



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

FEB 20 1985

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Applicability of a Dog Teratology Study
for Carbaryl

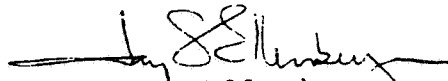
TO: Robert B. Jaeger, Section Head
Review Section # 1
Toxicology Branch
Hazard Evaluation Division (TS-769)

We have read Ray Landolt's memorandum of January 31, 1985 stating Toxicology Branch's position that a dog teratology study using carbaryl would not be required if the label directions for carbaryl pet products were changed to recommend a measured amount of carbaryl per application rather than a liberal application of some unknown amount. However, in reviewing your memorandum we feel that there are additional questions for which we must have a written answer by Toxicology Branch before upper management can proceed in deciding whether or not to require a dog teratology study for carbaryl. The questions that still remain to be addressed are:

- ° If we change the use directions for carbaryl pet product labeling to require a measured amount of carbaryl per application, is it Toxicology's opinion that the label statement "Do not use this product on pregnant dogs." is unnecessary?
- ° Has Dr. Dick Hill agreed that a dog teratology study with carbaryl is not necessary provided use directions for carbaryl specify a measured amount?
- ° How do we justify not requiring a dog teratology study in light of our position in the carbaryl registration standard which stated that "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." We further stated that we are requiring a dog teratology study in order to determine if carbaryl would be teratogenic in the dog if tested and evaluated according to current procedures and if so at what levels.

- The Agency has concluded in the past that the available data do not indicate that carbaryl constitutes a potential human teratogen or reproductive hazard under proper usage. However, one of the reasons we are asking for a repeat study is to address this concern. What is Toxicology's position regarding the potential of carbaryl as a human teratogen.

We feel that answers to the above questions will enable us to move forward on this teratology issue. If you have any questions please contact me.



Jay S. Ellenberger
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Registration Division (TS-767)