US EPA ARCHIVE DOCUMENT

RESIDUE CHEMISTRY BRANCH, HED

DATA REVIEW QUICK FORM

Date: AUG 11 1988

MEMORANDUM

SUBJECT: Petition Review for Establishment of Tolerance(s). Evaluation of Analytical Method(s) and Residue Data.

FROM: Stephanie H. Willett, Chemist SHW
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division, TS-769C

THRU: John H. Onley, Ph.D., Section Head John H. Onley
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Residue Chemistry Branch
Hazard Evaluation Division, TS-769C

TO: Hoyt L. Jamerson PM 43
Registration Division, TS-767C

and

Toxicology Branch
Hazard Evaluation Division, TS-769C

1. Petition No(s): 8E3637
2. RCB No(s): 3966
3. MRID No(s): None
4. Pesticide(s): metolachlor
5. Tolerance Proposal (RACs & Levels): 1.0 ppm on cabbage
6. Petitioner: IR-4 and the Ag. Exp. Stations of Florida, Wisconsin, North Carolina, New York, Virginia, Oregon, Oklahoma, Hawaii and Massachusetts

7. Tolerance Expression: 2-chloro-N-(2-ethyl-6-methyl phenyl)-N-2-methoxy-1-methylethyl) acetamide and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methyl phenyl) amino]-1-propanol and 4(2-ethyl-6-methyl phenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound

8. Established Pesticide Tolerances: 40 CFR 180.368

at levels ranging from 0.02 - 30 ppm

9. Established Food Additive Tolerances: 21 CFR 193.

None

10. Established Feed Additive Tolerances: 21 CFR 561.

None

11. Is Pesticide a Registration Standard Chemical? (Yes/No) _____

If yes, date Guidance Document issued: September 1986

12. Letter(s) of Authorization (if applicable): From C.B. Bussey of Ciba-Geigy. Authorizes EPA to use all data submitted by Ciba-Geigy in support of this IR-4 petition

13. Formulation(s): Dual® 8E Herbicide (EPA Reg No 100-597)

14. Inerts Status: cleared under 40 CFR 180.1001

15. Manufacturing Process: adequately described (See memo of A. Smith, 4/2/79). Technical metolachlor is ≈95% pure. The impurities are not expected to cause residue problems.

16. Proposed Use(s):

Transplant Cabbage - DUAL 8E

Apply a surface broadcast application with ground application equipment prior to transplanting or a broadcast application within 48 hours after transplanting. Do not incorporate. Use 1.25 to 3.0 pints (1.25 to 3.0 lb ai) per acre according to soil type in a minimum of 10 gallons of water per acre.

Note: Crop maturity may be delayed by DUAL 8E application. Weed control may be reduced on muck soils.

17. Plant Metabolism Data on: corn, soybeans, potatoes and lettuce

18. Plant Residues Comprised of: parent and several metabolites, mostly 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4(2-ethyl-6-methylphenyl)2-hydroxy-5-methyl-3-morpholinone

19. Plant Metabolism Data Translatable Here: corn, soybeans and lettuce

20. Nature of Plant Metabolism on the Subject RAC(s) of This Petition is is not adequately defined, for the purposes of this petition. The Residue of Concern is: parent, 2-[(2-ethyl-6-methylphenyl)-amino]-1-propanol and 4(2-ethyl-6-methylphenyl)2-hydroxy-5-methyl-3-morpholinone. Additional metabolism data are required for reregistration.

21. Animal Metabolism Data on: N/A

22. Animal Residues Comprised of: N/A

23. Animal Metabolism Data Applicable Here: N/A

24. Nature of Animal Metabolism Data is/is not adequately defined.
The Residue of Concern is: N/A

25. Analytical Method(s) (Give Reference and/or Brief Description)
Metolachlor and its metabolites are converted by acid hydrolysis to a mixture of CGA-37913 and CGA-49751. The acid extract is partitioned with methylene chloride, followed by column cleanup. CGA-37913 is determined by GLC with Coulson electrolytic detection that is specific for nitrogen. The chloroethanol derivative of CGA-49751 is determined by GLC with Dohrmann microcoulometric detection that is specific for chloride (see PAM II, Method I).

26. Has there been a Method Trial? (Yes, No) Yes

If yes, provide details: See memoranda of R. R. Watts dated July 28 and 29, 1976.

