing plant:



For the purposes of this Environmental Assessment, we have considered a food processing plant that utilizes a "single stage" water treatment operation (*i.e.*, either WWTP or a POTW is utilized, but not both) followed by final wastewater discharge to receiving waters or

---

[1] *Food Processing Business Sector Fact Sheet*, Wisconsin Department of Natural Resources Jul 27, 2006 (available at http //dnr wi gov/org/caer/cea/assistance/foodprocessing/ info htm#wastewater) (accessed May 3, 2007)

[2] Some of FMC Corporation's current customers have indicated that they send their wastewater directly to a POTW, however at least one of these customers has indicated that it planned to install an on-site WWTP to pre-treat wastewater prior to sending it to a POTW in the near future

discharge over land. We have considered land spreading as the worst-case sludge disposal scenario.

For the reasons discussed in Section 7 below, only HEDP is expected to be present in environmentally significant concentrations upon discharge to the environment through aquatic or terrestrial routes. Thus, the primary focus of this assessment is the potential introduction to the environment of HEDP and sodium salicylate resulting from the use of this FCS in aqueous mixtures.

Containers treated with the FCS solution are first filled to overflow with the solution, followed by an appropriate holding period. Containers are then inverted to allow the solution to drain. The drained solution is returned to a reservoir for reuse (*i e.*, recycled). Excess solution is then rinsed from the containers using sterile water.

Due to recycle of the PAA solution, it may be necessary to replenish the reservoir with fresh, concentrated PAA solution to maintain required efficacy levels of the active ingredients. Because the stabilizer used in the PAA solution, HEDP (1-hydroxyethylidene-diphosphonic acid), is substantially more stable than the active components of the PAA solution, and HEDP would not evaporate from the sterilant reservoirs, the HEDP concentration in treatment solution reservoirs is expected to increase as concentrated PAA solution is added. The rate of concentration is determined by the ratio of HEDP to PAA in the PAA solution (as well as the rate of addition and the reservoir volume). The effect of this recycle on the concentration of HEDP in the solution reservoir is taken into account in the calculation of environmental exposure to HEDP provided in the confidential portion of this assessment.

If treatment solution losses from overfilling are significant, regularly scheduled refilling of the reservoir to make up solution volume loss may occur before there is any need to add concentrated PAA solution supplement active ingredient strength. In this case, the increase in HEDP concentration in the reservoir is insignificant.

The various waste streams from the packaging treatment process (i.e., rinse water waste, spent treatment solution from reservoirs, and treatment solution overfill and leakage waste) are all routed to the main wastewater header of the food processing plant. Wastewater streams from various additional operations conducted in the food processing plant (including wastewater streams unrelated to packaging treatment operations) merge in the main wastewater header prior to being sent to wastewater treatment facilities. The environmental release calculations provided in the confidential portion of this assessment take into account the worst-case instantaneous HEDP concentrations in effluent streams (i.e., WWTP effluent released to receiving water or spread over land) that may result during draining full reservoir volumes over short durations, in which the HEDP content of the treatment solution has increased to its maximum level due to the process described above. Moreover, the HEDP content of sludge generated in WWTPs takes into account the periodic tank draining based on the typical periods reported by FMC.

As indicated above, some kinds of packaging equipment generate substantial waste volumes due to overfilling of containers, leakage, and other loss of treatment solution volume from the system other than through rinse water, reservoir draining, or on food packaging. The method used to estimate environmental release quantities set forth in the confidential supplement does not specifically address waste flow rates and concentrations associated with these overfilling and leakage sources of waste. Nevertheless, the method employed fully encompasses these sources based on the explanation that follows.

