Environmental Assessment

for Use of
for use as a Bleaching Agent
in the
Manufacture of Paper and Paperboard
Food Contact Materials

Environmental Assessment, 21 CFR § 25.35

Petitioner

Warwick International Limited
Mostyn, Holywell, Flintshire CH8 9HE
United Kingdom

Prepared by

Jim T. Hill, Ph.D.

January 22, 2001

000030

Environmental Assessment for Use of for use as a Bleaching Agent in the Manufacture of Paper and Paperboard Food Contact Materials

1. Date: January 22, 2001

2. Name of notifier: Warwick International Limited

3. Address: Mostyn, Holywell, Flintshire
CH8 9HE, United Kingdom

4. Description of the proposed action:

a. Requested action:
Approve the use of as a bleaching agent/aid in the manufacture of paper and paperboard that may come in contact with food.

Identity of :
, the food contact substance, is Warwick International, Ltd.'s trade name for a granular formulation of tetraacetylethylenediamine [TAED, CAS No.: 10543-57-4] which, when added to water in the presence of a peroxide source (such as hydrogen peroxide), generates peracetic acid that is used to bleach the pulp in the manufacture of food contact paper and paperboard, both coated and uncoated. The composition of is as shown below:

Ingredient	**% in PeroxyBoost™ Formulation**
TAED	

When is used in a pulp and paper mill for bleaching, it is added to a peracetic acid generating system in which it is reacts with hydrogen peroxide, in the presence sodium hydroxide (caustic soda) and a chelant (such as DTPA [CAS No.: 140-01-2] or DTPMPA [CAS NO.: 22042-96-2]) in the presence of water. The peracetic acid generating system uses the following percentages of ingredients:

	1.50%	(15 g/L) (Maximum)
Hydrogen peroxide	1.10%	(11 g/L)
NaOH	0.25%	(2.5 g/L)
Chelant	0.08%	(0.8 g/L)

In the generation of peracetic acid, in this system, the end products are 1 mole of diacetyl ethylenediamine (DAED) and 2 moles of peracetic acid per mole of TAED. Only DAED has a potential dietary residue resulting from the use of

000031

b. Need for action:

The technical effect of is a bleaching agent for pulp in paper mills, used in the manufacture of food contact paper and paperboard products. (TAED) is neither a bleach nor bioactive material in the absence of an oxygen donor, peroxide. TAED is the precursor of peracetic acid (peroxyacetic acid), a paper pulp bleach, which is approved for use by the Agency in manufacture of food contact paper and paperboard products. Neither TAED nor peracetic acid is present in the finished paper products. TAED is complete converted to Diacetyl ethylenediamine (DAED) while peracetic breaks down to oxygen (the bleach) and acetic acid a normal biodegradation product of carbon based foods. Acetic acid is an energy source for many microorganisms.

c. Location of use/disposal:

is presently approved for use in Europe as a bleaching aid (as a component of a peracetic acid generation system) in the manufacture of paper and paperboard products. The manufacturing process for paper and paperboard is the same in Europe, the United States and Canada. Paper and paperboard are made from pulp by the general process shown in Figure I. In this process, the pulp from wood is bleached and made into a stock preparation, which is used to produce the finished paper products.

is usually introduced into the slurry, via the peracetic generation system at the bleaching tower or head box. Alternate locations of addition are the stuff box and the machine chest. In all cases peracetic acid is generated prior to addition to the pulp slurry. Peracetic acid is generated in a closed system consisting of measured additions of the solid (granular powder) and liquid hydrogen peroxide with the chelant and caustic. The pH of the peracetic acid is maintained by the addition of sodium hydroxide and chelant is added to aid in the removal of staining metals (iron) from the pulp. The solid is added directly from a dispensing sack to water (measured volume) in a reaction vessel and stirred with the addition liquid hydrogen peroxide, caustic & chelant. The retention time in the delivery/reaction pipe is set to allow complete hydrolysis of the TAED and the generation of the peracetic acid.

The reaction products DAED and peracetic are both highly water soluble and are expected to be washed from the pulp in its processing or in the case of peracetic acid degraded to release oxygen and acetic acid. The oxygen from this reaction is completely used in the bleaching process.

No measurable quantities of either DAED or peracetic acid are found in the finished paper thus landfill or incineration of the paper are not considered a disposal method. Only DAED will be found in the white water (process water) as the peracetic acid is completely use and only acetic acid remains. Acetic acid a normal biodegradation product of carbon based foods. Acetic acid is also an energy source for many microorganisms.

000032

DAED will be released into the plant wastewaters. All paper mill wastewaters must be treated before release to either public wastewater treatment plants or surface waters, by permit. The waste treatment includes primary and secondary treatment as required

by local or state regulations. In all releases there is no expected environmental affects based on the ready biodegradation and low environmental toxicity of DAED.
TAED and/or DAED are water-soluble, are readily biodegraded, are non-adsorptive, have low toxicity, and have no demonstrated biological activity. Even if these materials were present in the treated wastewaters the receiving water and the environment will not be adversely affected.

