EN

Attachment No. 8

Environmental Assessment

This information is pertinent to Part IV of the FCN

1. **September 22, 2006**

2. **ECOLAB Inc.**

3. **ECOLAB Center**
   370 Wabasha Street
   St. Paul, MN 55102-1390

4. **DESCRIPTION OF THE PROPOSED ACTION**

a. Requested Action

It is proposed that C_{10}-C_{12} Ethoxylated Alcohol be permitted for use as a food-contact substance (FCS) through the premarket process utilizing the FDA Form 3480 "Notification for New Use of a Food Contact Substance." The FCS is proposed for use as a processing aid in rinse-aid products used in commercial dishwashing machines. The FCS will be used at concentrations up to 37 ppm in the final rinse water.

b. Need for Action

The purpose of the FCS in commercial rinse-aid products is to improve the sheeting of water. This will allow for the use of rinse-aid formulations that can contain a lower quantity of total surfactants. For example, a trial described in Attachment 2 of this notification demonstrated that a rinse-aid formulation containing the FCS was as effective as a similar formulation that did not contain the FCS despite containing 34% less total surfactant than the non-FCS formulation.

c. Location of Use/Disposal

Rinse-aid products formulated with the FCS will be used in commercial dishwashing machines in a variety of commercial establishments. These locations are likely to include, for example, restaurants, bars, cafeterias, child and adult day care centers, residential dining facilities, and medical institutions.

Rinse-aid products containing the FCS will be used in patterns corresponding to national population density, and will be widely distributed across the country. Consequently, disposal will occur nationwide, with liquid wastes from the 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 SUBSTANCE THAT IS THE SUBJECT OF THE PROPOSED ACTION

a. Chemical Name

C_{10}-C_{12} Ethoxylated Alcohol

b. Common Names

$C_{10\text{-}12}$ Alcohol 21 Ethylene Oxide Ethoxylate (specific for this polymer)

Alcohol ethoxylates, AEs, Alkyl polyethoxylates, Alcohol polyethoxylates, Polyethoxylene alcohols, Aliphatic polyoxyethylene glycol ethers (general terminology for these types of polymers)

c. Commercial Name

See Attachment 9 for commercial name.

d. CAS Registry Number

68002-97-1

e. Empirical Formulae

$CH_3(CH_2)_9(OCH_2CH_2)_xOH$ $x = 8 - 30$ MW = 510-1478 daltons

$CH_3(CH2)_{11}(OCH_2CH_2)_yOH$ $y = 8 - 30$ MW = 538-1506 daltons

f. Properties

See Attachment 9 for properties.

6. INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

a. Introduction of Substances into the Environment as a Result of Manufacture

To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of the FCS. Therefore, information regarding the site of manufacture for the substance is not routinely required, and is not provided (FDA 2006).

b. Introduction of Substances into the Environment as a Result of Use and Disposal

For a discussion of Ecolab's projected annual production volume of the FCS, see Attachment 9.

The entire annual production volume of the FCS discussed in Attachment 9 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 substance is expected to be introduced into the environment from the use of the FCS in the manufacture of rinse-aid products.

Alcohol ethoxylates are used extensively in industrial applications and for cosmetics and toiletry products. 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 FCS will be present at a maximum "at-use" concentration of 37 ppm (0.0037%) by weight in the final rinse water from the use of rinse-aids in commercial dishwashing machines.

During the final rinse cycle, an aqueous solution of the rinse-aid is introduced in to 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.

Calculation of the expected introduction concentration (EIC) may be found in Attachment 9.

Based on the low levels of the FCS in rinse-aid products, the subsequent dilution in the rinse water, and the widespread use of related ethoxylated alcohols in the U.S. in other commercial applications, the introduction of this substance from the use of 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 THE EMITTED SUBSTANCE IN THE ENVIRONMENT

The expected environmental concentration (EEC) is the concentration of the active moiety to which organisms would be exposed in the environment after consideration of, for example, spatial or temporal concentration or depletion factors such as dilution, degradation, sorption and/or bioaccumulation (FDA 2006). 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). The EEC is calculated in Attachment 9.