The losses due to overfilling and leakage of treatment solution are not made up to the treatment solution reservoir continuously, but rather, the treatment solution losses are made up only after the treatment solution reservoir has lost most of its volume. FMC informed us that a 600-gallon reservoir may lose as much as 400 gallons over an 8-hour period due to overfilling and leakage. This is equivalent to a waste flow rate of 50 gallons per hour (400 gallons – 8 hours). The lost solution is made up at the end of the 8-hour cycle. After approximately 6 cycles of this solution refilling process (i.e., 48 hours), when the treatment solution reservoir would otherwise be refilled on the 8-hour schedule, the treatment solution reservoir is entirely drained and refilled with fresh treatment solution. In calculating the worst case instantaneous environmental release concentrations of HEDP, we assumed that the entire treatment solution reservoir volume, which is 900 gallons (accounting for the 600 gallon treatment solution reservoir used for container treatment operations and the 300 gallon treatment solution reservoir for cap treatment operations) would be drained to the main wastewater header over a period of 2 hours. Moreover, we assumed as a worst case that the HEDP concentration in the solution would have increased 5-fold over this period (thus, the HEDP concentration would be 5-fold higher than its starting level). The instantaneous waste volume flowrate based on this method is 450 gallons per hour (900 gallons – 2 hours), which is substantially higher than the waste flow rate predicted based on solution loss due to leakage and overfilling (50 gallons per hour). Furthermore, the 5-fold increase in HEDP concentration is thought to be a highly exaggerative given that most of the treatment solution would be entirely replaced every 8-hours. Therefore, we think the assumptions on which the environmental release of HEDP are based are highly exaggerative as compared to actual use scenarios, and we submit that it is not necessary to further evaluate specific release quantities associated with treatment solution losses due to overfilling and leakage.

We estimated the concentration of HEDP that would be expected to persist in receiving waters after discharge of effluent from WWTPs and POTWs based on a conservative model of downstream wastewater treatment as suggested by FDA in its letter dated May 2, 2007. The diagram provided above provides an overview of the route of wastewater containing HEDP from its point of generation in treatment operations to its discharge to the environment. Direct discharge from the WWTP would result in higher concentrations of FCS in the environment than the indirect discharge from the POTW. Thus, we have assumed in determining the worst case environmental concentrations of the FCS components that food processing facilities would treat their wastewater only in an on-site WWTP and then discharge the WWTP effluent directly to receiving waters or to land application. We have also addressed disposal of sludge removed from the WWTP by assuming it is mixed with surface soil. All of these assumptions ensure that we are considering the worst-case potential environmental exposure HEDP. Calculations of the environmental discharge of HEDP are provided in the Confidential Supplement to this Assessment.

The calculations in the Confidential Supplement to this Assessment include dilution of wastewater from container treatment operations in the on-site WWTP upon mixing with wastewater from other operations in the food-processing plant, such as wash down of process vessels, tanks, floors, and pipes. In one case study of a bottling facility, container washing operations accounted for 62% of daily water used.[3] Thus, we have used a WWTP dilution factor of 0.38 in our calculations. In addition, as the wastewater is treated in the WWTP, the HEDP is expected to adsorb to the solids in the sedimentation tank, thus further reducing the concentration of HEDP in the WWTP effluent.

The calculations in the Confidential Supplement also include FDA's default 10-fold receiving water dilution factor to account for dilution expected to occur upon discharge of the treated wastewater to surface waters. Some food-processing facilities that operate primarily in the summer months, such as vegetable processors, are permitted by state agencies to discharge their wastewater to land application systems, where pollutants become nutrients for plants.[4] The current FCN covers the use of the FCS to sterilize food packaging for processed foods, not for produce. Moreover, the food processing facilities that would use the FCS for applications covered by the current FCN operate throughout the year, including winter months when absorption of pollutants by growing plants would not be a suitable means of environmental remediation. Although, land application systems are not an expected disposal route for the FCS under the current applications of interest, we have addressed this possibility.

Environmental concentration of HEDP present in sludge removed from on-site WWTPs has been estimated using the methodology described by Harrass et. al, 1991.[5]

i. pH Control

Although use of the FCS solution may have a slight impact on the pH of the water at a food processing facility, all of wastewater will be treated either at a WWTP or a POTW prior to release to the environment. WWTPs and POTWs routinely adjust the pH of wastewater prior to discharge to receiving waters. Local, state, and federal law impose limits on the pH of wastewater discharged to the environment. For example, 40 CFR Part 403.5 requires that wastewater discharged by POTWs may not be less than a pH of 5. In addition to pH requirements for discharge to POTWs, any effluent discharged to natural waters and POTWs will require a National Pollutant Discharge Elimination System (NPDES) permit and will have restrictions on the pH of the effluent. We do not think the intended use of FCS solution covered

