ENVIRONMENTAL ASSESSMENT

1. APRIL 11, 2007

2. 3M

3. 3M CENTER, BUILDING 230-BS-19
ST. PAUL, MN 55144, UNITED STATES

4. DESCRIPTION OF THE PROPOSED ACTION

a. Requested Action

It is proposed that amines, tallow alkyl, ethoxylated (e.g., [redacted]) 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." This substance is proposed for use as a component in repulpable tape adhesives. These repulpable tapes are used during the manufacture of food-contact paper and paperboard products. Amines, tallow alkyl, ethoxylated is intended to contact all Food Types under all Conditions of Use (as defined under 21CFR§176.170). This substance is added at a maximum level of 68% by weight to repulpable tape adhesives.

b. Need for Action

The use of the FCS as a substitute for other plasticizers in repulpable tape adhesives in food-contact paper and paperboard articles has the following desirable, intended technical effects: improvement of various desirable repulpable tape adhesive properties, such as low lamination adhesion, splice tensile, holding power, and shear.

c. Location of Use/Disposal

The adhesive, composed of the FCS and a butyl acrylate/methacrylate/acrylic acid copolymer (CAS No. 27083-50-7), will be incorporated into repulpable tapes at two 3M locations. These tapes will then be sold to paper mills and to manufacturing facilities (converters) that produce paperboard products. At these sites, the tapes are used to attach the ends of paperboard sheets (i.e., web) to cores, close the finished rolls, and splice pieces of paperboard together. Some of the paperboard products will be used as food-contact articles.

The manufacturing sites of the food-contact paper and paperboard articles are expected to be widely distributed throughout the United States. During the construction of paperboard articles, pieces of paperboard to which the repulpable tape is attached are cut off (i.e., trim). As a consequence of this step in the process, the FCS or polymer are not expected to be retained with the food-contact articles.

The facilities that recycle paperboard trim from the manufacture of paperboard articles are expected to be widely distributed throughout the United States. During the repulping process at these mills, the repulpable tape components, including the FCS, are expected to be removed from the paper pulp and remain in pulp wastewater. Prior to discharge into municipal waterways, the mills are expected to treat the wastewater in order to follow local and national wastewater discharge permits.

When food-contact articles are manufactured from paperboard containing recycled trim, these articles may contain residuals of the FCS and of the polymer. These residuals are expected to remain with these food-contact articles throughout their use. Disposal of food-contact articles containing residual FCS is expected to occur nationwide with the materials ultimately being recycled, deposited in municipal solid waste landfills, or combusted.

5. IDENTIFICATION OF THE SUBSTANCE THAT IS THE SUBJECT OF THE PROPOSED ACTION

a. Chemical Name (CAS)

Amines, tallow alkyl, ethoxylated

b. Common Name(s)

Tallow amine 15 EO

c. Commercial Name

d. CAS Registry Number

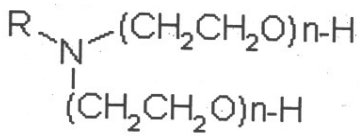
61791-26-2

e. Empirical Formula

$R\text{-}N(C_2H_4O)_xH\ (C_2H_4O)_yH$ $\quad x + y = 15 \quad$ R = Tallow alkyls

(This structure can be described as $C_{16\text{-}18}NEO_{15}$)

f. Structural Formula



g. Properties

Typical Chain Distribution for [redacted]	
Alkyl Chain Distribution for	**Percent of Product**
C_{12}	1
C_{14}	4
C_{16}	31
C_{18}	64

Typical Data for [redacted]	
Parameter	**Value**
Color	Maximum 7 Gardner
Equivalent Mass (Daltons)	869-952
Water Content	Maximum 1%
Appearance (20°C)	Liquid
Clear Point (°C)	15
Cloud Point (°C)	82
Density (g/cm^3 at 20°C)	1.03
pH (1% in water)	9-11
Viscosity (20°C)	300 mPa·s
Solubility (5% at 20°C)	
2-Propanol	Soluble
Ethanol	Soluble
Low aromatic solvent	Insoluble
Propylene glycol	Soluble
Water	Soluble
White spirit	Insoluble
Xylene	Soluble

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.

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

Both the FCS and the polymer, butyl acrylate/methacrylate/acrylic acid copolymer, are intended to be completely incorporated into the adhesive. Therefore, we expect very little, if any, of these substances to be introduced into the environment as a result of their use in the preparation of the adhesive and subsequent incorporation into repulpable tapes.

