

PMB/D/E SB
1947C

RESIDUE CHEMISTRY BRANCH, HED
DATA REVIEW QUICK FORM

NOV 30 1987

Date: _____

MEMORANDUM

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

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division, TS-769C

mjn

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division, TS-769C

PM

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

and

Toxicology Branch
Hazard Evaluation Division, TS-769C

1. Petition No(s): 7E3566
2. RCB No(s): 2839
3. MRID No(s): 403410-00, -01.
4. Pesticide(s): Methidathion
5. Tolerance Proposal (RACs & Levels):
Kiwifruit @ 0.1 ppm
6. Petitioner: IR-4 and Ag Exp Stn of CA and the
USDA.

7. Tolerance Expression: methidathion only
(O,O-dimethyl phosphorodithioate, S ester with 4-(mercapto-
methyl-2-methoxy-2,1,3,4-thiadiazolin-5-one)
8. Established Pesticide Tolerances: 40 CFR 180.298 (a)(b)
(a) parent only: RACs @ 0.05-12 ppm
(b) combined residue of parent + oxygen analog + sulfoxide
+ sulfone metabolites: meat, milk, poultry, and
eggs @ 0.05 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) Yes
(RCB Chapter)
If yes, date Guidance Document issued: 6/30/82
12. Letter(s) of Authorization (if applicable):
8/19/87 Ciba-Geigy authorizes access to all Ciba's
methidathion data.
13. Formulation(s): Supracide 2E Insecticide - Miticide,
EPA Reg. No. 100-501, an emulsifiable concentrate
containing 2 lbs ai/gal.
14. Inerts Status: Under RD purview, but presumably cleared since
this is a registered product.
15. Manufacturing Process: Detailed in Confidential Appendix A
of the Product Chemistry Chapter, 6/30/82. Impurities
are not expected to present a residue problem (3/16/72 memo,
R. Schmitt).

16. Proposed Use(s): _____

KIWIFRUIT (California only)

For the Control of scale insects (greedy scale, latania scale, ivy scale, oleander scale, parlatoria scale, and San Jose scale), apply one dormant full coverage spray with ground application equipment at the rate of 6 to 8 pints SUPRACIDE 2E per acre or 3 to 4 pints SUPRACIDE 2E per 100 gals and applying the resulting spray mixture at the rate of 175 to 200 gals. per acre. Do not make more than one application per year. Only apply during the dormancy period. Do not use after bud break as crop injury may occur.

* 6 to 8 pints/Acre equals 1.5 to 2 lbs. ai/Acre

17. Plant Metabolism Data on: alfalfa and beans, with supporting work on cotton, oranges, tomatoes, and artichokes.
(Ref. RCB Chapter, 6/30/82, p. 17; RCB reviews of PP# 6F1782 8/19/76, J. Worthington, and PP# 6F3331, 2/7/86, M. Frestone.)
18. Plant Residues Comprised of: _____
Predominantly parent, with minor amounts of oxygen analog, desmethyl metabolite, et al.. No evidence of hydrazine or hydrazides. (PP# 7F1983 review, 3/7/80, T. McLaughlin.) See #45.
19. Plant Metabolism Data Translatable Here: _____
All
20. Nature of Plant Metabolism on the Subject RAC(s) of This Petition (is) is not adequately defined.
The Residue of Concern is: Parent only

21. Animal Metabolism Data on: N/A. There are no animal feed items associated with this petition.
22. Animal Residues Comprised of: N/A. See #21.
23. Animal Metabolism Data Applicable Here: None. See #21.
24. Nature of Animal Metabolism Data is/is not adequately defined.
The Residue of Concern is: N/A. See #21.
25. Analytical Method(s) (Give Reference and/or Brief Description)
JAOAC, Vol. 63, No. 5, 1980, pp. 1105-1108, used by IR-4.
FPD-GLC method for separating and measuring residues of methidathion and its oxygen analog.
Extract RAC with acetonitrile; separate parent and oxon by adding petroleum ether; liquid-liquid partitioning and column clean-up steps. 10% DC200 on Gas Chrom Q column; FPD-GLC detection.
Similar in principle to the enforcement method of PAM II, which separates out methidathion and determines it by FPD-GLC. (Could be used to determine the oxon, too.)
Representative chromatograms were submitted by IR-4.

26. Has there been a Method Trial? (Yes, No) Yes (on PAM II method)

If yes, provide details: Sensitivity, 0.02 ppm. NDR in blanks,
cottonseed - 6, 12 ppm methidathion "spike" - 85-105% recovery;
oranges - 0.2, 0.4 " " " - 93-110% " .

If no, is a Method Trial needed? Use PAM II method for any
enforcement action; no additional MTD needed.

27. Residues Determined by Method(s): _____

Methidathion. The oxygen analog is phase-separated by
extraction and can be determined as a separate entity.

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

Kiwifruit/methidathion/0.01, 0.02, 0.05 ppm/90-100% recovery/
96% avg recovery.

Kiwifruit/methidathion oxygen analog/0.05, 0.10, 0.25 ppm/
70-78% recovery / 75% avg recovery.

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

Parent: 0.01 ppm

Metabolite(s) (specify): O-analog, 0.05 ppm

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

Kiwifruit, <0.01 ppm methidathion in controls (4 reps)
" <0.05 " O-analog " " " "

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

These Method(s) are located: In PAM II

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 to support this petition.