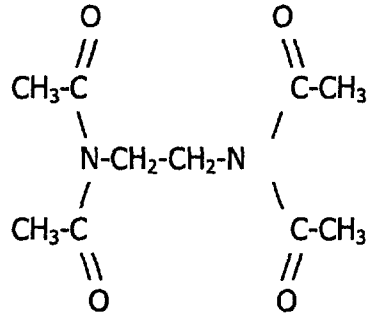
There are about 600 pulp and paper mills in the United States. The use of this bleaching system should not be limited or concentrated to a geographic or local area. A partial list of these mills is in Table I.

5. Identification of PeroxyBoost™:

a. Major Component TAED

Tetra-Acetyl Ethylene Diamine (TAED) is a novel chemistry, which provides for simple *in situ* generation of peracetic acid for use as a bleaching agent. This eliminates the need to stabilize and transport peracetic acid itself. TAED is stable as a dry solid. It is stable in aqueous solution unless a peroxide source is present. In this latter case TAED rapidly converts to peracetic acid (PAA: 2 moles per mole of TAED) and the byproduct Di-Acetyl Ethylene Diamine (DAED: 1 mole per mole TAED) that is itself then reasonably stable but is readily biodegradable. The relevant chemistries are shown below.

Structure of TAED and CAS Registry Number



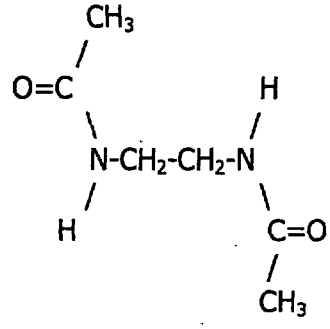
TAED (CAS 10543-57-4)

- Molecular Formula: $C_{10}H_{16}N_2O_4$
- Molecular Weight: 228

000033

In solution, in the presence of a peroxygen source (such as hydrogen peroxide) attack by peroxide is very rapid and releases two moles of peracetic acid and one mole of Diacetyl ethylenediamine.

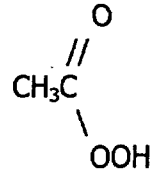
Structure of DAED and CAS Registry Number



DAED [CAS No. 871-78-3]

- Molecular Formula: **$C_8H_{12}N_2O_2$**
- Molecular Weight: 144

Structure of Peracetic Acid and CAS Registry Number



PAA [CAS No. 64057-57-4]

- Molecular Formula: **$C_2H_4O_3$**
- Molecular Weight: 98

Physical/Chemical Characteristic of PeroxyBoost™ (80% TAED)

Color

- TAED 80% is white to cream colored.

000034

Physical State

- The product is a granular solid at room temperature (25'C).

Odor

- The product has no discernible odor.

Melting Point

- $147^0C + 1^0C$ (TAED)

Boiling Point

- (TAED) Not applicable to this substance because it is a solid at room temperature

Density, Bulk Density, or Specific Gravity

- The bulk density at 20^0C is 430 – 530 g/L.

Solubility

- (TAED) 2g/100 ml (20^0C)

Vapor Pressure

- (TAED) The vapor pressure is estimated to be negligible since the product is a solid with a relatively large molecular weight (228) and will have strong internal colligative properties due to the orbital interactions between the amide nitrogens and the carbonyl carbons of adjacent molecules.

Disassociation Constant

- (TAED) Not applicable because TAED has no disassociable groups.

Octanol/Water Partition Coefficient

- (TAED) has a log $P_{o/w}$ of –0.06 or a $P_{o/w}$ of 0.876

pH

- This product, when dissolved in water, will not significantly alter the pH from that of the dissolving water because: (a) TAED has no ionizable groups and no groups which act as either Lewis or Brönsted acids or bases; and, (b) because the inerts in the 80% TAED have no ionizable groups and no groups which act as either strong Lewis or Brönsted acids or bases.

Stability

000035

- (TAED) is considered stable under the conditions tested (room temperature and 54^0C)

Oxidizing or Reducing Action

- The product has no significant oxidizing or reducing potential because there are no significantly reactive oxidizable / reducible groups in the compound or in the inerts.

Flammability

- Not applicable because the product contains no combustible liquids.

Explodability

- Not applicable because the product is not potentially explosive.

Storage Stability

- TAED 80% is expected to be stable for at least one year stored away from sunlight and at ambient temperature storage conditions. This is based on the absence of reactive or unstable groups in the TAED itself, on the result from an accelerated storage study at elevated temperature conducted with TAED, and on the known stability characteristics of the inerts in the products.

Viscosity

- Not applicable because this product is a solid at room temperature and other typical environmental conditions.

Miscibility (Guideline

- Not applicable because the product is not an emulsifiable liquid which is to be diluted with petroleum solvents.

Corrosion Characteristics

- TAED 80% is not expected to exhibit any significant corrosion potential. This is based on the absence of reactive or unstable groups in the TAED itself, on the result from metal stability tests at elevated temperature conducted with TAED, on the result from a corrosion potential test at elevated temperature conducted with TAED, and on the known characteristics of the inerts in the products.

Dielectric Breakdown Voltage

- Not applicable because the product is a solid and is not intended to be used around electrical equipment

b. Composition of [redacted]

List below all reagents, monomers, solvents, catalyst systems, purification aids, etc., used to manufacture the FCS, their chemical names, CAS Registry Numbers, impurities in each, the typical composition range of each in the total reaction mixture, and the maximum residual of each in the FCA intended to be marketed.

