Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE

ENVIRONMENTAL ASSESSMENT

1.	**Date**	July 24, 2000
2.	**Name of Applicant/Notifier**	Betz Dearborn, A Division of Hercules Incorporated 4636 Somerton Road Trevose, PA 19053
3.	**Address**	All communications on this matter are to be sent in care of Counsel for Notifier, Ralph A. Simmons, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4120.

4. Description of the Proposed Action

This Notification is submitted with respect to polyethyleneglycol monooleate (CAS Reg. No. 9004-96-0) for use as a filmer in boiler condensate systems. The product will be fed in steam headers to prevent condensate corrosion.

The subject additive may be further identified as Polyethyleneglycol (400) monooleate (PEG (400) monooleate, or PEG 400 MO), or as Poly(oxy-1,2-ethanediyl), α(1-oxo-9-octadecenyl)-ω-hydroxy. The product may be obtained from a variety of chemical suppliers. The Notifier's current supplier is Ethox Chemicals, which supplies the product under the trade name Ethox MO-9. The Notifier, Betz Dearborn, will market the product for use in boiler condensate systems under the trade name . The product may be used anywhere within the continental United States where there are food or other boilers to be treated.

The additive, PEG (400) MO, is intended for use as an anti-corrosive treatment in steam lines of boiler systems where the steam will contact food. Specifically, the product will be fed into the steam header continuously, so as to maintain a concentration of PEG (400) MO of no more than 2 parts per million (ppm). The PEG (400) MO will form a protective barrier on the inner surfaces of the steam header and steam lines, inhibiting corrosion.

5. Environmental Consequences of the Proposed Action

a. ***Production of the food-contact substance:***

There are no extraordinary circumstances that apply to the manufacture of the food-contact substance that would present a significant environmental effect from the proposed action. Therefore, information regarding the production of the food-contact substance is not provided.

b. ***Use and disposal of the food-contact substance:***

Assuming the FCN becomes effective in 2000, the first full year of sales would be 2001. An estimate of the total pounds of PEG (400) MO to be sold can be found in Attachment #1 to this Environmental Assessment. Also shown in this table are estimates of the PEG (400) MO projected for both industrial and food contact applications. For the year 2002, the second full year of sales, the amount of polymer subject to FDA compliance should double over 2001.

PEG (400) MO formulated products would be handled in customers' plants by means of 55 gallon drums, semi-bulk storage containers (300 gallons), or directly to bulk tanks. Normal standard chemical handling is needed for the product. 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.

In the Boiler system, the disposal of the injected chemical may occur by two routes. One is the physical transport of some amount of small droplets of the product by the steam during food processing, and the resultant ingestion of such foodstuffs. The other is the return of product to the boiler through the use of condensate in the boiler feed water. The greater amount of product would return to the Boiler via condensate return. The PEG (400) MO in the boiler will hydrolyze to its original components, PEG 400 and fatty acids. (The fatty acids are mainly oleic, minimum 70% according to the manufacturer.) The customer will dispose of this residual with the blowdown water of the treated Boiler system. The hydrolysis products, fatty acids, oleic acid and PEG 400 are permitted additives for direct addition to food, under 21 C.F.R. sections 172.860, 172.862 and 172.808, respectively.

Small food processors located in a city environment will most likely send their waste streams to municipal sewer systems (POTWs). 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 nearby rivers or streams.

PEG (400) MO is not volatile under the conditions proposed for plants that employ the product. When fed to the steam header the greater amount of product, estimated at 65%,[15/] would return to the Boiler via steam traps and condensate return lines. The maximum to be fed is 2 ppm. According to in-house research,[16/] at least 95% of the PEG (400) MO will hydrolyze in the Boiler to its original components, PEG 400 and fatty acids. The customer will dispose of this residual with the blowdown water of the treated Boiler system.

