Section H -
ENVIRONMENTAL ASSESSMENT - REVISED 2/11/98

EN

This section complies with 21 CFR 25.20(l) and our petition does not meet any categorical exclusions as listed in 21 CFR 25.32.

1.	Date	Revised February 11, 1998 (Originally submitted March 14, 1997)
2.	Petitioner	Betz Dearborn, Inc.
3.	Address	4636 Somerton Road Trevose, PA 19053

4. Description of the proposed action:

The copolymer of acrylic acid and polyethyleneglycol allyl ether (AA/PEGAE) is designed primarily as a dispersant in boilers to prevent the deposition of calcium, magnesium and silica salts on heat transfer surfaces. Accordingly, BetzDearborn, Inc. proposes that Section 21 CFR 173.310(c) of the regulations be modified so as to include use of AA/PEGAE in boilers that produce steam that will contact food.

The product (AA/PEGAE) or Coag 139 will be produced in our plant in
and could be used anywhere within the continental United States where there are food or other boilers to be treated.

Disposition of the polymer would occur by two routes. The first would result from the physical carryover of the polymer in steam during food processing, and the resultant ingestion of such foodstuffs. By far the greater amount of polymer would be found in the customer blowdown water from the treated boiler.

Our plant is located in essentially a rural area with no residential properties within, perhaps, a half mile; food boilers may be found in both urban and suburban areas. Small food processors located in a city environment will most likely send their waste streams to municipal sewer systems. Large food manufacturers such as Cargill, ADM, etc. have their own waste treatment facilities including primary and secondary, and possibly even tertiary treatment plants. Effluents, after suitable processing may be pumped to a municipal sewer system or if meeting state or local permit requirements, may be discharged to near-by rivers or streams.

5. Identification of the Chemical Substance

a. <u>Identity, Composition, Properties and Specifications of the Food Additive</u>

(1)	Common Name	Copolymer of the sodium salt of acrylic acid with polyethyleneglycol allyl ether
(2)	In-house Name(s)	Coag 139, (AA/PEGAE)

000927

(3)	Chemical Name(s)	2-propenoic acid, polymer with alpha-2-propenyl-omega-hydroxypoly(oxy-1,2 ethanediyl), sodium salt
(4)	CAS No.	86830-15-1
(5)	Molecular Weight* Mw)	~47,000
	(M_n)	4,500
(6)	Molecular Formula	2[$NaSO_4$ and/or HO and/or H]-$C_3H_4O_2(C_2H_4O)_nC_3H_6O)_x$-xNa where n ~10 and x ~7
(7)	Chemical Structure	

$R\text{-}(CH_2\text{-}CH)_{2.5}\text{---}(CH_2\text{-}CH)_{1.0}\text{-}R'$

| |

COO^-Na^+ $CH_2\text{-}O\text{-}(CH_2CH_2O)_x\text{-}H$

where R and R' may be $NaSO_4^-$ and/or HO- and/or H-

x ~10

(8) See attached IR and C^{13} NMR Scans Figures 1 and 2.

* By GPC comparison to polyacrylic acid standards

Figure 6 in Section I is a GPC chromatogram for the Coag 139 and a short description of what size exclusion chromatography (SEC) is and how molecular weight averages are calculated. GPC is a form of SEC. In the case of Coag 139, acrylic acid and PEGAE monomers are polymerized, i.e., covalently bonded to each other, through a free radical mechanism initiated with sodium persulfate. Once the initator reacts with the unsaturated region of the monomer molecule, a chain reaction begins whereby a new radical is formed which then proceeds to reach with another monomer molecule, and so on. There is a random distribution between the AA and PEGAE monomers incorporated into the polymer chain. Since the mole ratio of AA to PEGAE is 2.5:1.0 for Coag 139, this means that on average there will be a ratio of 2.5 acrylic acid molecules for every 1.0 PEGAE molecule in each polymer chain in some random order. These chain reactions can be terminated by several mechanisms. Sometimes a chain is terminated after only a few molecules react, and sometimes hundreds or thousands of molecules can react before termination occurs. MW averages are various statistical manipulations based on a given number of chains, or moles, of a given size, as compared to the entire size population of the polymer sample. Polyacrylic acid standards of known molecular weights were used to determine the MW's of Coag 139. (See Figure 6 for SEC Conditions for GPC Analysis of Coag 139, actual Chromatograph prepared 12/18/90)

b. Physical Properties (35% solution)

(1)	Appearance	Clear, yellow-amber liquid
(2)	Odor	Mild
(3)	Pour Point	24° F
(4)	Freezing Point	19° F
(5)	Specific Gravity	1.143 at 70° F
(6)	Viscosity (70 ° F)	104 cps (Brookfield)
(7)	pH (35% active)	11.90
(8)	Solubility (water)	100%

000928

c. Composition and Impurity Level

The final, neutralized product (Betz Coag 139) is comprised of the following components:

(1)

Specification	Wt. %
Copolymer of the Sodium Salt of Acrylic Acid with Polyethyleneglycol Allyl Ether	See Appendix I in the petition

(2) Analytical Methods for Acrylic Acid and Ethylene Oxide PEG/AE will be found in Appendix 1 of the Environmental Assessment.

