

ATTACHMENT 13

ENVIRONMENTAL ASSESSMENT
PART 1

Dimethyl Esters (C4-C10) ()

1. **Date:** August 17, 2006
2. **Name of Applicant:** Ecolab Inc.
3. **Address:** 370 N. Wabasha Street
St. Paul, Minnesota 55102

All communications regarding this food contact notification environmental assessment should be sent in care of the authorized representative

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4. **Description of the Proposed Action**

- a) **Requested approval:** The action requested in this submission is the notification of the use of Dimethyl Esters (C4-C10) as an adjuvant in commercial sterilants that may come into contact with certain low-acid foods that are prepared in aseptic packaging materials. Dimethyl Esters (C4-C10) are comprised of a mixture of dimethyl sebacate (DMS), dimethyl adipate (DMA), dimethyl glutarate (DMG), and dimethyl succinate (DMSu).
- b) **Need for action:** Dimethyl Esters (C4-C10) are intended to enhance the application of hydrogen peroxide and peroxyacetic acid by cause or causes unknown when applied to food packaging materials, manufacturing, filling, and packaging equipment at 1000-1500 ppm in a sterilizing solution.
- c) **Locations of use/disposal:** This product is for use in food processing/packaging facilities, such as beverage bottling plants 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, sterile water rinse is applied to the food packaging. The treatment solution and sterile water rinse

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ultimately run into drains, and enter the food processing plant waste water treatment facility, where it is collected and treated by the facility prior to it being sent to a publicly owned treatment works (POTW). The waste liquids may also be discharged directly to POTW.

5. Identification of the Chemical Substance that is the Subject of the Proposed Action:

Chemical Name: Butanedioic acid, Pentanedioic acid, Hexanedioic acid, and Decanedioic acid, dimethyl esters, Dimethyl Esters (C4-C10), Mixture

Common or Trade Name: Dimethyl Esters (C4-C10),

CAS Registry Numbers: 106-65-0 (dimethyl succinate or DMSu), 1119-40-0 (dimethyl glutarate or DMG), 627-93-0 (dimethyl adipate or DMA), 106-79-6 (dimethyl sebacate or DMS)

CAS Registry Name: Butanedioic acid, Pentanedioic acid, Hexanedioic acid, and Decanedioic acid, dimethyl esters, Mixture

The starting monomers are identified as follows: None used by Ecolab.

The molecular formulae for Dimethyl Esters (C4-C10) components are:

Name	n =	Molecular Formula	Molecular Weight
Dimethyl sebacate	6	C ₁₂ H ₂₂ O ₄	230.3
Dimethyl adipate	2	C ₈ H ₁₄ O ₄	174.2
Dimethyl glutarate	1	C ₇ H ₁₂ O ₄	160.2
Dimethyl succinate	0	C ₆ H ₁₀ O ₄	146.1

The typical physical properties of Dimethyl Esters (C4-C10) are as follows:

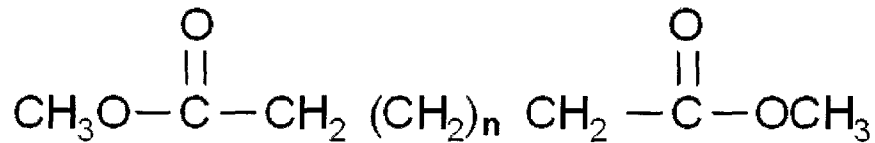
Density	DMS: 0.99 @ 20°C; DBE-3: 1.068 @ 20°C
Boiling point	DMS: 287-289°C; DBE-3: 215-225°C
Appearance	DMS: clear liquid; DBE-3: colorless liquid
Melting point	DMS: 23°C; DBE-3: 8°C
Purity	DMS: >98%; DBE-3: total diesters 99.90%

DBE-3: mixture of dimethyl adipate, dimethyl glutarate, and dimethyl succinate.

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The structural diagram for DMS (representative of the Dimethyl Esters (C4-C10) mixture) is:



Name	n =
Dimethyl sebacate	6
Dimethyl adipate	2
Dimethyl glutarate	1
Dimethyl succinate	0

6. **Request for a Categorical Exclusion Under 21CFR 25.32(j) and 21CFR 25.32(q)**

Not applicable.

