

**Attachment 8
Environmental Assessment**

- 1. Date:** June 9, 2006
- 2. Name of Applicant/Petitioner:** FMC Corporation, Chemical Products 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.
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4. Description of Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of a mixture of sodium salicylate, acetic acid, citric acid and water in an antimicrobial solution used to treat the surfaces of polymeric food packaging. The FCS is mixed with a peroxyacetic acid solution prior to application to the surface of the food packaging. After application of the solution to the food contact surfaces of the food packaging, the surface is rinsed with sterile water. Processed food is introduced into the food packaging after the sterile rinse. These operations all occur within a controlled environment. The FCS, in combination with a peroxyacetic acid mixture, reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food packaging prior to fill.

The FCS is for use in food processing facilities throughout the United States. The expected route of disposal for waste solution is the processing plant wastewater treatment facility. The treatment solution and sterile water rinse ultimately runs into drains, and enters the food processing plant water treatment facility, where it is collected and treated, along with other process water, by the facility prior to it being sent to a publicly-owned treatment works (POTW).

5. Identification of Substances that are the subject of the Proposed Action:

A description of the FCS mixture appears elsewhere in this Notification. The raw materials used in the FCS are acetic acid (CAS Reg. No. 64-19-7), citric acid (CAS Reg. No. 77-92-9), sodium salicylate (CAS Reg. No. 54-21-7), and water. The maximum concentration of the FCS components in the use-solution are described in the Confidential

Attachment to this Environmental Assessment. Although not the subject of this Notification, we include the raw materials in the peroxyacetic acid mixture, which are hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-diphosphonic acid (CAS Reg. No. 2809-21-4), sulfuric acid (CAS Reg. No. 7664-93-9) and water. Peroxyacetic acid (CAS Reg. No. 79-21-0) formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid. The concentration of the peroxyacetic acid components in the use solution are described in the Confidential Attachment to this 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 the FCS mixture.

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:

Introduction of diluted solutions of the adjuvant and antimicrobial mixture into the environment will result from the intended use of the mixture on food packaging, and the subsequent disposal of such water and drainage into the food processing plant wastewater treatment facility. The total amount of the mixture used at a typical facility can be estimated, although the actual amounts used will vary, depending on equipment used and the number of food packages processed.

i. pH Control

Although use of the FCS and peroxyacetic acid mixtures may have a slight impact on the pH of the water at the facility, all of the process water will go to an on-site wastewater treatment facility prior to release to the POTW. One purpose of this facility is to provide pH control for wastewater being discharged to a POTW. This allows the facility to comply with

any discharge requirements established by the POTW for the facility and to meet the statutory requirement that discharges to POTWs may not be less than a pH of 5.¹

ii. FCS Mixture

Treatment of the process water at the on-site wastewater treatment plant is expected to result in nearly 100% degradation of the acetic and citric acid components of the mixture. This expectation is based on the half-life of the acetic and citric acids (summary provided in Section 7 below). Thus, the only component that is likely to be present in measurable quantities in wastewater discharged to publicly-owned treatment works (POTWs) is sodium salicylate. Based on the information presented in the Appendix, we have calculated a maximum daily load of sodium salicylate of approximately 12 mg/L (part per million, ppm) in water released into the environment.

iii. Peroxyacetic Acid Mixture²

Treatment of the process water at the on-site wastewater treatment plant is expected to result in nearly 100% degradation of the peroxyacetic acid, hydrogen peroxide and acetic acid. This expectation is based on the half-life of these substances (summary provided in Section 7 below). Thus, the only components that are likely to be present in wastewater discharged to publicly-owned treatment works (POTWs), in addition to sodium salicylate, are HEDP and sulfuric acid. Based on confidential information located in this Notification, we have calculated a maximum daily load of HEDP of approximately 2.6 mg/L (ppm), and of sulfuric acid as sulfate of approximately 11 mg/L (ppm) in water released into the environment.

