Attachment 1: 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.
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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 benzoic acid, 2-hydroxy, monosodium salt, also referred to as sodium salicylate, as a component of aqueous mixtures that will be applied to plastic containers to reduce or eliminate pathogenic and non-pathogenic microorganisms that may be present on the packaging prior to introduction of food. 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 an adjuvant solution containing benzoic acid, 2-hydroxy, monosodium salt (CAS Reg. No. 54-21-7) (hereinafter referred to as "sodium salicylate"). FMC Corporation will generally supply the FCS to its customers as an aqueous solution containing acetic acid (CAS Reg. No. 64-19-7) and citric acid (CAS Reg. No. 77-92-9), in addition to sodium salicylate. Because acetic acid and citric acid are affirmed as GRAS under *21 C.F.R. § 184.1005* and *21 C.F.R. § 184.1033*, respectively, we have not included these components within the FCS definition for this FCN.

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 instructs its customers to mix the sodium salicylate solution with one of FMC's peroxyacetic acid (PAA) antimicrobial solutions and water, at appropriate concentrations, prior to application to food containers and their closures (e.g., caps or lids). FMC's PAA solutions are cleared in a separate FCN filed simultaneously; thus we have not addressed potential environmental release of the components of FMC's PAA solutions here.

Containers/closures treated with treatment solutions containing the FCS 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. The treatment solution is replenished as necessary with fresh sodium salicylate solution to maintain required efficacy levels of the active ingredients. The treatment solution reservoir is periodically drained to the main wastewater header of the food processing plant.

Three distinct waste streams are generated by the use of the FCS in the packaging application covered by this FCN. The first waste stream is generated as result of rinsing the excess treatment solution from the bottles after draining the treatment solution from the containers. 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).

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.

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 stages for a typical food processing plant:

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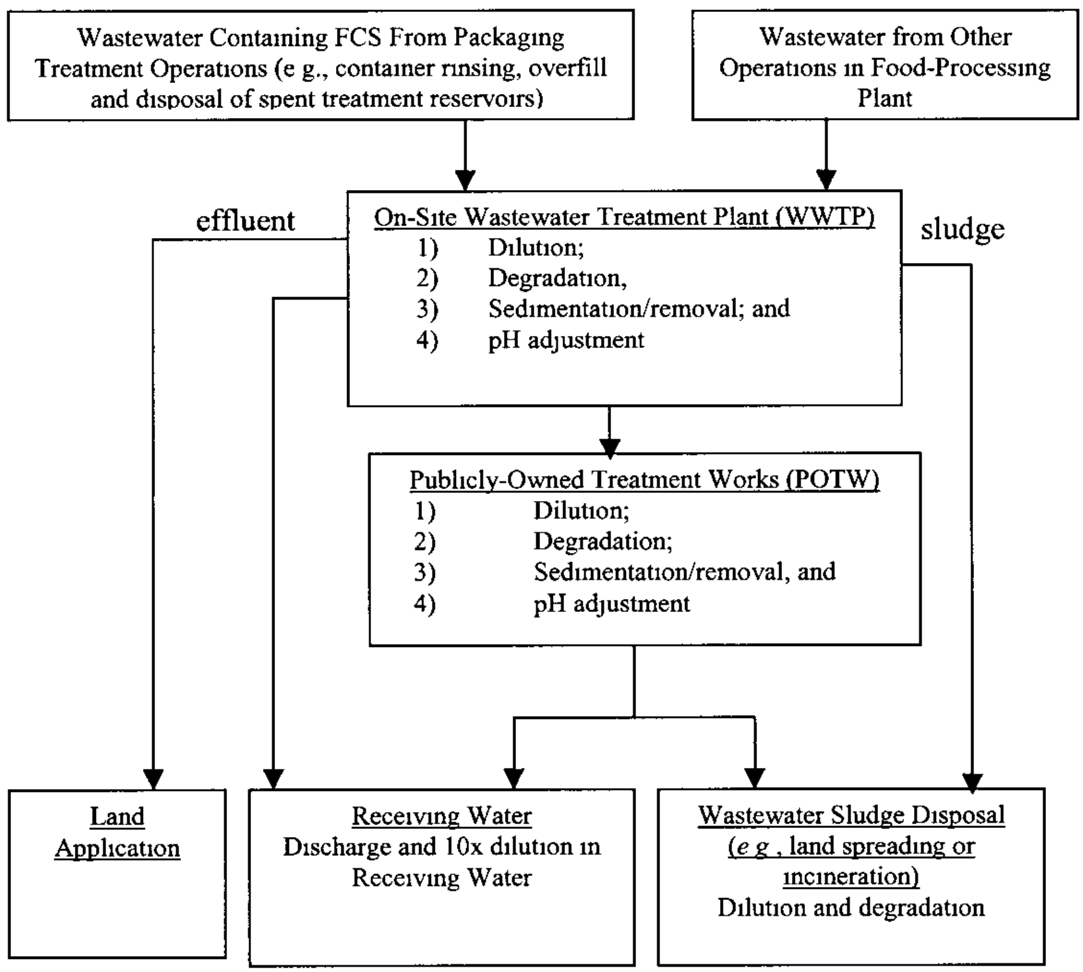
1 *Food Processing Business Sector Fact Sheet*, Wisconsin Department of Natural Resources: Jul 27, 2006 (available at http://dnr.wi gov/org/caer/cea/assistance/foodprocessing/ info.htm#wastewater) (accessed May 3, 2007)

