ENVIRONMENTAL ASSESSMENT FOR PROPOSED APPROVALS OF FDA REGULATED PRODUCTS

March 13, 2001

Ecolab, Inc.
370 Wabasha St. North
St. Paul, MN 55102

1. **DATE:** March 13, 2001

2. **NAME OF PETITIONER:** Ecolab Inc.

3. **ADDRESS**: 370 Wabasha St. North
St. Paul, MN 55102

4. DESCRIPTION OF PROPOSED ACTION

a). Requested approval: This petition is part of FCN #140 for the use of an aqueous antimicrobial solution [redacted] consisting of hydrogen peroxide, acetic acid, peroxyacetic acid and hydroxyethylidine-1,1-diphosphonic acid (HEDP) as a carcass wash to reduce the surface microbiological content of freshly killed beef carcasses. This product is applied directly to the exposed surface of the carcass via a sprayer after the hide is removed and the head and the hooves are cut off. When the product diluted to the use concentration (1 ounce of concentrate to 5 gallons of water), it consists of acetic acid [redacted] hydrogen peroxide [redacted], peroxyacetic acid [redacted], and hydroxyethylidine-1,1-diphosphonic acid [redacted]. (Concentrations listed are approximate and vary slightly with age of the product).

b.) Need for action: This product is an antimicrobial solution that is designed to reduce the bacterial count on the surface of freshly killed beef carcasses. By reducing the bacteria present, this will retard the bacterial degradation of the meat and reduce the content of pathogenic organisms on the surface of the carcass. This will produce a safer food supply and allow the treated meat to have a longer shelf life.

c.) Locations of use/disposal: This product is proposed for use in beef processing plants. The quantity used will ultimately depend on market penetration, number of carcasses treated and size of the facility.

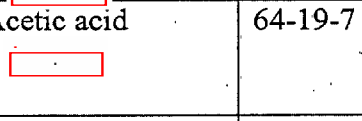
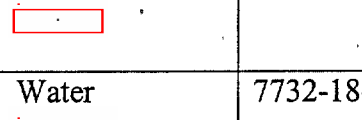
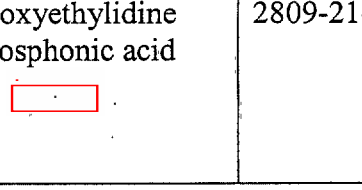
This product is designed to be applied to the surface of freshly killed beef carcasses following removal of the hide, head and hooves. This is accomplished by spraying the carcasses with the product as they move down a conveyor line. The carcasses are hung from a hook on a trolley. The trolley carries the carcass into a cabinet where spray nozzles are located in such a manner as to spray the surface of the beef carcass with sufficient product to accomplish the technical effect of surface pathogen reduction. The carcass exits the other side of the cabinet and continues processing.

After the product is sprayed onto the carcass, the majority of the product will drain off the meat and ultimately run into drains and enter the meat processing plant water treatment facility. Very minor quantities are lost to evaporation into the air.

5. IDENTIFICATION OF SUBSTANCES THAT ARE THE SUBJECT OF PROPOSED ACTION

The product will consist of the following chemicals in the approximate percentages listed. This represents the finished concentrated [redacted] formula. The product will undergo significant dilution prior to application to the beef carcasses.

The only raw materials used in this product are hydrogen peroxide, acetic acid and hydroxyethylidine-1,1-diphosphonic acid (HEDP). The peroxyacetic acid is formed by the reaction of acetic acid with hydrogen peroxide.

Chemical Substance % in concentrate	CAS No.	Structure	MW	Physical Form
Hydrogen peroxide [redacted]	7722-84-1	H-O-O-H	34	Clear liquid
Acetic acid [redacted]	64-19-7		60	Clear liquid
Peroxyacetic acid [redacted]	79-21-0		76	Clear liquid
Water [redacted]	7732-18-5	H-O-H	18	Colorless liquid
Hydroxyethylidine Diphosphonic acid [redacted]	2809-21-4		206	Colorless liquid

6. INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

a. Introduction of substances into the environment as a result of manufacture

Only negligible environmental releases are anticipated during the production of the subject additive. The manufacture of the product involves [redacted] Several of the components have vapor pressures capable of producing very small losses to the environment. Only the top surface of the mixture is open to the air, however, each mix tank is equipped with a scrubber eliminating virtually any material escaping from the tank and reaching the environment. With these safeguards in place, the total loss to the atmosphere is insignificant.

