

RESIDUE CHEMISTRY BRANCH, HED
PETITION REVIEW QUICK FORM

AUG 5 1987

FROM: Maxie Jo Nelson, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

mjn

THRU: Robert S. Quick, Section Head
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

PM

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

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

1. Petition No(s): 7F3529 RCB#: 2525 MRID#: 401951-01
7H5537 2526 thru -03
2. Chemical(s): Sethoxydim
3. Tolerance Proposal (RAC's & Levels): potatoes @ 4 ppm;
potato flakes and potato granules @ 8 ppm.
4. Petitioner: BASF Corporation
5. Tolerance Expression: combined residue of parent and metabolites
containing the 2-cyclohexen-1-one moiety (calculated as parent)
6. Established Tolerances: 40 CFR 180.412; 21 CFR 561.430.
0.1-40 ppm on RACS; 0.05-0.5 ppm on animal commodities;
0.5-75 ppm feed additive tolerances; no feed additive (21 CFR 193) tolerances.
7. Letter(s) of Authorization (if applicable): N/A.
8. Formulation(s): Poast® Herbicide, EPA Reg. No. 7969-58,
an emulsifiable concentrate containing 1.53 lbs ai/gal.
9. Inerts Status: Under RD purview.

10. Manufacturing Process: is discussed in the 12/4/80 review, E. Zager, PP# OG2396. Technical product is $\geq 95\%$ pure. Impurities are not expected to present a residue problem.
11. Proposed Use(s): _____

1 pt = 0.2 lbs ai

- The use pattern for Poast Herbicide involves postemergence application to potatoes and to grassy weeds at an early stage of their growth. Most annual grasses are controlled with a single application of 1 1/2 to 2 1/2 pints per acre depending on the region of the country. All applications must include 2 pints of oil concentrate and may be made with either ground or aerial equipment. Some annual grasses require 2 applications of 1/2 to 2 pints per acre. For the control of perennial grasses, 3 applications of Poast may be necessary depending on growing conditions. The first application for perennial grasses requires a rate as high as 2 1/2 pints per acre. The second and third applications, if needed, are made at rates up to 1 1/2 pints per acre. As for annual grasses, all applications must include 2 pints of oil concentrate and may be made with either ground or aerial equipment.
- Applications of Poast are timed according to the size of the grass weeds present. Therefore, in general, the first application of Poast is made 15-30 days after planting and the second application is made 14-21 days after the first. The third application would be made if a new flush of weeds occurs.
- In potatoes a preharvest interval of 30 days is imposed and no more than 5 pints per acre per season may be applied.
12. Plant Metabolism Data on: soybeans and alfalfa (PP# 3F2904), sugar beets (PP# 3F2950), and tomatoes (PP# 5F3284).
13. Plant Residues Comprised of: parent plus several metabolites containing the 2-cyclohexen-1-one moiety.
14. Plant Metabolism Data Translatable Here: #12
15. Nature of Plant Metabolism Data (is) is not adequately defined. The Residue of Concern is: per #5.
16. Animal Metabolism Data on: rats (PP# OG2396), lactating goats (PP# OG2396; PP# 3F2904), and laying hens (PP# 3F2904).

17. Animal Residues Comprised of: parent and several metabolites containing the 2-cyclohexen-1-one moiety (ref. 6/23/86 review, S. Malak, PP# 3F2904)
18. Animal Metabolism Data Applicable Here: #16
19. Nature of Animal Metabolism Data (is) is not adequately defined. The Residue of Concern is: per #5
20. Analytical Methods (reference or brief description):
BASF Methods 30B, 30G, and 30H. (FPD-GLC)
All discussed in 6/26/85 review, K. Arne, PP# 3F2904.
MTOS: in re PP# 2F2670 and PP# 3F2904.
Method 30 and its variants are all similar.
Method 30 is the enforcement method of PAM II.
Limit of detection is 0.05 - 0.2 ppm for DME and DME-OH (analyzed as 2 separate peaks; see #23), each, in potatoes and processed fractions, depending on the specific matrix.
21. Method Validation (crop recoveries):
Recovery was $88 \pm 7\%$ (N=28) from potatoes fortified (0.05-2 ppm) with sethoxydim, MSO (sethoxydim sulfoxide), and 5-OH-MSO₂ (sethoxydim sulfone) metabolites.
Recovery was $84 \pm 11\%$ (N=42) after fortification (0.05-10 ppm) with MSO and 5-OH-MSO₂ of whole potatoes, stock feed (pellet), sliced/pelleted potatoes, chips, add-back granules, stock feed granules, and granules. (All raw recovery data are available.)
22. Method Validation (control values):
For total residue (DME + DME-OH peaks) in potatoes and processed fractions, controls were almost always less than the limit of detection (per #20), depending on the matrix.
23. Residues Determined by Method: Parent and regulable metabolites as the dimethyl ester (DME) and hydroxy-DME derivatives of pentanedioic acids. (See discussion in PAM II, Method I.)
24. Enforcement Methodology (is) is not available. In PAM II.

components

Total residue (DME + DME-OH) uncorrected for recovery,

25. Residue Data (crop and residue range (ppm) from Proposed Use):
(0.5+0.5 lb a/A applications, 27-32 day PHI's, 17 trials, 13 states, 1983 and 1984)

MRID
401951-01

Potatoes: 0.3 - 1.6 ppm

(1X)

