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

NOV 25 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP #5F3284/5H5475. (RCB #1373,1374) Sethoxydim (Poast®) in/on fruiting vegetables. Amendment of 7/8/86. Accession No. 264583.

FROM: Cynthia Deyrup, Ph.D., Chemist
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Cynthia Deyrup

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

TO: R.J. Taylor, Product Manager No. 25
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Background

BASF Wyandotte Corporation proposed the establishment of a permanent tolerance on the raw agricultural commodity group, fruiting vegetables, at the level of 4.0 ppm for combined residues of 2-[1-(ethoxyimino)butyl]-5-(2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (sethoxydim, Poast®) and its metabolites containing the 2-cyclohexen-1-one moiety calculated as parent.

The following food and feed additive tolerances for residues of sethoxydim/metabolites are also proposed:

Processed Commodity	Proposed Tolerance (ppm)
Tomato Puree	8.0
Tomato Paste	24.0
Dried Tomato Pomace	12.0

Present Consideration

The present consideration consists of a cover letter from D.A. Yoder, BASF Wyandotte to R.J. Taylor, RD, a response addressing the deficiencies cited by RCB in its 10/9/85 review of PP #5F3284 (memo of C. Deyrup) and a revised Section F. The deficiencies cited in RCB's 10/9/85 review will be restated below, followed by the Petitioner's Response and RCB's Comments/Conclusions.

Deficiency 1

The petitioner will need to specify the method of application used in his field trials. If the data do not reflect his proposed use (i.e. application with either air or ground equipment), the petitioner has the option of submitting residue data reflecting aerial application or of limiting his proposed use to ground equipment application only in a revised Section B/label.

Petitioner's Response, re: Deficiency 1

Ground equipment was used in all field trials. The petitioner points out that data reflecting side-by-side comparison of aerial vs ground application for three different crops had been submitted with PP #3F2904. These trials involved soybeans, cottonseed, and sugarbeet roots. The petitioner contends that the results from these trials indicate that there is no significant difference in residue levels from ground equipment or aerial application. The petitioner claims that the need for air vs. ground residue data for each crop and use has not been a requirement. The petitioner requests that if this requirement has been changed, BASF should be allowed time to meet the new requirement without penalty to registration schedules. The petitioner also requests that RCB cite the location of the requirement in regulations or guidelines.

RCB's Comments/Conclusions

According to the Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry (§171-4(c)(2)(i), "Field experiments must reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed. Because of differences observed in residue levels resulting from ultra low volume (ULV) and aerial applications, these too should be represented unless the proposed label specifically prohibits such applications methods."

Aerial data for each new crop and use are considered because the growth habits of various crops could differ vastly. For example, residue levels found in onions could be independent of the mode of application, but residue levels in corn forage could be higher with aerial application (relative to ground

equipment application) if residues were lodged in the corn plant whorls. In this particular use on fruiting vegetables, the proposed PHI, 20 days, is significantly shorter than the PHI's included in the study which the petitioner has cited. In this side-by-side comparison, PHI's of 43-121 days were observed. RCB pointed out (PP #3F2904, memo of S. Malak, 6/23/86) that residue levels were markedly higher in the trial in which the shortest PHI was observed. Therefore, in its memo of 10/16/86, RCB concluded, "At this time, it is difficult to assume that aerial and ground applications will result in comparable residues at shorter PHI's of 7-20 days [memo of S. Malak, PP #3F2904]."

Taking into consideration the proposed PHI of 20 days, RCB concludes that residue levels reflecting ground equipment application only may not be translatable to tomatoes treated with aerial equipment. The petitioner has the option of submitting additional residue data reflecting aerial application of sethoxydim to tomatoes or of submitting a revised Section B restricting application to ground equipment use only. Deficiency 1 is not yet resolved.

Deficiency 2b

RCB concludes that the nature of the residue in ruminants is adequately understood, provided that the petitioner submits reproductions of TLC's that were used to identify metabolites in liver and kidney. Further work may be necessary if these chromatograms do not support the petitioner's structural assignments. See memo of K. Arne, 6/26/85, PP #3F2904.

Deficiency 2c

RCB concludes that the nature of the residue in poultry is not adequately understood. A poultry metabolism study submitted with PP #3F2904 was found to be deficient because only 41% of the radioactivity in liver was identified (PP #3F2904, memo of K. Arne, 6/26/85).

Petitioner's Response, re Deficiencies 2b and 2c

The petitioner states that these deficiencies were addressed in an amendment to PP #3F2904.

RCB's Comments/Conclusions

Poultry and goat metabolism studies were submitted with the amendment of 12/6/85 (PP #3F2904) and were discussed in detail in RCB's memo of 6/23/86 (memo of S. Malak). RCB concludes that the nature of the residue in ruminants and poultry is adequately understood. The residues of concern are sethoxydim and its metabolites containing the 2-cyclohexene-1-one moiety. Deficiencies 2b and 2c are resolved.

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Deficiency 4a

RCB does not consider it appropriate to translate available storage stability data on soybeans and soybean forage or on animal tissues to tomatoes, a highly acidic commodity. Therefore, the petitioner will need to submit storage stability data to cover the storage period, one year, on tomatoes or some other acidic commodity (e.g. citrus, apples, etc.)

Petitioner's Response, re: Deficiency 4a

Tomato samples were fortified with 3.0 ppm each of MSO and 5-OH-MSO_2, which are two metabolites derived from sethoxydim per se. Samples were stored in a freezer and analyzed according to Method 30B after storage periods of 8 and 15 months. The results of the storage stability study are given below. Since recoveries varied from day to day, recoveries were also carried out on samples fortified on the same day of the analysis.