---

3 Ait Hsine, E , Benhammou, A , Pons, M.-N Industrial water demand management and cleaner production potential a case of beverage industry in Marrakech – Morocco *Afrique Science* **2005**, *1*, 95-108

4 *Food Processing Business Sector Fact Sheet*, Wisconsin Department of Natural Resources July 27, 2006 (*available at* http //dnr wi gov/org/caer/cea/assistance/foodprocessing/info htm#wastewater) (accessed May 3, 2007)

5 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

in this Notification would unduly burden a WWTP's or POTW's ability to comply with the laws and regulations governing pH control of wastewater discharged to the environment.

ii. PAA and HEDP

The concentration of HEDP and peroxyacetic acid in a food packaging facility's wastewater are determined by dilution level of the treatment solution, dilution level from water used to rinse the containers, wastewater from other plant processes, and other factors that we have addressed in the calculations provided in the Confidential Supplement to this Assessment. Based on the half life of peroxyacetic acid, as discussed in Section 7 below, we would expect near 100% degradation of this component to environmentally benign degradation products during treatment in a WWTP or POTW. Thus, HEDP is the only component that is likely to be present in measurable quantities in wastewater discharged to the environment.

We can draw a similar conclusion regarding the concentration of the PAA present in sludge removed from WWTPs and POTWs, *i e* , we would only expect HEDP, not PAA, to be present in measurable quantities in the sludge. We have accounted for reduction of HEDP concentrations due to adsorption to the sludge based on a 80% sludge adsorption factor based on EPI Suite estimations.[6]

Thus, in the remainder of this Environmental Assessment we will focus on the potential environmental discharge of HEDP to receiving waters and in sludge mixed with surface soil.

Due to the processes described in Attachment 1, the HEDP concentration in the treatment solution reservoir is expected to climb over time. The spent solution will be emptied periodically and drained to the main wastewater header of the food processing plant. The combined total volume of typical recycle holding tanks is 900 gallons The detailed calculations included in the Confidential Supplement to this Assessment account for the rise in HEDP concentration during the time period in which a particular batch of solution is used, and the concentration of HEDP in the spent sterilant that is sent to the wastewater header reflects its maximum concentration.

We have not accounted for reduction in HEDP concentrations in WWTP effluent attributable to decomposition because the WWTP effluent concentrations were well below acceptable limits without this additional reduction factor.

7. Fate of Emitted Components in the Environment:

---

[6] The EPI (Estimation Programs Interface) Suite™ is a Windows® based suite of physical/chemical property and environmental fate estimation models developed by the EPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation (SRC). EPI Suite™ uses a single input to run the following estimation models KOWWIN™, AOPWIN™, HENRYWIN™, MPBPWIN™, BIOWIN™, PCKOCWIN™, WSKOWWIN™, BCFWIN™, HYDROWIN™, and STPWIN™, WVOLWIN™, and LEV3EPI™. EPI Suite™ was previously called EPIWIN EPI Suite™ runs off of one single input, a representation of the chemical structure in SMILES notation SMILES is "Simplified Molecular Input Line Entry System" Additional information is available at http //www epa gov/opptintr/exposure/docs/episuite htm

Peroxyacetic acid is not expected to survive treatment at the wastewater treatment facilities at food packaging plants. This compound rapidly degrades on contact with organic matter, transition metals, and upon exposure to sunlight. The half-life of PAA in buffered solutions was 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[7]

The maximum concentration of HEDP released to the environment via WWTP effluent discharged to receiving water is calculated in the Confidential Supplement to this Assessment as 3.8 mg/L, which represents the maximum concentration during disposal of spent treatment solution reservoirs, which is expected to occur approximately 2 hours out of every 48 hours.

