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

MAY 3 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3606/FAP#8H5553. Sethoxydim in or on Blueberries and Citrus Fruits.
Amendment of January 23, 1989.
DEB#: 5101, 5102 HED#: 9-1086 MRID#: None

FROM: Maxie Jo Nelson, Ph.D., Chemist
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: R. Taylor/V. Walters, PM Team 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch, FHA Support
Health Effects Division (H7509C)

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED FOR DEB

The petitioner must confirm that extracts from fortified samples were **stored** under the same temperature/time conditions as were extracts from the field trial samples. If this was not the case, the petitioner must demonstrate the stability of residues of sethoxydim and its metabolites in extracts by appropriate fortification studies.

CONCLUSIONS

1. The petitioner has **not** addressed the question DEB raised re the **storage** conditions of extracts of fortified samples vis-a-vis extracts of experimental field trial samples. The petitioner must confirm that extracts from fortified samples

were stored under the same temperature/time conditions as were extracts from the field trial samples. If this was not the case, the petitioner must demonstrate the stability of residues of sethoxydim and its metabolites in extracts by appropriate fortification studies. **This deficiency is not resolved.**

2. BASF has submitted revised supplemental labeling (1/23/89) for use of Poast® herbicide on citrus fruits (originally proposed as a total nte 2.5 lbs ai/A/season, 10-day PHI; now revised to a total nte **2.0** lbs ai/A/season, **15**-day PHI) to support the proposed tolerance of 0.5 ppm.

3. Residue results from 7 sites for oranges (4 CA, 2 FL, 1 TX), 6 sites for lemons (5 CA, 1 AZ), and 7 sites for grapefruits (5 CA, 1 FL, 1 TX) are now pertinent to the proposed revised use pattern for Poast® on citrus fruits. Accordingly, DEB now concludes that adequate field trial data and geographic representation exist for the use of Poast® on citrus fruits (in conjunction with the revised supplemental labeling). **This deficiency is resolved.**

4. DEB also concludes those field trial data on citrus support the requested tolerance of **0.5 ppm** for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent) in or on **citrus fruits.** This conclusion is **provisional**, pending an adequate response by the petitioner to the storage of extracts issue (see Conclusion #1).

5. Processing study data for citrus (oranges) indicate feed additive tolerances on **dried citrus pulp and citrus molasses** should be set at 3X the level found appropriate for citrus per se; the feed additive proposals are, thus, at **1.5 ppm.** The adequacy of the 1.5 ppm level is **provisional**, pending resolution of the storage of extracts issue (see Conclusion #1).

6. DEB finds the proposed tolerance of **4.0 ppm** for residues of sethoxydim and its metabolites in/on **blueberries** to be appropriate. This conclusion is **provisional**, pending satisfactory resolution of the storage of extracts issue (see Conclusion #1).

7. Established tolerances on **meat, milk, poultry, and eggs** will **not** be exceeded from the proposed use/proposed tolerances on citrus/citrus byproducts. This conclusion is **provisional**, pending satisfactory resolution of the storage of extracts issue (see Conclusion #1). Should citrus/citrus by-product tolerance levels need to be raised, DEB would have to reassess the adequacy of the animal commodity tolerances.

RECOMMENDATION

DEB continues to recommend against the establishment of the proposed tolerances on citrus fruits (0.5 ppm); dried citrus pulp (1.5 ppm) and citrus molasses (1.5 ppm); and, blueberries (4.0 ppm), pending resolution of the deficiency cited in Conclusion #1.

In addition, Conclusions #4, #5, #6, and #7 are only **provisionally** drawn, pending resolution of Conclusion #1.

DETAILED CONSIDERATIONS

BACKGROUND

By transmittal letter dated 1/23/89, the petitioner (BASF Corporation) has submitted its response to the two deficiencies cited by the Agency's letter (R. J. Taylor, PM 25) of 1/11/89. Those deficiencies were raised by DEB in its earlier review (M. Flood, 5/18/88) of this petition.