Coag 139 will contain the maximum concentration of active to be found in a commercial product. Typical BetzDearborn commercial products may contain up to 20% of the active polymer.

d. Establishment of Compositions

The composition of Coag 139 was basically established by C^{13} Nuclear Magnetic Resonance (NMR) techniques. The polymerization was considered complete, and the desired product obtained, by the disappearance of the signal relating to unsaturated carbon atoms (115-135 ppm) and the formation of broad peaks at 35 and 45 ppm which correspond to the CH_2-CH- backbone. The remainder of the spectrum showed only some minor shift changes caused by formation of polymer and pH adjustment, as compared to the monomers.

e. By-Products

Included above as residuals

6. Introduction of polymer into the environment:

At the production site, emission of the substances used to manufacture AA/PEGAE would include acrylic acid and the polyethyleneglycol allyl ether. Since the latter substance is purchased, the plant does not work with ethylene oxide itself. The actual polymerization is done in a closed vessel which is equipped with a scrubber. Acrylic acid, purchased in bulk, is pumped to the polymerization vessel using dedicated pumps and lines. Polyethyleneglycol allyl ether is pumped in from drums. During initial and final stage of the polymerization the scrubber is in use so that vapors from the ingredients are not emitted to the atmosphere. (In the case of the PEGAE, vapor pressure of a 500 molecular weight substance should be minimal.) The system is under a nitrogen atmosphere during the actual chemical reaction. Water used in the scrubbing system is discharged by permit to the city sewer system provided it meets any limitations described in the City of permit. Small amounts of AA/PEGAE (a few gallons), may be added to the scrubber water and disposed of in that manner. In any event we are still regulated by the limits in the sewer permit. Should the water effluent exceed city limits, it can be removed by a licensed waste vendor. Attached as Figure 3 is the most current City of Discharge Permit, Permit ; US EPA ID TXD This permit became effective February 1, 1995 and expires January 31, 1997.

Regarding emissions to the atmosphere it should be pointed out that more than one process vessel can be attached to a single scrubber so that individual emissions are combined. Our Air Permit allows BetzDearborn to operate the plant provided we adhere to the emissions stated in our standard exemptions. Please note there is no specific air permit number that has been issued to BetzDearborn. Rather, there is in effect an updated exemption which has been enclosed as Figure 4 and carries the Registration Number for our plant. The original letter of exemption will be found in Appendix IV in our FAP 4B4426 dated May 31, 1994. The new exemption is dated January 27, 1995.

> It is our understanding that exemption permits stay in effect until a change needs to be made such as the addition of new equipment, etc. At such times a new exemption permit would be requested.

While the possibility of accidental spills always exists for either component of the polymer, this event would not be considered a major contribution to atmospheric contamination. Attached are air and water permits from the State of indicating their approval of this manufacturing site (see Figure 4). Approval of AA/PEGAE for use in food boilers will have no impact on these existing permits since that portion of the production is minimal compared to the amount of the polymer destined for non-FDA applications. BetzDearborn feels confident in stating that our plant is in compliance with all federal, state and local regulations as pertains to the manufacture and use of the subject polymer.

Assuming our petition were to be approved in 1997, and the first full year of sales would be 1998, estimates of the total pounds of AA/PEGAE to be sold will be found in Appendix I of petition itself (see Column A). In Column B of Appendix I are the estimates of the pounds of AA/PEGAE that would be used by those businesses subject to FDA compliance. For the year 1999, the second full year of sales, the amount of polymer subject to FDA compliance should double over 1998.

Attached to this E.A. are copies of the raw material MSDS's that are used to manufacture the polymer AA/PEGAE. Also attached is a copy of the MSDS itself for AA/PEGAE, (see Appendix 2). Each of the MSDS's supplied shows the safety equipment needed for protection when handling the raw materials or when processing the finished polymer. Briefly, eye protection, special clothing and possibly special ventilation equipment may be called for when handling either the ingredients used to manufacture AA/PEGAE or the polymer itself. New employees are given general training in safety as well as special training in using respirators if required.

