ATTACHMENT 10

ENVIRONMENTAL ASSESSMENT FOR SODIUM XYLENE SULFONATE (SXS)

1. **Date:** July 19, 2006

2. **Name of Applicant:** Ecolab Inc.

3. **Address:** **Ecolab Center**
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.
185 Hansen Court, Suite 100
Wood Dale, IL 60191
Telephone: 630-274-3227
Facsimile: 630-274-3299
E-mail: dschmitt@exponent.com

4. **Description of the Proposed Action**

a) **Requested action:** It is proposed that sodium xylene sulfonate (SXS) be approved for use as an indirect food additive through the premanufacture process utilizing the FDA Form 3480 "Notification for New Use of a Food Contact Substance." SXS is proposed for use as an anionic surfactant, hydrotrope and coupling agent in rinse-aid products, which would result in concentrations of SXS no greater than 300 ppm (25% above the maximum current "at-use" concentration of 243 ppm) in the final rinse water from commercial dishwashing machines.

There is one technical grade product and three formulations that are utilized by Ecolab as sources of SXS in the manufacture of rinse-aid products. These four products and their manufacturers are listed in Table 1.

[redacted]

000109

Table 1. SXS Products and Manufacturers Used by Ecolab as Sources of SXS in Rinse-aid Products

These sites are located in industrial areas within the cities listed in the above table and bordered by industrial parks or undeveloped properties. The local wastewater treatment plants (POTW) are located less than 1 mile from the facility. Certain permitted wastes are discharged to the local POTW or wastewater is treated at the facility.

There is no RCRA solid process waste associated with this product. There are some airborne emissions from manufacture of technical grade SXS and the formulations that consist of low molecular volatile compounds that are components of materials used in the process. Airborne emissions are controlled with vapor combustion units or product recover condensers. These are appropriate control technology so that the plants operate within their air permits

Some SXS formulations are manufactured in foreign countries and are not subject to the waste permits and jurisdiction of the United States.

b) **Need for action:** The purpose of SXS in these products is to 1) help solubilize the slightly soluble nonionic surfactants that cause a sheeting effect and 2) impair water solids from crystallizing on the ware surface resulting in spotting and filming

c) **Locations of use/disposal:** SXS is added to rinse-aid product at various Ecolab sites in the United States (see Table 2). 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 SXS, 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 SXS 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: Sodium Xylene Sulfonate

Common or Trade Name: Benzenesulfonic acid, dimethyl, sodium salt; sodium dimethylbenzene sulfonate; xylenesulfonic acid, sodium salt; [redacted]

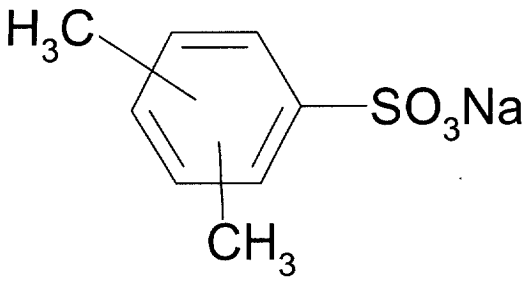
CAS Registry Number: 1300-72-7

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

Empirical formula: $C_8H_9SO_3 \cdot Na$

[redacted]

Structural Formula:



Properties:

Technical Product [redacted]	
Molecular Weight	208
Purity	92% (minimum)
Appearance	White to pale yellow powder
Odor	None
pH of 5% solution	7.0 - 9.5
Density	0.46 g/mL
Solubility in water	40%
10% Ethanol	>20%
3% Acetic Acid	Unknown
Typical aromatic or aliphatic HC solvent	NA

Formulations			
Property	[redacted]	[redacted]	[redacted]
Concentration (%)	40 minimum	40-42	40-41
Color, Klett	50 maximum	50 maximum	40 maximum
Appearance	Clear to light yellow liquid		
Density	1.16-1.19 g/mL at 25°C		
pH	7-9.5		
Boiling point	100-101°C		
Melting point	10 EC		
Viscosity	7 cps (5.6 centistokes) at 25°C		
Odor	Mild		

[redacted]

000112

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

A. As a Result of Manufacture

In the most recent Inventory Update Rule (2002 IUR)[1], the total recorded amount of SXS produced in the U.S. is >50 million pounds to 100 million pounds (i.e., SXS is a High-Production Volume (HPV) chemical). This amount is for all industrial and commercial uses, such as a component of detergents and other cleaning products, not just for the production of rinse-aids.

The technical product is made by the [redacted] and the three formulations are made by [redacted] at various sites around the United States (see Table 1 in Section 4a). These four manufacturers are responsible for all effluent, solid and airborne discharges from their own facilities, and these facilities are currently in compliance with emissions requirements. Product loss during manufacture is minimal and either is recycled or is eventually discharged to the local POTW.

[redacted]

There are no RCRA solid wastes from production of technical grade SXS or formulations of SXS.

Ecolab purchases SXS for addition into rinse aids at the sites listed in Table 2 (see Attachment 11 for the estimated amount of SXS 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 2 below). There will be no solid by-products or airborne discharges from production of rinse-aid products.