Chemical Name	CAS Reg. No.	Major Impurities	Typical Maximum Composition	Residual
(1)	(2)	(3)	(4)	(5)
Tetra acetyl ethylene Diamine (TAED)	10543-57-4	No Major Impurities		

c. Peracetic acid generation system

When [redacted] is used in a pulp and paper mill for bleaching, it is added to a peracetic acid generating system in which it is reacted with hydrogen peroxide, sodium hydroxide (caustic soda), and a chelant (such as DTPA [CAS #140-01-2] or DTPMPA [CAS #22042-96-2]) in the presence of water. The peracetic acid generating system uses the following percentages of these ingredients:

	1.50%	(15 g/L) (Maximum)
Hydrogen peroxide	1.10%	(11 g/L)
NaOH	0.25%	(2.5 g/L)
Chelant	0.08%	(0.8 g/L)

In generation of peracetic acid in this system, the end products of TAED are 1 mole of diacetyl ethylenediamine (DAED) and 2 moles of peracetic acid per mole of TAED. It is DAED, which has the potential for environmental residues resulting from the use of PeroxyBoost™.

000037

6. Introduction of substances into the environment:

a. Introduction into the environment as a result of manufacture
Warwick International Ltd. manufactures TAED and formulates in the United Kingdom under all applicable environmental laws and rules for the prevention of its introduction into the environment. There are no extraordinary circumstances that apply to the manufacture of that would cause an environmental risk.

b. Introduction into the environment as a result of use/disposal
There is no environmental release of the major component, (80% TAED) when used as a bleaching agent in food contact paper and paperboard products. This material is completely degraded to DAED and peracetic acid ($T_{½}$ = 1 sec). The immediate degradation product, DAED, is not introduced in to the environment as it is rapidly biodegraded by the biomass of either an in-plant waste treatment facility or by a public waste treatment plant.

- TAED is rapidly hydrolyzed to 1 mole DAED and 2 mole peracetic acid with the half-life of less that 1-second in the presence of an excess of hydrogen peroxide. (Confidential Appendix 1, pg 6)
- TAED and TAED are rapidly biodegraded by the secondary sewage effluent and is considered to be readily biodegradable under the OECD screening test. As reported in Proprietary Appendix 8 approximately 80% of both substances were removed by secondary sewage effluent by termination of the test. Both of these materials are mineralized. Both compounds are biodegraded by the same pathway to nitrogen compounds (ammonium, nitrate) and small carbon compounds that are incorporated into the biomass of the organisms.

At the termination of the pulp bleaching the pulp is washed, concentrated and machined to finished paper products. The white water, process water, bleaching solution and the wash waters are combined as wastewater continuous release only to a treatment facility (in-plant or public). In a "standard" pulp mill the wastewater out flow usually exceeds 6.67 million gallons per day based on US EPA's calculation of ~ 4 billion gallons water daily use and ~ 600 paper mills, with an average of 1000 tons paper per day paper/pulp mill. The estimated concentration of (as DAED) in the wastewater for normal use is ~ 40 ppb or ~ 100 ppb maximum use.

These figures are based on the following assumptions:

- 6.67 million gallons/day/mill water use (2.52×10^7 liters)
- Average paper mill output is 1000 tons/day [dry weight]
- 2 Kg/ton normal use of
- 5 Kg/ton maximum use
- TAED is 80% of
- All TAED is converted to DAED
- Conversion Factor for TAED to DAED is 0.63 (144/228)
- No loss of DAED by hydrolysis in the wastewater
- Conservative estimate of 100% of the hydrolysis products enter the wastewater
- The other materials in are either natural products (sodium acetate and do not significantly increase/modify the environmental levels or are in such small quantities that they have no effect on the total concentration

000038

Calculations

"Normal" use
2×10^6 mg/day (80% TAED) = 1.6×10^6 mg/day TAED used
1.6×10^6 mg/day x 0.63 (TAED ⇒ DAED) = 1.0×10^6 mg/day DAED formed

Weight used/volume of waste water = concentration (ppb)
1.0×10^6 mg/day DAED/2.52×10^7 liters/day water = 4.0×10^{-2} mg/l = 40 ppb

"Maximum" use
5×10^6 mg/day (80% TAED) = 4.0×10^6 mg/day TAED used
4.0×10^6 mg/day x 0.63 (TAED ⇒ TAED) = 2.5×10^6 mg/day DAED used

2.5×10^6 mg/day DAED/2.5×10^7 liters/day water = 1.0×10^{-1} mg/l = 100 ppb

No will enter the air (emissions) as both TAED and DAED are essentially non-volatile. No will enter the environment via solid waste, including sewage sludge, as and its degradation products are readily biodegradable and do not bind to the waste solids as indicated above.

Market volumes and percentage are considered Confidential Business Information and have been removed to a Confidential Section (Confidential Appendix 15) of this Document.

The low mammalian toxicity of loes not require any unusual worker personal protection devices. A MSDS fo provided elsewhere in this petition, is attached to the Environmental Assessment.

A summary of the mammalian toxicity follows in Section 8.