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



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

We estimated the concentration of sodium salicylate 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 sodium salicylate from its point of generation in package treatment operations to its discharge to the environment. This diagram shows many of the common treatment steps that may be employed by food processing facilities using the FCS. 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 to sodium salicylate. Calculations of the environmental discharge of the sodium salicylate are provided in the Confidential Supplement to this Assessment.

The calculations in the Confidential Supplement to this Assessment include dilution of wastewater from packaging 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, bottle washing operations accounted for 62% of daily water used.[3] Thus, we have used a WWTP dilution factor of 0.38 in our calculations for EEC for the bottle rinsing portion of the assessment. In addition, as the wastewater is treated in the WWTP, the components of the FCS solution decompose in the wastewater or adsorb to the solids in the sedimentation tank, thus further reducing the concentration of the FCS solution components 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.

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

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[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).

sodium salicylate 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 sodium salicylate content of the treatment solution has increased to its maximum level due to the process described above. Moreover, the sodium salicylate 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 bottles, 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 sodium salicylate, 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 closure treatment operations) would be drained to the main wastewater header over a period of 2 hours. 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). Therefore, we think the estimates of the environmental release of sodium salicylate are exaggerative, and we submit that it is not necessary to further evaluate specific release quantities associated with treatment solution losses due to overfilling and leakage.

Environmental concentrations of sodium salicylate present in sludge removed from on-site WWTPs have been estimated using the methodology described by Harrass et. al, 1991.[5]

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[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

i. pH Control

Although use of the FCS in packaging treatment solutions 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-PAA-water solution covered 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. Sodium Salicylate

The concentration of sodium salicylate in a food packaging facility's wastewater is determined by dilution level of the treatment solution, dilution level from water used to rinse the bottles, wastewater from other plant processes, and other factors that we have addressed in the calculations provided in the Confidential Supplement to this Assessment. We have accounted for reduction of sodium salicylate concentrations due to adsorption to the sludge based on a 75% sludge adsorption factor based on EPI Suite estimations.[6]

7. Fate of Emitted Components in the Environment:

The maximum concentration of sodium salicylate released to the environment via WWTP or POTW effluent discharged to receiving water is calculated in the Confidential Supplement to this Assessment as 3.0 mg/L. This value reflects the concentration of sodium salicylate immediately after a spent treatment solution reservoir is drained, which is expected to occur approximately once every 48 hours. Decomposition of sodium salicylate is estimated by EPI Suite[7] to be "days to weeks," and absorption to sewage sludge is estimated to result in 75% removal during treatment.

