



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

MAY 8 1986

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Low Volume/Minor Use Waiver Request for Biphenyl

TO: Geraldine Werdig, Chief
Data Call-In Staff
Registration Division (TS-767)

FROM: Margaret L. Jones *Werdig*
Review Section III
Toxicology Branch (TS-769)

THRU: William Burnam, Deputy Chief
Toxicology Branch (TS-769)

*WAB
5-7-86*

Chemical: Biphenyl; diphenyl

Caswell No.: 87

Record No.: 170255, 168362

Petitioner: Paper-Pak Corp.

Action Requested: Determine whether toxicology data requirements can be waived for biphenyl because the petitioner claims low volume/minor use exists. Consideration of the applicability of the dog chronic feeding study.

Conclusion: Biphenyl is a fungistat used in citrus wraps. As such it is a food use pesticide. Normally, a full complement of toxicity data is required to support registration of a food use pesticide. Benefits and Use Division has not allowed the waiver on the basis of low volume and minor use. In this case, therefore, the data requirements for a food use pesticide will apply. The teratology study in a second species cannot be waived on the basis of low volume/minor use. The attached 5/2/86 memorandum from Burnam to ~~Werdig~~ ^{Burnam} outlines the toxicology data requirements for a low volume/minor use pesticide both for food and non-food uses.

The above-referenced dog chronic feeding study is not mentioned in the request for a waiver of chronic toxicology data. Additional information will be necessary before we can respond to this portion of the request.



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SUBJECT: Low Volume/Minor Use Waivers - Follow-up Memo

TO: Anne Barton, Deputy Director
Hazard Evaluation Division (TS-769)

This is an addendum to my March 12, 1986 memo on the same subject of data waivers. Even though tolerances and food uses exist for certain pesticides, there may be cases in which a combination of factors allows for a reduction in the total toxicological data base needed. Such factors include the following:

1. Available acute, subchronic, teratogenic and mutagenic do not indicate a problem or predict a future problem.
2. Structure activity does not predict a major problem.
3. Residue data on crops shows minimal amounts present with no secondary residues in meat, milk, poultry or eggs.
4. Relevant human experience indicates safety.
5. Exposure to applicators and bystanders is low.

The minimum toxicological data needed prior to a discussion of data waivers for food use pesticides are the following:

1. Acutes
2. Subchronic rat feeding study
3. Subchronic dog feeding study
4. Teratology study in one species
5. Mutagenicity battery

These should be of Core-minimum quality or better.

For non-food use pesticides, the minimum data needed are the following:

1. Acutes
2. Subchronic dermal
3. Teratology study in one species
4. Mutagenicity battery
5. Exposure information

This is consistent with drafts of our "Non-food Use Data Requirements" paper and is tiered based on the outcome of these tests and evaluation of exposure.

I believe that we should require these above mentioned basic tests initially and encourage the submission of actual residue data and, where applicable, processing studies. After all such information are evaluated, it then may be possible to determine if such waivers are reasonable.

Wm L. Burnam 5-2-86

William L. Burnam, Deputy Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

cc:

Dr. Farber
Bob Coberly