These repulpable tapes containing the FCS will be sold to paper mills and to manufacturing facilities that produce paperboard products (i.e., converters) (See schematic in Nonconfidential Attachment 1). There are at least 200 paper mills or converters in 37 states that purchase 3M repulpable tapes. At these sites, the tapes are used to attach the ends of paperboard sheets (i.e., web) to cores, close the finished rolls, and splice pieces of paperboard together. Some of the paperboard products will be used as food-contact articles.

During the manufacture of food-contact paperboard articles, repulping tapes are used to splice rolls of paper together as the paperboard web or sheets are fed into the machines used to construct these articles[(1)]. During construction, paperboard pieces to which the repulpable tape is attached are cut off (i.e., trim). These trim pieces are expected to be recovered (recycled) and reused; however, according to the EPA, only approximately 48% of pre- and postconsumer paperboard is recovered[(2)].

Prior to and at repulping facilities, the recycled trim pieces are mixed with other recycled paperboard. At the repulping facilities, these mixtures of recycled paperboard are graded. Only certain grades are used to produce paperboard that will eventually be constructed into food-contact paperboard products. During the wet end, repulping process, the recycled paperboard is mixed with virgin stock in large vats of water[(3)] in various proportions, depending upon the specifications of the final paperboard product. In fact, during the whole repulping process, 11,000 – 26,000 gallons of water are used per

(1) Kline, J.E. 1991. Paper and Paperboard Manufacturing and Converting Fundamentals. Miller Freeman Publications, Inc. San Francisco. Pages 66, 67, 74-80, 92-97 (See copy attached).

(2) EPA, 2003. *Characterization of Municipal Solid Waste in the United States: 2003 Data Tables.* This report is available at http://www.epa.gov/msw/pubs/03data.pdf.

(3) Kline, J.E. 1991. *Op cit*.

ton of paper pulp[4,5]. As the pulp is mixed, many extraneous solid materials, such as staples, and water-soluble or -miscible chemical substances, such as surfactants, are removed from the paper pulp[6]. Solid materials will sink to the bottom of the vats or float on the surface and are removed physically (e.g., skimming). When soluble or miscible substances are retained in the water, such as the FCS, a nonionic surfactant, methods of substance removal are expected to be done in order to produce water that is relatively clean for reuse or safe for discharge as papermill wastewater. Prior to discharge into municipal waterways, the mills are expected to treat the wastewater to follow local and national wastewater regulations[7].

As a consequence of the use of the FCS in the repulpable tape adhesive during the manufacture of food-contact paperboard articles, approximately 90% of the FCS is estimated to be retained in the water used in the paper repulping process because of its water solubility. Calculations to determine the final concentration of the FCS in pulp wastewater are in the table in the Confidential Attachment. Assumptions used in these calculations include:

- Disposal of the tape will follow the disposal pattern of paper and paperboard, of which only 48% is recovered (recycled) according to the EPA (2003).
- The paperboard trim containing the FCS will not be recycled at only one facility but because of widespread distribution of the repulpable tape, this trim is expected to be recycled at a number of facilities.
- Paperboard trim containing the FCS is considered only a small fraction of total recycled paperboard and will be mixed with other recycled paperboard prior to and during the repulping process (See schematic in Nonconfidential Attachment 1).
- At the repulping facilities, recycled paperboard is graded for quality and only approximately 10% of recovered containers/packaging materials is of a quality good enough for use in the manufacture of food-contact articles (Estimated from Table 4 of EPA, 2003).
- During the repulping process, recipes based on final product specifications will result in only 10-25% of recycled paperboard pulped with virgin stock for eventual manufacture into food-contact articles.
- The worst case scenario would be the minimum volume of 11,000 gallons of water used per ton of paper pulp produced[8,9].

(4) Weyerhaeuser; http://www.weyerhaeuser.com/environment/sustainability/2002/Conserving%20Resources.pdf).

(5) National Academy of Engineering, National Research Council (NAE / NRC). 1999. Industrial Environmental Performance Metrics, Challenges and Opportunities, National Academy Press, Washington, DC. At (http://books.nap.edu/openbook.php?record_id=9458&page=R1)

(6) Kline, J.E. 1991. *Op cit*.

(7) NAE / NRC. 1999. *Op cit*.

(8) Weyerhaeuser. 2002 . *Op cit*.

(9) NAE / NRC. 1999. *Op cit*.

