



ATTACHMENT 3
ENVIRONMENTAL ASSESSMENT

000029

ENVIRONMENTAL ASSESSMENT

1. **Date:**

June 6, 2001

2. **Name of Notifier:**

Lonza Inc.

3. **Address:**

Lewis & Harrison, 122 C Street, NW, Suite #740, Washington, DC 20001

4. **Description of Proposed Action:**

The notification requests the use of a mixture of ethoxylated fatty acids (polyethylene glycol 400 monooleate and polyethylene glycol dioleate) as anti-corrosive agents for boiler systems¹. The ethoxylated fatty acids will be marketed under the trade name . The concentration of the ethoxylated fatty acids in this product is approximately 83%. Food manufacturing boiler systems.

is added continuously into the steam header in order to maintain a maximum concentration of 2 mg/kg in the steam.

will be produced at the notifier's manufacturing site identified below:

The manufacturing site is located in an industrial park on the outskirts of . The River is approximately one mile from the manufacturing site. To the east of the manufacturing site is undeveloped land (railroad tracks and woods); an industrial park is south of the site and north of the site is a residential area. 000030

¹This notification is very similar to a previously submitted notification (Food-Contact Notification Number 97). Both notifications are for the identical use (anti-corrosive agent in boiler systems) of ethoxylated fatty acids. The only difference is that this notification is for a mixture of ethoxylated fatty acids (mono and dioleate) while FCN Number 97 is limited to the monooleate.

5. Identification of Chemical Substances that are Subject to the Proposed Action:

The Food-Contact Substances covered by this notification are ethoxylated fatty acids and impurities associated with these fatty acids. Chemical identity information concerning these ingredients is presented below.

Chemical Names

- ◆ Poly(oxy-1,2-ethanediyl), α -[(9Z)-1-oxo-9-octadecenyl]- ω -hydroxy
- ◆ Poly(oxy-1,2-ethanediyl), α -[(9Z)-1-oxo-9-octadecenyl]- ω -[(1-oxo-octadecenyl)oxy]-, (Z,Z)-

Common/Trade Names

- ◆ Polyethylene glycol (400) monooleate
- ◆ Polyethylene glycol (400) dioleate

CAS Reg. Nos.

- ◆ 9004-96-0 (polyethylene glycol monooleate)
- ◆ 9005-07-6 (polyethylene glycol dioleate)

Molecular Weights

- ◆ Polyethylene glycol monooleate - 678
- ◆ Polyethylene glycol dioleate - 942

Chemical Formulas

- ◆ Polyethylene glycol monooleate - $(C_2H_4O)_9 C_{18}H_{34}O_2$
- ◆ Polyethylene glycol dioleate - $(C_2H_4O)_9 C_{36}H_{70}O_2$

Structures

- $CH_3(CH_2)_7CH=CH(CH_2)_7CO(OCH_2CH_2)_nOH$
(Polyethylene glycol monooleate)
- $CH_3(CH_2)_7CH=CH(CH_2)_7CO(OCH_2CH_2)_nOCO(CH_2)_7CH=CH(CH_2)_7CH_3$
(Polyethylene glycol dioleate)

000031

Impurities Associated with the FCS

Chemical Name	CAS Reg. No.	Typical Level	Max. Level

Chemical/Physical Properties

Properties	Value
Solubility	Dispersable in water

000032

6. Environmental Consequences of the Proposed Action:

a) Production of the Food-Contact Substance

There are no extraordinary circumstances that apply to the manufacture of [redacted] /ethoxylated fatty acids. Therefore, information about environmental introductions from the production of these substances need not be included in this Environmental Assessment.

b) Introduction of Substances into the Environment as a Result of Use/Disposal

The use of [redacted] may result in environmental releases into water as water is lost from the boiler system. Substances that may be released are the ethoxylated fatty acids, degradates of the ethoxylated fatty acids¹ and impurities associated with [redacted]. The concentration of these substances in boiler water can be estimated using the same assumptions that were employed for the FCN Number 97 Environmental Assessment². These assumptions are as follows:

- Approximately 5% of the water containing [redacted], its degradates and impurities is removed per hour; therefore, in a typical plant complete exchange of the water to which [redacted] is added occurs after 20 cycles.
- The maximum concentration of [redacted] in the boiler water system is 2 mg/kg.
- [redacted] is 49% polyethylene glycol 400 monooleate ([redacted]); 34% polyethylene glycol 400 dioleate ([redacted]); 15% polyethylene glycol 400 ([redacted]) and 2% C₁₂₋₁₈ unsaturated fatty acids.
- 65% of PEGOSPERSE 400 MO is recycled to the boiler and 35% remains in the steam used to treat food.
- Approximately 95% of the ethoxylated fatty acids are hydrolyzed into their components: polyethylene glycol 400 (PEG 400) and oleic acid.
- 282 g/mol is the molecular weight of oleic acid.
- 411 g/mol is the molecular weight of PEG 400
- 678 g/mol is the molecular weight of PEG 400 MO
- 942 g/mol is the molecular weight of PEG 400 DO

000033

¹The ethoxylated fatty acid degradates are the hydrolysis products: polyethylene glycol 400 (PEG 400) and oleic acid. The impurities are PEG 400, C₁₂₋₁₈ unsaturated fatty acids, ethylene oxide and 1,4-dioxane. Because ethylene oxide and 1,4-dioxane are present at extremely low concentrations in PEGOSPERSE 400 MO, environmental releases for these substances are considered trivial and have not been estimated.

