

ENVIRONMENTAL ASSESSMENT

Inspexx[™] 150

1. **Date:** April 18, 2011
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 Notification is the establishment of a clearance to permit the use of peroxyacetic acid up to 220 ppm, hydrogen peroxide, acetic acid and 1-hydroxyethylidene-1, 1-diphosphonic acid in aqueous antimicrobial solutions applied to de-feathered poultry carcasses, parts and organs. Mixtures containing these constituents have previously been cleared by FDA for the same uses (See 21 C.F.R. § 173.370).
- b) **Need for action:** This is applied to poultry carcasses, poultry carcass parts, or poultry organs through spraying, submersion, or both. The antimicrobial effect of peroxyacetic acid reduces populations of pathogenic and nonpathogenic microorganisms that may be present and retards the spoilage of the poultry. This should provide for safer poultry products for consumers.

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- c) **Locations of use/disposal:** This product is for use poultry processing plants throughout the United States. The expected route of disposal for waste solution is the processing plant wastewater treatment facilities.

Poultry processing facilities: Spray application of the diluted product will usually take place prior to chilling by submersion. A de-feathered, eviscerated carcass hung on a shackle is carried into a spray cabinet by a conveyor system. Spray nozzles inside the cabinet apply the diluted product to the carcass surface. The carcass then exits the spray cabinet for further processing. Application of the diluted product by submersion of multiple carcasses into a chiller bath will occur immediately following the spray application step. Carcasses are moved through the chiller bath by a paddle or auger-type conveyor, then exit the chiller bath for further processing. Carcass parts or organs may also be chilled by submersion in water containing *Inspexx™ 150*

- a. After the diluted *Inspexx™ 150* sprayed onto the poultry carcasses, the bulk of the solution drains off of the poultry carcass. The waste solution ultimately runs into drains and enters the poultry processing plant water treatment facility. The diluted product in chiller water will also be disposed of by pouring it down drains that lead to the poultry processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to a POTW. Very minor quantities are lost to evaporation into the air.

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

| Substance Description – Post Reaction | CAS Number | Concentrate |
|---|------------|-------------|
| hydrogen peroxide | 7722-84-1 | 11.2 |
| acetic acid | 64-19-7 | 31.4 |
| 1-hydroxyethylidene-1,1-diphosphonic acid | 2809-21-4 | 0.9 |
| Peroxyacetic acid | 79-21-0 | 15.2 |

Chemical Name: hydrogen peroxide
Common or Trade Name: hydrogen peroxide
CAS Registry Numbers: 7173-62-8
CAS Registry Name: hydrogen peroxide
The starting monomers are identified as follows: None used by Ecolab.

The structures and molecular weight for hydrogen peroxide are:

| Chemical Substance (% in concentrate) | CAS No. | Structure | MW (g/mol) |
|---------------------------------------|-----------|-----------|------------|
| 11.2 | 7173-62-8 | HO - HO | 34.01 |

The typical physical properties of hydrogen peroxide are as follows:

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| | |
|------------------|---------------------------------------|
| Appearance | Colorless liquid |
| pH | 4.6 |
| Specific gravity | 0.843 g/cm ³ (25°C / 77°F) |
| Flash point | Not applicable |
| Melting point | -0.43 deg C |
| Water solubility | Miscible with water |

Chemical Name: Acetic acid
Common or Trade Name: Acetic acid
CAS Registry Numbers: 64-19-7
CAS Registry Name: Acetic acid
The starting monomers are identified as follows: None used by Ecolab.