The process of manufacture of this product will involve the use of a dedicated tank. This tank will be used to produce consecutive batches and will not be cleaned or washed out between runs. Therefore under normal operating conditions, no loss to the environment is expected via the septic system. If there is required maintenance on the tank, any residual product is rinsed out of the tank and the rinse water is collected in drums, and is not sewered. The rinse water is then used as the water component of the next batch produced, thus eliminating any discharge of this material to a publicly owned wastewater treatment plant (POTW).

There are no extraordinary circumstances that pertain to the manufacture of this product. There are no emissions that are expected to result in any harm to the environment, violate any federal, state, or local law or threaten any habitat of an endangered species protected under federal law.

b. Introduction of substances into the environment as a result of use/disposal

Estimates of the quantity produced annually will vary greatly depending on market acceptance, performance, the availability of alternatives and the amount of meat that is treated. It is therefore not possible to give an accurate projection of the amount that will be sold in the future. However, some estimation of the quantity of may be made using past experience and judgement. It is projected that in the fifth year of production, approximately [redacted] of this product will be used.

This product is designed to be diluted and then applied to the surface of freshly killed beef carcasses. This is accomplished by spraying the carcasses with the product as they move down a conveyor line. The hide is removed, the head and the feet are cut off, and the carcasses are hung from a hook on a trolley. The trolley carries the carcass into a cabinet where spray nozzles are located in such a manner as to spray the carcass with sufficient product to accomplish the technical effect of surface pathogen reduction. The carcass exits the other side of the cabinet and continues processing.

The excess carcass wash drips off the meat and empties into a floor drain along with other beef wastes such as blood. This carcass wash is sprayed continuously as the carcasses pass through the cabinet. The estimates for the amount of carcass wash concentrate used range from about 70 to 225 oz. of concentrated product per conveyor line, per hour. The concentrate is diluted to the use solution before it is applied to the surface of the beef. The total amount used in the facility will depend on the number of carcasses sprayed, the flow rate, the number of processing lines running and the number of hours or shifts the facility operates. For the purpose of estimating total volume consumed, we will use relatively conservative (high) estimates.

If we assume the maximum use rate of 225 oz. of concentrated product per hour, a facility that operates 2 shifts (16 hours a day) and has 2 processing lines uses:

225 ounces/hour x 2 x 16 hours = 7200 oz.

or approximately 56 gallons of product per day. The discharge to the POTW is calculated in the table, below.

POTW LOADING OF DISCHARGES FROM BEEF PROCESSING PLANTS RESULTING FROM THE USE OF [redacted] [1][2]

Component	Percentage In Concentrate[3]	Use Rate (gpd)	Load to 25 Million Gpd – POTW (ppb)	Effluent From POTW (ppb) [4]
Hydrogen Peroxide	[redacted]	[redacted]	44	4
Acetic Acid			1536	154
Peroxyacetic Acid			268	27
HEDP			12	1
Water			NA	NA
Total Product			2240	224

[1] Assumes that the waste stream is directly sent to a POTW, although this is not the case. In meat processing facilities, effluents are sent to a pre-treatment facility. Essentially all of the components in this product will be degraded before they ever enter a POTW. Therefore, the results of these calculations are a drastic overestimation of the actual environmental releases.

[2] Assumes use of 56 gallons/day of [redacted] per meat processing facility; assumes a 25 million gpd POTW Treatment Facility

[3] Concentrations are approximate and depend on the age of the product, temperature, dilution, etc.

