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

2-aminoButane
Cas # 125.

MAY 8 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Low Volume/Minor Use Waiver Request for sec-Butylamine

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

FROM: Margaret L. Jones *M. L. Jones 5/1/86*
Review Section III
Toxicology Branch (TS-769)

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

*W. Burnam
5782*

Chemical: sec-Butylamine; Tutane®; Frucote®

Caswell No.: 125

Record No.: 169715

Petitioner: FMC Corporation; Brogdex Company; Penwalt Corporation

Action Requested: Determine whether toxicology data requirements can be waived for sec-Butylamine because the petitioner claims low volume/minor use exists.

Conclusion: Sec-Butylamine is a fungicide used on citrus under special conditions, which constitutes a food use. Normally, a full complement of toxicity data are required for registration of a food use pesticide. Benefits and Use Division did not verify the petitioner's low volume/minor use waiver request due to insufficient information to support the claim. If the claim cannot be supported, the normal data requirements for a food use pesticide will be required. The attached 5/2/86 memorandum from Burnam to ^{Burnam}Werdig outlines the minimum data requirements for a low volume/minor use pesticide, which will apply only if the claim can be supported by the petitioner.



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MEMORANDUM

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