7. Fate of Emitted Components in the Environment:

a. FCS Mixture

Acetic and citric acids dissociate into their respective salts and the acetate or citrate anions, which subsequently and rapidly biodegrade. In biodegradation studies of acetic acid,

¹ 40 CFR Part 403.5

² The fate of the components of this mixture were addressed in FCN 561 for a nearly identical use.

99% degraded in 7 days under anaerobic conditions.³ Citric acid biodegraded even faster, with 98% reduction after 48 hours.⁴ Therefore, both acetic and citric acids are not expected to concentrate in the wastewater discharged to the POTW.

No published sodium salicylate data were identified that addressed its environmental fate and effects. Sodium salicylate is estimated to degrade somewhat more slowly than acetic or citric acids. While no formal studies are available, calculations using EPA's standard software (EPI Suite v.3.12) estimated that approximately 75% would be removed in secondary wastewater treatment. The calculation of sodium salicylate concentrations in discharged processing water following treatment at the facility wastewater treatment facility does not include this 75% reduction although processing through several treatment steps in the facility treatment plant (including sedimentation, aerobic or anaerobic treatment, filtration and chemical disinfection of the effluent), will remove or decompose a significant amount of the sodium salicylate present in the wastewater. The final concentration of 12 ppm does include a 75% removal in the POTW, dilution at the POTW and 10-fold dilution by the receiving water body.

b. Peroxyacetic acid Mixture

Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment at the wastewater treatment facilities at food packaging plants. Both compounds are rapidly degraded 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.⁵ The half-life of hydrogen peroxide is concentration dependent, and is reported to range from 2.5 days in natural river water when initial concentrations of 10,000 ppm were introduced, and increased to 15.2 days when the concentration decreased to 250 ppm.⁶ In biodegradation studies of acetic acid, 99% degraded

³ U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Carboxylic Acids and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, Revised April 16, 2003. Copy in Appendix 1 of this Attachment.

⁴ See Footnote 3.

⁵ Peracetic Acid and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals, January 2001.

⁶ Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January 1993.

in 7 days under anaerobic conditions,⁷ and it is not expected to concentrate in the wastewater discharged to the POTW.

Decomposition of HEDP occurs at a moderately slow pace; 33% in 28 days, based on information provided by the manufacturer (MSDS). FDA has determined that HEDP is adsorbed to sewage sludge resulting in 50 to 80% removal during treatment.⁸ The calculations above of HEDP concentrations in discharged processing water assume that 50% of the HEDP remains in the water following treatment at the facility wastewater treatment plant and an additional 50% is removed at the POTW. Several treatment steps, including sedimentation, aerobic or anaerobic treatment, filtration and chemical disinfection of the effluent, will remove or decompose the HEDP that is present in the wastewater.

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, 2.6 ppm, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in water receiving treated effluent.

Sulfuric acid dissociates into the sulfate anion and hydrogen protons immediately upon introduction into aqueous systems. There were no biodegradation data identified for sulfate. Under anaerobic biodegradation, sulfate is reduced to sulfides (H_2S), bisulfide (HS^-) or thiosulfate ($S_2O_3^-$). Sulfur is an essential plant nutrient, and common sulfate-bearing minerals include gypsum ($CaSO_4 \cdot 2H_2O$), epsomite ($MgSO_4 \cdot 7H_2O$), and mirabilite ($Na_2SO_4 \cdot 10H_2O$).⁹ Sulfate has a secondary MCL of 500 ppm and occurs in natural waters. A 1969 community water study reported sulfate to be present in 645 of 658 groundwater supplies sampled at concentrations ranging from 1 to 480 mg/L (mean 43 of mg/L). Sulfate was present in all 106 surface water supplies sampled at concentrations ranging from 2 to 358 mg/L (mean 49 of mg/L).¹⁰ The maximum level of sulfuric acid as sulfate estimated to be released,

⁷ See Footnote 3.

