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

JAN 15 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: FAP#6H5515. Cyfluthrin in Food Handling Establishments.
Amendments of August 11 and 13 and September 25, 1987.
MIRD No. 403010-01, -02, 403015-01, -02, 403559-01
RCB No. 2719, 2720, 2876

FROM: Martha J. Bradley, Chemist *MJ Bradley*
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TO: George T. LaRocca, PM 15
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and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Summary of Remaining or Outstanding Deficiencies

The modifications in the tolerance enforcement method, Report No. 85883, third revision, must be checked by the laboratory personnel in Chemical Operations Branch, BUD to determine whether it conforms to the actual method as modified by the method trial. In addition, this Report should also be submitted without being stamped "Property of Mobay Corporation".

RCB Recommendation

RCB recommends against the proposed tolerances of 0.05 ppm on foods or feeds until the methodology questions have been resolved.

Background

Mobay Chemical Corporation has responded to our memo (M. Bradley) of May 29, 1987. The deficiencies listed in that memo

are repeated below in the same order along with the company response and our comments/conclusions.

Deficiency 1. There is no formal means of clearing inert ingredients for food additive use. Therefore, we defer to TB as to the safety of the use of the inerts in the proposed formulation (See Confidential Appendix).

Response. Mobay states that the inert ingredients have been cleared according to a TB review.

Comments/Conclusion 1. The inert ingredients have been cleared under 40 CFR 180.1001 (c), for pre and post harvest use. TOX has no objections to the proposed use.

This deficiency has been resolved.

Deficiency 2. Note 3 on the revised labeling (November 10, 1986 Draft) should be revised to reflect a 0.1% active ingredient (ai) concentration.

Response. The enclosed label draft dated 7/29/87 has been revised to reflect 0.1% active ingredient concentration in Note 3.

Comments/Conclusion 2. This deficiency has been resolved.

Deficiency 4a. Adequate analytical methods will be available for the determination of cyfluthrin per se in plant and animal commodities from PMSD when tolerances in PP#4F3046 are established.

Response. Mobay has included analytical residue method Reports 85823 (for plants) and 85883 (for animal commodities) in this FAP so that the regulation could proceed independently from PP#4F-3046.

Comments/Conclusion 4a. Mobay was requested to rewrite Method No. 85883 to incorporate modifications made during the Agency's method trial and to submit non-confidential copies of the two above methods (memo of M. Kovacs, May 19, 1987, PP#4F3046).

Mobay has submitted non-confidential copies of the two above Reports and has rewritten Report No. 85883. Since the revision of Report No. 85883 used in the method trial is not available to RCB, we have requested confirmation from Chemical Operations Branch, BUD, that the rewritten method conforms to the actual method as modified by the method trial. In addition, Report No. 85883 should be submitted without being stamped "Property of Mobay Corporation".

This deficiency has not been resolved.

Deficiency 4b. The petitioner needs to comply with the Residue Chemistry Data Requirements in 40 CFR 158.125(b)(15) regarding the testing of pesticide chemicals through the Food and Drug Administration (FDA) multiresidue methods. The protocols for the tests were published as Appendix II to the Pesticide Analytical Manual - Volume I (PAM I) January 1987. The FEDERAL REGISTER Notice, 51 FR 34249, of September 26, 1986 gives additional information on the testing.

Response. Mobay Report No. 94892 entitled "BAYTHROID, Multi-residue Method Trial." was submitted.

Comments/Conclusions 4b. The multiresidue data for Baythroid (Tempo, cyfluthrin) were transmitted to FDA December 4, 1987.

This deficiency is resolved.

Deficiency 4c. Confirmatory methods, Mobay Report Nos. 86232 and 87462, have been submitted that separate cyfluthrin from cypermethrin and permethrin, two closely related compounds. Clean, non-confidential, not stamped "property of" copies of these two confirmatory procedures should be submitted for publication in the Pesticide Analytical Manual, Vol. II (PAM II).

Response. Enclosed are "clean" copies of the confirmatory methods, Mobay Report Nos. 86232 and 87462, that separate cyfluthrin from cypermethrin and permethrin.

Comments/Conclusion 4c. This deficiency has been resolved.

Deficiency 5b. The submitted residue study is not applicable to the proposed uses in graineries, greenhouses, trucks, trailers, railcars, and vessels where food may be grown or bulk food or feed may be stored or transported. These uses are not considered food handling establishment uses and should be removed from the label or supporting data should be submitted.

Response. The enclosed label draft dated 7/29/87 reflects the deletion of the use sites, graineries, greenhouses, trucks, trailers, railcars, and vessels.

Comments/Conclusion 5b. This deficiency has been resolved.

Deficiency 6. Food processing plants handle animal feed items as well as human foods. Although no problem is expected from secondary residues in animal products from treated feed because no residues are expected in the feed, a feed additive regulation should be proposed for this use. Both food and feed additive regulations should be proposed including the tolerance and specifications of use such as maximum application rate and types of treatment (general surface, crack and crevice, spot).

Examples may be found in 21 CFR 193 and 561, especially 193.85, 193.375, 561.415, 561.434.

Response. Enclosed is a revised Section F, dated July 29, 1987, of this petition in which we propose a feed additive tolerance and revise the expression for the proposed food additive tolerance.

Comments/Conclusion 6. This deficiency has been resolved.

cc: M. Bradley, RF, Circu, PP4F3046, FAP6H5515, PMSD/ISB
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RDI:RSquick:01/14/88:RDSchmitt:01/14/88