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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

AUG 12 1986

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

**SUBJECT:** Fulfillment of the rabbit teratology requirement.  
EPA ID #038501; Caswell #398; Tox Branch Project #1303.

**TO:** Geraldine W. Werdig  
Chief, Data Call-In Program  
Registration Division (TS-767C)

**FROM:** Stephen C. Dapson, Ph.D. *Stephen C. Dapson*  
Pharmacologist, Review Section V  
Toxicology Branch/HED (TS-769C) *7/29/86*

**THRU:** Laurence D. Chitlik, D.A.B.T. *LDC*  
Section Head, Review Section V *7/31/86*  
Toxicology Branch/HED (TS-769C) *W. Testino*  
*7-31-86*  
and *8/12/86*  
Theodore M. Farber, Ph.D., D.A.B.T.  
Chief, Toxicology Branch  
Hazard Evaluation Division (TS-769C)

**Chemical:** Diphenylamine (also known as BIG DIPPER, NO SCALD,  
scaldip, N-phenyl-benzenamine)  
CAS Registry Number 122-39-4  
Molecular Formula - C<sub>12</sub>H<sub>11</sub>N

**Registrant:** Shield-Brite Corporation  
P.O. Box 519  
Kirkland, Washington 98033

**Action Requested:** "Would the attached reference to the rabbit teratology study fulfill the rabbit teratology requirement."

**Recommendation:** A simple reference to a study (supplied by the registrant) is not sufficient to fulfill the rabbit teratology study requirement. Furthermore, published papers rarely contain sufficient detail for a thorough evaluation of study quality and results. Therefore, the referenced study must be submitted to the Toxicology Branch for review before a decision can be made as to fulfillment of the requirement.

**Background:** The registrant submitted the following reference in response to a Data Call-In Notice for Diphenylamine (6/6/84) for a "teratology study in one species other than rats":

Edwards, J.A., Leeming, N.M., Clark, R., and Offer, J.M. (1983). "Effect of diphenylamine on pregnancy of the New Zealand white rabbit" conducted at Huntington, U.K., Huntington Research Centre, submitted to the World Health Organization (and also to the EPA) by Pennwalt Corporation, U.S.A.

This was published in:

World Health Organization/Food and Agriculture Organization of the United Nations "Plant Production and Protection" Paper #62 (1984)..

The registrant also presented the following results:

"Diphenylamine of 99.9% purity was not teratogenic to New Zealand white rabbits at doses up to and including 300 mg/kg bw/day, and was not mutagenic."