EN

REVISED ENVIRONMENTAL ASSESSMENT FOR *N*-(2-HYDROXYETHYL)OCTADECANAMIDE

1. **April 25, 2003**

2. **Ecolab Inc.**

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

4. **Description of the Proposed Action**

It is proposed that N-(2-hydroxyethyl)octadecanamide (SMEA) 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." SMEA is proposed for use as a processing aid in rinse-aid products at concentrations up to 3.36 ppm (10% above the maximum current "at-use" concentration of 3.05 ppm) in the final rinse water of commercial dishwashing machines.

SMEA (commercial name) is manufactured in by Degussa Goldschmidt. The site is in an industrial area southwest of downtown . This industrial site is northwest of a river and southeast of lands that are agricultural, undeveloped or contain low-density housing. The local wastewater treatment plant (POTW) is located downriver from the manufacturing site. All wastes resulting from manufacture of ends up in the plant wastewater beds and is eventually discharged to the POTW. There are no solid production wastes or airborne discharges from production of

SMEA is added to rinse-aid product at various Ecolab sites in the United States (see table on page 4). 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 SMEA, these products 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 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 SMEA 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

a. Chemical Name

N-(2-Hydroxyethyl)octadecanamide

b. Common Names

N-(2-hydroxyethyl)octadecanamide, Stearic MEA, SMEA, *N*-Stearoylethanolamine, Stearic acid monoethanolamine, *N*-(2-Hydroxyethyl)stearamine, Stearamide MEA, *N*-Stearoylethanolamide, Stearic acid monoethanolamide, *N*-(2-Hydroxyethyl)stearamide, Monoethanolamine stearic acid amide, Stearamide monoethanolamide

c. Commercial Name

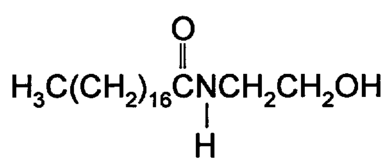
d. CAS Registry Number

111-57-9

e. Empirical Formula

$C_{20}H_{41}NO_2$

f. Structural Formula



000040

g. Properties

Molecular Weight	328
Purity	Approximately 100%
Appearance at 25 C	White to cream waxy flakes
Odor	Fishy
Water Solubility	Dispersible
pH (1% solution)	7 - 10
Specific Gravity	0.98 @ 25 C
Vapor Density	>1.0
Volatility	<1.0%
Melting Point	97-100 C
Boiling Point	>300 C
Acid Number	4.0 maximum
Amine Number	14 maximum

6. Introduction of Substances into the Environment

a. Production of the Substance

In the most recent Inventory Update Rule (IUR) under the Toxic Substances Control Act (TSCA) of the United States Environmental Protection Agency (EPA), the total recorded amount of SMEA produced in the U.S. for the 1998 reporting cycle was >1 million (1×10^6) to 10 million (1×10^7) pounds (EPA, 2002). This amount is for all industrial and commercial uses, not just for the production of rinse-aids. Based on its widespread use in industry and as a component of cosmetics, the amount of current or future production of SMEA is unlikely to be less than the minimal amount reported for 1998 (1×10^6 pounds).

is manufactured in by Degussa Goldschmidt, with total annual production confidential. Degussa Goldschmidt is responsible for all effluent, solid and airborne discharges from this facility, and this facility is currently in compliance with emissions requirements. Product loss during manufacture is 6% water and 1% monoethanolamine, which ends up in the plant wastewater beds and eventually discharged to the POTW. The General Wastewater Permit for this facility is Wastewater Notification Package No. 006. There are no solid production wastes or airborne discharges from production of

000041

Annually, approximately pounds of SMEA are used in the production of rinse-aid products. SMEA is added to these products at various Ecolab sites in the United States (see table below). 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
	NPDES No City of : Permit No. 2700
	NPDES No Local permits: No. 98-02 (facility to); No. (to state water)
	'/NPDES No. Underground Injection Control Permit
	; Water Treatment Plant Waste Water Permit Valley Storm Water Permit
	NPDES No. ;WRCB Storm Water Permit WDID # 4 19S012588 County Permit No. 14341.
	NPDES No. Sewer Discharge Permit No.
	NPDES No.
	NPDES Permit No. -

These Ecolab facilities produce at least 23 rinse-aid products, of which SMEA is only added to one product. In addition, the overall production of SMEA in the United States is at least 1×10^6 pounds. Thus, the use of SMEA in the production of this rinse aid 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 SMEA in all other industries. Only approximately of total annual production of SMEA is likely to be used in rinse-aid products.(1)

TO THE BEST OF OUR KNOWLEDGE, NO EXTRAORDINARY CIRCUMSTANCES APPLY TO THE MANUFACTURE OF THE FOOD CONTACT SUBSTANCE.