If no, is a Method Trial needed? N/A

27. Residues Determined by Method(s): Metolachlor and its two major metabolites

28. Method Validation (RACs/"spike chemical"/fortification level(s)/ recovery range/average recovery):

corn, soybeans, sorghum, peanuts / parent, CGA-37913, CGA 49751 (major metabolites) / 0.10 - 0.20 ppm / 70-94% (spiked w/ metabolites); 38-49% (spiked w/ parent)

29. Method Validation (limit of detection and/or sensitivity in ppm):

Parent: 0.08 - 0.1 ppm (combined residues)

Metabolite(s) (specify):

30. Method Validation (state crops and control values reported):

corn 0.01 - 0.02 ppm

31. Adequate Analytical Method(s) (are)/are not Available for Enforcement Purposes.

These Method(s) are located: PAM II, method I

32. PAM I Multiresidue Methods Data are available for parent pesticide tested via Protocols (I) II III IV (circle, as applicable). Additional multiresidue test information for parent compound that is needed: None

33. PAM I Multiresidue Methods Data are available for metabolite(s) tested via Protocols I II III IV (circle, as applicable). Additional multiresidue test information for metabolite(s) that is needed: N/A

34. Residue Data (RAC(s) and Processed Commodities)

Field trials were conducted in California, Florida, New York, North Carolina, Texas and Wisconsin. Application rates ranged from 1.5 lb (0.5X) to 8 lb (2.67X)/A.

Samples were harvested, shipped frozen and stored for periods of 3 to 17 months prior to analysis. Samples were analyzed using Ciba-Geigy method 338, which is essentially the same as the enforcement methodology. The method sensitivity is 0.01 ppm. Recoveries ranged from 53 to 100% for both metabolites. Control values ranged from ND to 0.03 ppm.

Metolachlor residues calculated from 2 derivatives (CGA-37913 and CGA-49751) formed in the methodology ranged from ND to 0.5 ppm at the maximum label rate. The residue levels are not likely to exceed 1.0 ppm when the pesticide is used as directed.

35. Frozen Storage Stability Data are/are not Available.

If yes, give RACs/fortification levels/length of storage/recovery range/conditions of storage (°C): corn/0.2 and 1.0 ppm/13 months/83-115%/-15°C (see Reg. Standard). Storage stability data submitted here indicates stability at subzero temperatures for up to 18 months.

36. Regional Registration is/is not involved.

If yes, list States in which use is sought: _____

If yes, indicate/explain (see 51 FR 11341, 4/2/86 - Policy on Minor Uses) if a bona fide "Minor Use" is involved: _____

37. Geographic Representation is/is not adequate. If no, list RAC(s) and States from which additional data are needed: _____

38. Residues will not exceed proposed tolerance(s) on (commodities) cabbage, when used as directed.

but may exceed proposed tolerance(s) on (commodities) _____

39. Livestock Feeding Studies on (species): N/A

40. Animal Feeding Levels: N/A

41. Animal Residue Ingestion Levels from Proposed RAC Tolerance(s) N/A Levels (proposed tolerance level x percent in diet): _____ ppm in beef cattle; _____ ppm in dairy cattle/goats; _____ ppm in hogs; _____ ppm in horses; _____ ppm in sheep; _____ ppm in poultry.

42. Livestock Tolerances are Adequate in (species) N/A, but not adequate in _____.

43. Livestock Tolerances Need to be Established: Yes/No. If yes, species/levels: N/A

44. Other Comments: The proposed use is not considered to be a minor use.

45. Other Considerations: _____

46. Additional Information Needed: _____

47. Additional Data Needed: RCB suggests that the petitioner submit a revised Section F to propose a tolerance without regional restriction for use of metolachlor on cabbage. Data submitted are adequate to support a full tolerance. The proposed use is not considered to be a minor use. Also the revised Section F will be in agreement with the submitted Section B.

48. RECOMMENDATIONS: against the proposed tolerance at this time. See No. 47.

49. Other Comments Under Recommendations:

50. Compatibility with Codex Tolerances? (Explain) There are no Codex, Mexican or Canadian limits established for metolachlor on cabbage, therefore no compatibility problems exist.

ATTACHMENT(S): (1) International Residue Limits Status Sheet

(2)

cc: RF, Circ, Reviewer, PP# 8F3637, PMSD/ISB, FDA.

Approved: JHOnley J.H.O - 8/11/88; RDSchmitt RDSchmitt 8/12/88.

F. Sura 8/4/88

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Metolachlor

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. 8E3637

RCB Reviewer S. H. Willett 8-3-88

Residue: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-2methoxy-1-methylethyl)acetamide *

Crop(s)	Limit (mg/kg)
cabbage	1.0

CANADIAN LIMITS:

☑ No Canadian limit (on cabbage)

Residue: ____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: ____

Crop(s)	Limit (mg/kg)

NOTES:

* and its metabolites 2-[2-ethyl-6-methylphenyl)amino]-1-propanol and 4(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound

Form revised 1986

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