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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 476-2178. Phosmet (Imidan™).

Response to Registration Standard: Submission
of 3/6/87 (Re Cottonseed Processing Studies).

RCB No.: 2114. MRID No.: 401111-01.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
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TO: George T. LaRocca, PM 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

By letter dated 3/6/87, Stauffer Chemical Company, registrant of Imidan™ products, has submitted an addendum (dated 2/14/87; assigned MRID No. 401111-01) to the study titled, "PHOSMET - Magnitude of The Residue On Cottonseed: Processed Food and Feed Studies", by Mark E. Burt, EPA MRID No. 00067068.

These data are submitted as a supplement to the registrant's letter of 1/20/87. That letter has already undergone RCB review and comment; see M. J. Bradley memo of 3/19/87.

Background

The Residue Chemistry science support chapter (dated 3/26/86) to the Phosmet Registration Standard states (pp. 124-127) that:

"...none of the submitted processing studies [on cottonseed] reported data for residues in the raw agricultural commodity [RAC] prior to processing ..." and, therefore, data from an additional processing study "are required to determine the adequacy of the tolerance for residues in cottonseed oil and to determine whether additional food/feed additive tolerances are needed."

In Stauffer's letter of 1/20/87, it is pointed out that there are two processing studies on cottonseed:

MRID No. 00067068: Reports FSDS Nos. A-25619 and A-25619-1, submitted as an amended registration action under EPA Reg. No. 476-1917. [See review of R. Loranger, 3/26/81; data filed in the amended uses file for phosmet. These same data are also in MRID No. 401111-01 (2/14/87), currently submitted, which will be filed in the Phosmet Registration Standard File]; and,

MRID No. 00112281: Reports FSDS Nos. A-10438 and A-10438-1, submitted with PP# 9F2188/FAP# 9H5211, 3/8/79. [See review of P. Errico, 6/6/79; data contained in Section D of the petition.],

both of which do contain residue data on the RAC prior to processing.

In our (M. Bradley) review of 3/19/87, we acknowledge the correctness of the registrant's claim. We also state, however, that:

"the processing studies are conflicting, one study [FSDS Nos. A-10438 and A-10438-1] showing concentration of the residue in refined and crude oil, the other study [FSDS Nos. A-25619 and A-25619-1] showing no concentration of the residue. Our conclusion on the need for an additional processing study awaits the submission of the additional information pertinent to Reports FSDS Nos. A-25619 and A-25619-1" which the registrant indicated was to be submitted.

That information has now been submitted and assigned MRID No. 401111-01. It consists of nothing more than the complete study, containing all the raw residue data. The results of the study are as previously reported (see R. Loranger review, 3/26/81).

Discussion

The data from the two processing studies which have been conducted on cottonseed are summarized below:

RESULTS OF PHOSMET COTTONSEED PROCESSING STUDIES

Commodity	Phosmet Residue		Phosmet Residue	
	FSDS No.	Levels (ppm)*	FSDS No.	Levels (ppm)*
Cottonseed	A-25619	0.134	A-10438	0.05
Hulls	A-25619-1	<0.05	A-10438-1	<0.05
Meal	"	0.081	"	<0.05
Crude Oil	"	<0.05	"	0.50
Refined Oil	"	<0.05	"	0.16
Soapstock	"	0.09	"	<0.05

* Residues of phosmet oxygen analogue were also analyzed for. No detectable residue was reported in any sample. Limit of Detection = 0.05 ppm.

We conclude that an additional cottonseed processing study is not necessary.

Based on the available data, we conclude that concentration of residues occurs only in the cottonseed oil fractions.

The only appropriate food/feed additive tolerance is thus for refined cottonseed oil, as presently established (21 CFR 193.275). [Crude cottonseed oil is not a regulable commodity.]

The concentration factor for combined residues of phosmet plus its oxygen analogue from the RAC (<0.10 ppm) to refined cottonseed oil (<0.21 ppm) is approximately 2X.

There is a 0.1 ppm tolerance established (40 CFR 180.261) for combined residues of phosmet plus its oxygen analogue in or on the RAC, cottonseed.

We therefore conclude that the presently established food additive tolerance level of 0.2 ppm for combined residues of phosmet plus its oxygen analogue in (refined) cottonseed oil (21 CFR 193.275) is adequate and appropriate.

The data gaps of the Phosmet Registration Standard dealing with: (1) cottonseed processing studies; and, (2) appropriate and adequate food/feed additive tolerances for cottonseed processing byproducts are now considered to be adequately resolved.

Conclusions

1. An additional cottonseed processing study is not necessary.
2. Concentration of residues has been shown to occur only in the cottonseed oil fractions.
3. The only appropriate food/feed additive tolerance(s) is for (refined) cottonseed oil under 21 CFR 193.275, as presently established.
4. The concentration factor for combined residues of phosmet plus its oxygen analogue from the RAC to refined cottonseed oil is approximately 2X.
5. There is a 0.1 ppm tolerance established (40 CFR 180.261) for combined residues of phosmet plus its oxygen analogue in or on the RAC, cottonseed.

We therefore conclude that the presently established food additive tolerance level of 0.2 ppm for combined residues of phosmet plus its oxygen analogue in (refined) cottonseed oil (21 CFR 193.275) is adequate and appropriate.

6. The data gaps of the Phosmet Registration Standard dealing with: (1) cottonseed processing studies; and, (2) appropriate and adequate food/feed additive tolerances for cottonseed processing byproducts are now considered to be adequately resolved.

Recommendations

RCB recommends the Registration Division advise the registrant, Stauffer Chemical Company, that the data gaps of the Phosmet Registration Standard dealing with: (1) cottonseed processing studies; and, (2) appropriate and adequate food/feed additive tolerances for cottonseed processing byproducts are now considered to be adequately resolved.

cc: RF, Circ, Reviewer (Nelson), Phosmet Registration Standard File, TOX, PM#15, ISB/PMSD (Eldridge).
 TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):4/29/87.
 RDI:SectionHead:RSQuick:5/5/87:DeputyChief:RDSchmitt:5/5/87.