[1] Under the Toxic Substances Control Act (TSCA) of the United States Environmental Protection Agency (EPA).

[redacted]

Table 2. Ecolab Facility Permits

Various Ecolab facilities produce at least 21 rinse-aid products. The overall production of SXS in the United States ranges from >50M - 100M pounds. The use of SXS for rinse-aid products is a small percent of total annual production (see Attachment 11 – Confidential Business Information). Thus, the use of SXS in the production of rinse-aids results in minimal, or no overall increases of environmental emissions from the Ecolab facilities and also results in no appreciable environmental impact when compared to the use of SXS in all other industries.

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 SXS, which is a component of rinse-aid products present at an "at-use" concentration of no greater than 300 ppm (0.030%) 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.

[redacted]

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.

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 11, which contains confidential business information (CBI).

Based on the dilution of SXS from use in rinse aids in the rinse water, and the total amount of SXS produced in the US for other commercial uses, the introduction of this substance from the use in rinse-aid products into local waterways is not 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 11 – Confidential Business Information for the calculation of the EEC).

This calculation does not take into account the fact that SXS is readily degraded in aquatic environments, and the effect of treatment of SXS 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 hydrotopes, including SXS, would

[redacted]

readily biodegrade in water under aerobic conditions[2]. SXS was 69% degraded in 5 days and 100% degraded in 8 days in raw sewage. In a modeled scenario, the default removal of hydrotopes from secondary activated sewage was predicted to be 87% in wastewater treatment plants[3].

SXS has a low potential for adsorption to sediment soils due to its low log Kow (-1.86). There is no available data on the anaerobic degradation of SXS or hydrotopes, but considering the ready aerobic biodegradability and SXS's low log Kow (-1.86), the presence of SXS in anaerobic environments is expected to be negligible.

8. Environmental Effects of Released Substances

The following table summarizes the available data[4] on the environmental effects of SXS.

Table 3. Ecotoxicity Data for SXS

Component	Fish 96-hr LC50 (ppm)	Daphina magna 48-hr EC50 (ppm)	Green algae 96-h EC50 (ppm) (*Selenastrum*)
SXS	>400	>400	230

SXS is of low toxicity to aquatic organisms, with LC_{50} and EC_{50} determined to be practically non-toxic according to EPA guidelines[5,6]. Green algae are the most sensitive species. SXS had no acute toxicity two fish and aquatic invertebrates at concentrations tested (>400 ppm). The acute toxicity values range from 230 ppm for effects to green algae to >400 ppm for effects to *Daphnia magna* and fish. When the toxicity data is compared to the EEC (see Attachment 11 – 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 SXS to the environment.

---

2 All environmental fate data are from: HERA Hydroptopes: Human and Environmental Risk Assessment on ingredients of household cleaning products. Edition 1, September 2005.

3 Calculated using Simpletreat with v3.0 defaults for a readily biodegradable chemical and assuming a log Kow value of –2.7 and calculated Henry's Law constant of 4.9×10^{-18} Pa.m3.mol-1.

4 All ecotoxicity data are from HERA Hydroptopes: Human and Environmental Risk Assessment on ingredients of household cleaning products. Edition 1, September 2005.

5 Hazard Evaluation Division, Standard Evaluation Procedure: Acute toxicity for freshwater fish. 1985. US EPA, NTIS.

6 Hazard Evaluation Division, Standard Evaluation Procedure: Acute toxicity for freshwater invertebrates. 1985. US EPA, NTIS.

[redacted]

000116

9. Use of Resources and Energy

Resources and energy utilization to produce or dispose of either SXS or rinse-aid products containing SXS are not expected to be affected by the action. Overall US production of SXS is expected to remain essentially unchanged as a consequence of this action because the market share of SXS that is utilized in rinse aid products is only a small fraction of total production volumes. Therefore, we do not expect any significant effect on use of energy and resources with approval of this notification.

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
1730 Rhode Island Ave. NW, Ste 1100
Washington, DC 20036
Telephone: 202-772-4915
Fax: 202-772-4979
E-mail: ntran@exponent.com

Carolyn Scrafford, MPH
Exponent, Inc.
Managing Scientist
1730 Rhode Island Ave. NW, Ste 1100
Washington, DC 20036
Telephone: 202-772-4928
Fax: 202-772-4979
E-mail: cscrafford@exponent.com

[redacted]

13. **Certification**

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

July 19, 2006
Date

Donald Schmitt, Authorized Representative of Ecolab

[redacted]

000118

14. References

HERA. 2005. Hydroptopes: Human and Environmental Risk Assessment on ingredients of household cleaning products. Edition 1, September 2005.

US Environmental Protection Agency (EPA). 1985. Hazard Evaluation Division, Standard Evaluation Procedure: Acute toxicity for freshwater fish. US EPA, NTIS.

US Environmental Protection Agency (EPA). 1985. Hazard Evaluation Division, Standard Evaluation Procedure: Acute toxicity for freshwater invertebrates. US EPA, NTIS.

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

[redacted]

000119