For the reader's convenience, those two deficiencies are restated below (using the same wording/numbering of the Agency's 1/11/89 letter to the petitioner), followed by the petitioner's response, and our comments/conclusions.

DEB DEFICIENCY #4:

"Storage stability data on various raw agricultural commodities (RACs) are sufficient to support the submitted residue analyses. However, since there was a time period between extraction of the RAC and final analyses, you must confirm that extracts from fortified samples were stored under the same temperature/time ~~con~~ditions as were extracts from the field trial samples. If this was not the case, you must demonstrate the stability of sethoxydim [and metabolites] residues in extracts by appropriate fortification studies."

BASF RESPONSE TO DEFICIENCY #4:

This amendment submission includes a memo of certification which confirms that extracts from fortified samples were stored under the same temperature/time conditions as were extracts from the field trial samples.

DEB COMMENTS/CONCLUSIONS RE DEFICIENCY #4:

The "memo of certification" BASF has submitted does **not** address itself to the question of conditions of **storage** of extracts from fortified samples vis-a-vis extracts of field trial samples, as claimed.

Instead, it provides confirmation that fortification/recovery samples are subjected to the same **analysis** procedures as are experimental field trial/control samples.

This deficiency has not been resolved.

DEB DEFICIENCY #6:

"There are insufficient residue data reflecting the proposed maximum use conditions--a total of 2.5 lbs ai/A season, preharvest interval, 10 days--to support the proposed tolerance of 0.5 ppm for residues of sethoxydim [and metabolites] in/on citrus. Additional field trials in California and Florida for each citrus crop are necessary. Poast® should be applied at levels reflecting maximum use conditions."

BASF RESPONSE TO DEFICIENCY #6:

BASF proposes the maximum use conditions (originally proposed as a total of 2.5 lbs ai/A/season; preharvest interval, 10 days) be changed to a total of **2.0** lbs ai/A/season; preharvest interval, **15** days to support the proposed tolerance of 0.5 ppm for residues of sethoxydim [and metabolites] in/on citrus fruits.

Revised supplemental labeling (dated 1/23/89) for use of Poast® herbicide on citrus which contains this preharvest interval increase (page 10) and total lbs ai/A/season decrease (pages 7 and 10) is submitted as part of this amendment.

DEB COMMENTS/CONCLUSIONS RE DEFICIENCY #6:

~~As~~ part of this amendment, BASF has also submitted a Table 1 (incorporated into this review) which summarizes the residue trials for Poast® on citrus pertinent to the proposed revised supplemental labeling.

As shown by that Table, with the proposed PHI increased to 15 days, and the total lbs ai/A/season decreased to nte 2.0 lbs ai/A/season, the data originally submitted [MRID#s 404926-01 thru -03] provide residue results from 7 sites for oranges (4 CA, 2

FL, 1 TX), 6 sites for lemons (5 CA, 1 AZ), and 7 sites for grapefruits (5 CA, 1 FL, 1 TX), which can be utilized to support the petitioner's tolerance request on citrus fruits.

Accordingly, DEB now concludes that adequate field trial data and geographic representation exist for the use of Poast® on citrus fruits (in conjunction with the proposed supplemental labeling). **This deficiency is resolved.**

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Table 1
Sethoxydim Residues in Citrus
Applicable to Four Applications
of 0.5 lb ai/A (total of 2.0 lb ai/A) PHI 15 days
Proposed Tolerance - 0.5 ppm

ORANGES (BASF 87/5072, MRID No. 40492601)

RCN	Test Site	Application Rate (lb ai/A)	PHI	Sethoxydim Equivalents DME (ppm)	DME-OH (ppm)
3042	Reedley, CA	5 X 0.5	14	<0.05	<0.05
5332	Westlaco, TX	5 X 0.5	10	<0.05 - 0.09	<0.05 - 0.06
5333	Dinuba, CA	5 X 0.5	14	<0.05	<0.05
5392	Lake Alfred, FL	5 X 0.5	11	<0.05	<0.05
5393	Lake Alfred, FL	6 X 0.5	11	<0.05	<0.05
3026	Reedley, CA	4 X 0.5	3	<0.05	<0.05
3043	Riverdale, CA	4 X 0.5	15	<0.05	<0.05