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

⁹ Sposito, G. *The Chemistry of Soils*. Oxford University Press, 1989. New York, NY.

¹⁰ U.S. EPA. 1990. National Primary and Secondary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals. Federal Register. Vol. 55. No. 143. 30370.

11 ppm, is not expected to result in a measurable increase in sulfate in the soil or aquatic environments.

8. Environmental Effects of Released Substances:

As noted above, waste solution (from application and drainage) as well as other plant process water will be directed to an on-site wastewater treatment facility. There, it is expected that decomposition of many of the components will occur prior to water being discharged. Below is a summary of the decomposition reactions and, if applicable, environmental persistence and ecotoxicity of each component of both mixtures.

Acetic acid: Summary ecotoxicity data cited on the supplier MSDS and from the High Production Volume (HPV) Assessment Plan for Carboxylic Acids and Salts¹¹ indicate that acetic acid is not highly toxic to aquatic plant and animal species. In water, acetic acid dissociates into the acetate anion and hydrogen proton. The acetate anion readily biodegrades, with 99% consumed after 7 days (anaerobic conditions, in the presence of activated sludge). The LC₅₀ values for fathead minnow are reported as 106-122 mg/L (24-hour), 92-106 mg/L (48-hour), and 79-88 mg/L (96-hour). The 48-hour LC₅₀ for rainbow trout is 105 mg/L and the 48-hour EC₅₀ for *Daphnia* is 65 mg/L. Toxicity thresholds for algae were reported on the MSDS for green algae (*Scenedesmus quadricauda*; 4000 mg/L), blue-green algae (*Anacystis aeruginosa*; 90 mg/L), and euglenoid (*Entosiphon sulcatum*; 78 mg/L).

Citric acid: Summary data from the HPV Assessment Plan for Carboxylic Acids and Salts¹² indicates that citric acid is of low toxicity to aquatic plants and animals. In water, citric acid dissociates rapidly to the citrate anion, which biodegrades rapidly (98% removal in 48 hours). The 96-hour LC₅₀ for bluegill sunfish is 1,516 mg/L, while the LC₅₀ of the trisodium salt of citric acid for the guppy ranged from >18,000 to 32,000 mg/L. The 24, 48 and 72-hour EC₅₀ values (three separate studies) for *Daphnia magna* were 1,535 mg/L, 5600-10,000 mg/L, and 120 mg/L, respectively. A study with the algae, *Scenedesmus subspicatus*, resulted in an 8-day threshold level of 640 mg/L.

¹¹ See Footnote 3.

¹² See Footnote 3.

Sodium Salicylate: Based on EPI Suite estimations,¹³ 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 48-hour EC₅₀ for *Daphnia magna* is approximately 1,450 mg/L.¹⁴ The 96-hour LC₅₀ values for fish were 1,370-2,160 mg/L and 266 mg/kg for *Pimephales promelas* and *Cyprinus carpio*, respectively.^{15,16} The estimated 96-hour EC₅₀ value for algae is 97,500 mg/L.¹⁷

The calculated environmental exposure to sodium salicylate is a maximum of 12 mg/L (ppm), including 75% reduction during treatment at the POTW as well as dilution at the POTW and by the receiving water. This level of exposure is up to several orders of magnitude below the LC₅₀ of *Daphnia*, fathead minnow, carp, and algae. FMC expects that all acetic and citric acids, as well as the majority of the sodium salicylate will decompose before release.

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 below. However, the environmental release is anticipated to be well below concentrations found to have a negative impact on aquatic organisms. The 48-hour EC₅₀ for *Daphnia magna* ranges from 0.50 to

¹³ 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>.

¹⁴ Anderson, B.G. 1946. The toxicity thresholds of various sodium salts determined by the use of *Daphnia magna*. Sewage Works J. 18:82-87 (as cited in EPA's ECOTOX database).

¹⁵ 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).