The structures and molecular weight for acetic acid are:

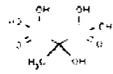
| Chemical Substance (% in concentrate) | CAS No. | Structure | MW (g/mol) |
|--|---------|---|---------------|
| 31.4 | 64-19-7 |  | 60.05 |

The typical physical properties of Acetic acid are as follows:

| | |
|------------------|---------------------------------|
| Appearance | Clear, colorless liquid |
| pH | 2.4-3.4 |
| Specific gravity | 1.0446 g/cu cm @ 25 deg C |
| Flash point | 103 deg F (39 deg C) Closed cup |
| Melting point | 16.6 deg C |
| Water solubility | Miscible with water |

Chemical Name: 1-hydroxyethylidene-1,1-diphosphonic acid
Common or Trade Name: Etidronic Acid
CAS Registry Numbers: 2809-21-4
CAS Registry Name: 1-hydroxyethylidene-1,1-diphosphonic acid
The starting monomers are identified as follows: None used by Ecolab.

The structures and molecular weight for HEDP are:

| Chemical Substance (% in concentrate) | CAS No. | Structure | MW (g/mol) |
|--|-----------|---|---------------|
| 0.9 | 2809-21-4 |  | 206.0 2 |

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The typical physical properties of 1-hydroxyethylidene-1,1-diphosphonic acid are as follows:

| | |
|------------------|--|
| Appearance | Colorless to pale yellow liquid |
| pH | 1 - 2 |
| Specific gravity | 1.45 @ 20 C |
| Flash point | Not Applicable |
| Melting point | Not Available |
| Water solubility | Miscible with water , 6.90E+05 mg/L 20 C |

Chemical Name: Peracetic/peroxyacetic Acid

Common or Trade Name: Peracetic/peroxyacetic Acid

CAS Registry Numbers: 79-21-0

CAS Registry Name: Peracetic/ peroxyacetic acid

The starting monomers are identified as follows: Hydrogen Peroxide and acetic acid

The structures and molecular weight for peracetic acid are:

| Chemical Substance (% in concentrate) | CAS No. | Structure | MW (g/mol) |
|--|---------|--|---------------|
| 15.2 | 79-21-0 | $\begin{array}{c} \text{CH}_3\text{C O O H} \\ \\ \text{O} \end{array}$ | 76.05 |

The typical physical properties of Peracetic acid are as follows:

| | |
|------------------|---------------------------------|
| Appearance | Colorless to pale yellow liquid |
| pH | 1 - 3 |
| Specific gravity | 1.13 @ 20 C |
| Flash point | Not Applicable |
| Melting point | 0.1 C |
| Water solubility | Miscible with water |

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

Not applicable.

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

The following Environmental Assessment (EA) demonstrates that Ecolab's *Inspexx*™ 150 have minimal to no known environmental effects.

A. As a result of manufacture

There are no extraordinary circumstances surrounding the manufacture of *Inspexx*™ 150. Ecolab will not manufacture any of the components, but will purchase them from suppliers and formulate them into their proposed commercially marketable product. Because Ecolab is neither producing the components nor actually using the product, Ecolab does not expect to increase the environmental load of components or product beyond some small quantity of effluent water due to routine cleaning and maintenance of on-site processing materials.

Ecolab purchases the components for addition into the product at the sites listed in Table 1 (see Attachment 11 for the estimated amount of produce wash formulated annually by Ecolab). Ecolab is responsible for all effluent, solid, and airborne discharges from these secure facilities and these facilities are currently in compliance with emissions requirements. Liquid production wastes are regulated under local, state, and federal permit numbers (see Table 1 below). There will be no solid by-products or airborne discharges from production of the product.

Table 1. Ecolab Facility Permits

| Location | Industrial Wastewater Discharge Permits |
|----------------------|--|
| City of Industry, CA | NPDES No. CAS000001 CA SWRCB Storm Water Permit WDID # 4 19 I 012588 L.A. County Permit No. 16771. |
| McDonough, GA | NPDES No. GAR000000 |
| Joliet, IL | NPDES No. ILR002878 City of Joliet Permit No. 2700 |
| Eagan, MN | NPDES Permit No. MNR05348S |
| Huntington, IN | NPDES No. IWDP2016 |
| Garland, TX | NPDES No. TXR05K870 Sewer Discharge Permit No. 0026 |
| Martinsburg, WV | WV/NPDES No. WV0020061 Underground Injection Control Permit #0304-00-003 |
| San Jose, CA | Sab Hise/Santa Clara WPCP Industrial waste Discharge Permit No SJ-304B |

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Introduction of dilute solutions of *Inspexx*™ 150 into the environment will take place primarily via release in wastewater treatment systems.

