ATTACHMENT 9

ENVIRONMENTAL ASSESSMENT FOR ALCOHOLS, C12-15 ETHOXYLATED PROPOXYLATED

1. **Date:** December 12, 2008

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

Donald Schmitt
Exponent, Inc.
1011 Warrenville Road, Suite 215
Lisle, IL 60532
Telephone: 630-743-7702
Facsimile: 630-743-7799
E-mail: dschmitt@exponent.com

4. **Description of the Proposed Action**

a) **Requested action:** It is proposed that Alcohols, C12-15 ethoxylated propoxylated be approved for use as an indirect food additive through the premanufacture process utilizing FDA Form 3480 "Notification for New Use of a Food Contact Substance." The FCS is proposed for use as a component of rinse-aid products, which would result in concentrations of the FCS no greater than 37 ppm in the final rinse water from commercial dishwashing machines.

There is one product manufacturer utilized by Ecolab as the source of the FCS in the manufacture of rinse-aid products. The manufacturer has provided the relevant manufacturing facility information in their Food Additive Master File (FAMF) #811.

b) **Need for action:** The purpose of the FCS in these products is to cause a sheeting effect of water. Rinse-aids reduce the surface tension of water causing the use-solution to spread out on the ware surface. A faster drainage of water prevents water solids from spotting/filming and aids in the drying process. The FCS reduces the contact angle of water (i.e., results in a flatter

water droplet) and therefore a lesser amount of water in each water droplet. Having less water in a water droplet results in faster drying of each drop.

c) **Locations of use/disposal:** The FCS is added to rinse-aid product at various Ecolab sites in the United States (see Table 1). These sites are secure production facilities situated on the edge or within a few miles of small/medium towns in largely industrial areas. The types of environments present at and adjacent to these locations include water sources. There will be no solid by-products or airborne discharges from production of rinse-aid products.

Regarding disposal of the rinse-aid products containing the FCS, these products are used in dishwashing machines and will be used in patterns corresponding to national population density. Their wide distribution will correspond with the following commercial establishments: restaurants, bars, cafeterias, child and adult day care centers, residential dining facilities and medical institutions. Consequently, disposal will occur nationwide, with liquid wastes from use of these products in commercial dishwashing machines ultimately being discharged to local POTWs, which are regulated under local, state, and federal agencies. Solid byproducts, consisting of packaging only, will ultimately be deposited in landfills, incinerated, or recycled (where possible). Environments potentially affected by disposal or discharge of the FCS from rinse-aid products will be watersheds or groundwater receiving leachate from land disposal sites or POTWs and areas subject to air emissions from landfills and incineration sites. There will be no direct airborne discharges from use of rinse-aid products.

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

Chemical Name: Alcohols, C12-15, ethoxylated propoxylated

Common or Trade Name: Alcohol alkoxylate; tradename is provided in Attachment 10 (Confidential Business Information)

CAS Registry Number: 68551-13-3

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

Empirical formula: See FAMF #811

Structural Formula: N/A

Properties:

Alcohols, C12-15, ethoxylated propoxylated	
Molecular Weight	See FAMF No. 811
Form	Liquid
Appearance	Yellow
Odor	Product Specific
pH	Approximately 7
Solubility in Water	Insoluble

* Additional information can be found in FAMF No. 811.

6. Environmental Assessment - Introduction of the Substance into the Environment

The following Environmental Assessment (EA) demonstrates that Ecolab's formulation of the FCS in rinse-aid products will have minimal to no known environmental effects.

A. As a Result of Manufacture

Ecolab will not manufacture the FCS, but will purchase it from a vendor and formulate it into its proposed commercially marketable rinse-aid products. Because Ecolab is neither producing the FCS nor actually using it, Ecolab does not expect to increase the environmental load of alcohols, C12-15, ethoxylated propoxylated beyond some small quantity of effluent water due to routine cleaning and maintenance of on-site processsing materials. The manufacturer of the FCS is responsible for all effluent, solid and airborne discharges from their own facilities, and these facilities are currently in compliance with emissions requirements. Relevant discharge permits for this plant(s) can be found in FAMF No. 811.

Ecolab purchases the FCS for addition into rinse aids at the sites listed in Table 1 (see Attachment 10 for the estimated amount of the FCS purchased annually by Ecolab for use in rinse-aids). 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 rinse-aid products.

Table 1. Ecolab Facility Permits

Location	Industrial Wastewater Discharge Permits
City of Industry, CA	NPDES No. CAS000001 CA SWRCB Storm Water Permit WDID # 4 19S012588 L.A. County Permit No. 14341.
San Jose, CA	San Jose/Santa Clara Water Treatment Plant Waste Water Permit #SJ304B S.C. Valley Storm Water Permit #SWRB, WDID# 243S0026629604
McDonough, GA	NPDES No. GAR000000
Joliet, IL	NPDES No. ILR002878 City of Joliet Permit No. 2700
Eagan, MN	NPDES Permit No. MN-G611000
Hebron, OH	NPDES No. OHR000003 Local permits: No. 98-02 (facility to Hebron); No.4PB00005*6D (Hebron to state water)
Garland, TX	NPDES No. TXR05B61 Sewer Discharge Permit No. 0026
Martinsburg, WV	WV/NPDES No. WV0020061 Underground Injection Control Permit #0304-00-003

The entire annual volume of the FCS discussed in Attachment 10 will be completely incorporated into rinse-aid products and will function in the finished rinse-aids. Essentially 100% of it is expected to remain with the rinse-aid products throughout their manufacture and storage prior to use. As such, little or no FCS is expected to be introduced into the environment from the use of the FCS in the manufacture of rinse-aid products.