Over thirty years of research has documented that alcohol ethoxylates are readily biodegradable surfactants. Numerous laboratory studies have been performed that demonstrate the biodegradation of alcohol ethoxylates in surface waters (Talmage 1994). The length of the alkyl chain does not appear to affect the biodegradation rate. There is evidence that with an increase in the moles of ethylene oxide (EO) from 1-20 moles, biodegradation rates appear unaffected, but as the moles of EO increase from 20 to 50 moles, biodegradation rates are slightly decreased (Talmage 1994; Birch 1982, 1984, 1991a, 1991b). However, in screening studies, alcohol ethoxylates with higher moles of EO also were found to be readily biodegradable (Nielsen 1986; Morris et al. 1991). For example, a linear $C_{16,18}$ alcohol with an average of 50 moles EO was shown to be readily biodegradable in the OECD 301B "Sturm" biodegradation test (Morris et al. 1991). Therefore, while no biodegradation data specific to the FCS ethoxylate *per se* are available, the large biodegradation database on linear alcohol ethoxylates (covering a wide range of alkyl chain lengths and moles of EO) suggests that it is also a readily biodegradable surfactant.

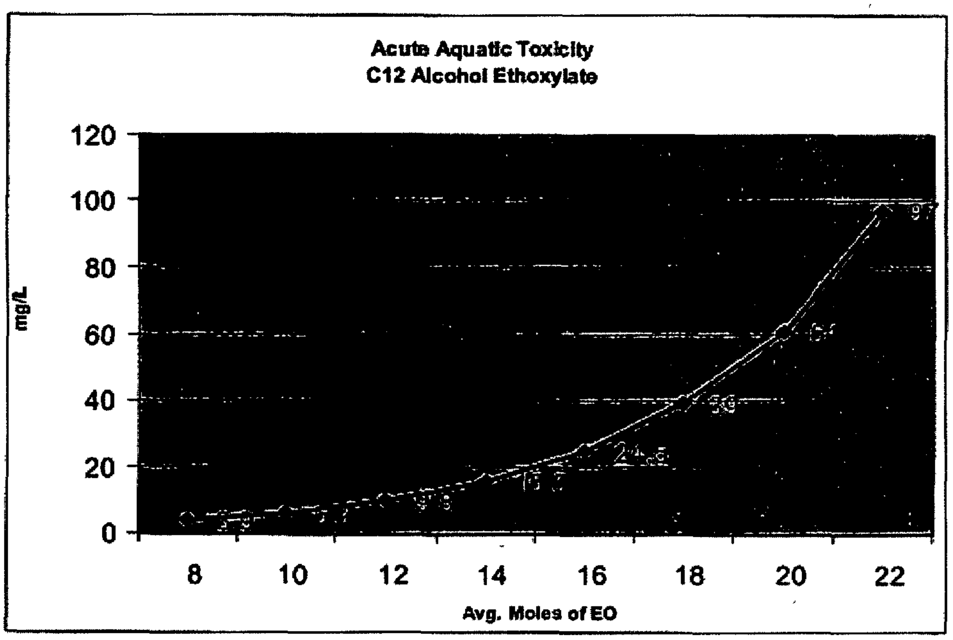
Because this substance ultimately ends up in wastewater after use, an extensive environmental monitoring study was performed to determine the extent of removal of alcohol ethoxylate during secondary wastewater treatment (McAvoy et al. 1998). McAvoy and associates monitored ten wastewater treatment plants in the US and found that the removal of alcohol ethoxylates averaged 94% and 97% during properly operating trickling filter and activated sludge wastewater treatment, respectively. These high removals were confirmed in tests that simulated secondary (biological) wastewater treatment (Talmage 1994; Nielsen 1986).

8. ENVIRONMENTAL EFFECTS OF THE RELEASED SUBSTANCE

Linear primary alcohol ethoxylates are acutely toxic to aquatic organisms (Talmage 1994), with the toxicity varying relative to alkyl chain length and number of EO units. Overall, research has established that as the number of moles of EO increases from 2-20, there is a more than 100-fold decrease in the toxicity of alcohol ethoxylates (see figure on the next page) (Talmage 1994; Wong et al. 1997). In general, linear and primary alcohol ethoxylates are more toxic than the branched or secondary structures (though the linear structures are more biodegradable in treatment plants). For linear alcohol ethoxylates, toxicity to fish and invertebrates increases as the alkyl chain length increases and decreases with increasing moles of EO (Talmage 1994). This is consistent with data from Wong et al. (1997) that shows that toxicity to fathead minnows and *Daphnia magna* decreases as the structure becomes less hydrophobic (i.e., at low alkyl or high EO chain lengths). This pattern is also confirmed by the ECOSAR model used by the US EPA.

