ENVIRONMENTAL ASSESSMENT

1. Date: February 16, 2007

2. Name of Applicant/Petitioner: Arkema Inc.

3. Address:

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4. Description of Proposed Action:

a. Requested action:

The action requested in this notification is the establishment of a clearance to permit the general use of N-ethyl-N-hydroxyethanamine, CAS Registry Number 3710-84-7, as a polymerization regulator (short-stopper) in the radical polymerization of vinyl chloride homopolymers and copolymers that will be used in food contact applications.

b. Need for action:

The food contact substance N-ethyl-N-hydroxyethanamine will be used at a maximum level of 500 ppm (425 ppm anhydrous material) per weight of vinyl chloride monomer. It is intended for use with all food types (aqueous, acidic, low alcoholic, fatty and dry foods) under Conditions of Use A through H, as described in Table 2 of 21 CFR 176.170(c).

The FCS is intended to be used with all types of food contact articles manufactured from vinyl chloride homopolymers and/ or from vinyl chloride copolymers ("PVC") complying with 21 CFR § 177.1950, § 177.1960, and/or § 177.1980, or other rigid vinyl chloride polymers described under an effective food contact notification. PVC may be used in used in single use applications, (e.g. bottles, blister packs, transparent packs and punnets), and repeated use applications (e.g. piping and piping appurtances).

c. Locations of use/disposal:

The manufacture of the FCS will be done at an Arkema Inc. facility in the US. This FCS has been manufactured at the facility for at least twenty years in accordance with all federal and state regulatory requirements.

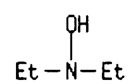
We anticipate the FCS will be used by manufacturers of PVC. PVC manufacturers are located across the United States. The FCS as a short-stopper in the manufacture of suspension-PVC (S-PVC). The FCS is not expected to be released into the environment from any PVC manufacture facility as it is contained within a sealed reaction vessel. Additionally, the PVC produced in the reaction vessel occurs through a free-radical polymerization process and is initiated with an organic peroxide free radical. At the conclusion of the polymerization process, any un-reacted peroxide initiator will be decomposed with the FCS.

The FCS and its decomposition products will be disposed of as part of the process waters at the PVC manufacture facilities.

5. Identification of Substances that are the subject of the Proposed Action:

The substance that is the subject of this Notification is N-ethyl-N-hydroxyethanamine (FCS). The CAS Registry Number is 3710-84-7. The FCS may also be identified as DEHA.

The molecular structure for the FCS is given below. The molecular formula is $C_4H_{11}NO$, and its molecular weight is 89.1.



A description of the product composition appears in the FCN.

6. Introduction of Substances into the Environment:

a. **Introduction of substances into the environment as a result of manufacture:**

Under 21 CFR § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of DEHA. Consequently, information on the manufacturing site and compliance with relevant emissions requirements are not provided here.

b. **Introduction of substances into the environment as a result of use/disposal:**

At low levels (ppm), the FCS is highly reactive and is not expected to survive transit through the PVC manufacture process given: 1) the low level of FCS used, 2) the level of dissolved oxygen content of the PVC process water, and 3) the effects of dilution after mixing with other aqueous waste streams.

Any remaining FCS in the reaction water is likely destroyed quickly since the FCS acts as an oxygen scavenger for the dissolved oxygen (DO) in the PVC process waters. The maximum amount of DO in water is 8.9 ppm. From the following reaction:

$$4(C_2H_5)_2\text{-N-OH} + 9O_2 \rightarrow 8CH_3COOH + 2N_2 + 6H_2O$$

it requires four (4) moles of FCS per nine (9) moles of oxygen. Once the solid PVC particles are removed from the water during the centrifugal drying process, the remaining water, or centrate water (CW), is further processed. As much as 90% of this CW is re-used in other parts of the plant in many PVC facilities and it is during this recycling of the CW that any remaining FCS is removed since the CW is continuously exposed to air (oxygen).