000042

1 of estimated total SMEA production is used in rinse-aid products.

b. Use and Disposal of the Food-Contact Substance

This action involves SMEA, which is a component of rinse-aid products. SMEA will be present at a maximum "at-use" concentration of 3.36 ppm (0.000336 %) by weight in the final rinse water from the use of rinse-aids in commercial 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. The principal route of environmental introduction of SMEA 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) in ppb is as follows (from FDA, 1998):

A x B x C x D, where

A =

B =

C =

D =

$$= 8.711 \times 10^{-3} \text{ ug/L/day}$$

Thus, the EIC is 8.711×10^{-3} ppb.

Based on the low levels of SMEA in rinse-aid products, the subsequent dilution in the rinse water, the total amount of SMEA produced in the US for other commercial uses, and it's widespread presence in biological systems, 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 the Emitted Substance into the Environment

No published ecological studies are available that utilize SMEA; however, biodegradation would be expected because SMEA occurs naturally in various plant and animal tissues, including fish and slime molds, and is readily hydrolyzed by N-acylethanolamine amidohydrolase (amidase) into stearic acid and ethanolamine derivatives (See FAMF 656, Volume I, Safety Information).

000043

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). As a consequence, with an EIC of 8.711×10^{-3} ppb, the EEC is estimated to be 8.711×10^{-4} ppb. Thus, the introduction of this substance from the use in rinse-aid products into local waterways does not appear to be environmentally significant.

Because many if not all aliphatic acid ethanolamines are likely hydrolyzed by N-acylethanolamine amidohydrolase and many of these compounds likely occur naturally in various plant and animal tissues, the ecotoxicity of aliphatic acid ethanolamines is likely comparable to the ecotoxicity of SMEA under similar conditions of use. Thus, aliphatic acid ethanolamines are likely hydrolyzed to their corresponding aliphatic acid and ethanolamine derivatives.

Environmental transport and distribution characteristics of stearic acid have been estimated using the EQC model (Version 1.07; Level III) (Mackay et al., 1996). The data input for this model include molecular weight, melting point, water solubility, vapor pressure, and octanol/water partition coefficient. The model was run assuming water to be the only source of emissions. The results demonstrate the strong impact of water solubility on environmental fate and that the most relevant compartments are sediment and water. Fatty acids with long alkyl chain lengths and low water solubility, such as stearic acid, have sediment as the dominant compartment. Environmental exposure would be expected to result in equilibrium with cations in the environment, suggesting that modeling results from the corresponding sodium salt may be the most appropriate data. The distribution percentages of stearic acid were 14.3% in water and 85.7% in sediment. The distribution percentages of the corresponding sodium salt were 94.7% in water and 5.3% in sediment. Whether stearic acid partitions into sediment or in water, it, as an aliphatic acid, is expected to be readily biodegradable.

Ethanolamine appears to have minimal or no adverse effects on the environment, except possibly for algal growth inhibition. Ethanolamine degrades anaerobically and aerobically with acetaldehyde as an intermediate degradation product (Knapp et al., 1996). Acetaldehyde then oxidizes to acetic acid, which enters the tricarboxylic acid cycle. Ethanolamine has a very low soil sorption tendency, based on a Quantitative Structure Activity Relationship (QSAR) analysis (Koch and Nagel, 1988). Consequently, ethanolamine is unlikely to persist in soil for any length of time. Toxicity in fish is low. In 30-to-100-day subchronic studies, no-effect concentrations in brook trout for survival and growth were 14,100 to >20,000 ug/L (Mayer et al., 1986). The 96-hour LC50 in the fathead minnow was 2,100 mg/L (Newsome et al., 1991; Newsome et al., 1993b). For comparison, diethanolamine and triethanolamine have 96-hour LC50s of 47,000 and 1,800 mg/L, respectively. In *Selenastrum capricornutum*, an undefined "substituted ethanolamine" (Nabholz, 1990; cited in Newsome et al., 1993a) had a 96-hour EC50 of 0.04 mg/L. For comparison, the 96-hour EC50 for ethylenediamine was 61 mg/L (algal data for specific ethanolamine derivatives were not included in this citation). In *Daphnia magna*, the 24-hour EC50 for ethanolamine was 140 mg/L. For comparison, the 24-hour EC50s for ethylenediamine, diethanolamine, and triethanolamine were 16 mg/L, 180 mg/L, and 1390 mg/L, respectively (Newsome et al., 1993a).