7. **Environmental Assessment - Introduction of the Substance into the Environment**

The following Environmental Assessment (EA) demonstrates that Ecolab's formulation of Dimethyl Esters (C4-C10) will have minimal to no known environmental effects.

A. As a result of manufacture

There are no extraordinary circumstances surrounding the manufacture of the food contact substance (FCS) Dimethyl Esters (C4-C10). Ecolab will not manufacture the Dimethyl Esters (C4-C10), but will purchase them from other vendors and mix them at an Ecolab facility to form its proposed commercially marketable product, . Because Ecolab is neither producing the dimethyl esters nor actually using them, Ecolab does not expect to increase the environmental load of dimethyl esters beyond some small quantity of effluent water due to routine cleaning and maintenance of on-site processing materials.

B. As a result of use/disposal

The food contact substance Dimethyl Esters (C4-C10) will be used at a level not to exceed 1500 ppm in water. Introduction of the FCS will take place primarily via release into the wastewater generated in the beverage bottling plant. The components of the FCS are water-soluble and are expected to remain in the wastewater streams and be discharged indirectly into the environment by way of a POTW. A detailed description of the calculation of the EIC is presented in Attachment 14, which contains confidential business information (CBI). A description of the calculation of the EIC is provided below.

To determine the EIC for each component of Dimethyl Esters (C4-C10), we first estimate the daily amount of each component used at a typical bottling plant based on the

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percent component, the concentration of the total FCS mixture, flow rate and duration, and use patterns.

The maximum concentration at which each component of Dimethyl Esters (C4-C10) may be introduced into the environment from the wastewater stream entering a POTW were calculated assuming:

- 100% of the amount used per day will ultimately be discharged to the wastewater from the bottling plant. Residue studies have shown there to be trace amounts of each component found on the bottle following the wash but these residue levels are negligible and, to be conservative, were not considered in the EIC calculations.
- The only waste water produced by the plant is from the process of washing and rinsing the bottles. This is a very conservative assumption since we know that the bottles that are involved in this process are used to package very specialized drinks and beverages and therefore is most likely a small proportion of the packaging occurring at any given bottling plant.
- The number of 1-L bottles washed per day at a typical plant was based on the total amount of any component used per day at a plant and the amount of that component needed to wash one. The fifth year production estimate of [redacted] and the projected number of plants using [redacted] in five years was used in this estimate.
- The components of Dimethyl Esters (C4-C10) were not degraded in the on-site wastewater treatment facility.
- The level of each component in the wastewater discharge from the plant will be diluted upon entering the POTW, assuming a typical POTW with a daily flow of 1.0 million gallons a day (3.79×10^6 L/day)¹. The components of the FCS were not degraded with treatment at the POTW.

A detailed description of the calculation of the EIC is presented in Attachment 14, which contains confidential business information (CBI).

8. Fate of Substances Released into the Environment

Using a highly conservative assumption that no degradation of these components occurs at the POTW during treatment, the EIC also represents the concentrations entering the body of water that receives the POTW effluent. The concentration of these components in the receiving body of water will be lower due to mixing of the effluent with the receiving body of water. The expected environmental concentration (EEC) is the concentration of the active moiety that organisms would be exposed to in the

¹ The daily flow rate at a typical POTW was determined by calculating an average flow rate using the lower end of the existing flow range weighted by the number of facilities with that flow range in operation in 2000, as presented in the Clean Watersheds Needs Survey (2000), Table C-3. The formula is: $[(0.001 \times 6,583) + (0.101 \times 6,462) + (1.001 \times 2,665) + (10.001 \times 487) + (100.001 \times 46)] / (6,583 + 6,462 + 2,665 + 487 + 46) = 1.0$ million gallons day).

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environment after consideration of, for example, spatial or temporal concentration or depletion factors such as dilution, degradation, sorption and/or bioaccumulation (FDA, 1998). Based on dilution factors for POTWs available from the EPA, applying a dilution factor of 10 to the EIC to estimate the EEC is normally appropriate (FDA, 1998). Based on the EEC, the introduction of this substance into local waterways does not appear to be environmentally significant (see Attachment 14 – Confidential Business Information for the calculation of the EEC).