Oxygen scavenger reactions:

Step 1. 2 Et_2NOH + O_2 $\Rightarrow$ 2 Et-N($\rightarrow$O)=$CHCH_3$ (Nitrone) + 2 H_2O

Step 2. 2 Et-N($\rightarrow$O)=$CHCH_3$ (Nitrone) + 2 H_2O $\Rightarrow$ 2 EtNHOH (Ethylhydroxylamine) + 2CH_3CHO (Acetaldehyde)

Step 3. 2 EtNHOH (Ethylhydroxylamine) + O_2 $\Rightarrow$ 2CH_3CH=NOH (Acetaldoxime) + 2H_2O

Step 4. 2CH_3CHO (Acetaldehyde) + O_2 $\Rightarrow$ 2CH_3COOH (Acetic acid)

Step 5. 2CH_3CH=NOH (Acetaldoxime) + 2H_2O $\Rightarrow$ 2CH_3CHO (Acetaldehyde) + 2NH_2OH (Hydroxylamine)

Step 6. 2CH_3CHO (Acetaldehyde) + O_2 $\Rightarrow$ 2CH_3COOH (Acetic acid)

Step 7. 2NH_2OH (Hydroxylamine) $\Rightarrow$ N_2 + 2H_2O

Overall Reaction in Oxygen Scavenging:

2 Et_2NOH + 4O_2 $\Rightarrow$ 4CH_3COOH (Acetic acid) + N_2 + 2H_2O

According to D.M. Ellis et. al. (see Attachment 9 of the FCS), nitrone will also undergo oxidation. This leads to the formation of acetaldoxime and acetaldehyde. Continued exposure to excess oxygen due to mixing of the CW in the presence of air will facilitate the oxidation of acetaldehyde to acetic acid (or acetate).

Page 10 of Attachment 11 of the FCS describes the general scheme of oximes oxidation.

Based on the FCS reactions for the CW described above, the only decomposition products that are likely present in the water are acetic acid (or acetate if the pH of the CW is >4.8). Some PVC manufacturers will buffer the PVC slurry so the pH may be >4.8. Some PVC manufacturers do not buffer the PVC slurry and consequently, the HCl produced during the polymerization reaction will result in a pH of about 3.5.

A large PVC producer uses approximately 450,000 gallons/day in the entire facility. Assuming there is 7,000 gallons of water in a typical PVC reactor, which eventually becomes CW, there are about 6 batches produced per reactor per day and a PVC plant will typically have 3 – 5 reactors, **the volume of CW** water expected from a typical PVC facility is:

(7,000 gallons/batch) x (6 batches/day) x 4 reactors = 168,000 gallons water/day.

This amount of water (which becomes the CW) is eventually diluted with other waters from the PVC plant totaling 450,000 gallons, a 67% dilution.

Total By-Products from FCS Degradation:

When using 100 ppm FCS to stop the polymerization reaction, there is about 15 ppm FCS remaining that eventually forms acetic acid or acetate. In a typical size PVC reactor, this residual FCS equates to about 3.3 moles. As shown above, it required four moles of FCS to destroy nine moles DO. For every four mole of FCS, eight moles of acetic acid (or acetate), two moles of nitrogen gas and six moles of water are produced. The total amounts of degradation products produced from the FCS are:

Acetic Acid (Acetate): (3.3 mole FCS remaining/reaction batch) x (6 batches/day) x 4 reactors = 79.2 moles FCS used per day at a typical PVC facility to destroy DO. Since there are eight moles of acetic acid produced per four moles of FCS, there is a total of 158.2 mole of acetic acid produced per day; about 9,500 grams or 9.5 kg/day.

** Assuming there is no biological degradation of acetic acid/acetate, the concentration of acetic acid in the wastewater is:

9,500 grams in 450,000 gallons water x 1000 mg/gram x 1 gallon/3.785 liters = 5.6 mg/l or 5.6 ppm.

Nitrogen Gas: (3.3 mole FCS remaining/reaction) x (6 batches/day) x 4 reactors = 79.2 moles FCS used per day at a typical PVC facility to destroy DO. Since there are two moles of nitrogen gas produced per four moles of FCS, there are a total of 39.6 moles of nitrogen produced per day; about 1,100 grams or 1.1 kg/day.

** The nitrogen gas may be lost during mixing of the CW in the various processing steps.

7. Fate of Emitted Components in the Environment:

No FCS will be introduced into the environment as a result of its use in PVC manufacture as a short-stopping agent as described above. Consequently, there is no need to account for its fate in the environment. Regarding the decomposition product acetic acid, acetic acid will not survive in the environment as it is readily biodegraded.

