



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

SEP 22 1987

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3452. Sethoxydim in or on Brassica leafy
vegetables and cucurbits.

Amendment of August 19, 1987.

RCB No.: 2785. MRID Nos.: 403098-00, -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
Hazard Evaluation Division (TS-769C) *RM*

TO: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The petitioner, BASF Corporation, has now submitted an amendment to PP#6F3452. This amendment consists of a transmittal letter dated August 19, 1987; an amended Section B; supplemental labeling for Poast® Herbicide (EPA Reg. No. 7969-58); an amended Section F; and, a copy of the reject letter (R. J. Taylor) dated July 21, 1987.

This amendment was submitted in response to RCB's review dated April 9, 1987 (M. Nelson).

Deficiency Remaining to be Resolved

Note: This deficiency is fully discussed in the Detailed Considerations Section that follows in this review, which see for details.

1. Deficiency #2 concerning a revised Section F remains outstanding pending clarification of what crop group(s) the petitioner is now seeking tolerances for and, if more than the Brassica leafy vegetables crop group is involved, further revision of the Section F.

Recommendations

RCB recommends against establishment of tolerances for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent) in or on Brassica leafy vegetables at 5 ppm (and cucurbit vegetables at 2 ppm, if still applicable) until such time as the one remaining deficiency [ref. Deficiency #2 in the body of this review] is resolved.

Clarification of the crop group(s) for which tolerances are currently being sought and, if appropriate, a further revised Section F should be submitted.

DETAILED CONSIDERATIONS

The outstanding deficiencies of this petition, as listed in the July 21, 1987 reject letter, are reiterated below, followed by the petitioner's responses, and RCB's discussions/conclusions.

RCB's Deficiency #1 (item 3 of the reject letter)

"The method of application (air or ground) was not specified, and must be. If no aerial data are available, proposed labeling must be limited to ground application."

Petitioner's Response to Deficiency #1

The petitioner has submitted an amended Section B and revised supplemental labeling for Poast® Herbicide (EPA Reg. No. 7969-58) which specify "ground only" method of application in conjunction with the proposed uses.

RCB's Comments/Conclusions re Deficiency #1

The requested revised labeling and an amended Section B have now been submitted. This deficiency is resolved.

RCB's Deficiency #2 (item 5 of the reject letter)

"The proposed tolerance (9.0 ppm) on the Brassica leafy vegetables crop group, for which data on all representative commodities were submitted, is too high. A revised Section F proposing a tolerance of 5 ppm is needed."

Petitioner's Response to Deficiency #2

The petitioner has submitted as part of this amendment a revised Section F proposing a tolerance of 5 ppm be established for the Brassica leafy vegetables crop group (only).

RCB's Comments/Conclusions re Deficiency #2

The original Section F to this petition proposed crop group tolerances for Brassica leafy vegetables and cucurbit vegetables. The revised Section F no longer proposes the establishment of a tolerance for the cucurbit vegetables crop group (@ 2 ppm). We believe this to be an oversight on the petitioner's part, or a simple misunderstanding based on the possibly misleading wording of the stated deficiency.

Written clarification is requested of the petitioner as to whether a tolerance is still being sought for the cucurbit vegetables crop group.

If so, a revised Section F proposing the appropriate tolerances for both the Brassica leafy vegetables (@ 5 ppm) and cucurbit vegetables (@ 2 ppm) crop groups should be submitted.

[Note: If a tolerance is no longer being sought for the cucurbit vegetables crop group (which we doubt), then the revised Section F submitted as part of this present Amendment, proposing only a tolerance for the Brassica leafy vegetables crop group, is adequate and appropriate, and no additional Section F need be submitted.]

RCB's Deficiency #3 (item 6 of the reject letter)

"Sethoxydim has not been tested for recovery via the FDA multiresidue protocols, as required by Section 158.125(b)(15) of Title 40 of the Code of Federal Regulations. Refer to Appendix II of PAM-I for information on these protocols and for reporting forms."

Petitioner's Response to Deficiency #3

The petitioner has submitted as part of this amendment the following report (assigned MRID# 403098-01):

L. A. Sears, "Investigation of Multiresidue Pesticide Analytical Methodologies for the Determination of Sethoxydim and its Metabolites." May, 1987. BASF Document Number: 87/5042, 41 pages.

RCB's Comments/Conclusions re Deficiency #3

The aforecited report contains data for sethoxydim and its two major (plant) metabolites, sethoxydim sulfoxide (MSO) and 5-hydroxy sethoxydim sulfone (5-OH-MSO₂) from testing via FDA's Multiresidue Protocols I-III (Protocol IV is not applicable to this class of compounds).

The petitioner reported (p. 18):

"Sethoxydim and its metabolites cannot be successfully determined by gas chromatography under the conditions specified in the PAM I methods. Because of the thermal instability of these compounds, analysis using typical GC conditions is very difficult. The GC conditions from Protocol I did produce peaks that exceeded the minimum sensitivity level. The subsequent Florisil cleanup column required in Protocol I, however, gave no recovery of the sethoxydim compounds."

This deficiency is considered resolved, at least for purposes of this present petition. The aforecited report is being sent to FDA for the future updating of PAM I. Should FDA indicate to us that additional information is needed for completeness of the entry, then the petitioner will be notified of any remaining data requirements.

cc: RF, Circ, Reviewer (M. Nelson), PP#6F3452, PM#25, TOX, PMSD/ISB (Eldridge).
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):9/18/87.
RDI:SectionHead:RSQuick:9/21/87:DeputyChief:RDSchmitt:9/21/87.