7. Fate of substances release into the environment

Based on the data showing that and its hydrolysis products are readily biodegradable. The product label instructs the waste streams must be treated (in plant or public facilities) before release to environmental waters. will not be released to the environment. This material is rapidly degraded by environmental bacterial and by the biomass of the sewage treatment facilities. TAED/DAED has been shown to easily biodegrade, aerobic and anaerobic metabolism has been demonstrated at levels as high as 20 ppm (Proprietary Appendix 12).

The reaction products DAED and peracetic are both highly water soluble and are expected to be washed from the pulp in its processing or in the case of peracetic acid degraded to release oxygen and acetic acid. The oxygen from this reaction is completely used in the bleaching process.

No measurable quantities of either DAED or peracetic acid are found in the finished paper thus landfill or incineration of the paper are not considered a disposal method. Only DAED will be found in the white water (process water) as the peracetic acid is completely degraded only

acetic acid remains. Acetic acid a normal biodegradation product of carbon based foods. Acetic acid is also an energy source for many microorganisms.

is not expected to bioconcentrate as the Octanol/Water partition = $P_{o/w}$ of 0.876.

There is no environmental release of the major component, (80% TAED) when used as a bleaching agent in food contact paper and paperboard products. This material is completely degraded to DAED and peracetic acid ($T_{½}$ = 1 sec). The immediate degradation product, DAED, is not introduced in to the environment as it is rapidly biodegraded by the biomass of either an in-plant waste treatment facility or by a public waste treatment plant.

TAED is rapidly hydrolyzed to 1 mole DAED and 2 mole peracetic acid with the half-life of less that 1-second in the presence of an excess of hydrogen peroxide.

TAED and DAED are rapidly biodegraded by the secondary sewage effluent and is considered to be readily biodegradable under the OECD screening test. Approximately 80% of both substances were removed by secondary sewage effluent by termination of the test. Both of these materials are mineralized. Both compounds are biodegraded by the same pathway to nitrogen compounds (ammonium, nitrate) and small carbon compounds that are incorporated into the biomass of the organisms.

At the termination of the pulp bleaching the pulp is washed, concentrated and machined to finished paper products. The white water, process water, bleaching solution and the wash waters are combined as wastewater continuous release only to a treatment facility (in-plant or public). In a "standard" pulp mill the wastewater out flow usually exceeds 6.67 million gallons per day based on US EPA's calculation of ~ 4 billion gallons water daily use and ~ 600 paper mills, with an average of 1000 tons paper per day paper/pulp mill. The estimated concentration of PeroxyBoost™ (as DAED) in the wastewater for normal use is ~ 40 ppb or ~ 100 ppb maximum use.

No will enter the air (emissions), as both TAED and DAED are essentially non-volatile. No will enter the environment via solid waste, including sewage sludge, as and its degradation products are readily biodegradable and do not bind to the waste solids as indicated above.

Warwick International Ltd. manufactures TAED and formulates in the United Kingdom under all applicable environmental laws and rules for the prevention of its introduction into the environment. There are no extraordinary circumstances that apply to the manufacture of that would cause an environmental release.

8. Environmental effect of released substances

TAED and DAED are not expected to have any adverse environmental effects based on their low aquatic, avian, and mammalian toxicity. In an **implausible worst-case scenario**, the levels of DAED entering the directly from the waste steam with a minimal dilution of 10x would cause no measurable adverse impact attributed to PeroxyBoost™.

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TAED and DAED have a remarkable low toxicity values for aquatic organisms. Depending on species, the no effect levels were 2,000 to 25,000 time higher than the calculated maximum concentrations in the waste stream and 20,000 to 250,000 that level with minimal dilution. The aquatic toxicity is summarized in Table 2 (summary from Proprietary Appendix 2 & 12).

Acute avian toxicity is minimal; the Bobwhite Quail LD50 is greater than 2,000 mg/Kg and the NOEL of less than 2,000 (early weight loss, recovered in 14 days). Similar values were reported for the Mallard (duck). Details of the Quail study are in Proprietary Appendix 14. Thus, the safety factor is greater that 20,000 for the estimated LC_{50}.

Mammalian toxicity values are low with NOEL values 25 mg/Kg/day for oral administration to 5,700 mg/Kg/day dermal exposures. These studies are summarized in Table 3, and below:

Mutagenicity

TAED was found to be non-mutgenic with and without metabolic activation in the categories of mutations in bacteria (Salmonella) in the literature and in sponsored studies, and DNA damage/ chromosome aberrations in the *in vitro* Sister Chromatid Exchange assay (CHO V9 cells) tested with and without metabolic activation. (See Comprehensive Toxicology Profile (CTP) Appendix 11, and Proprietary Appendix 2, pg 33, for details).

DAED, the breakdown product, was found to be non-mutagenic with and without metabolic activation in the categories of mutations in bacteria (Salmonella) as reported in the literature. (See CTP, Appendix 11, for details).