These calculations do not take into account the fact that these components are readily degraded in aquatic environments. DMA was 58% biodegraded after 7 days and 84% after 14 days. DMSu has a biodegradation of 95% in 3 days in activated industrial sludge. DMG was 70% degraded after 7 days and 98% degraded after 28 days in activated sludge. Based on these environmental fate properties, the majority of these components are most likely degraded at the packaging plant and any remains of these components are expected to be fully degraded at the POTW. Therefore, these components are not likely to be found in treated water released from the POTW into the environment. It is important to note that the EECs presented in Attachment 14 do not account for this degradation and therefore are overestimates of the actual concentration most likely present in the receiving bodies of water.

The following data is representative of Dimethyl Esters (C4-C10) and has been calculated from data derived by the American Chemistry Council's Aliphatic Ester Panel.

A. Physical/chemical properties

² Vapor pressure:	0.011 Pa @ 25°C
Octanol-water partition coefficient:	3.4 log P _{ow}
Water solubility:	120mg/L @ 25°C

B. Environmental depletion mechanisms

² Photodegradation half-life:	1.1 days
Hydrolysis half-life:	3.6 years
Transport:	
Soil	60.1%
Air	2.5%
Water	36.7%
Sediment	0.7%

² All data in these tables from American Chemistry Council's Aliphatic Esters Panel, 2001. High production volume chemical challenge program test plan for aliphatic esters category [online]. <http://www.epa.gov/chemrtk/alipestr/c13466.pdf>. Accessed on 22 March 2006, pp 57, 62.

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9. Environmental Effects of Released Substances

The following table summarizes the available data³ on the environmental effects of the components of Dimethyl Esters (C4-C10). There is little data available for DMS, however, due to its similar structure and function, we made the assumption that the effects seen in DMSu, DMA, and DMG will be similar.

Exotoxicity Data for Components of Dimethyl Esters (C4-C10)

Component	Fish 96-hr LC50 (ppm)	Daphnia magna 48-hr EC50 (ppm)	Green algae 96-h LC50 (ppm)
DBE	18-24	112-150	NA
DMSu	50-100	3317	11.9
DMG	30.9	1275	7.2
DMA	25.7	497	4.4

The components of Dimethyl Esters (C4-C10) are of low toxicity to aquatic organisms, with LC₅₀ and EC₅₀ ranging from practically non-toxic to slightly toxic. The acute toxicity values range from 4.4 ppm for DMA effects to green algae to 3317 ppm for DMSu effects to *Daphnia magna*. When the toxicity data is compared to the EECs calculated in Attachment 14, the EECs are at least an order of magnitude lower than the toxicity values. Again, it is important to note that the EECs used in this comparison are based on several highly conservative assumptions; mainly that 100% of the solution will enter the waste water and that no degradation of the components occurs before release into the receiving body of water.

Based on the modeled EECs and the available toxicity data, we conclude that there will be no adverse effects to the environment and organisms in from the potential release of the components of Dimethyl Esters (C4-C10) to the environment.

10. Use of Resources and Energy

The Dimethyl Ester (C4-C10) mixture is meant to enhance the application of products containing hydrogen peroxide and peroxyacetic acid that are already on the market. Ecolab will not be producing the dimethyl esters; however, by formulating the dimethyl esters into a new product, it will cause an overall increase in dimethyl ester production and use.

Based on the projected five year market volume (see Attachment 14), the amount of dimethyl esters produced for the proposed use of this FCS will be a very small fraction of the total dimethyl esters currently produced for all other uses (for inclusion in the high production volume challenge program, a substance must have a yearly production volume of greater than one million pounds/year) (ACC, 2001; SOCMA, 2001). Therefore, we do not expect any significant effect on use of energy and resources with approval of this notification. In addition,

³ All ecotoxicity data are from the "Dibasic ester Group High Production Volume Robust Summaries and Test Plan" available at: <http://www.epa.gov/oppt/chemrtk/dbe/c13453tc.htm>.

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the use of the FCS will lead to reduction in the amount of the sterilant used because it increases its efficacy.

11. Mitigation Measures

No adverse environmental effects have been identified in this environmental assessment. Therefore mitigation measures are not necessary.