MRID
401951-02

Potatoes: 2.8, 2.9 ppm (1986 CA trial, 4 x 1.0 lb a/A applications, 15 day PHI - to get potatoes for a processing study)
Potato Chips: 2.2 - 2.7 ppm < 1X concentration
Potato Flakes: 4.3 - 5.9 ppm ~ 2X "
Potato Granules: 5.2-5.6 ppm ~ 2X "
Peeled Potatoes: 1.0, 1.1 ppm -
Stock Feed (abrasion peel) - "wet" : 1.0, 1.1 ppm < 1X concentration
Stock Feed (pulp waste) - "dry" : 5.2, 5.4 ~ 2X concentration

(4X)

Other Comments: ① Stock Feed = processed potato waste = culls, trimmings, abraded peel, pulp wastes from flake and granules processing.
② Potato processing followed standard commercial procedures. Schematics submitted.
③ Storage stability data are discussed under #34.
④ No data here reflect aerial application, but we waive that for this root crop use.

- (26.) Residues will not exceed proposed tolerance on (commodities)
potatoes @ 4 ppm or potato flakes and potato granules
@ 8 ppm. A feed additive tolerance (revised Section F) needs
to be proposed for "processed potato waste (wet and dry)" @ 8 ppm.
(Ref. 2/20/87 memo, C. Trichilo, Potato Waste as a Livestock Feed Item.)

27. Livestock Feeding Studies on (species): lactating dairy cows
(PP# 0G2396) and goats (PP# 3F2904); laying hens (PP# 0G2396
and PP# 3F2904 (refer to 1/12/84 J. Onley and 6/26/85 K. Arne reviews)).
28. Animal Feeding Levels: cows - 0, 0.6, 50 ppm; goats - 0, 30,
75, 100, 300 ppm; hens - 0, 1, 10, 100 ppm and 0, 25, 80, 250 ppm.
29. Animal Residue Ingestion Levels from Proposed Crop Tolerance
FAT @ 8 ppm (8 ppm x 50%)
Levels (proposed tol. level x % in diet): 4 ppm in
(8 ppm x 25%)
beef cattle; 2 ppm in dairy cattle/goats; 4 ppm in hogs; 2.4 ppm in horses; 1.6 ppm
(8 ppm x 30%)
(8 ppm x 20%)
in sheep; 0.8 ppm in poultry.
(8 ppm x 10%)

30. Livestock Tolerances are Adequate in (species) all species.

[Note: established meat/milk/poultry/egg tolerances support a 40 ppm established tolerance on alfalfa, a major feed item. The addition of potatoes as a feed item will not engender the need for higher animal commodity tolerances. Other feed items (eg soybeans) also have higher established tolerances than those being proposed for potato feed items.]

31. Livestock Tolerances Need to be Established: yes (no) If yes
(species/levels): Already established in 40 CFR 180.412.

32. Other Comments: ① There is no Registration Standard on sethoxydim.
② There is adequate geographic representation (WA, OR, CA, ID, ND, MN, WI, MI, ME, NJ, NY, VA, and GA).

③ Raw data and representative chromatograms were submitted.

④ Proposed tolerance level (potatoes) is based on 95% confidence interval, corrected for recovery.

③③. Other Considerations: No information is available on the recoveries of sethoxydim and its metabolites via each (and all) of the FDA multiresidue protocols as required by 40 CFR 158.125(b)(15).
The petitioner is referred to Appendix II of PAM I for information on these protocols and for reporting forms.
(Also ref. 6/9/87 memo from P. Corneliusen, FDA, re Pesticide Registrant Testing of Pesticide Chemicals Through Multiresidue Methods.)

34. Storage Stability: Potato field trial samples were stored up to 27 months frozen. A concurrent storage stability study (26 months) was run. Potatoes were fortified with 1 ppm each of MSO and 5OH-MSO₂. Residues were still stable after 26 months; recoveries were 98 and 96 %, respectively.

Storage stability data have previously been submitted on other crops (soybeans, strawberries) demonstrating stability after 31 months storage.

35. Recommendations:

Negative at this time for the reasons cited in #26 and #33.

The petitioner will need to submit a revised Section F incorporating a feed additive tolerance proposal for "potato processing waste (wet and dry)" at 2 ppm. The results of testing sethoxydim per se and metabolites (MSO and 5-OH MSO₂ at a minimum), separately, through each of the (4) FDA multiresidue protocols also will need to be submitted.

36. Compatibility with Codex Tolerances: No. See Attachment.

Attachment: International Residue Limits Status sheet.

cc: RF, Circ, Reviewer, PMSD/ISB, TOX, PP# 7F3529.

Approved: Quick R/IRX 8/4/87; Schmitt R 28 8/5/87

INTERNATIONAL RESIDUE LIMIT STATUS

J. Jones
7/29/87

CHEMICAL Sethoxydim (Poast®)

CODEX NO. _____

CODEX STATUS: _____

☒ No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

PROPOSED U.S. TOLERANCES:

Petition No. 7F3529/7H5537

RCB Reviewer Nelson

Residue: per 40 CFR 180.412

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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potatoes	4
" flakes	8
" granules	8

CANADIAN LIMITS:

☐ No Canadian limit

Residue: _____

sethoxydim ^{1/}

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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potatoes	0.1 ^{2/}
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MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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NOTES:

^{2/} Negligible residue limit

^{1/} Canadian tolerances on other commodities (non-negligible) also include metabolites containing the cyprohe-2-ene moiety in addition to parent.