Acute Toxicity

TAED was tested for acute toxicity, Oral LD_{50} (rat), acute dermal (rabbit), acute eye irritation (rabbit), and skin sensitization (guinea pig) assays. The LD_{50} was 7.94 (6.46-9.77); The acute dermal showed mild irritation; the acute eye results were non-irritant; and the skin sensitization assay showed TAED to be 0% sensitization and a weak grade 1 sensitizer. (See CTP, Appendix 11, and Appendixes 3 & 4, for details)

The sponsor in an acute oral limit test in the rat tested DAED. No deaths were reported at the 2g/kg dose level. A literature report on sensitization in the guinea pig reported DAED as a non-sensitizer. (See CTP, Appendix 11, for details)

Short Term Toxicity (7-28 days): None

Subchronic Toxicity

a. 90-Day Oral Toxicity of TAED in Rats*

On the basis of this study, tetraacetyl ethylenediamine (TAED) when administered to Sprague-Dawley rats orally for 13 weeks at dose levels of 25, 500, and 1000 mg/kg/day, resulted in a NOEL of 25 mg/kg in males and females based on microscopic changes in the liver.

000041

b. 13- Week feeding study of TAED in the Rat*

In a study reported in the literature, rats (species and number of animals not reported) were fed TAED per day for 13 weeks. A no effect level (NOEL) of 25 mg/kg body weight per day was reported.

The NOELs established in the above-summarized GLP study (25 mg/kg/day) is consistent with that reported in the above literature reported study (also 25 mg/kg/day) for TAED. The same literature report also provides a NOEL for the TAED in-use breakdown product, DAED, as 5,700 mg/kg/day in a rat 90-day study

b. 90-Day Dermal Toxicity of TAED in Rats*

This study was designed to determine the toxicity of tetraacetyl ethylenediamine (TAED) when delivered by dermal application once daily for six hours to the skin of Sprague Dawley rats for 90-days. The only treatment-related finding was found at the high-dose, 2000 mg/kg/day, which was minimal hepatic centrilobular hypertrophy (cytomegaly) in 8/10 and 4/10, males and females, respectively. Minimal centrilobular hypertrophy was not noted in the lower dosed rats that died on study or had gross lesions associated with the liver.

Based on the effects in this study, the no-effect-level (NOEL) for tetraacetyl ethylenediamine (TAED) when administered to Sprague-Dawley rats dermally for 6 hours/day for 90 days would be equal to or greater than 200 mg/kg/day.

Reproductive and Developmental Toxicity Studies

Prenatal Developmental Toxicity of TAED in Rats was tested. TAED was given by the oral route to pregnant Crl: CD (SD) BR rats during the organogenesis period (from day 6 to day 15 of pregnancy), with the day of positive vaginal smear considered as day 0 of gestation

No clinical signs, behavioral changes, death or abortion were noted in the dams of any group. A dose-related lower mean body weight gain and mean daily food consumption was observed in the dams at the higher doses. No embryotoxic effects were found in any group. The mean fetal weight and the mean placental weight were lower in the high dose group. There were no dose-related malformations or changes in the frequency of malformed fetuses.

Based on the above findings and considerations, it may be concluded that the NOEL for dams was 40 mg/kg/day and for fetuses 200 mg/kg/day (i.e., the highest dose tested). TAED was found; therefore, not to produce developmental effects at doses which did produce weight decreases in the maternal animals. The effects used to establish these NOELs are not considered to be severe in determining an ADI.

Chronic Toxicity: None

Carcinogenicity: None

Based on the review of the minimal environmental impact of its use as a bleaching agent will not present any unique emissions circumstances that would violated any environmental law or regulation to control the introduction of this material into the environment.

9. Use of resources and energy

use as a bleaching agent as proposed will reduce the amount of chlorine (as chlorine gas, chlorine dioxide, hypochlorite) presently used in the bleaching of paper pulp. However, is not expected to completely replace chlorine in most uses. The amount of chlorine replaced by is dependent on several economic factors including the relatively low cost of the chlorine bleaches. is expected to cause no significant effect on the use of natural resources when compared to the present bleaches. However, TAED (peracetic acid generator) does significantly reduce the adverse environmental impact of halogen compounds.

10. Mitigation measures

No adverse environmental effects have been identified with the use of as a bleaching agent. Therefore, no mitigation measures have been proposed.

11. Alternative to the proposed action

No adverse environmental impacts have been identified with the use of as a bleaching agent. Therefore, no alternatives to the proposed action have been proposed.

12. List of preparers

John A. Todhunter, Ph.D. (Toxicology), DABT, BCFE, FAIC, RAC
President, SRS International Corporation
Michael G. Farrow, Ph.D. (Genetics), RAC
Vice President, Health Care Group
Jim T. Hill, Ph.D. (Biochemistry)
Vice President, Specialty Chemicals Group

13. Certification

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Warwick International Ltd."

9/2/01
Date

Jim T. Hill, Ph.D.
Notification Agent
Warwick International, Ltd.

