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PMSD/ISB
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RESIDUE CHEMISTRY BRANCH, HED
PETITION REVIEW QUICK FORM

FROM: ALFRED SMITH, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: HOYT JAMERSON, PM 43
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

- Petition No(s): 8E3597 (RCH # 3196; Acc. Nos. 404465-00 to -01)
SETHOXYDIM, 2-[1-(ETHOXYIMINO)BUTYL]-5-[2-(ETHYLTHIO)PROPYL]
- Chemical(s): -3-HYDROXY-2-CYCLOHEXENE-1-ONE
- Tolerance Proposal (RAC's & Levels):
LENTILS AT 20 PPM
- Petitioner: INTERREGIONAL RESEARCH PROJECT No. 4, (IR-A),
AND AGRICULTURAL EXPERIMENT STATIONS OF IDAHO
AND WASHINGTON
- Tolerance Expression: SETHOXYDIM AND ITS METHYLENOLITES
CONTAINING THE 2-CYCLOHEXENE-1-ONE MOIETY (CALCULATED AS)
E995 (0.5 PPM); MILK (0.05 PPM);
- Established Tolerances: §180.412: MEAT, FAT, AND MEAT BYPRODUCTS
OF CATTLE, GOATS, HOGS, HORSES, AND SHEEP (0.2 PPM); ALFALFA FORAGE
AND HAY (40 PPM); COTTONSEED AND PEANUT HULLS (5.0 PPM);
PEANUTS (25 PPM); SOYBEANS AND HAY (10 PPM); SUGAR BEETS (0.1 PPM); SUGAR
BEET TOPS (3.0 PPM); SWEET POTATOE SEEDS (1.0 PPM).
- Letter(s) of Authorization (if applicable): BASE CORP. LETTER OF 9/21/87, KAREN R. BLUNDE II, SENIOR
REGISTRATION SPECIALIST
- Formulation(s): POAST® HERBICIDE, (1.5 LBS AE/GALLON)
- Inerts Status: CLETHIO LINDEN §180.1001(c)

10. Manufacturing Process: SUBMITTED AND DISCUSSED IN PPR 062396 (E. VASIK, 12/4/80). IMPURITIES NOT EXPECTED TO POSE A RESIDUE PROBLEM.
11. Proposed Use(s): POST-EMERGENCE GROUND SPRAY APPLICATION AT RATE OF 2.5 PINTS/ACRE (0.47 LB AI/A). IF ADDITIONAL GRASS CONTROL IS NEEDED, APPLY A POST-EMERGENCE SPRAY AT 1.5 PINTS/ACRE (0.28 LB AI/A) AT 14-21 DAYS AFTER FIRST APPLICATION. DO NOT APPLY TO LENTILS WITHIN 50 DAYS OF HARVEST (PHI). ALWAYS ADD 2 PINTS OF OIL CONCENTRATE/ACRE (CONTAINING EPA EXEMPT INGREDIENTS). DO NOT SPRAY MORE THAN 4 PINTS POST/A (0.95 LB AI/A). DO NOT ALLOW LIVESTOCK TO GRAZE IN TREATED AREAS OR FEED ON TREATED LENTILS.
12. Plant Metabolism Data on: SOYBEANS, COTTON, SUGAR BEETS, ALFALFA, AND TOMATOES TREATED WITH RADIOLABELLED C¹⁴-SETHOXYDIM
13. Plant Residues Comprised of: PARENT COMPOUND SETHOXYDIM AND ITS METABOLITES: SULFOXIDE AND SULFONE OF SETHOXYDIM HYDROXY METABOLITES; SULFOXIDES OF HYDROXY METABOLITE
14. Plant Metabolism Data Translatable Here: SEE ITEM 12 ABOVE
15. Nature of Plant Metabolism Data is ~~not~~ adequately defined.
The Residue of Concern is: THE PARENT COMPOUND SETHOXYDIM AND ITS METABOLITES CONTAINING THE 2-CYCLOHEXENE-1-ONE MOIETY
16. Animal Metabolism Data on: RATS, LACTATING GOATS, AND LAYING HENS WITH RADIOLABELLED C¹⁴-SETHOXYDIM

17. Animal Residues Comprised of: THE PARENT COMPOUND SETHOXYDIN, AND ITS METABOLITES; SULFOXIDE AND SULFONE OF SETHOXYDIN; HYDROXY METABOLITES; SULFOXIDES OF HYDROXY METABOLITES.

18. Animal Metabolism Data Applicable Here: POULTRY, RATS, AND GOATS

19. Nature of Animal Metabolism Data is ~~not~~ adequately defined.

The Residue of Concern is: THE PARENT COMPOUND SETHOXYDIN, AND ITS METABOLITES CONTAINING THE 2-CYCLOHEXENE-1-ONE MOIETY.