We believe the polymer is not volatile under the conditions proposed for plants that employ our product. If one assumes there is a 1 % carryover of the subject polymer into the steam, then 99% of the polymer will be found in the blowdown water from the boiler. In a typical food plant equipped with four, 10,000 lb./hr. boilers, and assuming a blowdown rate of 5%/hr., and making the further assumption that polymer in the boiler has cycled up to 100 ppm, we would have:

4 boilers @ 10,000 lb./hr. x 5% blowdown x 0.01% polymer x 24 hr. day =
40,000 x 0.05 x 0.0001 x 24 = 4.8#/day of AA/PEGAE for 4 boilers per day per food plant/mill

Assuming such a food processor was located in the Philadelphia area where, depending on the actual physical location of the plant, at least 100,000,000 to 200,000,000 million gallons per day of waste effluent is processed through the municipal system, the 4.8# AA/PEGAE is diluted as follows:

$$\frac{4.8\#\ AA/PEGAE}{8.34\#\ /gal. \times 100{,}000{,}000\ \frac{gal.}{day}} \cong 0.006\ ppm\ AA/PEGAE$$

Even if 1000 plants were to discharge their effluents to such a municipal facility, the level of AA/PEGAE would be far lower than the LD_{50} value of 5000 mg/L of Coag 139, equivalent to 1750 mg active AA/PEGAE. This further assumed that none of the active polymer is degraded in the waste treatment facility.

These values are orders of magnitude less than mortality rate for fathead minnows or Daphnia Magna. Note that the 1% carryover in the steam has been ignored in the above calculations.

000931

7. Fate of Emitted Substance in the Environment

a. Exposure to the atmosphere through product handling

AA/PEGAE formulated products would be handled in our customers' plants by means of 55 gallon drums, semi-bulk storage containers (300 gallons), or directly to POF tanks. Transfer would be accomplished using gravity. Alternately, the product could be transferred to make-down tanks by means of a sample lance under vacuum. Short of leaks or spills, no measurable amount of product would be expected to enter the environment in this situation.

Release to the environment through the steam would be minimal since vaporous carryover is negligible.

b. Exposure to freshwater and/or marine waters through boiler blowdown

Boiler blowdown in food production boilers nominally ranges between 2% and 10% of the feedwater and represents the most likely means of our product entering the environment. AA/PEGAE feed levels would be such that residual polymer in the boiler at equilibrium would range from 30 to 250 ppm, with a mean between of 100-200 ppm. A boiler producing 10,000 pounds of steam per hour would have a blowdown of 500 pounds per hour at the 5% blowdown rate:

500 #/hr. * (100 # polymer/1,000,000 # BetzDearborn) = 0.05 # of AA/PEGAE/hr.
= 1.2 #/day for a single boiler

Since typical blowdown from a food processing plant would contain 100-200 ppm of the subject polymer, and since typical boiler water usage for a food processor might represent 5% of the plant's total water intake, then blowdown would be initially diluted 20 fold when combined with plant effluents from all sources, and would be further diluted on entering a municipal sewer system, or if permitted, when discharged to a receiving stream/river.

Since the LD_{50} for Daphnia Magna is at least 5000 mg/L (1750 mg/L on a 100% active basis), a 20 fold dilution of the 200 ppm blowdown value means that, prior to any additional dilutions, the approximate 10 ppm level of active AA/PEGAE is well below the LD_{50} that would be harmful to Daphnia Magna, or to fathead minnows.

Some of the polymer may thermally decompose in the boiler. The extent of decomposition will depend on the pressure, the percentage blowdown (cycles of concentration) and the ratio of the boiler volume to blowdown

rate (residence time). Certainly additional polymer would undergo biodegradation in a waste treatment plant.
The polymer is composed of an acrylic acid monomer copolymerized with an ether linked ethylene glycol side chain. Thermal decomposition of acrylic acid and methacrylic acid polymers has been extensively studied in our labs using radio-labeled monomers. We have found that decarboxylation starts to occur at around 1500 psig to form carbon dioxide and a partially aliphatic polymer. A similar mechanism is expected for the acrylic acid portion of this polymer. The ether linkage is expected to cleave to form polyethyleneglycol chains of various lengths depending on the point of cleavage.