In a typical food plant equipped with four, 10,000 lb/hr boilers, assuming a blowdown rate of 5% per hour, and making the further assumption that the PEG (400) MO and the hydrolysis products in the boiler have cycled up to 20 times, the respective concentrations in the boiler water are calculated as follows:

PEG (400) MO:	(2 ppm x 0.65) x 0.05 x 20 = 1.3 ppm, or 0.00013%
Oleic acid:	(2 ppm x 0.65) x 0.95 (282 m.w./678 m.w.) x 20 = 10.3 ppm, or 0.00103%
PEG 400:	(2 ppm x 0.65) x 0.95 x (400 m.w./678 m.w.) x 20 = 14.4 ppm, or 0.00144%

The amount of each residual substance disposed of per day for the 4-boiler plant is thus:

4 boilers @ 10,000 lb/hr x 5% blowdown x 0.00013% PEG (400) MO x 24 hr/day =
40,000 x 0.05 x 0.0000013 x 24 =
<u>0.048 lb/day of PEG 400 MO</u>

4 boilers @ 10,000 lb/hr x 5% blowdown x 0.00103% oleic acid x 24 hr/day =
40,000 x 0.05 x 0.00001 x 24 =
<u>0.48 lb/day of oleic acid</u>

[15/] See steam header scheme in Appendix I.
[16/] See thermal stability data in Appendix II.

4 boilers @ 10,000 lb/hr x 5% blowdown x 0.00144% PEG 400 x 24 hr day =
40,000 x 0.05 x 0.000014 x 24 =
0.67 lb/day of PEG 400

Typical blowdown from a food processing plant would contain PEG (400) MO, oleic acid, and PEG 400 at the levels calculated. Assuming typical boiler water usage for a food processor represents 5% of the plant's total water intake, then blowdown would be initially diluted 20-fold when combined with plant effluents from all sources. The blowdown would be further diluted on entering a municipal sewer system, or if permitted, when discharged to a receiving stream/river.

Assuming, conservatively, no dilution of the boiler blowdown prior to release, the concentrations of PEG (400) MO and its hydrolysis products in municipal waste water may be calculated as follows. For a food processor located in a typical urban area, such as Philadelphia where, depending on the actual physical location of the plant, at least 100,000,000 to 200,000,000 gallons per day of waste effluent is processed through the municipal system, the PEG (400) MO and hydrolysis products released would be diluted to the following concentrations:

(0.048 lb/day PEG (400) MO) ÷ (100,000,000 gal/day x 8.34 lb/gal)
$\cong 6 \times 10^{-5}$ mg/l, or *ppm,* PEG (400) MO

(0.48 lb/day oleic acid) ÷ (100,000,000 gal/day x 8.34 lb/gal)
$\cong 6 \times 10^{-4}$ *ppm* oleic acid

(0.67 lb/day PEG) ÷ (100,000,000 gal/day x 8.34 lb/gal)
$\cong 8 \times 10^{-4}$ *ppm* PEG

Note that using a municipal waste water volume in the calculations of 100,000,000 gallons per day gives the worst-case dilution scenario and, thus, the highest release concentrations. Moreover, it is conservatively assumed that none of the PEG (400) MO, the PEG 400 and the fatty acids are degraded in the waste water treatment facility.

The levels of these compounds in plant effluent may be compared to available data on the toxicity of these compounds to fish. The relevant data are summarized as follows:

PEG (400) MO	Daphnia magna LC_{50}	10.7 mg/l
	Fathead Minnow LC_{50}	17.1 mg/l
Oleic acid	Fathead Minnow LC_{50}	285 mg/l
PEG 400	Goldfish LC_{50}	>5000 mg/l

The calculated release of PEG (400) MO, oleic acid, and PEG 400, without accounting for dilution with other food plant effluents, are all at least 5 orders of magnitude below their respective LC_{50}'s. Therefore, even if multiple plants simultaneously discharge to the municipal facility, there will be no adverse impact on the aquatic environment as a result of these releases.