20. Analytical Methods (reference or brief description):

PPM, VOL. II, METHOD I: GAS-LIQUID CHROMATOGRAPHIC DETERMINATION OF RESIDUES OF PAST AND ITS METABOLITES IN SOYBEAN SEED, SOYBEAN SEED PROCESS FRACTIONS, CHICKEN TISSUES, BEEF TISSUES, MILK, AND EGGS

21. Method Validation (crop recoveries): LENTILS FORTIFIED AT LEVELS OF 0.05-20.0 ppm. RECOVERIES WERE 84-100%.

22. Method Validation (control values): UNTREATED LENTILS HAD <0.05-0.06 ppm SETHOXYDIN-EQUIVALENT RESIDUES.

23. Residues Determined by Method: RESIDUE METHOD IS SAME AS IN ITEM 20. (SEE ALSO THIS PETITION, VOL. 2, SEC. D, p. 57)

24. Enforcement Methodology is ~~not~~ available.

25. Residue Data (crop and residue range (ppm) from Proposed Use):

RESIDUE DATA FROM WASHINGTON AND IDAHO.

Crop: LENTILS (SEED): 0.25-24.8 PPMGEOGRAPHICAL REPRESENTATION IS ADEQUATE. THE TWO STATES REPRESENT GREATER THAN 90% OF U.S. PRODUCTION

Crop: _____

Crop: _____

Other Comments: THE PETITIONER CLAIMS THAT THE MAXIMUM RESIDUE LEVEL OF 24.8 PPM IS AN OUTLIER AND SHOULD NOT BE INCLUDED AS A VALID DATA POINT. WITHOUT THIS POINT THE MAXIMUM LEVEL IS 16.8 PPM. HOWEVER, ONLY 7 SAMPLES ARE AVAILABLE FROM THE PROPOSED USE, AND THE RANGE OF VALUES FROM THE PROPOSED USE VARIES CONSIDERABLY. AS A RESULT, THE EXCLUSION OF THE MAXIMUM RESIDUE VALUE CANNOT BE STATISTICALLY SUPPORTED.

26. Residues will not exceed proposed tolerance on (commodities)

and will exceed proposed tolerance on (commodities) LENTILS.A LEVEL OF 30 PPM IS REASONABLE AND SHOULD BE PROPOSED.27. Livestock Feeding Studies on (species): LACTATING COWS;
LAYING HENS28. Animal Feeding Levels: LACTATING COWS (0, 0.6, 50 PPM);
LAYING HENS (0, 1, 10, 100 PPM)29. Animal Residue Ingestion Levels from Proposed Crop Tolerance Levels (proposed tol. level x % in diet): N/A ppm in beef cattle; _____ ppm in dairy cattle/goats; _____ ppm in hogs; _____ ppm in horses; _____ ppm in sheep; _____ ppm in poultry.30. Livestock Tolerances are Adequate in (species) N/A, but not adequate in N/A

31. Livestock Tolerances Need to be Established: ~~yes~~ no. If yes
(species/levels): _____

32. Other Comments: REFERENCE ITEMS 29, 30, 31. LABEL RESTRICTION PROHIBIT GRAZING OF LIVESTOCK IN TREATED AREAS OR THE FEEDING OF TREATED LENTILS. THE RESTRICTIONS PRECLUDE THE LIVESTOCK INGESTION OF SETHOXYDIM RESIDUES FROM THE PROPOSED USE. ADDITIONALLY, ^{SHOULD} A DIVERSION OF TREATED LENTILS TO LIVESTOCK FEED OCCUR, THEN INGESTED RESIDUES WOULD BE ADEQUATELY COVERED BY EXISTING TOLERANCES FOR MEAT, MILK, POULTRY, AND EGGS (\$180.412).

33. Other Considerations: _____

34. Additional Data Needed: _____

35. Recommendations: THE PROPOSED TOLERANCE IS NOT ACCEPTABLE.

36. Other Comments under Recommendations: ~~THE PROPOSED TOLERANCE OF 20 PPM IS TOO LOW TO COVER RESIDUES FROM THE PROPOSED USE. A LEVEL OF 30 PPM IS ADEQUATE AND SHOULD BE PROPOSED~~

37. Compatability with Codex Tolerances: THERE ARE NO CODEX, CANADIAN, OR MEXICAN TOLERANCES FOR SETHOXYDIM ON LENTILS. THEREFORE, NO COMPATABILITY PROBLEMS EXIST.

SUBJECT FILE (SETHOXYDIM), PMSD/ISB,
cc: RF, Circ, Reviewer, Thompson, TOX, EEB, EPB, FDA, PP# 8E3597
Approved: ERrico 2/16/88 ; Schmitt 2/16/88