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: No metabolite information is available. None is needed to support this petition (tolerance expressed in terms of parent only).

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

Methidathion < 0.01 ppm

O-analog < 0.05 ppm

One field trial only (CA, 1985-86)

Single application at dormancy; 235-day PHI

1.5 and 3 lbs ai/A rate, (proposed use rate: 1.5-2 lbs ai/A)

4 reps/application rate/chemical

frozen stored as chopped RAC: 12 months (parent); 14-15 months (O analog)

" " " crop extract: 0-20 days " ; 0-5 days " "

all reported residue values are below method sensitivity (NDR), even those at the exaggerated rate,

mature fruit was harvested.

Representative chromatograms were submitted.

This field trial is not properly validated by frozen storage stability data of adequate duration. Either a longer frozen storage study (≥ 12 months) or additional field trials adequately supported by new or existing (see #35) frozen storage data must be submitted. See #47.

35. Frozen Storage Stability Data (are) are not Available.

If yes, give RACs/fortification levels/length of storage/recovery range/conditions of storage (°C): See # 47 also.

Kiwifruit/0.01, 0.02, 0.05 ppm parent/5 1/3 months/82-110% (99%)/chopped, -20°C.

Kiwifruit, 0.05, 0.1, 0.25 ppm D-analog/~8 mos/73-82% (78%)/chopped, -20°C.

36. Regional Registration (is) is not involved.

If yes, list States in which use is sought: CA only

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

Yes, Kiwifruit is on the list of "minor" crops.

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

Regional registration limited to CA is being sought for this minor crop use.

38. Residues will not exceed proposed tolerance(s) on (commodities)

Judgment deferred, pending resolution of #34 and #47.

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

39. Livestock Feeding Studies on (species): N/A. See #21.

40. Animal Feeding Levels: N/A. See #21

41. Animal Residue Ingestion Levels from Proposed RAC Tolerance(s)
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) _____

but not adequate in _____

43. Livestock Tolerances Need to be Established: Yes/No. If yes,
species/levels: N/A. See #21

44. Other Comments: _____

45. Other Considerations: No residues of dimethyl nitrosamine
have been shown to be present in crops, meat and milk by
a method sensitive to 0.01 ppm. (Ref. RCB Chapter,
6/30/82, p. 50.)

46. Additional Information Needed: _____

47. Additional Data Needed: The lack of adequate frozen storage stability data is a data gap in the Reg. Std (see RCB chapter, 6/30/82, p 51) and in PP# 6F3331 (see 9/22/87 review, G. Otakie, deficiency 5b). In this present petition, the RAC was stored >6 months longer than storage stability data validate. Because of this ongoing problem we are taking a conservative position. The petitioner will need to submit frozen storage validation data of ≥ 12 months duration to support the residue data of this petition. Alternatively, additional field trial data on Kiwifruit that is supported by appropriate (duration, recovery) frozen storage stability data may be submitted to augment existing data.

48. RECOMMENDATIONS: _____

Negative, for the reasons discussed in #34, 38, and 47. Appropriate frozen storage stability and/or additional field trial data need to be submitted.

49. Other Comments Under Recommendations: _____

P. M., note a tolerance with Regional Registration is involved.

50. Compatibility with Codex Tolerances? (Explain) _____

No conflict exists because there is no Codex tolerance for methidathion/Kiwifruit. See Attachment. No applicable Canadian or Mexican tolerances either.

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

(2)

cc: RF, Circ, Reviewer, PP# 7E3566, TOX, PMSD/ISB.

Approved: RSQuick R/IRW 11/30/87; RDSchmitt RDSchmitt 11/30/87

SUMMARY OF DEFICIENCIES: PP# 7E3566 ; RCB# 2839

1. A single field trial with Kiwifruit was submitted. RAC samples of methidathion and controls were stored (-20°C) for 12 months prior to analysis. The supporting frozen storage stability study reflects only $5\frac{1}{3}$ months storage of kiwifruit spiked with methidathion. There are no other frozen storage stability data for methidathion on other RACs to supplement these data.

The petitioner will need to submit either ① additional frozen storage stability data for methidathion/Kiwifruit reflecting ≥ 12 months storage; or, ② additional field trials of methidathion/Kiwifruit which reflect frozen storage of $\leq 5\frac{1}{3}$ months storage. If such trials involve longer storage of samples prior to analysis, frozen storage stability data to validate the storage will need to accompany the field trial data.

2. Pending validation of the field trial data by adequate frozen storage stability data, we defer judgment on the adequacy/appropriateness of the proposed tolerance level. [Note: 0.05 ppm may be more appropriate. That would sync with several other RACs and avoid unnecessary proliferation of tolerance levels.]

INTERNATIONAL RESIDUE LIMIT STATUSCHEMICAL MethidathionCODEX NO. 51CODEX STATUS:☒ No Codex Proposal
Step 6 or above (on Kiwi)

Residue(if Step 8): _____

parent compound

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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PROPOSED U.S. TOLERANCES:Petition No. 7E3566RCB Reviewer NelsonResidue: on RAC crops, parentonly. 40 CFR 180.298(a)

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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Kiwifruit0.1CANADIAN LIMITS:☒ No Canadian limit (on Kiwi)

Residue: _____

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