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INITIAL SUBMISSION: LETTER FROM [] TO USEPA REPORTING RESULTS OF GUINEA PIG MAXIMIZATION TEST ON [], DATED 120299 (SANITIZED)		
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CONFIDENTIAL		

A 02

INITIAL SUB-MISSION

A 03

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MR 29557

December 2, 1999

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

RE: TSCA s.8(e) Substantial Risk Notice

Dear Sir or Madam:

[ ] is submitting information describing the results of a Guinea Pig Maximization Test (GPMT) on a more concentrated form of a new lubricant additive component that was the subject of a US PMN filed earlier this year [ ]. We do not intend to manufacture or sell the concentrated form of this substance in the US or abroad.

The original PMN substance [ ] is manufactured as a [ ] for use as a new lubricant additive component in [ ]. The original PMN [ ] cited the results of a GPMT on the [ ] material which displayed mild skin sensitization potential. The purpose of this notice is to describe the results of a recent GPMT conducted on the [ ] material [ ] to meet regulatory data requirements for a European PMN as prescribed in the European Union Notification of New Substances Regulations, 1993. Based on the results of this test, the [ ] material would be considered a moderate skin sensitizer according to the Magnusson and Kligman ranking system.

The following is a summary of the results of the GPMT conducted on the [ ] material as excerpted from a draft report entitled, "Dermal Sensitization Study in the Guinea pig, Maximization Method".

"The skin sensitization potential of the test material was evaluated in the Guinea Pig Maximization Test. At 48 hours following challenge application of the undiluted test material, 60% of the treated animals exhibited a "positive" reaction ranging from moderate to severe erythema. Edema was also noted in four out of twenty treated animals during the post-challenge observation. For the rechallenge, the test material was diluted to 50wt% in olive oil to reduce the dermal irritation responses noted during challenge. At 48 hours post-rechallenge, 30% of the treated animals exhibited a "positive" reaction ranging from slight to moderate erythema. Based on the conditions of this test and the results of the challenge and rechallenge, the test material displayed moderate skin sensitization potential."

The Quality Assurance Department of the test lab contracted to perform the study has not yet formally reviewed and approved this test report. We will provide a copy of the final report and a substantiation of

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Company Sanitized

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confidentiality as soon as we receive an "8EHQ" reference number.

We are claiming both the company identification and product description as confidential business information. Public disclosure of the identity of our company and product chemistry could endanger our competitive standing in the worldwide lubricant additives market.

If you have any questions, please contact me directly. Please send all correspondence pertaining to this report to my attention.

Sincerely yours,

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business
anger our

his report

CERTIFICATE OF AUTHENTICITY

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