000043

14. References:

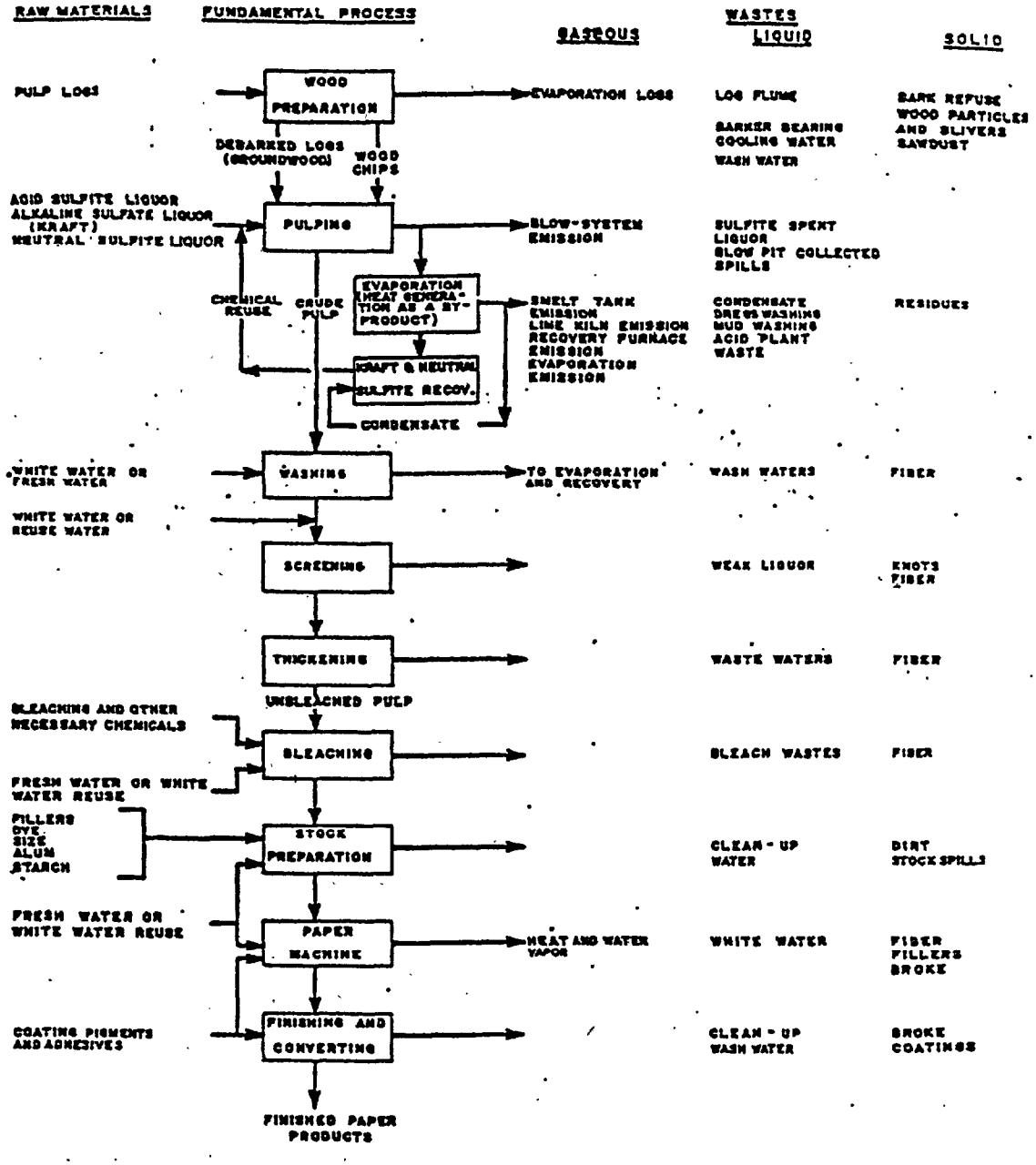
Gilbert, P.A. (1992) in "TAED", in *The Handbook of Environmental Chemistry,* Vol. 3, Part F, Ed. 0. Huntziznger, Springer-Verlag, Berlin & Heidelberg (Appendix #2, pg. 33 ff)

EPA Survey of Paper Mills - *Development Document for Effluent Limitations Guidelines and Standards for the Pulp, Paper and Paperboard and Builders' Paper and Board Mills. Point source Categories*, EPA 440/1-82/025, Environmental Protection Agency, October 1982. pp 77-82.

Proprietary/Confidential Appendixes

1. Confidential Data for Identity, Use, Exposure, Reagents, Manufacturing Process, Impurities, and Physical Properties.	1-19
2. Mutagenesis (Salmonella)	1-39
3. Acute Toxicity Battery	1-59
4. Acute Dermal Toxicity	1- 5
5. 90-Day Oral Toxicity	1-342
6. 90-Day Dermal Toxicity	1-148
7. Prenatal Development	1-198
8. Biodegradation Studies	1-127
9. Human Dietary Exposure	1-7
10. Efficacy Data	1-12
11. Comprehensive Toxicology Profile (CTP)	1-8
12. Daphnia	1-13
13. Rainbow Trout	1-50
14. Bobwhite Quail	1-36
15. Confidential Business Section (Environmental Assessment)	1-2