²Since this notification and FCN Number 97 involve essentially the same substances used in the same manner the market volume(s) for the substances and the amount(s) released to the environment are anticipated to be practically identical.

Therefore, the maximum concentrations for the ethoxylated fatty acids (PEG 400 MO and PEG 400 DO) oleic acid and PEG 400 in the boiler system water are as follows:

- PEG 400 MO

$$[20 \times 0.05 \times 0.65 \times 0.49 \times 2 \text{ mg/kg}] = 0.64 \text{ mg/kg (ppm)}$$

- PEG 400 DO

$$[20 \times 0.05 \times 0.65 \times 0.34 \times 2 \text{ mg/kg}] = 0.44 \text{ mg/kg (ppm)}$$

- PEG 400

PEG 400 is an aggregate from three sources: (i) the hydrolysis of PEG 400 MO; (ii) the hydrolysis of PEG 400 DO; and (iii) residual PEG 400 in

$$[20 \times 0.95 \times 0.65 \times 0.49 \times 2 \text{ mg/kg} \times [(411 \text{ g/mol}/678 \text{ g/mol})]] +$$

$$[20 \times 0.95 \times 0.65 \times 0.34 \times 2 \text{ mg/kg} \times [(411 \text{ g/mol}/942 \text{ g/mol})]] +$$

$$[20 \times 0.95 \times 0.65 \times 0.15 \times 2 \text{ mg/kg}] = 14.7 \text{ mg/kg (ppm)}$$

- Oleic Acid

The oleic acid concentration is an aggregate of two sources: (i) the hydrolysis of PEG 400 MO and (ii) from the hydrolysis of PEG 400 DO.

$$[20 \times 0.95 \times 0.65 \times 0.49 \times 2 \text{ mg/kg} \times [(282 \text{ g/mol}/678 \text{ g/mol})]] +$$

$$[20 \times 0.95 \times 0.65 \times 0.34 \times 2 \text{ mg/kg} \times [(546 \text{ g/mol}/942 \text{ g/mol})]] = 9.8 \text{ mg/kg (ppm)}$$

As noted above, the concentration of the ethoxylated fatty acids, oleic acid and PEG 400 in the boiler system from the use of _____ is expected to be the same as those estimated from the use of FCN Number 97.

000034

The table below compares these estimated concentrations.

Substance	Boiler Concentration	
	FCN Number 97	Subject Notification
Oleic Acid	10.3 ppm	9.8 ppm
PEG 400	14.4 ppm	14.7 ppm
PEG 400 MO	1.3 ppm	0.64
PEG 400 DO	-----	0.44

The table shows that the use of _____ results in a slightly higher concentration of oleic acid and a slightly less concentration of PEG 400 in boiler water compared to FCN Number 97. However, these difference are inconsequential when compared to the absolute concentration of each substance present. In addition, the concentration of PEG 400 MO is slightly lower from _____ use compared to FCN Number 97. _____ also contains the dioleate (PEG 400 DO), which is not present in FCN Number 97. However, the monooleate and dioleate are chemically very similar and the aggregated concentration is still less than the concentration of the monooleate, in boiler water, from the use of FCN Number 97.

c) **FATE OF SUBSTANCES RELEASED INTO THE ENVIRONMENT**

The notifier wishes to reference the environmental fate information/data presented in FCN Number 97 since, as noted above, the nature and magnitude of the environmental releases from the use of the substances covered by this notification and those for FCN Number 97 are essentially the same.

d) **ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES**

The notifier wishes to reference the environmental effects information/data presented in FCN Number 97 since, as noted above, the substances covered by this notification and FCN Number 97 are essentially the same.

7. **Use of Resources and Energy**

The ethoxylated fatty acids covered by this notification are a substitute for the ethoxylated fatty acid that is currently being used as an anti-corrosive agent for food manufacturing boiler systems. Consequently, the notifier does not expect that the use of the substances covered by this notification will lead to a significant change in the use of resources and energy.

8. **Mitigation Measures**

Mitigation measures need not be considered because no potential adverse effects have been identified.

9. **Alternatives to Proposed Action**

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

10. **List of Preparers**

This EA was prepared for Lonza Inc., by Christina Swick and Eliot Harrison of Lewis & Harrison. Ms. Swick's training and background is in environmental health sciences and Mr. Harrison's background is in biology and chemistry.

11. **Certification**

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

Name: Eliot I. Harrison

Title: Agent for Lonza

Signature:

A rectangular box with a red border, containing a redacted signature. The signature is illegible due to the redaction.

Date: June 6, 2001

000036