[4] Assumes a 90% degradation rate at the POTW

7. FATE OF EMITTED SUBSTANCES

Air Discharges

Small amounts of acetic acid and hydrogen peroxide will be emitted into the air. Hydrogen peroxide is not stable in sunlight, and undergoes photolytic decomposition. Both the hydrogen peroxide and acetic acid will be removed from the air by rain. Only small quantities of these chemicals are anticipated to be released into the air and are not expected to result in any adverse environmental effects. The remaining components in the formula are not very volatile and are expected to remain dissolved in the water matrix and enter the drain. These chemicals will enter the water treatment facility.

The Occupational Safety & Health Administration (OSHA) has set permissible exposure limits (PEL's) of 10 ppm for acetic acid and 1 ppm for hydrogen peroxide. Based on the significant amount sprayed and the proximity of workers to the spray cabinets, industrial hygiene practices such as proper ventilation and personal protective equipment may be necessary. Initial monitoring may be necessary to ensure the ambient levels of these chemicals are below the respective PEL's. See section Appendix 1 of this section for component MSDSs.

Water Discharges

This product will be collected in drains at the facility and mixed with other discharges, including waste streams containing organic materials and biological wastes such as blood. Upon contact with these materials, the active ingredients (peroxides) in the carcass wash will degrade into simple molecules such as acetic acid, water, oxygen and carbon dioxide. The wastewater goes through several processing steps including dissolved air flotation, anaerobic treatment, activated sludge and chlorination/dechlorination prior to release to the POTW.

Hydrogen peroxide

Hydrogen peroxide will react with organic molecules and also undergo enzymatic degradation via catalase, glutathione peroxidase or other nonspecific peroxidases. Microbial action can also degrade it to water and oxygen.

$$H_2O_2 \rightarrow H_2O+O_2$$

Acetic acid

Acetic acid is not an environmentally hazardous material and may be used as a carbon source for living matter.

Peroxyacetic acid

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.

$$H_2O + CH_3COOOH \rightarrow CH_3COOH + H_2O_2$$

Summary

As outlined above, all the components in the formula are likely to undergo rapid degradation to simple non-toxic molecules. These reactions take place rapidly due to the chemically unstable nature of the active ingredients. Based on these reactions, only water, oxygen, acetic acid and carbon dioxide will be released into the environment.

8. ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES

All of the components in this product break down to simple non-toxic molecules. This process will occur long before leaving the waste treatment area of the facility. No adverse environmental effects are expected to result from the use of this material.

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

Acetic acid: As can be seen from the table presented in section 6, potential worst case release to the environment (maximum 10 ppb) is much lower than the reported toxicity values to aquatic organisms. The reported 96-hr fish LC_{50}'s are in the range of 80 ppm allowing a greater than 1000-fold safety factor (see Appendix 2 for available data on the environmental effects of acetic acid).

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

Hydroxyethylidine diphosphonic acid (HEDP): Data on HEDP are available from the suppliers (see MSDS for HEDP in Appendix 1) and are summarized here. The data indicate that HEDP is practically non-toxic to many aquatic and avian organisms however, it is "slightly toxic" to oysters (EC_{50} between 10 and 100 ppm on EPA's standard rating scale for toxicity to aquatic organisms). As noted above, the potential release levels of this substance to the environment are well below the EC_{50}, being on the order of 1 ppb thus allowing a greater than 1000-fold safety factor.

9. USE OF RESOURCES AND ENERGY

Due to the rather 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.

This product may replace the use of chlorine dioxide solutions that are currently used in this application. Although the products have very similar use profiles, they are very different. Both products are produced by renewable resources and degrade into environmentally acceptable products. The net effect is that there is not a significant difference in the use of energy or resources of the two products.

Based on the use patterns of this product, no effects are anticipated on endangered species. Use of this product will not adversely impact any property listed in the National Register of Historic Places.

10. MITIGATION MEASURES

None necessary.

11. ALTERNATIVES TO THE PROPOSED ACTION

None.

12. PREPARER

Robert M. Harrington, Ph.D.
Corporate Toxicologist
Director, EH&S Compliance
Ecolab Inc.

13. CERTIFICATION

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of Ecolab Inc.

/s/

/s/

Robert M. Harrington, Ph.D.
Corporate Toxicologist
Director, EH&S Compliance

3/13/01
Date