



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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F03646/FAP#8H05558. Sethoxydim (Poast® Herbicide, EPA Reg. No. 7969-58) in or on Sugar Beet Roots and Process Fractions. Amendment of 8/2/91. MRID No. 419661-01, CB Nos. 8540, 8541, 8542, DP Barcodes: D167888, D167906, D167908.

FROM: William D. Wassell, Chemist
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William D. Wassell 2/18/92

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Summary of Deficiencies Remaining to be Resolved:

- o Replacement of magnitude of residue data for sugar beet tops generated by Craven Laboratories.
- o Deficiencies of the processing study.
- o Submission of a revised Section F for the food additive tolerance (requirement deferred until the deficiencies of the processing study are satisfied).

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Summary/Background:

BASF Corporation, Research Triangle Park, NC, is proposing an increase in the tolerance level for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-cyclohexen-1-one (sethoxydim) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in sugar beet roots from 0.1 to 1.0 ppm, and further an increase in tolerance levels in sugar beet molasses from 0.5 to 9.0 ppm. The request is being made in conjunction with a request to decrease the pre-harvest interval from the current interval of 100 days to an interval of 60 days. Tolerances are established for residues of the herbicide sethoxydim and its metabolites under 40 CFR §180.412 for various raw agricultural commodities including sugar beet tops at 3.0 ppm and under 40 CFR §186.2800 for feed commodities including sugar beet molasses at 0.5 ppm.

Since the completion of the original review (R.W. Cook, 12/6/88), a FIFRA '88 Phase 4 Review of the chemical has been completed (L. Cheng, 2/22/91) and allegations concerning the validity of data generated by Craven Laboratory have been raised. These issues impact upon conclusions that were made in the original review and will be discussed in the Detailed Considerations Section of this review.

The registrant has submitted an amendment to the petition (dated 8/2/91) consisting of a revised Section F that proposes a food additive tolerance level of 9.0 ppm for residues of the herbicide sethoxydim in or on sugar beet molasses and a magnitude of residue report for residues of sethoxydim and its metabolites in or on sugar beet process fractions.

Conclusions:

1. CBTS can draw no conclusions from the submitted sugar beet processing study until the deficiencies outlined in the Magnitude of Residue - Process Products Section of this review are addressed.
2. Storage stability data for sethoxydim have been considered under PP3F2904 (J. Onley, 1/24/84; and F.D. Griffith, 4/4/84, memo of conference). We have previously concluded there data are adequate (V.F Boyd, PP6F3405, 9/25/86).
3. Until the deficiencies of the processing study are addressed, we can draw no conclusions on the adequacy of the existing animal commodity tolerances to cover the increased dietary burden of the proposed tolerances.
4. CBTS concludes, for the purpose of the subject petition only, the nature of the residue in plants is adequately delineated. **Note: This does not negate the CBRS requirement for an additional plant metabolism study.**

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5. Upon satisfying the deficiencies of the sugar beet processing study, CBTS concludes this study should fulfill the reregistration requirements for that study.
6. Craven Laboratories analyzed sugar beet tops from several field trials to support the current petition for reducing the PHI to 60 days. Upon review of the Craven data, we have requested the registrant to provide magnitude of residue data reflecting the maximum use pattern from several areas. CBTS concludes, in the absence of this data, the petition is not supported by adequate geographical representation of the major sugar beet growing regions.
7. When the questions raised in this petition have been resolved, Section F will also need to be revised to include the omission "and its metabolites containing the 2-cyclohexen-1-one" moiety and requesting an amendment to "40 CFR Part 186".

Recommendations:

For reasons 1, 3, 6 and 7 stated above, CBTS can not at this time recommend for the establishment of the proposed increase in tolerance levels for sugar beet roots from 0.10 to 1.0 ppm and for sugar beet molasses from 0.5 to 9.0 ppm for residues of the herbicide sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) or for the proposed decrease of the pre-harvest interval from 100 days to 60 days.

Note to PM: DCI's for the replacement of Craven Laboratory data may not have been sent to the registrants as of this time.

Detailed Considerations:

Magnitude of Residue - Process Products:

A field residue study was conducted in North Dakota in order to obtain sugar beet roots for use in a processing study. Poast® Herbicide was applied twice at nominal rates of 2.0 lbs ai/A by ground equipment in 20 GPA. This rate is equivalent to 4 times the proposed maximum application rate. The interval between applications was 29 days and samples for processing were harvested 28 days after the last application. Samples were harvested at normal maturity and were received at the processing facility 5 days after harvest.

The sugar beet roots were processed in a manner similar to commercial procedures. Briefly, the raw beets were sliced into narrow slivers and from these the raw juice was extracted with hot water. The spent beet pulp was removed, pressed and dried in an oven. The raw juice was purified with lime, carbon dioxide and filtration in several steps. The purified juice was concentrated by evaporation of the moisture and from this "thick juice" commercial white sugar

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was crystallized. The sugar was removed by centrifugation. The liquid was subjected to two additional crystallization steps and the resultant liquid was the molasses.

The raw beets and the process commodities were analyzed by BASF and according to BASF Analytical Method 30B with slight modifications. Briefly, the method consists of a solvent extraction of the residues with methanol. After extraction, the extract is treated with calcium hydroxide and the precipitate is removed. The extract is then acidified and partitioned with methylene chloride. The methylene chloride extract is concentrated and oxidized with basic hydrogen peroxide. The oxidized residues were then esterified and the extract was purified by silica gel column chromatography. The residues are quantitated as the sethoxydim metabolites DME and DME-OH by gas chromatographic analysis utilizing a wide-bore fused silica column and flame photometric detection (sulfur mode). A limit of quantitation for each analyte of 0.05 ppm sethoxydim equivalents is specified.