If all trim with attached repulpable tape containing the FCS were recycled at one facility, the potential concentration of the FCS is estimated to be 8.56 ug/kg (ppb) in the untreated papermill effluent. However, it is likely that the trim will be recycled at more than one facility because of the widespread distribution of the repulpable tapes; we estimate up to 15 different facilities would recycle trim containing the FCS, based on 3M information. Consequently, the potential concentration of the FCS in the untreated effluent of any single facility is estimated to be 0.57 ug/kg (ppb) (See calculations in Confidential Attachment 1). It is likely, however, that at least some of the papermills will treat the wastewater and remove a portion of surfactants (including the FCS) in the wastewater. Thus, based on usage patterns and expected treatment of effluent, the concentration of the FCS in untreated effluent wastewater should be no more than 0.6 – 9 ppb, depending upon the number of paper repulping mills utilizing recycled paperboard containing the FCS.

The FCS is intended to compete with and replace other chemically-similar substances already in repulpable tape adhesives used during the manufacture of food-contact paperboard articles (see Format Item 9) and, upon substitution, methods of paperboard production will remain unchanged. This substance (amines, tallow alkyl, ethoxylated) is also manufactured for other commercial and industrial uses, including industrial surfactants, pesticide inert ingredients, household detergent and personal care products. Based on the TSCA substances inventory and the number of commercial products of this substance (See Nonconfidential Attachment 2), the percentage of amines, tallow alkyl, ethoxylated used in repulpable tape is only less than 2% of total production (See Confidential Attachment 1). Thus, the amount of this substance introduced into municipal waterways from its use in repulpable tapes is minor compared to potential releases into municipal waterways from the other commercial and industrial uses. As a consequence of this, the use of the FCS in repulpable tapes will not significantly alter potential levels of surfactants in municipal wastewater.

The FCS has no function in the finished food-contact paper and paperboard articles. Only approximately 10% is estimated to remain with the finished food-contact articles; however, once in the food-contact articles, essentially all of the FCS is expected to remain with these food-contact articles throughout their use.

As such, little or no additional substances are expected to be introduced into the environment from the use of the FCS in repulpable tapes used during manufacture of food-contact paper and paperboard articles, particularly when compared to other nonionic surfactants used for industrial and commercial applications.

c. Introduction of Substances into the Environment as a Result of Disposal

The FCS is intended to compete with and replace other chemically-similar substances already in repulpable tape adhesives used during the manufacture of food-contact paperboard articles (see Format Item 9). Consequently, disposal of preconsumer paperboard trim and food-contact articles containing the FCS in landfills or by combustion will not alter levels of potential leachates or emissions compared to paperboard trim or food-contact paperboard articles already disposed of in municipal waste.

Based on the estimates of potential exposures that were calculated to demonstrate the safety of this FCS and also because the EPA estimates that only 52% of paperboard is disposed of in landfill or by combustion, we expect only very low levels of substances to leach from the food-contact articles into landfills. Moreover, even if very small amounts of substances migrate from the food-contact articles into landfills, we expect only extremely low quantities to enter the environment. This finding is based on the regulations of the Environmental Protection Agency (EPA), governing municipal solid waste landfills, i.e., 40 CFR Part 258.[(10)]

With regard to combustion, the EPA reports that the amount of municipal solid waste (MSW) generated in the United States in the year 2003 was 230 million tons[(11)]. After materials recovery, the total amount of MSW disposed of in 2003 was 164 million tons, of which, 33 million tons were combusted**.** The FCS is composed of carbon, oxygen, hydrogen, and nitrogen elements commonly found in MSW. The complete combustion of the FCS will produce carbon dioxide, nitrogen, and water.

The potential market volume of the FCS is projected to be only a small percentage of total market volume for ethoxylated tallow amines (<2%), because these substances are used extensively in industry, for pesticide formulations, and in commercial household products. In addition, the FCS is intended to replace other substances in the production of repulpable tapes used during the manufacture of food-contact paperboard articles (See Format Item 9). Consequently, adding the paperboard trim from manufacture and food-contact articles containing the FCS to waste that is combusted will not alter significantly the emissions from municipal waste combustors.

Because of the low levels of combustion products compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion of paperboard trim and food-contact articles containing the FCS will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i.e., EPA's regulations in 40 CFR Parts 60 and 62[(12)] and local government air emission regulations.

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(10) GPO. Protection of Environment, Chapter I--Environmental Protection Agency:
Part 60--Standards of Performance for New Stationary Sources;
Part 62--Approval and Promulgation of State Plans for Designated Facilities and Pollutants
Part 258--Criteria for Municipal Solid Waste Landfills.

(11) EPA, 2003. *Op cit*.

