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August 28, 1997

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Document Control Office (7407)  
Attention: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U. S. Environmental Protection Agency  
Washington, DC 20460-0001

Subject: Substantiation of Confidentiality Claim for Section 8(e) Document Control Number 8EHQ-97-13980

Re: Your letter dated July 25, 1997, received by us on July 30, 1997

Dear Mr. Gross:

In response to your letter on the above subject, please note that Attachment 1 (Support Information for Confidentiality Claim of TSCA Section 8(e) Document Control Number 8EHQ-97-13980) contains the responses to the routine substantiation questions for the above TSCA Section 8(e) submittal. In Attachment 1 "Company" is [

].

If you have any questions, please contact me at [ ].

Sincerely,

[ ]  
[ ]

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SUPPORT INFORMATION for CONFIDENTIALITY CLAIM

TSCA Section 8(e) Document Control Number 8EHQ-97-13980

1. Q. Is your company asserting this confidential business information (CBI) claim on its own behalf?  
A. Yes
2. Q. For what period do you assert your claim(s) of confidentiality?  
A. We request that the claim(s) be confidential for a period of 10 years or until the study on which the claim(s) are based is made publicly available. When taken out of context from the study as a whole, the submitted information can be commercially damaging to products containing this substance. A period of 10 years will give The Company time to finalize this study and perform additional confirming studies as necessary. In addition this is the period of time covered by confidentiality agreements in place with the contractor and consultant used for this project.
3. Q. Has the information that you are claiming as confidential been disclosed to any other governmental agency or to EPA at any other time?  
A. No.
4. Q. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming as CBI.  
A. The building and specific office suite Company where these records are maintained is accessible only by employee key card or access and registration our Reception area. Only 5 people in this department, one of which is the Executive Assistant who controls access to all department files, handle files with this type of information. Except for these 5 individuals no one is allowed free access to the files. These 5 individuals handle requests for information in the files and CBI information is not released to the requestor.
5. Q. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s)?  
A. The data is being developed by a contract testing laboratory which is under a confidentiality agreement with the Company. The data

was also reviewed with a toxicology consultant who is also under a confidentiality agreement with the Company.

The confidentiality agreements restrict the consulting laboratory and toxicology consultant from discussing or releasing information with respect to this test data for a period of 10 years to anyone except when required by their national regulatory authority or with the written permission of the Company.

6. Q. Does the information claimed as confidential appear or is it referred to in any of the following:

Q. a. Advertising or promotional material for the chemical substance or the resulting end product.

A. No

Q. b. Material Safety Data Sheets or other similar materials (such as technical data sheets) for the substance or resulting products.

A. No

Q. c. Professional or trade publications; or

A. No

Q. d. Any other media or publications available to the public or your competitors.

A. No

7. Q. Has EPA, another federal agency or court made any confidentiality determination regarding information associated with this substance?

A. No

8. Q. Describe the substantial harmful effects that would result to your competitive position of the CBI information is made available to the public. Address each piece of information claimed CBI separately.

A. 1. Confidentiality claim with respect to Submitter, Company and Product Trade Name.

The connection between the submitter, the chemical substance and the trade name material is well known. There

are only three (3) domestic manufacturers of this substance. Release of the identity of the submitter, the company or the product trade name quickly leads to a direct association With either of the other items. Therefore the linkage of any of these identifiers to the unsubstantiated health effects described in the TSCA 8(e) notice could seriously damage the reputation of several of existing and developing products. This is especially true since we are trying to enter the [PVC plasticizer] market with several new formulations as more desirable alternatives to [ ] against larger more sophisticated competitors. Should current or anticipated customers of products containing this substance deselect the products because of the unsubstantiated health effects reported in this notice, it would mean a loss of approximately [ ].

2. Confidentiality Claim with respect to Study Number.

All studies done for the Company by Huntingdon Life Sciences are identified with [ ]. Therefore an educated observer can readily associate the lab study number with the Company and the products that contain the substance notified. Should current or anticipated customers of products containing this substance decide to deselect the products because of the unsubstantiated health effects reported in this notice, it would mean a loss of approximately [ ].

9. Q. Has the substance been patented in the US or elsewhere?

A. No

10. Q. Is this substance/product commercially available, and if so, for how long has it been available on the commercial market.

A. The substance and products have been commercially available for approximately 45 years in the US.

Q. a. If on the commercial market, are your competitors aware that the substance is commercially available in the US?

A. Yes

Q. b. If not already commercially available describe what stage of research and development (R & D) the substance is in, and estimate how soon a market will be established.

- A. Not applicable as this is a commercial substance.
- Q. c. What is the substance used for and what type of product(s) does it appear in.
- A. The substance is a plasticizer for PVC and other polymers. The substance appears to consumers as a plasticizer in PVC flooring or as a component in adhesives.
11. Q. Describe whether a competitor could employ reverse engineering to identically recreate the substance.
- A. Not applicable, since substance identity is not claimed confidential.
12. Q. Do you assert that disclosure of this information you are claiming CBI would reveal?
- Q. a. Confidential process used in manufacturing the substance
- A. No
- Q. b. If a mixture, the actual portions of the substance in the mixture, or
- A. No
- Q. c. Information related to the effects of the substance on human health or the environment.
- A. To the substance; No. To the Trade Name Product; Yes.
13. Q. Provide the Chemical Abstract Service Registry Number for the product, if known.
- A. The CASRN was identified on the TSCA Section 8(e) Notice as CASRN 120-55-8 and has not been claimed as CBI.
14. Q. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting.
- A. No

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