

3-15-89



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

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MAR 15 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: EPA Reg. No.: 279-3057. Bifenthrin: Contamination of the product TALSTAR 10 WP with cypermethrin. Registrants request to market TALSTAR 10 WP containing approximately 1000 ppm (0.1%) cypermethrin.

TOX CHEM No.: 463F (Bifenthrin)
271DD (Cypermethrin)

TOX PROJECT No.: 9-1017

Record No.: 241253

FROM: John Doherty *John Doherty* 3/15/89
Section I, Toxicology Branch I (IRS)
Health Effects Division (H7509C)

TO: George LaRocca
Product Manager #15
Registration Division (H7505C)

THROUGH: Edwin Budd
Section Head
Section I, Toxicology Branch I (IRS)
Health Effects Division (H7509C)

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3/15/89
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Background

The Agency has been informed in a letter from the FMC Corporation dated March 1, 1989 (refer to letter from Eunice M. Cuirle, attached) that in an apparent accident during the formulation process at the FMC Corporation, [REDACTED] pounds of the product CYNOFF WP (containing the pyrethroid cypermethrin, also referred to as CRACKDOWN WP, EPA Reg No. 279-3070) were mixed in with [REDACTED] lbs of the product TALSTAR 10 WP (containing the pyrethroid bifenthrin).

[REDACTED]

COMMERCIAL/FINANCIAL INFORMATION IS NOT INCLUDED 1

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[REDACTED]

Toxicology Branch was asked to specifically comment on the safety of the FMC Corporation's proposal to use and dispose of contaminated TALSTAR 10 WP.

Toxicology Branch Comments

1. Since there were no details provided, Toxicology Branch I (TB-I) cannot comment on the FMC Corporation's plans or procedures to dispose of the TALSTAR 10 WP product contaminated with [REDACTED] ppm of cypermethrin.

TB-I has no objections, however, to FMC's proposal to dispose of [REDACTED] ppm of cypermethrin provided that relevant guidelines for disposal of pesticides are followed.

2. With regard to labelling of TALSTAR 10 WP containing approximately 1000 ppm (0.1%) or less, the following comments apply.

i. Both TALSTAR 10 WP and CRACKDOWN WP (see attached labels) have the signal word WARNING. The small quantity of contaminating cypermethrin and related inerts from the product CRACKDOWN WP should not necessitate a change in the label signal word for the TALSTAR 10 WP product.

ii. The label for the cypermethrin product contains the precautionary statement "May cause allergic skin reactions". The product TALSTAR 10 WP does not. The basis for inclusion of this precautionary statement on products containing cypermethrin relates to the fact that some sensitization studies in guinea pigs were determined to be positive when technical cypermethrin was assessed.

3. Cypermethrin is regarded by the Agency as a Category C oncogen based on an increased incidence of lung tumors in one sex (females) of one strain of mice. The Agency determined that quantitative risk assessments for the individual registrations and tolerances for cypermethrin need not be developed.

Bifenthrin is also classified by the Agency as a Category C oncogen based on an increased incidence of lung tumors, liver tumors and bladder tumors (leiomyosarcomas). Based on the multiplicity of tumor types and the presence of the relatively rare bladder tumors, the Agency has recommended developing quantitative oncogenic risk assessments for the registrations and tolerances associated with bifenthrin.

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Overall, TB-I does not consider the presence of 0.1% or less of cypermethrin in the bifenthrin product to affect the bifenthrin product with regard to oncogenic considerations. The procedures already being utilized for oncogenic risk assessment for TALSTAR 10 WP should be sufficient to also evaluate any oncogenic risks associated with TALSTAR 10 WP contaminated with cypermethrin.

4. The toxicity data base for cypermethrin for developmental toxicity, chronic feeding and oncogenicity testing and mutagenicity/ genetic toxicity testing is considered complete. There are no indications that the presence of 0.1% cypermethrin or less in TALSTAR 10 WP will substantially affect the toxicological characteristics of the product.

5. TB-I defers to DEB to determine if there will be residues of cypermethrin in RACS resulting from the use of contaminated TALSTAR 10 wp on crops that do not have tolerances for cypermethrin.

6. The inerts in the product Crackdown (EPA Reg No.: 279-3070) have been cleared under CFR 180.1001 (c and e). There should be no problem regarding improper application of inerts.

7. Copies of the "one liners" for both cypermethrin (TOX CHEM No.: 271DD) and bifenthrin (TOX CHEM No.: 463F) are attached for your information.

8. Based on toxicological considerations only, TB-I has no objection to the packaging and selling of TALSTAR 10 WP contaminated with cypermethrin at levels of 0.1% or less.