LEMONS (BASF 87/5071, MRID No. 40492602)

RCN	Test Site	Application Rate (lb ai/A)	PHI	Sethoxydim Equivalents DME (ppm)	DME-BH (ppm)
3044	Reedley, CA	5 X 0.5	14	<0.05	<0.05
5327	Dinuba, CA	5 X 0.5	13	<0.05	<0.05
5325	Phoenix, AZ	6 X 0.5	10	<0.05	<0.05
3028	Parlier, CA	4 X 0.5	3	<0.05	<0.05
3029	Reedley, CA	4 X 0.5	3	<0.05	<0.05
3045	Riverside, CA	4 X 0.5	15	<0.05	<0.05

GRAPEFRUITS (BASF 87/5070, MRID No. 40492603)

RCN	Test Site	Application Rate (lb ai/A)	PHI	Sethoxydim Equivalents DME (ppm)	DME-BH (ppm)
3046	Reedley, CA	5 X 0.5	14	<0.05	<0.05
5328	Fort Pierce, FL	5 X 0.5	11	<0.05 - 0.18	<0.05 - 0.11
5329	Westlaco, TX	5 X 0.5	10	<0.05 - 0.49[a]	<0.05 - 0.11[a]
5330	Dinuba, CA	5 X 0.5	13	<0.05	<0.05
3030	Parlier, CA	4 X 0.5	3	<0.05	<0.05
3031	Reedley, CA	4 X 0.5	3	<0.05	<0.05
3047	Riverside, CA	4 X 0.5	15	<0.05	<0.05

(a) Higher numbers are from lower branches only; composite from all branches: DME (ppm) - 0.06 - 0.22; DME - OH (ppm) - <0.05

DEB also concludes those field trial data (see Table 1) support the requested tolerance of 0.5 ppm for the combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent) in or on citrus fruits. This conclusion is **provisional**, however, pending an adequate response by the petitioner to the storage of extracts issue (discussed under Deficiency #4, above, and summarized in Conclusion #1).

Processing study data on citrus (oranges) show the appropriate level for setting the requested feed additive tolerances on dried citrus pulp and citrus molasses is at 3X that found appropriate for citrus per se; the current proposals are, thus, at 1.5 ppm. The adequacy of the 1.5 ppm level is **provisional**, pending resolution of the storage of extracts issue (discussed under Deficiency #4, above, and summarized in Conclusion #1).

OTHER CONSIDERATIONS

We also point out the **provisional** nature of DEB's conclusion (see Conclusion #5a, M. Flood review, 5/18/88, this petition) that the proposed tolerance of **4.0 ppm** for residues of sethoxydim and its metabolites in/on **blueberries** is appropriate. That, too, is dependent upon satisfactory resolution of the storage of extracts issue (discussed under Deficiency #4, above, and summarized in Conclusion #1).

A final **provisional** conclusion which has been drawn (see aforecited M. Flood review) is that established tolerances on **meat, milk, poultry, and eggs** will **not** be exceeded from the proposed use (and proposed tolerances). An unequivocal conclusion on that can not be drawn until DEB is certain what appropriate tolerance levels are for citrus/citrus by-products, and that will require satisfactory resolution of the storage of extracts issue (discussed under Deficiency #4, above, and summarized in Conclusion #1).

cc: Reviewer (M. Nelson), Reading File, Circulation (7), PP# 8F3606/FAP#8H5553, ISB/PMSD (E. Eldredge), R. Schmitt.

H7509C:DEB:Reviewer(MJN):CM#2:Rm810:557-7423:typist(mjn): 3606SETH.CIT:4/29/89.
RDI:SectionHead:RSQuick:5/2/89:ActingBranchSeniorScientist: RALoranger:5/2/89.