(12) GPO. Title 40. *Op cit.*

7. FATE OF THE EMITTED SUBSTANCE IN THE ENVIRONMENT

No information need be provided on the fate of substances released into the environment as a result of use and disposal of food-contact articles containing the FCS in landfills and by combustion, because, as discussed under Format Item 6 above, only very small quantities, if any, of substances will be introduced into the environment by these routes. Therefore, the use and disposal of the food-contact articles containing the FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CRF Parts 60 and 258.[13]

As for release of the FCS into the environment as a result of use in paper mills and converters, this substance is a nonionic surfactant and, in general, will affect the environment similar to the effects of other nonionic surfactants. However, its estimated concentrations in untreated papermill wastewater are very low and there are likely other surfactants present in the papermill effluent, thus, potential adverse environmental fate effects are expected to be minimal.

These nonionic surfactants, alkylamine ethoxylates (AAEs), have not been well studied for environmental fate; however, one review article[14] was found from a literature search and another older document[15] was reviewed for information concerning the chemically-related alkyl ethoxylate (AEs) surfactants. Most of the information presented in these documents concerned the AEs; however, there is some information on AAEs and comparisons to AEs can be made. Many of the physical properties are comparable between AAEs and AE; however, Krogh and associates (2003) state that because AAEs have two ethoxy chains, rather than the one of the AEs, the polar bonds of the AAEs are likely stronger than those of the AEs. In addition, there were environmental fate data presented in the AKZO NOBEL Material Safety Data Sheet (MSDS) (A copy is in Nonconfidential Attachment 3).

Based on the two published documents, the major environmental fate problem for AEs and AAEs is enhancement of the mobility of other substances in the environment (as with other surfactants). Mobility of other substances, such as pesticides, is increased with increased aqueous concentrations of the surfactant and/or increased hydrophobicity of the surfactant molecule (i.e., increased alkyl chain length).

Both AEs and AAEs adsorb to soil (as do other surfactants); however, studies with AEs indicate that both adsorption and desorption processes are rapid and reversible [16,17]. The adsorption and desorption processes for AAEs are also likely reversible but because of the nitrogen atom present in the molecule, the rate may be slower than for AEs, depending upon the

(13) GPO. Title 40. *Op cit.*

(14) Krogh, K.A., B. Halling-Sorensen, B.B. Mogensen, and K.V. Vejrup. 2003. Environmental properties and effects on nonionic surfactant adjuvants in pesticides: a review. *Chemosphere* 50:871-901 (See copy attached).

(15) Arthur D. Little, Inc. 1981 Human Safety and Environmental Aspects of Major Surfactants. NTIS, Springfield, VA 22161. Excerpts from Chapter 3 (Alcohol Ethoxylates) (See copy attached).

(16) Krogh *et al*. 2003. *Op cit.*

(17) Arthur D. Little, Inc. 1981. *Op cit.*

pH of the environment. The only log Critical Micelle Concentration (CMC) value (0.002 g/L) was for a related AAE, $C_{18}NEO_{20}$ (the structure of the FCS can be described as $C_{16\text{-}18}NEO_{15}$). CMC values decrease with increasing alkyl chain length and with decreasing ethoxy chain length. The FCS has an alkyl chain length of approximately 18 (as a tallow) and an ethoxy chain length of 15 (See Section 5), thus the CMC value is likely less than the value reported in the Krogh and associates (2003) article. When surfactant concentrations are below the CMC, binding to soil matrices is decreased.

AAEs are rapidly biodegraded via a "two-phase" route. Initially there is a rapid removal of the alkyl side chain from the nitrogen bound to the two ethoxylate side chains and then there is further degradation of these two intermediates to carbon dioxide, ammonia, water and biomass[(18)]. Information presented in the AKZO NOBEL MSDS verified that the FCS is "inherently biodegradable, with a <70% DOC, 28 days, as tested under OECD Guideline 301E.

In conclusion, there are numerous factors indicating that the FCS, under the proposed conditions of use, will not significantly impact the aquatic environment from its presence in untreated papermill wastewater. These factors include the very low (0.6 – 9 ppb) aqueous concentration of the FCS in the effluent and its rapid and thorough biodegradation. In addition, the FCS will be substituted for other chemically-similar substances and there will be other surfactants in the untreated papermill wastewater. Consequently, under the proposed conditions of use, the FCS is not expected to significantly impact the environment in and around waterways into which it was introduced and threaten a violation of applicable laws and regulations.