12. Alternatives to the Proposed Action

Because the current action has minimal to no known adverse environmental effects, it is unnecessary to propose alternatives to the proposed action.

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13. **List of Preparers**

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14. **Certification**

I, Donald Schmitt, certify that the information presented is true, accurate, and complete to the best knowledge of Ecolab.

August 17, 2006

Date

Donald Schmitt, Authorized Representative of Ecolab

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15. References

American Chemistry Council's Aliphatic Esters Panel, 2001. High production volume chemical challenge program test plan for aliphatic esters category [online].
<http://www.epa.gov/chemrtk/alipestr/c13466.pdf>. Accessed on 22 March 2006, pp 57, 62.

Synthetic Organic Chemical Manufacturers Association (SOCMA) Dibasic Esters (DBE) Group High Production Volume Robust Summaries and Test Plan; AR210-13453;2 A.D.

US Food and Drug Administration (FDA). 1998. Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications. CMC 6, Revision 1.

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**ENVIRONMENTAL ASSESSMENT
PART 2
Peroxyacetic Acid Solution ()**

1. **Date:** August 17, 2006
2. **Name of Applicant:** Ecolab Inc.
3. **Address:** 370 N. Wabasha Street
St. Paul, Minnesota 55102

All communications regarding this food contact notification environmental assessment should be sent in care of the authorized representative

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4. **Description of the Proposed Action**

- a. **Requested approval:** The action requested in this submission is the notification of the use of peroxyacetic acid solution () as a commercial sterilant that may come into contact with certain low-acid foods that are prepared in aseptic packaging materials. is comprised of a mixture of glacial acetic acid, hydrogen peroxide, 1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP), -Peroxyacetic acid, and water.
- b. **Need for action:** is intended for use as a sterilant applied to food packaging materials, manufacturing, filling, and packaging equipment at 6597 ppm peroxyacetic acid by weight.
- c. **Locations of use/disposal:** This product is for use in food processing/packaging facilities, such as beverage bottling plants 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, sterile water rinse is applied to the food packaging. The treatment solution and sterile water rinse ultimately run into drains, and enter the food processing plant waste water treatment facility, where it is collected and treated by

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the facility prior to it being sent to a publicly owned treatment works (POTW). The waste liquids may also be discharged directly to POTW.

5. Identification of the Chemical Substance that is the Subject of the Proposed Action:

Chemical Name: Mixture

Common or Trade Name: , peroxyacetic acid solution ()

CAS Registry Numbers: 7722-84-1 (hydrogen peroxide), 64-19-7 (glacial acetic acid), 79-21-0 (peroxyacetic acid), 7732-18-5 (water), and 2809-21-4 (1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)).

The starting monomers are identified as follows: None used by Ecolab.

The molecular formulae for peroxyacetic acid solution components are:

Name	Molecular Formula	Molecular Weight
Glacial acetic acid	C ₂ H ₄ O ₂	34
Hydrogen peroxide	H ₂ O ₂	60
1-Hydroxyethylidene-1,1-diphosphonic acid	C ₂ H ₈ O ₇ P ₂	206
Water	H ₂ O	18
-Peroxyacetic acid	C ₂ H ₄ O ₃	76

The only raw materials used to produce are hydrogen peroxide, acetic acid, and HEDP. The peroxyacetic acid is formed as the result of an equilibrium reaction between acetic acid and hydrogen peroxide.

The typical physical properties of are as follows:

Density	HEDP: 1.45 g/cm ³ @ 20°C; H ₂ O ₂ : 1.2 g/cm ³ @ 20°C Peroxyacetic acid: 1.226 g/cm ³ @20°C Acetic acid: 1.05 g/cm ³ @20°C
Boiling point	HEDP: 105°C H ₂ O ₂ : 115°C Peroxyacetic acid: 105°C Acetic acid: 118°C
Appearance	HEDP: clear colorless liquid H ₂ O ₂ : Clear, colorless liquid Peroxyacetic acid: Colorless liquid Acetic acid: Clear colorless mobile liquid.
Freezing point	HEDP: -40°C

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	H ₂ O ₂ : -52°C Peroxyacetic acid: 0.1°C Acetic acid: 16.7°C
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6. **Request for a Categorical Exclusion Under 21CFR 25.32(j) and 21CFR 25.32(q)**

Not applicable.