a. Available data on ethoxylated alcohols

The range in toxicity has been discussed in the literature. Talmage (1994) provides an extensive review of the available toxicity information for alcohol ethoxylates. The LC_{50} values for fish fall into the range of 0.4 mg/L ($C_{16,18}AE_{14}$ for the brown trout) to 10 mg/l, while the range for invertebrates was 0.29-0.4 ($C_{14\text{-}15}AE_7$ for *Daphnia magna*) to 20 mg/L. For fathead minnows, 96-hour LC_{50} values ranged from 0.48 of $C_{12\text{-}15}AE_7$ to 3.6 mg/L of $C_{12\text{-}15}AE_{12}$. Most LC_{50} values were <5 mg/L. The most conservative value found in the literature was a study reported by Versteeg et al. (1997, reporting data from Masters et al. 1991), in which the EC_{50} determined for *Daphnia magna* was 0.12 mg/L for a $C_{14\text{-}15}$ EO_7 alkyl ethoxylate. The trend toward lower toxicity with greater EO chain length is best illustrated in a study by Gloxhuber and Fischer (1968, as reported in Talmage 1994) using golden orfe. The authors used products with pure alcohol content (C_{12}) but varied the EO content from 2 to 20 EO units. LC_{50} values increased from 1.9 mg/L for $C_{12}AE_2$ to 150 mg/L for $C_{12}AE_{20}$. Thus, the high EO content compounds are much less toxic than the corresponding low EO content compounds of the same alkyl chain length. For algae, the response differed in that growth was shown to decrease with increasing EO chain length (Talmage 1994, reporting data by Ernst et al. 1983).



Data from chronic toxicity studies are also summarized in Talmage and indicate that the most sensitive no observable effect concentrations (NOECs) were 0.18 mg/L and 0.24 mg/L for fathead minnow larvae and *Daphnia*, respectively, each for $C_{14\text{-}15}AE_7$. Similar to the acute toxicity trend, Wildish (1974, as reported in Talmage 1994) showed that the incipient lethal level of $C_{12}AE_4$ and $C_{12}AE_{23}$ to Altlantic salmon parr were 1.5 and 22.5 mg/L, respectively. Other data on higher EO chain lengths were not reported but would be expected to show the same decrease in toxicity with increasing EO length.

The observed decrease in toxicity with increasing EO chain length for aquatic species can best be attributed to the hydrophilicity of the molecule. Longer EO chains make the alcohol ethoxylate molecule less fat soluble, which hinders emulsification of or penetration into the gill membranes. This would explain the different algal response where growth decreased with increasing EO chain length and increased with lipophilicity. Algae may use the more lipophilic alcohol ethoxylate as a carbon source (Talmage 1994).

b. Projected acute toxicity for FCS

While the aquatic toxicity of the FCS has not been directly measured, a reasonable prediction may be made based on the available data on the acute aquatic toxicity of other ethoxylated alcohols.

For this purpose, the tested ethoxylated alcohol that is most similar to the FCS is the $C_{12}EO_{20}$. As noted above, this compound has an acute LC_{50} of 150 mg/L in golden orfe. As the FCS is a $C_{10-12}EO_{21}$ (i.e., it has a slightly lower alkyl chain distribution and slightly higher degree of ethoxylation), the LC_{50} for the FCS in golden orfe is expected to be >150 mg/L.

The data summarized above indicate that ethoxylated alcohols may be of greater toxicity to certain other species than to golden orfe. Thus, we also will consider the projected toxicity to these other organisms. Because most of the available data are for compounds with a lower degree of ethoxylation, this will involve extrapolating from the existing data to the expected toxicity for an ethoxylated alcohol with 21 moles of EO.

Projecting toxicity from lower to higher degrees of ethoxylation is supported by available same-species data for two homologous pairs of compounds that differ only in the degree of ethoxylation. As noted above, the LC_{50} of $C_{12}EO_2$ in golden orfe is 1.9 mg/L, while the LC_{50} for $C_{12}EO_{20}$ is 150 mg/L. The ratio between the LC_{50} for the EO_{20} and EO_2 homologs is 79.