FDA has determined that HEDP is adsorbed to sewage sludge resulting in 80% removal during treatment.[8] HEDP that is removed via sedimentation or filtration will slowly degrade into carbon dioxide, water and phosphates. Phosphate anions are strongly bound to organic matter and soil particles, and phosphate is a required macronutrient of plants. However, given the maximum level estimated to be released, 3.8 mg/L, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in water receiving treated effluent.

HEDP will be adsorbed to sludge during treatment in the WWTP. This sludge could be used as a soil amendment in land application resulting in an environmental release. As shown in the Confidential Supplement to this Assessment, the estimated concentration of HEDP in sludge is 48,500 mg/kg (without chemical addition) or 16,200 mg/kg (with chemical addition). Harrass, et. al. (1991)[9] provided a soil amendment dilution factor of 2.5% after incorporation. Thus, we calculated a final soil concentration of HEDP resulting from the uses of the FCS of 1,213 mg/kg of soil (without chemical addition) or 405 mg/kg of soil (with chemical addition).

As previously explained, we do not think that food processors operating using the FCS in the applications covered by this Notification would discharge their wastewater in land applications. Nevertheless, we calculated the maximum concentration of HEDP released to the environment if the WWTP effluent were directly discharged to land to be 38 mg/L (see Confidential Supplement).

8. Environmental Effects of Released Substances:

As noted above, wastewater from container treatment operations as well as wastewater from other operations at the food processing plant will be directed to an on-site WWTP or a POTW, or both. It is expected that the PAA component of the FCS will completely decompose in the WWTP or POTW prior to water being discharged to the environment. Below is a

---

7 Peracetic Acid and its Equilibrium Solutions JACC No 40 European Centre for Ecotoxicology and Toxicology of Chemicals, January 2001

8 Environmental Decision Memo for Food Contact Notification No 000140 http //www cfsan fda gov/~rdb/fnsi0140 html

9 See Footnote 5

summary of the decomposition reactions and, if applicable, environmental persistence and ecotoxicity of each component of both mixtures.

Peroxyacetic acid: Decomposes rapidly to acetic acid and hydrogen peroxide (which decomposes into water and oxygen) when exposed to transition metals (such as Fe, or Mn) and organic material. The fate of acetic acid is discussed above. However, the environmental release is anticipated to be well below concentrations found to have a negative impact on aquatic organisms. The 48-hour EC_{50} for *Daphnia magna* ranges from 0.50 to 1.1 mg/L; the 96-hour EC_{50} for *Oncorhynchus mykiss* and *Lepomis macrochirus* ranges from 0.91 to 2.0 mg/L and 1.1 to 3.3 mg/L, respectively.[10]

1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP): Jarworska et al. (2002)[11] have summarized the aquatic toxicity of HEDP. The available data are shown below:

Environmental Toxicity Data for HEDP

Species	Endpoint	mg/L
Short Term		
Lepomis macrochirus	96 hr LC_{50}	868
Oncorhynchus mykiss	96 hr LC_{50}	360
Cyprinodon variegates	96 hr LC_{50}	2180
Ictalurus punctatus	96 hr LC_{50}	695
Leciscus idus melanatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr LC_{50}	165 – 500
Planemonetes pugio	96 hr LC_{50}	1770
Crassostrea virginica	96 hr LC_{50}	89
Selenastrum capricornutum	96 hr LC_{50}	3
Selenastrum capricornutum	96 hr NOEC	1.3
Algae	96 hr NOEC	0.74
Chlorella vulgaris	48 hr NOEC	≥100
Pseudomonas putida	30 minute NOEC	1000
Long Term		
Oncorhychus mykiss	14 day NOEC	60 -80
Daphnia Magna	28 day NOEC	10 - <12.5
Algae	14 day NOEC	13

A recent risk assessment of phophonates by the Human and Environmental Risk Assessment Project[12] included a discussion of aquatic toxicity resulting from chelation of

[10] Peracetic Acid and its Equilibrium Solutions JACC No. 40 European Centre for Ecotoxicology and Toxicology of Chemicals, January, 2001.