¹⁶ 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).

¹⁷ ECOSAR v.0.99g.

1.1 mg/L; the 96-hour EC₅₀ for *Oncorhynchus mykiss* and *Lepomis macrochirus* ranges from 0.91 to 2.0 mg/L and 1.1 to 3.3 mg/L, respectively.¹⁸

Hydrogen peroxide: Decomposes rapidly to water and oxygen when exposed to transition metals (such as Fe or Mn) and organic material. It is not expected to enter the environment after treatment at the facility wastewater treatment plant. The 96-hour LC₅₀ is 16.4 µg/L and 37.4 µg/L for *Pimephales promelas* and *Ictalurus punctatus*, respectively. The 24-hour EC₅₀ for *Daphnia magna* is 7.7 mg/L. Several algae species are reported to have less than 5% of the original chlorophyll content when exposed to hydrogen peroxide concentrations ranging from 1.7 to 17 mg/L for 24-48 hours.¹⁹

Sulfuric acid: Dissociates rapidly in water into sulfate ions and hydrogen protons. The acute 24-hour EC₅₀ of sulfuric acid to *Daphnia magna* is 29 mg/L, the acute 96-hour LC₅₀ to *Lepomis macrochirus* is 16-28 mg/L at a pH of 3.25-3.5; and the NOEC for epilimnetic lake phytoplankton is 0.13 mg/L at a pH of 5.6.²⁰ Chronic toxicity to fish and aquatic invertebrates is reported to range from 0.025 to 0.31 mg/L, and from 0.13 to 0.15 mg/L, respectively. Biodegradability data for sulfuric acid or the sulfate anion were not identified. The calculated environmental exposure to sulfate as sulfuric acid is a maximum of 11 mg/L (ppm), and assumes that no decomposition occurs during wastewater treatment. This concentration is at the low end of the range of sulfate concentrations found in natural waters.

1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP): Ecotoxicity and environmental persistence of HEDP are available from the supplier (see MSDS for Dequest 2010 in Attachment II), and are summarized here. Aquatic invertebrate acute toxicity (*Daphnia magna*) is 527 mg/L (48-hour; EC₅₀); freshwater fish acute toxicity (LC₅₀) is 348 mg/L for rainbow trout (*Oncorhynchus mykiss*) and 868 mg/L for Bluegill sunfish (*Lepomis macrochirus*); and aquatic plant toxicity (EC₅₀) is 3 mg/L for the algae, *Selenastrum capricornutum*. Biodegradation study results were variable. Zahn-Wellens dissolved organic carbon removed 33% after 28 days; modified OECD screening theoretical carbon dioxide

¹⁸ Peracetic Acid and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 2001.

¹⁹ Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 1993.

²⁰ Sulfuric Acid. OECD SIDS, UN Environmental Program Publication. January 2001.

evolution was 2% after 70 days; modified SCAS dissolved organic carbon removed 90%; and closed bottle BOD₃₀/COD was 5%.

The calculated environmental exposure to HEDP is a maximum of 2.6 mg/L (ppm), and included an assumption that 50%²¹ removal of the substance occurs during facility wastewater treatment and that there is an additional 50% removal at the POTW, as well as dilution at the POTW and by the receiving waters. This level of exposure is orders of magnitude below the LC₅₀ of *Daphnia*, rainbow trout and Bluegill sunfish and lower than the EC₅₀ of the algal species tested. As indicated above, hydrogen peroxide and peroxyacetic acid are not expected to survive treatment processes at the wastewater treatment facilities. FMC expects that all peroxy compounds and acetic acid, as well as the majority of the HEDP will decompose or be removed before release.

10. Use of Resources and Energy

The use of the FCS mixture 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 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 FCS mixture. Thus, the use of the subject mixture 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

²¹ See Footnote 8.

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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13. Certification

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

Date: June 9, 2006



/ John B. Dubeck

Counsel for FMC Corporation