Introduction of the components of *Inspexx*TM 150 into the environment will result from use of the product as an antimicrobial agent in processing water and spray application onto carcasses, and the subsequent disposal of such water and spray drainage into the processing plant wastewater treatment facility, and to publicly-owned treatment works (POTWs).

Poultry:

*Inspexx*TM 150 is diluted to a maximum of 100 ppm peroxyacetic acid before application to the surface of the poultry carcass as a spray. This carcass wash is sprayed continuously as the carcasses pass through the spray cabinet. After spray application, the excess carcass wash drains off and is flushed to the wastewater treatment plant. The amount of *Inspexx*TM 150 diluted solution applied by spray to an individual carcass is approximately 0.25 gallons for each poultry carcasses (in this example, chickens are considered, as they constitute the majority of poultry processed in the U.S.).

After spraying, the carcass is placed in the chiller bath, which will contain a maximum of 30 ppm peroxyacetic acid. The chiller bath is normally filled once per day with approximately 25,000 gallons of water. Fresh make-up water will be added to the bath at the rate of approximately 0.5 gallons/bird. About 200,000 birds are sprayed and submersed per day at a typical processing facility.

Based on the above information, an estimate of the daily use of *Inspexx*TM 150 in a poultry processing plant can be calculated as follows:

Spray Application:

200,000 carcasses x 0.25 gallons of spray/carcass = 50,000 gallons (200 ppm solution)

50,000 gallons x 7.5 ounces product concentrate /100 gallons = 29.3 gallons of *Inspexx*TM 150

Chiller Bath:

25,000 gallons (initially) x 1 ounce product concentrate /50 gallons = approximately 4 gallons of *Inspexx*TM 150

Make up water is required at the rate of 0.5 gallons/carcass, and we assume 200,000 carcasses are processed/day. Thus, 100,000 gallons of water are added to the bath during the course of the day, which is treated at the rate of 1 ounce of product concentrate per 50 gallons. 100,000 gallons x 1 ounce product/50 gallons water = 15.6 additional gallons of *Inspexx*TM 150

The total amount of *Inspexx*TM 150 used for both spray and chiller bath applications per day is approximately 48.9 gallons in a typical poultry processing plant. For purposes of this example, it is assumed that all of the product used on carcasses will ultimately reach the drain and be discharged to the on-site wastewater treatment facility.

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As noted in the previous discussion of the release of *Inspexx*TM 150 components, it is not expected that any of the constituents of the

antimicrobial solution except HEDP will survive initial treatment at the on-site wastewater treatment facility. Therefore, we have only estimated the potential release of this component.

A detailed description of the calculation of the environmental introduction concentration (EIC) is presented in Attachment 11, which contains confidential business information (CBI). A description of the calculation of the EIC is provided below.

To determine the EIC for the HEDP component, we employed the fifth year production estimate for the product. The maximum concentration at which each component of the product 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.
- The only component of *Inspexx*TM 150 that was not degraded upon use and/or at an on-site wastewater treatment facility will be HEDP
- The level of HEDP component in the wastewater discharge will be diluted upon entering the POTW, assuming a typical POTW with a daily flow of 32,175 million gallons a day (1.22 x 10¹¹ L/day)¹. The HEDP component of the *Inspexx*TM 150 was not degraded with treatment at the POTW.

A detailed description of the calculation of the EIC is presented in Attachment 11.