Based on the low levels of SMEA in rinse-aid products, the subsequent dilution in the rinse water, the total amount of SMEA produced in the US for other commercial uses, and it's widespread presence in biological systems, 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 have any adverse environmental effect.

8. Environmental Effects of the Released Substance

Rinse-aid products will be manufactured at various facilities around the country and their use and disposal will also be widespread throughout the country. Also, only approximately of the total US production of SMEA will be used in rinse-aid products. Consequently, the impact of SMEA from use in rinse aids on ecological systems at any one site will be minimal or nonexistent.

9. Use of Resources and Energy

Resources and energy utilization to produce or dispose of either SMEA or rinse-aid products containing SMEA are not expected to be affected by the action. Overall US production of SMEA is expected to remain essentially unchanged as a consequence of this action because the market share of SMEA that is utilized in rinse aid products is only based on 1998 production volumes.

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

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.

000045

12. List of Preparers

Susan D. Phillips, Senior Associate Scientist at ENVIRON International Corporation. M.S. in Pharmacology and Toxicology. Consultant in chemical, toxicological, and pharmacological sciences.

13. Certification

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

______________________________ April 25, 2003
Signature of Responsible Official Date

Susan D. Phillips Senior Associate Scientist
Name and Title of Responsible Official (Printed)

14. References

(Copies of these references are in FAMF No. 656)

Knapp, J.S. et al. 1996. The Anaerobic Biodegradation of Diethanolamine by a Nitrate Reducing Bacterium. Biodegradation. 7(3):183-189.

Koch, R. and M. Nagel. 1988. Quantitative Structure Activity Relationships In Soil Ecotoxicology. Sci. Total Environ. 77(2-3):269-276.

Mackay et al. 1996. Evaluating the Environmental Fate of a Variety of Types of Chemicals Using the EQC Model. Environ. Toxicol. Chem. 15(9):1627-1637.

Mayer, FL, Jr. et al. 1986. Relation Of Survival To Other End Points In Chronic Toxicity Tests With Fish. Environ. Toxicol. Chem. 5(8):737-748.

Newsome, L.D. et al. 1991. A QSAR Study of the Toxicity of Amines to the Fathead Minnow. Sci. Total Environ. 109-110:537-552.

Newsome, L.D. et al. 1993a. Quantitative Structure-Activity Predictions For Amine Toxicity To Algae and Daphnids. Gorsuch, J. W. et al. (Ed.). *Environmental Toxicology And Risk Assessment, 2nd Volume. ASTM STP No. 1216.* Gorsuch et al. (Eds.). American Society for Testing and Materials, Philadelphia, Pennsylvania. Pages 591-609.

Newsome, L.D. et al. 1993b. Validation and Upgrade of a QSAR Study of the Toxicity of Amines to Freshwater Fish. *Environmental Toxicology And Risk Assessment. ASTM STP*

No. 1179. Landis et al. (Eds.). American Society for Testing and Materials, Philadelphia, Pennsylvania. Pages 413-426.

United States Environmental Protection Agency (EPA). 2002. The 1998 TSCA Inventory Update Rule (IUR). Non-Confidential Production Volume Information Submitted by Companies for Chemicals Under the 1998 Inventory Update Rule. http:/www.epa.gov/oppt/iur/iur1998/index.htm.

United States Food and Drug Administration (FDA). 1998. Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications. CMC 6, Revision 1 (a copy is not attached and is not in FAMF No. 656).

000047