UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

000975

DATE: November 8, 1979

SUBJECT: PP#9G2151/9H5223-EUP-RLU: Proposal to Establish a Temporary Tolerance of 0.1 PPM of the Insecticide, Monitor, in Peanuts; Peanut Hulls at 0.4 PPM; and a Feed Additive Tolerance of 0.2 PPM in Peanut Meal. Amendment of 5/23/79 Caswell #378A

FROM: David Ritter
Toxicologist, Toxicology Branch/HED (TS-769)

TO: Marilyn Mautz, Team #16
IRB/Registration Division (TS-767)

Petitioner: Mobay Chemical Co.
Kansas City, MO.

Action Proposed

1. Revise Section D to include additional data;

2. Revise Section F to include a Feed Additive Tolerance for peanut meal;

3. That EPA reconsider its previous rejection by TOX (my review of PP#5F1571, 9/16/75) based on data from laboratories other than IBT.

Conclusions:

1. Upon reconsideration we conclude that there are not sufficient valid tox data to support a conclusion that the proposed temporary tolerance of 0.1 ppm Monitor in peanuts is safe.

2. Peanut hulls and peanut meal are not human food items.

3. We defer to RCB as to residues in meat, milk, eggs and poultry (see the S. Hummel review of 6/28/79).

Detailed Considerations:

I. Tolerance in the human food item, peanuts.

   a. Toxicology Branch rejected the initial proposal on the basis that chronic toxicity data in laboratory animals, having been performed at Industrial Biotest Laboratories (IBT), had not been validated and certified (see the Ritter review of 12/26/78). The data referenced in the present amendment were analyzed in the review of Mr. Ritter, 9/16/75, PP#5F1517.

EPA FORM 1320-6 (REV. 3-76)

TOX Branch concluded: ppm?

1) Three month dog study (FFB Bayer AG #2164, 6/26/70) NOEL of 1.5 based on ChE inhibition. However, since only two dogs/sex/group were used, and no histopathology was reported, we must rate this study as CORE Supplementary. Full pathological reports may elevate this rating to CORE Minimum.

2) Three month rat feeding study (FF Bayer AG #2165, 5/20/70) NOEL of 2 ppm based on RBC ChE inhibition. However, since no histological reports were submitted, this study likewise must be rated as CORE Supplemental. This rating may be elevated to CORE Guideline by submission of the histopathological reports.

b. Questions as to the potential for teratogenicity of this material have not been resolved. See the J. Doherty memo of 4/10/78, EPA Reg. No. 3125-280.

c. To date, no validation and certification of any chronic study was received, nor have we been given any assurance that such will be forthcoming.

d. In view of the lack of any validated studies on Monitor by IBT, there are only (2) 90-day studies viable. These studies at present are not adequate to support a temporary tolerance.

In addition to submitting the requested data for these two(2) studies; reproduction and teratology study and mutagenicity data are required.