8. ENVIRONMENTAL EFFECTS OF THE RELEASED SUBSTANCE

No information need be provided on the environmental effects of substances released into the environment as a result of the use and disposal of food-contact articles containing the FCS in landfills and by combustion, because, as discussed under Format Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment. Therefore, the use and disposal of the food-contact articles containing the FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR Parts 60 and 258.[(19)]

As for release of the FCS into the environment as a result of use in paper mills and converters, this substance is a nonionic surfactant and, in general, will affect the biota of the environment similar to the effects of other nonionic surfactants. AAEs have not been well studied for toxicity to aquatic organisms, however, one review article[(20)] was found from a literature search and another older document[(21)] was reviewed for information concerning the related AE

(18) Krogh *et al*. 2003. *Op cit.*
(19) GPO. Title 40. *Op cit.*
(20) Krogh *et al*. 2003. *Op cit.*
(21) Arthur D. Little, Inc. 1981. *Op cit.*

surfactants. In addition, there were ecotoxicity data presented in the AKZO NOBEL Material Safety Data Sheet (MSDS) (A copy is in Nonconfidential Attachment 3).

There were at least two acute aquatic toxicity studies presented in the Krogh *et al*. (2003) document. These studies were conducted with an AAE having a comparable structure to that of the FCS. An acute toxicity study (following OECD Guideline 201) was conducted in the green algae, *Selenastrum capricornutum*, utilizing $C_{14\text{-}18}NEO_{15}$ as the test substance (See Table 6 of the article); the resultant EC_{50} was 4.1-4.9 mg/L. This value is comparable to or larger than values derived from testing the same species with AEs under similar conditions. Acute studies in salmon (*Salmo salar*) were mentioned in the body of the text but were not included in Table 6 of the article. Of these studies, the only one that tested an AAE comparable in size to the FCS resulted in a LC_{50} of 5-10 mg/L; the formula for this AAE was $C_xNOE_{12\text{-}25}$. Other LC_{50} values in salmon were 0.09 – 0.78 mg/L, however, the formulae for these studies were either not given or smaller than the FCS (C_xNEO_2). In general, the shorter the ethoxy chain length the more toxic the substance and when the alkyl chain length is greater than 12 carbons (or less than 10), toxicity to aquatic organisms is decreased[(22)]. Thus, the FCS, with a long alkyl chain length (16-18) and ethoxy chain length of 15, is likely to be comparable to or less toxic than many of the AEs examined in the Krogh *et al.* (2003) article. Data presented in the AKZO NOBEL MSDS verified that the FCS is toxic to aquatic organisms, with a 96-hour LC_{50} of 1.3 mg/L in *Oncorhynchus mykiss* (rainbow trout), a 48-hour EC_{50} of 1.7 mg/L in *Daphnia magnus*, and a 4-hour EC_{50} of 180 ppm in nitrifying bacteria.

In conclusion, the FCS, as a nonionic surfactant, has the potential to negatively affect aquatic organisms in a comparable manner to other nonionic surfactants; however, because the estimated concentration of the FCS in the untreated papermill wastewater is very low (0.6 – 9 ppb), the FCS is not expected to significantly adversely affect aquatic organisms present in the environment in and around waterways into which the FCS will be introduced.

9. USE OF RESOURCES AND ENERGY

Resources and energy utilization to produce or dispose of the FCS or food-contact articles containing the FCS are not expected to be affected by the action. Overall US production of repulpable tapes used during manufacture of food-contact articles is expected to remain essentially unchanged as a consequence of this action because the FCS is intended to compete with and replace other substances already in repulpable tapes used during the manufacture of food-contact articles. Consequently, there is essentially no effect on the use of natural resources and energy.

(22) Krogh *et al*. 2003. *Op cit.*

10. MITIGATION MEASURES

Mitigation measures for the proposed action need not be considered because no potentially adverse effects have been identified.

11. ALTERNATIVES TO THE PROPOSED ACTION

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

12. LIST OF PREPARERS

Susan D. Phillips, Manager at ENVIRON International Corporation. She has a M.S. in Pharmacology and Toxicology and is a 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 3M.

_____ _____

Signature of Responsible Official Date

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Name and Title of Responsible Official (Printed)

14. REFERENCES

Complete citations for all information referenced in the EA are in footnotes within the EA. There are no copies of the regulatory citations either attached or in **FAMF No. 768** because they are readily available on the internet**.** Of the published references cited, t three are not readily available on the internet and copies of these are in Nonconfidential Attachment No. 3.

One document cited in the EA concerning manufacturers of amines, tallow alkyl, ethoxylated is in Nonconfidential Attachment No. 2.

15. ATTACHMENTS

Four attachments are present, Three non-confidential and one confidential.

NONCONFIDENTIAL ATTACHMENT 1

Use and Fate of Repulpable Tape (Schematic)