Although we have not firmly established the identity of the polymer after cleavage of the ether linkage, we have established that it is not an acrylate homopolymer (PAA) as might be expected from the structure. This was done by first exposing the polymer to boiler water in an autoclave at 600 psig for up to 6 hours. The exposed polymer was then used in a "calcium chelation" test to determine its affinity for soluble calcium ions (reference Nalco US Patent 4,457,847, "Carboxylate Polymers for Internal Scale Control Agents In Boiler Systems," Lorenc, W. F.). The thermally exposed polymer showed much lower calcium chelation values than polyacrylic acid. If the AA/PEGAE had decomposed to polyacrylic acid, the chelation values of the autoclaved polymer should have risen.

Polymer	Calcium Chelation Value
PAA (Polyacrylic Acid)	351
AA/PEGAE (unexposed)	62
AA/PEGAE (autoclaved 2 hrs)	17
AA/PEGAE (autoclaved 2 hrs)	20

c. Exposure in food containing AA/PEGAE as a result of carryover

If we assume that some AA/PEGAE is carried over into the food by means of physical entrainment of boiler water droplets in the steam, then this represents another mechanism whereby AA/PEGAE can enter the environment.

Using a treatment level of 2 mg/L to the feedwater and 50 cycles operation, and assuming that there is no thermal degradation of AA/PEGAE, then at equilibrium, we would expect the boiler water to have a concentration of 100 mg/L. Based on marketing information, approximately half of the boilers BetzDearborn treats are watertube and half are firetube. 0.1% - 1.0% carryover rate has been used. The amount of solid food cooked by steam has been estimated to be 25% based on a private communication from Technical Consultant (see Appendix VI in the petition). Further, BetzDearborn has called some 72 institutions and determined that 28% employ boiler steam; the balance use self-contained steam generation where our products are not involved. If 0.62 pounds of steam are required to cook one pound of food and if the daily, solid food consumption is 1.5 Kg, then the amount of AA PEGAE ingested is:

200 $\frac{Mg}{Kg}$	x 0.01	x 0.25	x 1.5 Kg of $\frac{food}{day}$	0.45 # $\frac{Steam}{Kg\ Food}$	= 0.34 mg of AA/PEGAE per day per person

Polymer Concentration →

% Carryover →

% Solid food cooked by steam →

Solid food consumed per day →

Pounds of steam to cook one pound of food →

Such food, after ingestion, would be handled in sanitary sewers where further environmental contact would be minimized.

d. Biodegradation of the Additive Material

The general protocols for determining the aquatic toxicity of fathead minnows and Daphnia Magna are attached as Appendix VII A and Appendix VII B respectively.

Figure 5 presents aquatic toxicity and biodegradation data. See Appendices VII A and VII B in the petition itself.

Test procedures used to determine measures of biodegradation were from the OECD collection:

301 D Closed Bottle Test
302 B Zahn-Wellens/EMPA Test

These will both be found in Appendix VIII A and VIII B in the petition.

The results of the closed bottle test showed a 5 day and 28 day BOD of 0 mg O_2/g and 36 mg O_2/g respectively. AA/PEGAE attained 23% biodegradation after 28 days. The required level of 60% biodegradation was not reached and therefore can not be classified as readily biodegradable by this test. However, due to the stringency of this test, it does not necessarily mean that the test compound is not biodegradable under environmental conditions. Additional acclimation time or co-metabolism may allow for more complete biodegradation of AA/PEGAE.

The classification for the Zahn-Wellens test are as follows:

0 - 19%	=	Not readily biodegradable
20 - 69%	=	Inherently biodegradable
70 - 100%	=	Ultimately biodegradable

The Zahn-Wellens study for AA/PEGAE resulted in 14% degradation of the additive as measured by percent loss of DOC (dissolved organic carbon). We would have to conclude that our data (14%) falls into the first category, not readily biodegradable. The conditions of this test do not necessarily provide optimal parameters for biological degradation. We feel that, given more time, organisms would become acclimated to AA/PEGAE and would further biodegrade.

8. Environmental Effects of Released AA/PEGAE

Since the polymer is employed as a boiler water additive, and would not be expected to be volatile, little or none would be expected to be found in the atmosphere. Similarly, the amount in food, if any, would not be expected to have an environmental impact since the compound could be altered by digestion. Boiler blowdown is the single largest contributor of AA/PEGAE to the environment.

At the levels found in food plant effluents there should be no effect on aquatic or mammalian life as dilution would be expected from other municipal streams.