Storage period (months)		% Recovery (uncorrected) MSO	% Recovery (uncorrected) 5-OH-MSO_2	% Recovery (corrected) MSO	% Recovery (corrected) 5-OH-MSO_2
8		83	70		
		87	67		
	avg	85	69	91	84
15		67	79		
		74	81		
	avg	71	80	108	93

RCB's Comments/Conclusions

The data in the above table indicate that losses of MSO and 5-OH-MSO_2 in tomatoes are minimal after 15 months.

Storage stability data on MSO and 5-OH-MSO_2 only were submitted. RCB would have preferred a storage stability study on field treated tomatoes treated according to the proposed use so that the storage stability of all the residues of concern could have been investigated. However, according to the tomato metabolism study submitted with the original petition, MSO and 5-OH-MSO_2 account for 72-81% of the identified residue 14-21 days after treatment (proposed PHI, 20 days), and no parent is present. The petitioner submitted residue data from 17 tomato field trials in which PHI's of 18-30 days were observed and the maximum proposed treatment rate, 0.9 lb. a.i./A per season, was applied. These trials were conducted in MN, MI, VA, NC, FL, TX, MS, and CA. The petitioner also submitted residue data (reflecting the maximum proposed treatment rate) from 9 bell pepper trials with PHI's ranging from 18 - 22 days and data from one eggplant field trial with a PHI of 22 days.

RCB concludes that the storage stability data support the residue data. Deficiency 4a is resolved.

Deficiency 4b

Although the proposed use allows application by ground and air equipment (except in CA), there is no indication that any of the data reflect application by air equipment. The petitioner should specify the method of application used in his field trials. If aerial application was not used, the petitioner has the option of submitting residue data which reflect aerial application or of restricting application to ground equipment only in a revised Section B/label.

Petitioner's Response, re: Deficiency 4b

The petitioner's response to this deficiency was detailed in the response to Deficiency 1 above.

RCB's Comments/Conclusions

Because the proposed PHI is considerably shorter than the PHI's observed in the petitioner's study comparing residue levels from aerial and ground application on other crops (see PP #3F2904), RCB concludes that either residue data on fruiting vegetables reflecting aerial application or a revised Section B/label prohibiting aerial application is needed (See RCB's Comments/ Conclusions under Deficiency 1). Deficiency 4b is not yet resolved.

Deficiency 4c

No description of the fractionating process was provided. Therefore RCB is unable to determine whether the processing study reflected common commercial practice. The petitioner will need to provide details of his fractionation study. At this time RCB is unable to judge whether the proposed food and feed additive tolerances are adequate.

Petitioner's Response, re: Deficiency 4c

The petitioner submitted a description of the tomato processing study as well as an account on tomato processing from "Tomato Production, Processing and Quality Evaluation," by W.A. Gould, (2nd edition, AVI Publishing Co., Westport, CN).

RCB's Comments/Conclusions

RCB concludes that the tomato processing study adequately reflects common commercial practice. Deficiency 4 c is resolved.

Deficiency 5a

RCB at this time can make no estimate on the transfer of residues resulting from the proposed use to meat, milk, poultry and eggs until our questions on the nature of the residue have been satisfied (PP #3F2904, memo of K. Arne, 6/26/85).

Petitioner's Response, re: Deficiency 5a

The petitioner's response with regard to the nature of the residue in ruminants and poultry was described under Deficiencies 2b and 2c above.

RCB's Comments/Conclusions

The nature of the residue in ruminants and poultry is adequately understood. The residues of toxicological concern were determined in the feeding study submitted with PP #3F2904. RCB concludes that the tolerances established for sethoxydim/metabolites in milk, meat, poultry, and eggs will not be exceeded by the proposed use on fruiting vegetables. Deficiency 5a is resolved.

Deficiency 5b

The petitioner should submit a revised Section F in which he proposes a tolerance for fruiting vegetables and food/feed additive tolerances on "Tomato products, concentrated" and tomato pomace, dried. The proposed tolerance for tomato puree should be deleted. The proposed tolerance should reflect the residue levels found in the commodity bearing the highest residues, i.e., tomato paste.

Petitioner's Response, re: Deficiency 5b

In a revised Section F, the petitioner proposes tolerances for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) on the following commodities:

Fruiting Vegetables	4.0 ppm
Tomato Products, Concentrated	24.0 ppm
Tomato Pomace, Dried	12.0 ppm

RCB's Comments/Conclusions

The petitioner has submitted a revised Section F. Deficiency 5b is resolved.

Recommendations

RCB recommends against establishing the proposed tolerances on fruiting vegetables, concentrated tomato products, and dried tomato pomace because of our Comments/Conclusions under

Deficiencies 1 and 4b. Either residue data reflecting aerial application or a revised Section B/label restricting application to ground equipment is required.

Other Considerations

Neither Codex, Canada, nor Mexico has established a tolerance for residues of sethoxydim/metabolites on fruiting vegetables or processed tomato commodities. There will be no compatibility problem if the proposed tolerances are established.

Attachment 1 (Codex sheet)
cc: Circu, EEB, EAB, Deyrup, 5F3284/5H5475, R.F., PMSD/ISB, FDA
RDI:JHOnley:11/21/86:RDSchmitt:11/24/86
TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:11/24/86

Attachment #1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Sethoxydim (Poast)

J. Lee 11/18/86

CODEX NO. _____

CODEX STATUS:

☑ No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 5F3284

RCB Reviewer C. Deyrup

Residue: parent plus metabolites containg 2-cyclohexene-1-one moiety

Crop(s)	Limit (mg/kg)
Fruiting vegetables	4
tomato Products, concentrated	24
tomato Pomace, dried	12

CANADIAN LIMITS:

☐ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)
potatoes	0.1 *

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

* Negligible residue type limit

Form revised 1986

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