Gray, Jeff

From: Dixon, Melisa D

Sent: Tuesday, October 17, 2006 1:48 PM

To: Gray, Jeff

Cc: Handagama, Nareshkumar B; Lennon, Kendal R; Shaffer, Douglas P; Dixon, Melisa D; Knight, Tony Alan

Subject: KIF - 56% Acetic Acid Information

Attachments: FMC_fnea0561.pdf

Jeff,
For your use, please find attached the PDF Environmental Assessment (EA) for FMC Corporation, Chemical Products Division and a link (http://www.dolphinmsds.com/online/loadMSDS.asp?sheetRecNum=552252) to the MSDS of Eastman Chemical Dilute Acetic Acid, 56%.

The attached EA addresses the environmental impact of 56% acetic acid on aquatic life. Please note the acetic acid portion (top of pg 27) of section 8, "Environmental Effects of Released Substances" of the EA. Naresh will address any chemical concerns regarding the attached during the KIFJPT telecom on Wednesday at 2:30pm. Please advise if you need clarification and or additional information.

Lisa

Environmental Assessment

1. Date: October 21, 2005

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. Telephone: 202-434-4125.

4. Description of Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of a mixture containing peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and water, where the maximum concentration of HEDP in solution will not exceed 1%, to ensure the sterility of surfaces of authorized polymeric food packaging. After application of the mixture (solution) to the food contact surfaces of the food packaging, the surface is rinsed with sterile water. Sterile food is introduced into the food packaging immediately after the sterile rinse. These operations all occur within a controlled environment. The antimicrobial effect of peroxyacetic acid reduces populations of pathogenic and non-pathogenic microorganisms that may be present on the food packaging.

This product 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 facilities.

After the treatment solution is applied to the food packaging and allowed to drain, a following rinse of sterile water is applied to the food packaging. 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 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 confidential description of the composition of the FCS mixture appears in the Notification. The raw materials used in this product are hydrogen peroxide (CAS Reg. No. 7722-81-1), acetic acid (CAS Reg. No. 64-19-7), HEDP (CAS Reg. No. 2809-21-4), 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 HEDP in solution will not exceed 1.0%.

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 FCS mixture into the environment will take place primarily via release in wastewater treatment systems. Introduction of the components of the FCS mixture into the environment will result from the intended use of the FCS 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 FCS 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.

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 peroxyacetic acid and hydrogen peroxide and acetic acid (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 HEDP. Based on confidential information located in this Notification, we have calculated a maximum daily load of HEDP of approximately 0.018 part per million (ppm), equivalent to 18 parts per billion (ppb), in water released into the environment.

7. Fate of Emitted Components in the Environment:

Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment at the primary 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.[1] The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to 15.2 days when the concentration decreased to 250 ppm.[2] In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions;[3] 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). The calculations above of HEDP concentrations in discharged processing water assume that 100% of the HEDP remains in the water following treatment at the first wastewater plant. This is a very conservative assumption, as several treatment steps, including sedimentation, aerobic or anaerobic treatment, filtration and chemical disinfection of the effluent, will remove or decompose at least a portion of 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, 18 ppb, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in soils amended with wastewater sludge, or in water receiving treated effluent.

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

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

3 U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001. Copy in Appendix 1 of this Attachment.

8. Environmental Effects of Released Substances:

As noted above, waste antimicrobial solution (from application and drainage) will be directed to an on-site wastewater treatment facility. There, it is expected that decomposition of all of the components excluding HEDP 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 in the formulation.

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 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.[4]

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 wastewater treatment. The 96-hour LC_{50} is 16.4 μg/L and 37.4 μg/L for *Pimephales promelas* and Ictalurus punctatus, respectively. The 24-hour EC_{50} 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.[5]

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

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

Acetic acid: Summary ecotoxicity data cited on the supplier MSDS and from the High Production Volume (HPV) Assessment Plan for Acetic Acid and Salts[6] 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 anion is readily biodegradable, with 99% degraded after 7 days (anaerobic conditions, in the presence of activated sludge). The LC_{50} for fathead minnow is 106-122 ppm (24-hour), 92-106 ppm (48-hour), and 79-88 ppm (96-hour). The 48-hour LC_{50} for rainbow trout is 105 ppm and the 48-hour EC_{50} for *Daphnia* is 65 ppm. Toxicity thresholds for algae were reported on the MSDS for green algae (*Scenedesmus quadricauda*; 4000 ppm), blue-green algae (*Anacystis aeruginosa*; 90 ppm), and euglenoid (*Entosiphon sulcatum*; 78 ppm).

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; EC_{50}); freshwater fish acute toxicity (LC_{50}) is 348 mg/L for rainbow trout (*Oncorhynchus mykiss*) and 868 mg/L for Bluegill sunfish (*Lepomis macrochirus*); and aquatic plant toxicity (EC_{50}) 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 evolution was 2% after 70 days; modified SCAS dissolved organic carbon removed 90%; and closed bottle BOD_{30}/COD was 5%.

The calculated environmental exposure to HEDP is a maximum of 0.018 ppm, and included an assumption that no decomposition of the substance occurs during wastewater treatment. This level of exposure is orders of magnitude below the LC_{50} of Daphnia, rainbow

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6 U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001. Copy in Appendix 1 of this Attachment.

trout and Bluegill sunfish, and two orders of magnitude below the EC_{50} of algae. As indicated above, hydrogen peroxide and peroxyacetic acid are not expected to survive wastewater treatment processes at the facility treatment plant. Since this wastewater will be discharged to a local POTW for further treatment before release into the environment, FMC expects that all peroxy compounds and acetic acid, as well as the majority of the HEDP will decompose before release.

9. 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 use of alternative methods of ensuring the sterility of food packaging; such action would have no environmental impact.

12. List of Preparers

Lester Borodinsky, Ph.D., Staff Scientist, 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: October 21, 2005

John B. Dubeck

Counsel for FMC Corporation