MEMORANDUM

Tox. Project No.: 8-0355
Tox. Chem. No.: 331A

To: Lois Rossi
Product Manager #21
Registration Division (TS-767C)

From: Judith W. Hauswirth, Ph.D. Section Head, Section VI Toxicology Branch/HED (TS-769C)

Thru: Theodore M. Farber, Ph.D., Chief Toxicology Branch/HED (TS-769C)

Action Requested: Review report of possible 6(a)(2) data.

Discussion: In a letter dated January 4, 1988, Kopper Company, Inc. reports that their contract testing laboratory which is conducting a dermal sensitization study on Sapstain Control Chemical NP-1 has sent them a preliminary report that indicates their product could be a skin sensitizer and that the response could be dose-related. They also report signs of severe skin irritation with either slightly or undiluted test material.

Koppers claims that individual testing of the components of this product were negative for skin sensitization and they have not received reports from workers of dermal sensitization due to contact with the product. They have initiated a review of the product labels and material safety data sheets and will amend the documents accordingly to warn workers and customers. They also intend to due additional testing on the product.

A final report on the dermal sensitization study should be sent to the Agency by March 1, 1988.

Recommendations/Conclusions:

TB feels that the registrant is adequately dealing with the potential dermal sensitization of this product. However, we cannot comment adequately on the possibility of dermal sensitization until we have reviewed a final report of the study and any other additional information that the registrant may compile, as they claim to be in the process of doing.