7. **Environmental Assessment - Introduction of the Substance into the Environment**

The following Environmental Assessment (EA) demonstrates that Ecolab's formulation of [redacted] will have minimal to no known environmental effects.

A. As a result of manufacture

There are no extraordinary circumstances surrounding the manufacture of the food contact substance. Ecolab will not manufacture the components of the food contact substance, but will purchase them from other vendors and mix them at an Ecolab facility to form its commercially marketable product, [redacted]. Because Ecolab is neither producing the components nor actually using them, Ecolab does not expect to increase the environmental load of the components beyond some small quantity of effluent water due to routine cleaning and maintenance of on-site processing materials.

B. As a result of use/disposal

Peroxyacetic acid solution will be used at a level not to exceed that needed to provide 6597 ppm peroxyacetic acid by weight. Introduction of the food contact substance (FCS) will take place primarily via release into the wastewater generated in the beverage bottling plant. The components of the FCS are water-soluble and are expected to remain in the wastewater streams and be discharged indirectly into the environment by way of a POTW. A detailed description of the calculation of the EIC is presented in Attachment 14, which contains confidential business information (CBI). A description of the calculation is provided below.

To determine the EIC for each component of the FCS, we first estimate the daily amount of each component used at a typical bottling plant based on the percent component, the concentration of the total FCS mixture, flow rate and duration.

The maximum concentration at which each component of the FCS may be introduced into the environment from the wastewater stream entering a POTW were calculated assuming:

- 100% of the amount used per day will ultimately be discharged to the wastewater from the bottling plant. Residue studies have shown there to be non-detectable amounts of each component found on the bottle following the wash.

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- The only waste water produced by the plant is from the process of washing and rinsing the bottles. This is a very conservative assumption since we know that the bottles that are involved in this process are used to package very specialized drinks and beverages and therefore is most likely a small proportion of the packaging occurring at any given bottling plant.
- The number of 1-L bottles washed per day was based on the total amount of any component used per day and the amount of that component needed to wash one. The fifth year production estimate of was used in this estimate.
- The components of the FCS were not degraded in the on-site wastewater treatment facility.
- The level of each component in the wastewater discharge from the plant will be diluted upon entering the POTW, assuming a typical POTW with a daily flow of 1.0 million gallons a day (3.79×10^6 L/day)⁴. The components of the FCS were not degraded with treatment at the POTW.

A detailed description of the calculation of the EIC is presented in Attachment 14, which contains confidential business information (CBI).

8. Fate of Substances Released into the Environment

Using a highly conservative assumption that no degradation of these components occurs at the POTW during treatment, the EIC also represents the concentrations entering the body of water that receives the POTW effluent. The concentration of these components in the receiving body of water will be lower due to mixing of the effluent with the receiving body of water. The expected environmental concentration (EEC) is the concentration of the active moiety that organisms would be exposed to in the environment after consideration of, for example, spatial or temporal concentration or depletion factors such as dilution, degradation, sorption and/or bioaccumulation (FDA, 1998). Based on dilution factors for POTWs available from the EPA, applying a dilution factor of 10 to the EIC to estimate the EEC is normally appropriate (FDA, 1998). Based on the EEC, the introduction of this substance into local waterways does not appear to be environmentally significant (see Attachment 14 – Confidential Business Information for the calculation of the EEC).

These calculations do not take into account the fact that these components are readily degraded in aquatic environments. Treatment of the plant's waste water at the on-site treatment

⁴ The daily flow rate at a typical POTW was determined by calculating an average flow rate using the lower end of the existing flow range weighted by the number of facilities with that flow range in operation in 2000, as presented in the Clean Watersheds Needs Survey (2000), Table C-3. The formula is: $[(0.001 \times 6,583) + (0.101 \times 6,462) + (1.001 \times 2,665) + (10.001 \times 487) + (100.001 \times 46)] / (6,583 + 6,462 + 2,665 + 487 + 46) = 1.0$ million gallons day).

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plant will most likely result in 100% degradation of the hydrogen peroxide, acetic acid, and peroxyacetic acid.