Figure 1

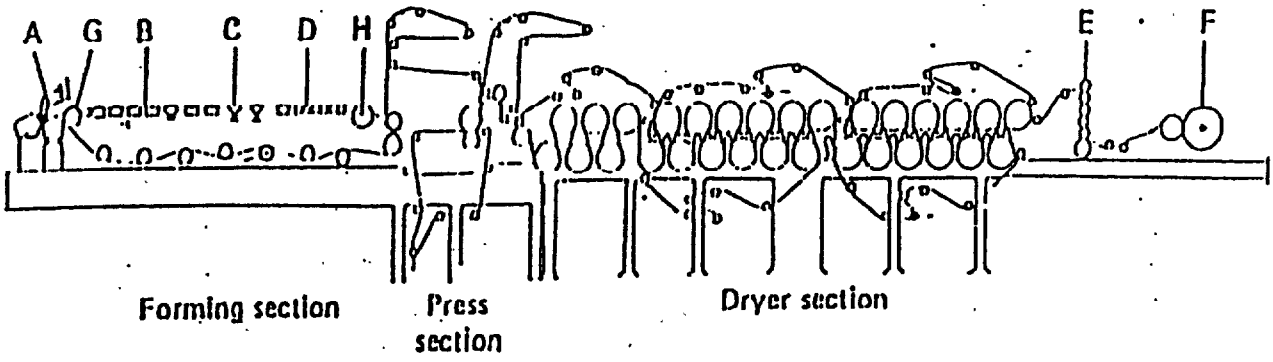


GENERAL FLOW SHEET
PULPING AND PAPERMAKING PROCESS

000045

Figure 2

Fourdrinier Paper Machine



Fourdrinier paper machine with (A) headbox, (B) Fourdrinier wet end with foil boxes, (C) wet and (D) dry suction boxes, pickup and closed transfer of web through the press section, dryer section, (E) calender, and (F) reel. G and H are the breast roll and couch roll, respectively.
(Courtesy of Beloit Corporation)

Table 1

PULP & PAPER MILLS TABULATION

Table compiled from this edition of the directory

	Companies (1)	Establishment (incl Hdqtrs units)	Paper Mills (2)	Pulp Mills (Total)	Groundwood	Other Mechanical (3)	Semichemical	Sulphite	Kraft	Miscellaneous (4)
Alabama	20	25	20	27	3	2	2	—	14	6
Alaska	2	2	—	1	—	—	—	1	—	—
Arizona	2	2	2	5	4	1	—	—	1	2
Arkansas	9	12	12	10	1	2	—	—	7	—
California	33	39	31	6	—	2	—	—	2	2
Colorado	2	2	1	—	—	—	—	—	—	—
Connecticut	17	18	8	1	—	—	—	—	—	1
Delaware	2	3	3	1	—	—	—	—	—	1
Florida	12	13	10	9	—	1	—	1	7	1
Georgia	35	38	24	19	1	1	1	—	12	4
Idaho	2	3	2	1	—	—	—	—	1	—
Illinois	17	19	12	3	—	—	—	—	—	3
Indiana	11	15	13	3	—	—	1	—	—	2
Iowa	3	3	3	1	—	—	1	—	—	—
Kansas	2	3	2	—	—	—	—	—	—	—
Kentucky	8	10	8	4	—	—	1	—	2	1
Louisiana	11	13	13	18	3	—	3	—	10	2
Maine	20	22	20	20	8	1	—	1	7	3
Maryland	7	7	5	2	—	—	—	—	1	1
Massachusetts	37	46	32	5	—	—	—	—	—	5
Michigan	36	42	35	13	2	1	3	—	3	4
Minnesota	12	14	13	10	4	3	—	—	2	1
Mississippi	12	16	12	10	2	1	—	—	6	1
Missouri	4	4	3	1	—	1	—	—	—	—
Montana	1	1	1	1	—	—	—	—	1	—
New Hampshire	16	17	12	2	—	—	1	—	1	—
New Jersey	22	26	15	3	—	—	—	—	—	3
New Mexico	2	3	2	—	—	—	—	—	—	—
New York	53	65	52	12	2	2	—	1	1	6
North Carolina	19	23	18	16	—	5	1	—	6	4
Ohio	32	37	28	10	—	2	2	—	1	5
Oklahoma	7	7	7	6	—	1	1	—	1	3
Oregon	17	24	18	21	4	6	1	—	7	3
Pennsylvania	37	41	33	8	—	1	2	1	3	1
Puerto Rico	1	1	—	—	—	—	—	—	—	—
South Carolina	11	14	13	11	1	3	1	—	6	—
Tennessee	19	20	15	12	2	1	1	—	2	6
Texas	16	16	12	11	3	1	—	—	6	1
Vermont	8	8	7	1	—	—	—	—	—	1
Virginia	17	19	14	11	1	2	2	—	4	2
Washington	20	28	17	24	6	—	2	5	6	5
West Virginia	3	3	2	1	—	—	—	—	—	1
Wisconsin	45	62	48	34	6	4	1	4	4	15
TOTAL U.S.	371	786	598	354	51	42	27	14	124	96
Alberta	10	11	4	9	3	1	—	—	4	1
British Columbia	32	46	13	35	15	1	—	1	17	1
Manitoba	3	3	3	5	1	1	—	1	1	1
New Brunswick	11	12	7	13	5	—	2	2	3	1
Newfoundland	2	3	3	4	3	—	—	1	—	—
Nova Scotia	6	6	5	6	2	1	—	2	1	—
Ontario	32	47	34	33	10	3	1	1	9	9
Quebec	53	84	57	70	31	6	2	5	9	17
Saskatchewan	4	4	3	2	1	—	—	—	1	—
TOTAL CANADA	133	216	129	177	71	13	5	13	45	30
TOTAL MEXICO	48	77	53	16	2	—	—	—	6	8

Notes: (1) Subsidiaries and autonomous divisions of parent companies are counted as separate units. Totals of this column reflect elimination of duplication of names in more than one state or province.
(2) Includes mills manufacturing paper and/or paperboard, regardless of whether or not one or more pulp mills are located at the site.
(3) Includes mechanical pulp for building board, defibrated cold soda and chemimechanical wood pulp mills.
(4) Includes 110 deinking, 5 rag, 1 soda, 2 rope, 3 flax, 5 bagasse and 3 cotton linters pulp mills.