The general protocols for determining the aquatic toxicity of Fathead minnows and Daphnia Magna are included in Attachments #2 and #3 to this EA. The data on PEG (400) MO are in-house; the data for oleic acid and PEG 400 are from Handbook of Environmental Data on Organic Chemicals, Karel Verschueren, 3rd Edition.

The foregoing calculations account for 65% of the PEG (400) MO added to steam boiler heads. The remaining 35% of the added PEG (400) MO, as discussed previously, is expected to be included in the steam and, thus, to enter food during cooking. Under the conditions of the steam heads, the PEG (400) MO is not expected to be hydrolyzed; thus, to the extent it enters the food, it will be consumed as such. The PEG (400) MO consumed in food is expected to be metabolized and will enter the environment, if at all, as metabolic products. These will be handled in sanitary sewers where further environmental contact will be minimized.

Finally, tests have been conducted to determine the extent of biodegradation of the additive in the environment. Test procedures used were from the OECD collection:

301 D Closed Bottle Test

302 B Zahn-Wellens/EMPA Test

These will both be found in Attachments #4 and #5 to this EA.

The results of the closed bottle test showed a 5 day and 28 day BOD of 481 mg O_2/g and 916 mg O_2/g respectively. PEG (400) MO attained 39% 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 PEG (400) MO.

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 PEG (400) MO resulted in 27% degradation of the additive as measured by percent loss of DOC (dissolved organic carbon). Thus, in this test the substance falls into the second category, inherently biodegradable. These data indicate that primary degradation is likely to occur in waste treatment. Additionally, with acclimation of the organisms to PEG (400) MO, a significant portion of the material would be further degraded. The oleic acid will biodegrade easily in soil and aquatic systems. On average, PEG 400 will degrade 60% in a synthetic sewage, as demonstrated in the Closed Bottle 28-day test (26% degradation) and the Zahn Wellens 28-day test (96% degradation). (See Attachment #6).

6. Alternatives to the Proposed Action

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified. BetzDearborn, Inc. believes that the proposed use of a product containing PEG (400) MO should be considered an advance in boiler water technology. The product when employed at the recommended levels reduces corrosion in the steam condensate and as a consequence a cleaner Boiler system can be achieved.

7. Attachments

Estimate of Total Pounds PEG (400) MO Sold in 2001-02 *[Confidential]*

General Protocols for Aquatic Toxicity Determinations: Fathead Minnows

General Protocols for Aquatic Toxicity Determinations: Daphnia Magna

Biodegradation Protocols from OECD: 301 D Closed Bottle Test

Biodegradation Protocols from OECD: 302 B Zahn-Wellens/EMPA Test

Summary of Biodegradation Data

8. List of Preparers

Rosa Crovetto

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

9. Certification

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

Date: July 14, 2000

Donna M. Ware
Manager of Food Additives
Betz Dearborn, A Division of Hercules
Incorporated

Part V — CERTIFICATION

The Notifier, by the undersigned, hereby certifies that the information provided herein is accurate and complete to the best of his knowledge.

Respectfully submitted,

BetzDearborn, Inc., a Division of Hercules, Inc.

By: ______________________________
Ralph A. Simmons
Keller and Heckman LLP

COUNSEL FOR BETZDEARBORN

ATTACHMENT #6

Summary of Biodegradation Data

BetzDearborn Inc.
4636 Somerton Road, Trevose, PA 19053

PRODUCT: PEG 400 _DATE

AQUATIC TOXICOLOGY

NO DATA AVAILABLE

BIODEGRADATION

COD (mg/gm): 1670
TOC (mg/gm): 590
BOD-5 (mg/gm): 0
BOD-28 (mg/gm): 942

Closed Bottle Test
% Degradation in 28 days: 26
Zahn-Wellens Test
% Degradation in 28 days: 96

MAMMALIAN TOXICOLOGY

Oral LD50 RAT: >20,000 MG/KG

Dermal LD50 RABBIT: 3,000 MG/KG

Ames Assay BACTERIA: NEGATIVE