The second point of direct comparison relates to $C_{12-15}EO_7$ and $C_{12-15}EO_{12}$ in fathead minnow. Specifically, the LC_{50} for $C_{12-15}EO_7$ is 0.48 mg/L, while the LC_{50} for $C_{12-15}EO_{12}$ is 3.6 mg/L. The ratio of the LC_{50}s for the EO_{12} and EO_7 homologs is 7.5. This ratio is lower than the one calculated for the first pair of homologous compounds because the C_{12-15} alcohol was tested over a narrower EO range. The LC_{50} for the FCS in fathead minnow is expected to be well above the 3.6 mg/L determined for $C_{12-15}EO_{12}$, given the higher degree of ethoxylation.

Based on the data on these two homologous series, it is reasonable to conclude that, in general, toxicity will decrease by at least one order of magnitude when the degree of ethoxylation is increased from EO_7 to EO_{21}.

The predicted toxicity of the FCS to golden orfe and fathead minnow is addressed above. Based on all of the data on ethoxylated alcohols summarized here, it appears that the most sensitive species for these compounds is Daphnia, for which the lowest LC_{50} is 0.12 mg/L, reported for $C_{14-15}EO_7$. A very conservative estimate of an LC_{50} for the FCS in Daphnia thus would be >1.2 mg/L.

Chronic aquatic toxicity can likewise be projected based on the available data on homologous compounds. The no-observable effect concentrations (NOECs) for $C_{12}AE_4$ and

$C_{12}AE_{23}$ to Altlantic salmon parr (1.5 and 22.5 mg/L) again indicate that the toxicity of the FCS will be at least one order of magnitude less than that of a low-ethoxylation counterpart. In this species, the toxicity of the FCS is expected to be very close to that of the $C_{12}AE_{23}$, or ca. 20 mg/L. Similarly, the NOEC in both Daphnea and fathead minnow larvae is projected to be at least one order higher than the NOECs for $C_{14-15}EO_7$, or ≥ 2 mg/L.

c. Toxicity of FCS in the environment

The projected aquatic toxicity values for the FCS may be compared to the expected environmental concentration (EEC) calculated in Attachment 9. The EEC is roughly three orders of magnitude lower than the lowest acute and chronic toxicity values projected above. Based on the large margin of safety, the food-contact substance is not expected to be toxic to organisms in the environment as a result of its release at the calculated levels from the use of rinse-aid products into local waterways. Therefore, we do not expect that anticipated environmental introductions resulting from the proposed action will have any adverse environmental effect.

9. USE OF RESOURCES AND ENERGY

The subject food-contact substance, C_{10}-C_{12} ethoxylated alcohol, 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. These may include, for example, a variety of surface-active agents that are either regulated under 21 C.F.R. Section 178.3400 for use as emulsifiers or surfactants for food-contact use or are generally recognized as safe (GRAS) for use in food-contact applications. The resources and energy utilization to produce, use, and dispose of rinse-aid products are not expected to be affected by this action.

10. MITIGATION MEASURES

Measures to avoid or mitigate potential adverse environmental impacts were not considered because no potential adverse effects have been identified.

11. ALTERNATIVES TO THE PROPOSED ACTION

Alternatives to the proposed action were not considered because no potential adverse effects have been identified.

12. LIST OF PREPARERS

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Holly H. Foley, Staff Scientist, Keller and Heckman LLP. Consultant in preparation of food additive petitions and food contact notifications for submission to FDA.

13. CERTIFICATION

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

[redacted]   9.22.06

Signature of Responsible Official   Date

David J. Ettinger /Partner

Name and Title of Responsible Official (Printed)

14. ATTACHMENTS

Commercial Name. . . . . Attachment 9
Properties. . . . . Attachment 9
Ecolab's Annual Product-Volume of FCS . . . . Attachment 9
Expected Introduction Concentration: . . . . Attachment 9
Expected Environmental Concentration: . . . . Attachment 9
Environmental Effects of the Released Substance: . . . . . . .Attachment 9

15. REFERENCES

Except as noted below, the following references are attached to this Environmental Assessment.

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