Control samples were fortified with the sethoxydim metabolites designated as MSO and 5-OH-MSO₂ and analyzed concurrently with treated and untreated samples. The residue levels in the treated samples were not corrected for apparent residue levels in control samples or for procedural recoveries. It is unclear as to whether or not the recovery samples were corrected for apparent residue levels in the controls. Treated samples were analyzed in duplicate. Table 1 contains a summary of concurrent fortification recovery data and Table 2 contains a summary of the residue data.

Table 1. Recovery of MSO and 5-OH-MSO₂ from Fortified Sugar Beets Samples.

Commodity	Fortification Level (ppm)	MSO Recovery (%)	5-OH-MSO ₂ Recovery (%)
Sugar Beets	0.5	106	80
	10.0	83	76
Dehydrated Pulp	0.05	94	82
	2.5	92	92
Molasses	0.5	102	116
	50.0	76	88
Sugar	0.10	85	85
	2.0	90	75

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Table 2. Sethoxydim Residue Data for Treated Sugar Beet Process Fractions.

Commodity	Residue (ppm of Sethoxydim equivalents)		
	as DME	as DME-OH	Total
Sugar Beets	3.8	0.27	4.1
	4.2	0.45	4.6
Dehydrated Pulp	1.5	<0.05 (0.03)	1.6
	1.6	0.14	1.7
Molasses	40.9	2.6	43.5
	30.1	1.1	31.2
Sugar	0.26	<0.1 (0.02)	0.36
	0.22	*	*

*Sample was lost during the extraction and therefore, was not analyzed for DME-OH.

CBTS can draw no conclusions from the submitted sugar beet processing study until the following deficiencies are addressed:

1. The registrant must provide additional information on the calculation of fortification recoveries. This information should include correction of recovery for apparent residue levels in the control samples. If this correction was not done, then please recalculate the recoveries taking into the account these residues.
2. CBTS requests a discussion explaining the large variation of the residue levels between the duplicates of the molasses samples.
3. The revised Section F of the food additive petition must be revised to correct an omission in the tolerance statement, but we will defer this requirement until the other deficiencies of the processing study are addressed. The revised Section F should include the following statement:

This petition proposed that 40 CFR Part 186 be amended by establishing tolerances for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following animal feeds.

Storage Stability:

Storage Stability data for sethoxydim has been previously considered under PP3F2904 (J. Onley, 1/24/84; and F.D. Griffith, 4/4/84, memo of conference). We have previously concluded these data are adequate (V.F Boyd, PP6F3405, 9/25/86).

Magnitude of Residue - Meat, Milk, Poultry, and Eggs:

The animal feed items of concern are sugar beet tops, molasses and dehydrated pulp. These commodities are fed at levels ranging from 10 to 30% for beef and dairy cattle and from 0 to 15% for poultry or swine. Until the deficiencies of the processing study are addressed, we can draw no conclusions on the adequacy of the existing animal commodity tolerances to cover the increased dietary burden from the proposed use.

Other Considerations - FIFRA '88 Phase 4 Review:

The FIFRA '88 Phase 4 review of the chemical has been completed (L. Cheng, 2/22/91) and several data gaps have been cited. The data gaps most germane to the subject petition will be discussed here.

Plant Metabolism:

CBRS has requested an additional plant metabolism study to be conducted on sugar beets or potatoes while metabolism studies on alfalfa, soybeans and tomato have been identified as adequate for Phase 5 Review. **For the purposes of the subject petition only**, CBTS concludes the nature of the residue in plants is adequately delineated. **Note: This does not negate the CBRS requirement for an additional plant metabolism study.**

Animal Metabolism:

The Phase 4 Review indicates the need for a ruminant metabolism study, but the ruminant feeding study has been found to be adequate for Phase 5 Review provided no new metabolites are uncovered in the metabolism study. **For the subject petition only**, CBTS will base conclusions on the previously submitted ruminant feeding study once the deficiencies of the processing study are addressed.

Magnitude of Residue - Process Products:

CBRS has requested a sugar beet processing study in order to satisfy the reregistration requirements for sethoxydim. **Upon satisfying the deficiencies noted above**, CBTS concludes

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the submitted sugar beet processing study should fulfill the reregistration requirements for that study.

Other Considerations - Craven Laboratory Data:

A review of the impact of Craven Analytical data on the sethoxydim registrations has been completed (L. Cheng, 9/23/91); this review indicates that Craven Laboratories generated data to support the registration of sethoxydim on sugar beets. Craven Labs analyzed sugar beet tops from several field trials that were being used to support the current petition. Current Agency policy dictates that this data may not be utilized to make regulatory decisions prior to the resolution of the issues involving the validity of Craven data. Upon review of the Craven data, we have requested the registrant to provide magnitude of residue data reflecting the maximum use pattern using ground and aerial equipment on sugar beets from WA, NE and MI to replace the Craven data. CBTS concludes, in the absence of this data, the petition is not supported by adequate geographical representation of the major sugar beet growing regions.

cc: W.D. Wassell, M. Flood, A. Rathman, W. Hazel, D. Edwards, N. Kotey (SRRD, H7508W),
RF, Circ., PP8F3646/FAP8H5558, PIB/FOD (Furlow), sethoxydim SF, sethoxydim
Rereg. File
RDI: RS Quick: 2/14/92: RA Loranger: 2/14/92
H7509C:CBTS:WDWassell:wdw:CM#2:Rm 814B:305-6135:12/12/91
Disk: WDW-1, File: WDW-22