Although no specific tests have been made on AA/PEGAE's effect on plant life, References A and B present investigations of certain alcohol ethoxylates and alkylphenol ethoxylates on microorganisms and on higher plants. While simple molecules of these types can have an effect on plant life, the concentrations are significantly higher than those encountered in food plant effluents. For example, Reference A states that Barley and Rye Grasses exposed to 50 mg/L of an ethoxylated alcohol showed no differences in effect over the controls. On the other hand, although certain alkylphenol ethoxylates have been used as wetting agents, they are in general more likely to have an adverse effect on plant life than linear ethoxylates. However, based on Reference B, adverse effects on mature plants is much less likely to occur below 0.01%, or approximately 100 ppm. The amount of ethoxylation can make a difference with the maximum effect for alkylphenols coming at 10 or so moles of ethoxylation. The fact that AA/PEGAE is linear, as opposed to aromatic, that it is a polymer, and is not expected to exceed low ppm in the plant effluent, should mitigate any adverse effects in the environment.

9. Use of Resources and Energy

While the polymer is destined to become part of a new treatment program promulgated by BetzDearborn, it has the potential for replacing some of the older polymers use in boiler formulations such as sodium polyacrylate. On the basis of an improved treatment to prevent scale build-up on heat transfer surfaces, the application of our polymer should lead to improved steam production with lower fuel costs and lower stack emissions.

10. Mitigation measures

Measures to protect the environment during manufacture of AA/PEGAE have included the use of scrubbers in the tanks used to prepare the subject polymer. Biodegradation data shows that the polymer is not readily degradable under the time conditions specified in the test procedures; however, there is the possibility that with additional time bacteria might better acclimate to this molecule.

11. Alternatives to the proposed action

BetzDearborn, Inc. believes that the proposed use of a polymer consisting of acrylic acid and polyethyleneglycol allyl ether should be considered an advance in boiler water technology. The polymer when employed at the recommended levels reduces scale buildup in the boiler, and as a consequence downtime is reduced, fuel usage and costs are lowered, and production capacity for steam is maintained.

12. List of Preparers:

Lawrence M. Barnett
MS in Chemistry
41 years experience in the Chemical Industry

Keith Bair
MS in Polymer Science
21 years experience in the Chemical Industry

Paul Burgmayer
Ph.D. in Chemistry
11 years experience in the Chemical Industry

Donna M. Ware
BS Chemistry
MBA Business
12 years experience in the Chemical Industry

Persons/Agencies Consulted

a. Alan Schellhamer (BetzDearborn PaperChem)
b. Norris Johnston (BetzDearborn Industrial)

13. Certification

The undersigned officials certify that the information presented is true, accurate and complete to the best of the knowledge of our firm responsible for preparation of the Environmental Assessment.

Date:	February 11, 1998
Signature of Responsible Official:	[redacted] per DMW)
	Lawrence M. Barnett
Title:	FDA Coordinator
Signature of Responsible Official:	[redacted]
	Donna M. Ware
Title:	Manager of Food Additives

000937

15. a. List of Figures referred to in Section H - Environmental Assessment

Figure 5 - Section H
(E.A.)

EN

BetzDearborn Inc.
4636 Somerton Road, Trevose, PA 19053

PRODUCT: COAGULANT 139 _DATE

AQUATIC TOXICOLOGY

Fathead Minnow 96 Hour Static Screen with 48-Hour Renewal

0% Mortality: 5000 mg/L

Daphnia magna 48 Hour Static Screen

0% Mortality: 5000 mg/L

BIODEGRADATION

COD (mg/gm): 300
TOC (mg/gm): 90
BOD-5 (mg/gm): 0
BOD-28 (mg/gm): 36

Closed Bottle Test
% Degradation in 28 days: 23
Zahn-Wellens Test
% Degradation in 28 days: 14

MAMMALIAN TOXICOLOGY

Oral LD50 RAT: >5,800 MG/KG

Dermal LD50 RABBIT: >5,800 MG/KG

Skin Irritation Score RABBIT: 0.17

Eye Irritation Score RABBIT: 0.3
Note - Reversible by 24hr

Ames Assay BACTERIA: NEGATIVE

90 Day Feed Study RAT:
Note - NOEL: 20,000 ppm

Non-Ames Mutagenicity MOUSE: NEGATIVE
Note - Micronucleus Cytogenetic Assay

Reproductive Toxicity HYDRA: A/D=1.17

Note - Hydra developmental toxicity screen: material does not target embryo

15. b. List of Appendices in Section H - Environmental Assessment

1. Analytical Method for Measuring Acrylic Acid monomer, Polyethylene Glycol Allyl Ether and Ethylene Oxide

2. MSDS's for Coag 139 Production