TO THE BEST OF OUR KNOWLEDGE, NO EXTRAORDINARY CIRCUMSTANCES PERTAIN TO THE MANUFACTURE OF THE FCS.

B. As a Result of Use/Disposal

This action involves alcohols, C12-15, ethoxylated propoxylated, which is a component of rinse-aid products present at an "at-use" concentration of no greater than 37 ppm (0.0037%) by weight in the final rinse water from the use of these products in dishwashing machines. These machines would likely be used in the following commercial establishments: restaurants, bars, cafeterias, child and adult day care centers, residential dining facilities and medical institutions.

During the final rinse cycle, an aqueous solution of the rinse aid is introduced into the dishwashing machine potable water sump from an automatic dispenser. From the sump, the use solution is sprayed onto the dishware. At the end of the final rinse cycle, the rinse water is drained off and disposed of through the sewage system.

Thus, the principal route of environmental introduction of the FCS follows from the disposal of liquid wastes through the sewage system into waterways. This disposal route is governed by the EPA's regulations in 40 CFR Subchapter D and/or O and local government wastewater regulations.

Alcohol ethoxylates are used extensively in industrial applications, detergents, household cleaners, cosmetics, and personal care products such as shampoos. Consequently, the use of the FCS in the production of rinse-aids will result in no appreciable environmental impact when compared to the use of similar ethoxylated alcohols in all other industries.

The expected introduction concentration (EIC) was calculated based on guidance from FDA (FDA, 1998). A detailed description of the calculation of the EIC is presented in Attachment 10, which contains confidential business information (CBI).

Based on the dilution of the FCS from use in rinse aids in the rinse water, and widespread use of related ethoxylated alcohols in the U.S. in other commercial applications, the introduction of this substance from the use in rinse-aid products into local waterways is not expected to be environmentally significant. Therefore, we do not expect that any limited increase in environmental introductions resulting from the proposed action will threaten a violation of the EPA's regulations governing wastewater or have any other adverse environmental effect.

7. Fate of Substances Released into the Environment

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 from the use of rinse-aid products into local waterways does not appear to be environmentally significant (see Attachment 10 – Confidential Business Information for the calculation of the EEC).

This calculation does not take into account the fact that alcohol ethoxylates and the FCS are readily degraded in aquatic environments and the effect of treatment of the FCS in the water entering the POTW. In a review of the human and environmental risk assessment (HERA) of household cleaning products, it was determined that alcohol ethoxylates (AE) such as the FCS would readily biodegrade in water under aerobic conditions and are biodegradable under anaerobic conditions as well. In addition, overall AE removals of greater than 90% have been generally observed in sewage trewtment[1].

8. Environmental Effects of Released Substances

Linear primary alcohol ethoxylates are acutely toxic to aquatic organisms with the toxicity varying relative to alkyl chain length and the number of EO units. The following table summarizes the available data[1] on the environmental effects of closely related homologues of C12-15 ethoxylated propoxylated alcohol, these are C12-15, alcohol ethoxylates, EO units of 1-5. Specific information on the EO units of the FCS may be found in FAMF No. 811 provided by the FCS supplier. A reasonable prediction may be made based on the available data on the aquatic toxicity of these related homologues.

Table 2. Ecotoxicity Data[1]

Component AE	Species	EC50/LC50/EC10 (mg/l)	Test Duration
C12-15 (EO3)	Algae (*Selenastrum capricornutum*)	EC50 = 0.74	48h
C12-15 (EO3)	Invertebrate (*Daphnia magna*)	EC50 = 0.14	48h
C12-15 (EO3)	Fish (Bluegill sunfish)	LC50 = 1.5	96h
C12-15 (EO3)	Fish (*Salmo gairdneri*)	LC50 = 1.3-1.7	96h
C12-15 (EO3)	Fish (*Salmo gairdneri*)	LC50 = 1.0	96h
C12-15 (EO3)	Green algae (*Chlorella vulgaris*)	EC10 = 2.179 (growth rate)	Chronic

When the toxicity data is compared to the EEC (see Attachment 10 – Confidential Business Information), the EEC is well below 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 no degradation of the FCS occurs before release into the receiving body of water.

Based on the modeled "worst case" EECs and the available toxicity data, we conclude that there will be no adverse effects to the environment and organisms from the potential release of the FCS to the environment.

9. Use of Resources and Energy

Resources and energy utilization to produce or dispose of either the FCS or rinse-aid products containing the FCS are not expected to be affected by the action. The FCS is expected to compete with, and to some degree replace, other substances that are currently used in formulating rinse aids for use in commercial dishwashing machines. Therefore, we do not expect any significant effect on use of energy and resources with approval of this notification.

---

1 All ecotoxicity data are from the manufacturer's MSDS and/or HERA Alcohol Ethoxylates: Human and Environmental Risk Assessment on ingredients of household cleaning products. Version 1, May, 2007.

Effects upon endangered or threatened species and upon property listed in or eligible for listing in the National Register of Historical Places are not expected as a result of the action.

10. Mitigation Measures

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

11. 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.

12. List of Preparers

Nga Tran, Ph.D, MPH
Exponent, Inc.
Senior Managing Scientist
1150 Connecticut Ave. NW, Ste 1100
Washington, DC 20036
Telephone: 202-772-4915
Fax: 202-772-4979
E-mail: ntran@exponent.com

13. Certification

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

December 12, 2008

Date

Donald Schmitt, Authorized Representative of Ecolab

14. References

HERA. 2007. Alcohol Ethoxylates: Human and Environmental Risk Assessment on ingredients of household cleaning products. Version 1, May 2007.

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