- Hydrogen peroxide will react with organic molecules and also undergo enzymatic degradation via catalase, glutathione peroxidase or other nonspecific peroxidases. Microbial action can degrade it to water and oxygen.
- Acetic acid is not an environmentally hazardous material and may be used as a carbon source for living matter.
- Peroxyacetic acid rapidly undergoes degradation by reaction with organic molecules, enzymatic degradation by some peroxidases and is degraded by metal catalysis into hydrogen peroxide and acetic acid.

The only compound likely to be present in any measurable quantity in wastewater discharged to a POTW is HEDP. Decomposition of HEDP was 33% in 28 days, based on data provided in the supplier's MSDS. The calculations described above are conservative since it was assumed that 100% of the HEDP remains in the wastewater.

9. Environmental Effects of Released Substances

It is expected that all of the components of this FCS, excluding HEDP, will be broken down into non-toxic molecules in the form of water, acetic acid, oxygen, and carbon dioxide. It is also expected that these reactions will occur prior to the water being discharged to the POTW. A summary of the reaction products and the expected toxicity of each component of the FCS is provided below.

Hydrogen peroxide: Decomposes rapidly to water and oxygen and is not expected to enter the environment after wastewater treatment.

Acetic acid: Summary ecotoxicity data on the supplier's MSDS (Attachment 4) and from the High Production Volume (HPV) Assessment Plan for Acetic Acid and Salts⁵ indicate that acetic acid is not highly toxic to aquatic organisms (see table below).

Peroxyacetic acid: Decomposes rapidly in water to acetic acid and hydrogen peroxide and is not actually expected to enter the environment, after wastewater treatment.

HEDP: Ecotoxicity data on the supplier's MSDS are available (Attachment 4) and are summarized in the table below. HEDP is practically non-toxic to aquatic organisms.

Ecotoxicity Data for Components of Peroxyacetic Acid Solution

Component	Fish 96-hr LC50 (ppm)	Daphnia magna 48-hr EC50 (ppm)	Green algae 96-h LC50 (ppm)
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⁵ U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acids and Salts Panel, American Chemistry Council, June 28, 2001.

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Acetic acid	75-251	65	4000
HEDP	368 - 868	527	3

The components of peroxyacetic acid solution are of low toxicity to aquatic organisms, with LC₅₀ and EC₅₀ ranging from practically non-toxic to slightly toxic. The acute toxicity values range from 3 ppm for HEDP effects to green algae to 4000 ppm for acetic acid effects to green algae. When the toxicity data is compared to the EECs calculated in Attachment 14, the EECs are at least an order of magnitude lower than the toxicity values. Again, it is important to note that the EECs used in this comparison are based on several highly conservative assumptions; mainly that 100% of the solution will enter the waste water and that no degradation of the components occurs before release into the receiving body of water.

Based on the modeled EECs and the available toxicity data, we conclude that there will be no adverse effects to the environment and organisms in from the potential release of the components of peroxyacetic acid solution to the environment.

10. Use of Resources and Energy

Due to the limited use of this product, the simple precursors used in developing the product and quantities that will be used, only a minimal amount of renewable natural resources will be consumed in the production and distribution of this product. The starting raw materials for the production of [redacted] will be commercially purchased commodity chemicals and will meet Food Chemical Codex requirements for food grade materials. The actual amount of resources used will depend on the market penetration and demand for the finished product. No resources should be used in treating/disposing of spent product. Disposal of unused product will represent a rare event. Infrequently, the product may be spilled and enter the treatment facility directly.

11. Mitigation Measures

No adverse environmental effects have been identified in this environmental assessment. Therefore mitigation measures are not necessary.

12. Alternatives to the Proposed Action

Because the current action has minimal to no known adverse environmental effects, it is unnecessary to propose alternatives to the proposed action.

13. List of Preparers

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14. Certification

I, Donald Schmitt, certify that the information presented is true, accurate, and complete to the best knowledge of Ecolab.

August 17, 2006

Date



Donald Schmitt, Authorized Representative of Ecolab

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15. References

U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acids and Salts Panel, American Chemistry Council, June 28, 2001.

US Food and Drug Administration (FDA). 1998. Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications. CMC 6, Revision 1.

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