The existing data relating to the depletion mechanisms for the FCS or decomposition product acetic acid introduced into the aqueous environment are summarized in the following tables:

FCS

Biodegradation (ISO 7827 method)[1]	17% after 28 days
Biodegradation (unacclimated system at 700 mg/L)[2]	biodegradable

Ready biodegradability prediction[3]	Yes
Total biodegradation in waste water treatment[4]	92%

Acetic acid

Biodegradation[2]	96% after 20 days
Ready biodegradability prediction[3]	Yes
Total biodegradation in waste water treatment[4]	91%

[1] Elf Atochem Unpublished study report, #41110 (1992)
[2] Verschueren, K. (1983) Handbook of Environmental Data on Organic Chemicals. 2nd ed. Van Nostrand Reinhold Co.
[3] BIOWIN model version 4.02.
[4] Biowin/EPA draft method.

The FCS and acetic acid are highly water-soluble and have low log K_{ow} values. Thus, they are not anticipated to be persistent in the environment or to have bioaccumulative potentials. As shown in the tables of biodegradation data above, the FCS and acetic acid also are biodegradable, with over 90% predicted removal from wastewater treatment systems. Furthermore, the worst-case estimate of the influent concentration of FCS or its decomposition products (15 ppm) discharged to wastewater treatment systems is well below that to elicit inhibition of sludge microbes (see data in section 8 below). Thus, the low loading rate of FCS or its decomposition products is not anticipated to adversely affect the proper functioning and performance of POTWs.

8. Environmental Effects of Released Substances:

Again, no FCS will be introduced into the environment as a result of its use in PVC manufacture as a short-stopping agent as described above. Consequently, there is no need to account for its environmental effects. Regarding the decomposition product acetic acid, acetic acid will not survive in the environment as it is readily biodegraded.

Theoretically, even if the FCS and its decomposition product acetic acid were not biodegraded, but were released at the maximum concentrations of 15 ppm and 5.6 ppm, respectively, the concentrations introduced into the environment would be very low.

The existing data relating to the aquatic toxicity of the FCS and its decomposition product acetic acid are summarized in the following tables:

FCS

Test Organism	Endpoint	Concentration (ppm)
Bacteria[1] (*Pseudomonas putida*)	EC_{50} (16 hour growth inhibition)	37
Daphnia magna[2]	48 hour NOEC	90
Guppy[3]	96 hour NOEC	85

Acetic acid[4]

Test Organism	Endpoint	Concentration (ppm)
Bacteria (*Pseudomonas putida*)	EC_{50} (growth inhibition)	2850

Protozoa *(Uronema parduczi)*	NOEC (growth inhibition)	1350
Algae *(Scenedesmus quadricauda)*	NOEC (growth inhibition)	4000
Daphnia magna	24 hour NOEC	47
Bluegill	96 hour NOEC	75
Mosquito fish	96 hour NOEC	251
Fathead minnow	96 hour LC_{50}	88

[1] Elf Atochem unpublished study report (September 9, 1992)
[2] Elf Atochem unpublished study report (June 5, 1992).
[3] Krachtwekentuigen laboratorium unpublished study report #87.0733-G (March 1, 1988).
[4] Verschueren, K. (1983) Handbook of Environmental Data on Organic Chemicals. 2nd Ed. Van Nostrand Reinhold Co.

Given the low levels (ppm) of FCS used, that the FCS is highly reactive and is not expected to survive transit through the PVC manufacture process, is readily biodegradable and its ultimate degradation products are readily biodegradable, use of the FCS is not expected to pose a significant hazard to the environment.

9. Use of Resources and Energy:

The use of the FCS will not require additional energy resources for treatment and disposal of wastewater, as the FCS byproducts readily degrade. The raw materials used in the production of the compound are commercially manufactured materials that are produced for use in a variety of chemical reactions and production processes. Moreover, as the FCS will be used in place of other short-stoppers that are currently permitted for use, the use of the FCS as described will not lead to a net increase in the consumption of resources and energy. Additionally, use of the FCS is not expected to lead to a significant increase in the total market volumes of PVC food contact articles.

10. Mitigation Measures:

Based on the foregoing, no significant adverse environmental impacts are expected to result from the intended use of the FCS. Thus, the use of the subject food-contact substance is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action:

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in the Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of other products by the PVC manufacturing industry; such action would have no environmental impact. In view of the excellent properties of DEHA as a short-stopper for PVC, and the absence of any identified significant environmental impact that would result from its use, the clearance of the use of the FCS as described herein appears to be environmentally safe and desirable in every respect.

12. List of Preparers:

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13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: 16 February 2007

Gerry Franco, Global Business Director, Amines

Arkema Inc.