¹ See FDA Guidance (May 2006) and Table C-3, Appendix C, 1996 *Clean Water Needs Survey*, U.S. Environmental Protection Agency. NOTE: this estimate of total flow of wastewater is below the 2004 estimated flow of 33,657 million gallons per day and therefore is a conservative estimate compared to EPA's most recent data.

8. Fate of Substances Released into the Environment:

Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment at the primary wastewater treatment facilities at poultry processing 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

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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.

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) using the 28 day test method OECD 302B . The calculations in attachment 11 for 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, 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.

Using a highly conservative assumption that no degradation of the HEDP component 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 11 – Confidential Business Information for the calculation of the EEC).

It is important to note that the EECs presented in Attachment 11 do not account for degradation and therefore are overestimates of the actual concentration most likely present in the receiving bodies of water.

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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.

9. Environmental Effects of Released Substances:

The Tables in Attachment 11 summarize the available data¹ on the environmental effects of the components of the produce wash product. There are no ecotoxicity data available for *Inspexx*TM 150 itself.

The components of *Inspexx*TM 150 are of low to moderate toxicity to aquatic organisms. When the toxicity data is compared to the EEC calculated in Attachment 11, the EEC is at least an order of magnitude lower than the toxicity values. Again, it is important to note that the EEC 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 EEC and the available toxicity data, we conclude that there will be no adverse effects to the environment and organisms from the potential release of HEDP and the other components of *Inspexx*TM 150.

10. Use of Resources and Energy:

The use of the antimicrobial mixture, *Inspexx*TM 150, 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 mixture components is not significant.

The addition of *Inspexx*TM 150 to the options available to poultry processors is not expected to increase the use of peroxyacetic acid antimicrobial products; rather, Ecolab expects to provide a replacement product for those peroxyacetic acid products already in use.

Based on the projected five year market volume (see Attachment 11), the amount of HEDP produced for the proposed use of this FCS in the *Inspexx*TM 150 formulation will be a very small fraction of the total HEDP currently produced for all other food uses. Therefore, we do not expect any significant effect on use of energy and resources with approval of this notification.

11. Mitigation Measures:

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

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¹ All ecotoxicity data are from: Evonik Degussa Corporation, Safety Data Sheet, 2009, Hyprox 350 Hydrogen Peroxide; Solvay Chemicals, Inc., Safety Data Sheet, 2008, Interrox Hydrogen Peroxide 35%: Technical Grade, Rhodia Inc., Safety Data Sheet, 2006, Briquest ADPA-60AW; Thermphos USA Corp., Safety Data Sheet, 2008, Dequest 2010 Deflocculant & Sequestrant; Celanese Ltd., Safety Data Sheet, 2008, Acetic Acid; Millennium Petrochemicals, Inc., A Lyondell Company, Safety Data Sheet, 2007, Glacial Acetic Acid, >80%

12. Alternatives to the Proposed Action:

The alternative of not approving the action proposed herein would simply result in the continued use of nearly identical products by the poultry processing industry; such action would have no environmental impact

13. List of Preparers:

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14. Certification:

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

Date  4/21/2011

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15. References

Evonik Degussa Corporation, Safety Data Sheet, 2009, Hyprox 350 Hydrogen Peroxide

Solvay Chemicals, Inc., Safety Data Sheet, 2008, Interlox Hydrogen Peroxide 35%, Technical Grade

Rhodia Inc., Safety Data Sheet, 2006, Briquest ADPA-60AW

Thermphos USA Corp., Safety Data Sheet, 2008, Dequest 2010 Deflocculant & Sequestrant

Celanese Ltd., Safety Data Sheet, 2008, Acetic Acid

Millennium Petrochemicals, Inc., A Lyondell Company, Safety Data Sheet, 2007, Glacial Acetic Acid, >80%

U.S. Food and Drug Administration (FDA). 1998. Guidance for industry, environmental assessment of human drug and biologics applications. U.S. Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). CMC 6, Revision 1. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070561.pdf>. Accessed July 22, 2010.

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