



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

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Dog Teratology Study for Carbaryl

TO: Jay Ellenberger, PM 21
Registration Division (TS-767)

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

Theodore M. Farber
4/10/85

Robert B. Jaeger, Section Head
Review Section #1
Toxicology Branch/HED (TS-769)

RBJ 4/14/85

FROM: Ray Landolt
Review Section #1
Toxicology Branch/HED (TS-769)

April 4, 1985

It is regrettable that my memorandum of January 31, 1985 generated additional correspondence by failing to preconceive your concerns for a dog teratology study. The following four paragraphs are in response to the respective four questions raised in your memorandum of February 20, 1985.

1.a. To retain the label statement "Do not use this product on pregnant dogs" on the carbaryl dust formulation would be prudent in light of the effects reported in the dog teratology studies. It is worth repeating that no observable effect levels were also reported in these dog teratology studies.

b. There is presently an apparent lack of use experience data on the carbaryl dust formulation applied to dogs and cats. I request that you initiate a comprehensive survey of the basic manufacturer of carbaryl, all formulators, distributors, veterinarians, small animal breeders and the PIMS data for the incidence of any adverse effects to dogs and cats associated with the use of carbaryl during pregnancy.

c. Carbaryl is registered for use on cats without a teratology study in cats to support this use. The above survey may determine the need for a cat teratology study and/or a change in the label caution recommending not to use on pregnant cats.

2. Dr. Theodore Farber through a personal communication with Dr. Dick Hill stated the concern for a dog teratology study could be resolved by a change in the directions for use from "apply liberally" to "apply a measured amount of dust."

3. The following quote on page 13 of the carbaryl Registration Standard appears to be an administration concern that is not apparent in the Toxicology Chapter to the Registration Standard.

"Although it appears from current data that carbaryl has only low teratogenic potential, the results of the dog studies continue to be a concern that has never been fully resolved. Because of the problems identified in the dog studies, particularly the presence of maternal toxicity at all doses tested, it is not clear that carbaryl would prove to be teratogenic in the dog if tested and evaluated by current procedures or, if so, at what levels. Therefore, the Agency is requesting the teratology study be repeated in the beagle dog."

To repeat the dog teratology study would serve to confirm the results of the existing two dog teratology studies. While these two studies were of questionable quality, they do indicate the sensitivity of the dog to carbaryl that can be resolved with the labeling requested in the Registration Standard: "Do not use this product on pregnant dogs". It should be recognized that this data was suggested by RD and OPP as being appropriate for defining the hazards to dogs, not to humans. Therefore, TB requests RD to inform us as to whether this request for a "pet" teratology, study represents a policy decision that all present or future registered pesticide applications to "pets" will require an evaluation of the teratogenic potential in an appropriate domestic animal species e.g. dog, cat, etc.?

4. Toxicology Branch's concern regarding the potential of carbaryl as a human teratogen is reiterated from the Toxicology Chapter, Registration Standard, Federal Register, Vol. 45, No. 241, December 12, 1980 page 81871 and the Carbaryl Decision Document of December 1980. "In view of the overall weight of evidence of studies which are valid and interpretable, the Agency has concluded that carbaryl would not constitute a potential human teratogenic or reproductive hazard under proper environmental usages".