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

7 See Footnote 6.

Sodium salicylate that is removed via sedimentation or filtration will degrade relatively rapidly. The half-life in soil was estimated by EPI Suite to be 720 hours and salicylic acid was "readily biodegradable" in soils and activated sludge.[8]

Sodium salicylate 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 sodium salicylate in sludge is 10,025 mg/kg. Harrass, et. al. (1991)[9] provided a soil amendment dilution factor of 2.5% after incorporation. Thus, we calculated a final soil concentration of sodium salicylate resulting from the uses of the FCS of 251 mg/kg of soil.

As previously explained, we do not think that food processors using this FCS would discharge their wastewater in land applications. Nevertheless, we calculated the maximum concentration of sodium salicylate released to the environment if the WWTP effluent were directly discharged to land to be 30 mg/L (see Attachment 2).

8. Environmental Effects of Released Substances:

As noted above, wastewater from container/closure 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. Below is a summary of the decomposition reactions, environmental persistence, and ecotoxicity of sodium salicylate.

Sodium Salicylate: Based on EPI Suite estimations,[10] sodium salicylate is expected to biodegrade within days to weeks. EPI Suite also estimates that approximately 75% of the sodium salicylate will be removed in secondary wastewater treatment. The no observable effects concentration (NOEC) for change in biomass in *Lemna minor* was 60 mg/L[11] The 96-hour LC_{50} values for fish were 1,370-2,160 mg/L and 266 mg/kg for *Pimephales promelas* and *Cyprinus carpio*, respectively.[12,13] An acute EC_{10} of 304 mg/L sodium salicylate was published for

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8 Hazardous Substances Data Bank Environmental Fate/Exposure Summary for Salicylic Acid, National Library of Medicine http://www toxnet nlm nih gov/cgi-bin/sis/search/f? /temp/~ZrtgrM.1. EPI Suite v. 3.12.

9 See Footnote 5

10 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

11 Wang, W H ; Lay, J P *Ecotoxicology and Environmental Safety* **1989**, 17 308-316

12 Geiger, D.L , Northcott, C.E., Call, D J , and Brooke, L.T 1985 Acute toxicities of organic chemicals to fathead minnows (Pimephales promelas), Volume 2 Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, Superior, WI 326 pp (as cited in EPA's ECOTOX database).

Daphnia magna and an EC_{50} of 80 mg/L[14]. In the Environmental Decision Memo for FCN 634, the Environmental Review Group (ERG) estimated the lowest acute NOEC in the aquatic environment is 60 mg/L, based on data for *Lemna minor*.

The calculated environmental exposure to sodium salicylate discharged to water is a maximum of 3.0 mg/L (ppm), including 75% reduction during treatment at the WWTP as well as dilution the receiving water. This level of exposure is below the LC_{50} of *Daphnia*, fathead minnow, carp, and algae. It is also well below the level of 60 mg/L set by FDA. As indicated above, it is expected that the acetic acid and citric acid, as well as the majority of the sodium salicylate will decompose before release to the environment.

The toxicity of sodium salicylate to terrestrial organisms has been measured for earthworms. The LC_{100} was 1% (w/w) dry weight. There was a reduction in growth rate of hatchlings at less than 1%. The acute toxicity to rats and rabbits was also measured with an LD_{50} of 891 mg/kg bw and 1300 mg/kg bw respectively.[15] Application of wastewater directly to land would be at a concentration of 30 mg/L.

Sodium salicylate 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 sodium salicylate in sludge is 2,210 mg/kg. Harrass et al (1991)[16] have given a dilution factor for application to soil of 2.5% after incorporation. Accordingly, the sodium salicylate concentration would be 251 mg/kg of soil. As discussed above, this concentration is below any level of concern for toxicity to terrestrial organisms.

9. Use of Resources and Energy

The use of the FCS 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 FCS 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 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.

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13 Loeb, H A. and Kelly, W H 1963. Acute oral toxicity of 1,496 chemicals force-fed to carp. U.S Fish & Wildlife Service, Special Scientific Report-Fisheries, No 471, Washington, DC. 124 pp. (as cited in EPA's ECOTOX database)

14 See Footnote 11

15 IUCLID Data Set for Salicylic acid, European Commission, European Chemicals Bureau, Feb 19, 2000

16 See Footnote 5.

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

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

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