[11] 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

[12] See Footnote 4

nutrients, rather than direct toxicity to aquatic organisms. The lowest toxicity endpoints, those shown above for algae, *Selenastrum capricornutm*, *Daphnia magna*, and *Crassostrea virginica* are considered to result from chelation of nutrients, not from direct toxicity of HEDP[13]. 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.[14] FDA in its Finding of No Significant Impact (FONSI) for FCN No. 691 determined that the lowest relevant endpoint for this use pattern was 10 mg/L.

Biodegradation study results were variable. Zahn-Wellens dissolved organic carbon removed 33% after 28 days; modified OECD screening theoretical carbon dioxide evolution was 2% after 70 days; modified SCAS dissolved organic carbon removed 90%; and closed container BOD_{30}/COD was 5%.

The calculated environmental exposure to HEDP from effluent release from a WWTP to receiving waters is 3.8 mg/L. It was assumed that 80%[15] of the HEDP was removed by sedimentation to sludge in the WWTP prior to discharge and that the HEDP concentration was further diluted 10-fold upon discharge to the receiving waters. This level of exposure is below the 10 mg/L level of concern determined by FDA. As indicated above, hydrogen peroxide and peroxyacetic acid are not expected to survive treatment processes at the wastewater treatment facility. FMC expects that all peroxy compounds and acetic acid, as well as the majority of the HEDP will decompose or be removed before release. The concentration of sulfuric acid in the effluent due to use of the PAA mixture is below levels commonly found in the environment.

If effluent from the WWTP were discharged directly to land rather than to receiving waters, the maximum short-term effluent concentration of 38 mg/L would represent the concentration in soil. HEDP present in the surface water is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. The NOEC for soil dwelling organisms was >1000 mg/kg soil dry weight for red worms and >980 mg/kg for oats[16]. The 14-day median lethal dose (LD_{50}) for birds was greater than 284 mg/kg body weight.[17] Application of the wastewater to land will result in phosphorus

---

[13] See Footnote 11

[14] The Environmental Review Group concluded during its review of FCN No 691 that "excess nutrients are expected to be present in industrial wastewater as eutrophication is a well known phenomenon seen in industrial wastewaters from food processing facilities " Memorandum re FCN No. 691 from Katrina E White, Ph D , Environmental Review Group, Division of Chemistry Research and Environmental Review (HFS-246), to Division of Food Contact Notifications (HFS-275) (Jan 18, 2007) (on file with Keller and Heckman LLP)

[15] See Footnote 8

[16] Finding of No Significant Impact (FONSI) and supplement to the environmental record for FCN 728, July 17, 2007

[17] See Footnote 12

concentrations in soil that are a small fraction of total phosphorus concentrations currently found in the environment and used in fertilizers.[18]

HEDP will be adsorbed to sludge during treatment in the WWTP. This sludge could be used as a soil amendment in land application resulting in an environmental release. As shown in the Confidential Supplement to this Assessment, the estimated concentration of HEDP in sludge is 16,218 mg/kg Harrass et al (1991)[19] have given a dilution factor for application to soil of 2.5% after incorporation. The HEDP concentration would be 405 mg/kg of soil. As discussed above, this concentration is below any level of concern, either for toxicity to terrestrial organisms or as a significant source of phosphorus. The estimated amount of sludge generated from this use pattern would result in an annual land application to 1.26 hectares at a rate of 4.4 kg/m^2.

9. Use of Resources and Energy

The use of the PAA solution will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. 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 production processes. Energy used specifically for the production of the PAA solution 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 FCS-PAA-water solution. Thus, the use of the subject solution is not reasonably expected to result in any new environmental problem requiring 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. The alternative of not approving the action proposed herein would simply result in the continued use of alternative methods of ensuring the sterility of food packaging; such action would have no environmental impact.

12. List of Preparers

Diana G. Graham, Ph.D., Staff Scientist, Keller and Heckman LLP, 50 California Street, Suite 1500, San Francisco, CA 94111.

Christopher D. Stillabower, Attorney, Keller and Heckman LLP, 1001 G Street N.W., Suite 500 West, Washington, D.C. 20001.

---

18 Phosphorus in soil, http //taipan nmsu edu/mvpfpp/phosphor htm

19 See Footnote 5

13. Certification

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

Date. December 31, 2007

John B. Dubeck
Counsel for FMC Corporation