000047

TAED
Warwick International, Ltd.
Environmental Assessment
9-R
Page 18

Table 2
Acute Aquatic Toxicity (PeroxyBoost™)

Species	Test duration	EC_{50} ($mg\,L^{-1}$) for DAED	TAED	TriAED	Comments
Algae					
Chlorella vulgaris	14 day	>500	>500	>500	No effects on growth rate at highest concentrations tested
Invertebrates					
Daphnia magna	48 h	>800	>800	>400–800	Insufficient mortalities at highest concentration of DAED and TAED to allow calculation of EC_{50}
Gammarus pulex	72 h	>800	>800	>800	No deaths at highest concentration tested
Fish					
Carrassius auratus	96 h	40000–75000	>2500	>21200	No deaths at highest concentration of TAED and TriAED tested
Idus leuciscus	48 h	—	>200		No mortalities at highest test concentration
Brachydanio rerio	96 h	—	>1500	-	No mortalities at highest test concentration

000048

Table 3
Mammalian Toxicity Summary

List the toxicology studies that the notifier believes justifies a conclusion that the intended use of this FCS is safe. Typically, the studies listed here should include the genetic toxicity studies and animal studies that are addressed in the *Safety Narrative* section of the toxicology data package, which is associated with this notification.

TYPE OF STUDY	SPECIES TESTED	SUBSTANCE TESTED	EFFECTS OBSERVED	NOEL
1. Ames	Salmonella	TAED	negative	N/A
2. Ames	Salmonella	TAED	negative	N/A
3. Ames	*Salmonella*	*DAED**	*negative*	*N/A*
4. E. coli	*E. coli*	*DAED**	*negative*	*N/A*
5. SCE	CHO V9	TAED	negative	N/A
6. Oral LD_{50}	Rat	TAED	LD_{50}=7.94	N/A
7. Oral Limit	*Rat*	*DAED**	*no deaths at 2g/kg*	*N/A*
8. Dermal Irritation	Rabbit	TAED	mild irritant	N/A
9. Eye Irritation	Rabbit	TAED	non-irritant	N/A
10. Sensitization	*Guinea Pig*	*DAED**	*non-sensitizer*	N/A
11. Sensitization	Guinea Pig	TAED	non-sensitizer	N/A
12. 90 Day Oral	Rat	TAED	Decreased BW, M&F Decreased FC, M&F Sig. increase in hematology parameters, mostly mid & high doses Enlarged livers, M&F, high dose Increase in abs. & rel. organ wts in high dose M & mid & high F Mild bilateral degeneration of Seminiferous tubules in 2 high dose M	25mg/kg
13. 90 Day Dermal	Rat	TAED	Minimal hepatic centrilobular centrilobular hypertrophy in 8/10 & 4/10 M&F	≥200mg/kg
13. 13 wk Feed	Rat	TAED	none reported	25mg/kg
14. Prenatal Devel.	Rat	TAED	BW & FC loss at mid & high dose dams; No embryotoxic effects	40mg/kg

** DAED is a breakdown product of TAED and is biodegradable.*

000049

Part VI — LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, as appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment. Notifiers need not list other components of their notification not specifically referenced in this form.

Attachment name	Attachment page number(s)

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.

000055

FDA Form 3480

Part IV – LIST OF ATTACHMENTS

Attachment Name	Attachment Page Numbers
FDA Form 3480: Continuation Pages	
Part II Identification on Identity, Use, and Exposusre	
Section A.1.e Composition	3-A
Section A.1.f Characterization	3-B, 3-C
Sections A.2.a. Manufacturing Process - Reagents	Appendix 1
Section A.2.b. Manufacturing Process – Times, Temperatures, etc.	Appendix 1
Section A.3.a. Physical Properties and Specification	5-A thru 5-D
Part IV Environmental Impact of FCS	
Section B Environmental Assessment	9A-9-X & Appendix 15
Confidential Appendixes	
1. Confidential Data for Identity, Use, Exposure, Reagents, Manufacturing Process, Impurities, and Physical Properties.	1-19
2. Salmonella	1-39
3. Acute Toxicity Battery	1-59
4. Acute Dermal Toxicity	1- 5
5. 90-Day Oral Toxicity	1-342
6. 90-Day Dermal Toxicity	1-148
7. Prenatal Development	1-198
8. Biodegradation Studies	1-127
9. Human Dietary Exposure	1-7
10. Efficacy Data	1-12
11. Comprehensive Toxicology Profile (CTP)	1-8
12. Daphnia	1-13
13. Rainbow Trout	1-50
14. Bobwhite Quail	1-36
15. Confidential Business Section (Environmental Assessment)	1-2