

CHEMISTRY BRANCH I - TOLERANCE SUPPORT, HED
DATA REVIEW QUICK FORM

FEB 22 1991

Date: _____

MEMORANDUM

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

FROM: GARY F. OTAKIE, Chemist
Tolerance Petition Section II
CHEMISTRY BRANCH I - TOLERANCE SUPPORT
Hazard Evaluation Division, H7509C

Gary F. Otakie

THRU: ELIZABETH T. HAEBERER, SECTION HEAD
Tolerance Petition Section II
CHEMISTRY BRANCH I - TOLERANCE SUPPORT
Hazard Evaluation Division, H7509C

Elizabeth T. Haebener

TO: HOYT L. JAMERSON PM 43
Registration Division, H7505C

and

Toxicology Branch - HFA SUPPORT
Hazard Evaluation Division, H7509C

1. Petition No(s): 1 E 3926
2. DEB No(s): 7340
3. MRID No(s): 416889-00 AND 41689-01
4. Pesticide(s): METALAXYL
5. Tolerance Proposal (RACs & Levels):
GINSENG AT 3.0 PPM
6. Petitioner: IR-4 AND THE AGR. EXP. STATION OF
NEW JERSEY ON BEHALF OF AGR. EXP. STATIONS IN
NORTH CAROLINA AND WISCONSIN

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7. Tolerance Expression: METALAXYL AND ITS METABOLITES
PER 40 CFR 180.408 (a)
8. Established Pesticide Tolerances: 40 CFR 180.408 a AND b,
VARIOUS RACS AND COMMODITIES OF ANIMAL ORIGIN FROM
0.1 PPM ON BEETS, BROCCOLI, GRAIN CROPS, PINEAPPLES ETC.
TO 20.0 PPM ON PEANUT HAY, 0.05 PPM EGGS, 0.02 PPM
MILK, 0.05 AND 0.4 PPM IN MEAT AND FAT RESPECTIVELY
OF CATTLE GOATS, HOGS, HORSES, SHEEP AND POULTRY
9. Established Food Additive Tolerances: 21 CFR 193.277
1.0 PPM IN WHEAT MILLING FRACTIONS TO 7.0 PPM
IN CITRUS OIL
10. Established Feed Additive Tolerances: 21 CFR 561.273
0.4 PPM IN APPLE POMACE (WET) TO 16.0 PPM
IN TOMATO POMACE (PP%)
11. Is Pesticide a Registration Standard Chemical? (Yes/No)
If yes, date Guidance Document issued: _____
12. Letter(s) of Authorization (if applicable): GIBA-GEIGY TO
EPA DATED OCTOBER 25, 1982 FROM KAREN S. STUMPF
13. Formulation(s): RIDOMIL[®] 2E (EPA REG. NO. 100-602) WITH
2 LBS A.I. /GAL OR 25.1% W/W A.I.; AND RIDOMIL[®] 5G
(EPA REG. NO. 100-608), GRANULAR, 5% W/W A.I.
14. Inerts Status: UNDER RD
15. Manufacturing Process: CONFIDENTIAL APPENDIX B TO FRSTP,
AND IN PP# IF2500, 3/9/82, P.V. ERIGO; DER DOES
NOT FORSEE ANY RESIDUE PROBLEMS ON FRUITING VEGETABLES
FROM IMPURITIES IN THE TECHNICAL AT THE LEVELS GIVEN
(SEE 6F3387, 9/26/86 MEMO OF F.D. GRIFFITH).

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16. Proposed Use(s): AS A SYSTEMIC FUNGICIDE TO CONTROL
DISEASE CAUSED BY MEMBERS OF OOMYCETE CLASS OF FUNG
- APPLY METALAXYL AT 0.75 LB A.I./A TO SOIL
SURFACE IN SPRING BEFORE PLANTS BEGIN GROWING.
- MAKE ADDITIONAL APPLICATIONS OF METALAXYL AT
MONTHLY INTERVALS AT 0.5 LB A.I./A, UP TO
TO FOUR SUPPLEMENTAL APPLICATIONS
WITH LAST APPLICATION OF 0.75 LB A.I./A
MAY BE MADE (I.E. TOTAL MAX. OF 5 APPLICATIONS
AND 3 LBS A.I./A); 9 DAY PHI
17. Plant Metabolism Data on: POTATOES, GRAPES AND LETTUCE
18. Plant Residues Comprised of: METALAXYL, AND FROM HYDROLYSIS
OF METHYL ESTER BOND, RING METHYL OXIDATION AND
HYDROXYLATION TO FORM CGA-62826, CGA-100255
AND CGA-94684 (SEE FRSTR PP 3-12).
19. Plant Metabolism Data Translatable Here: POTATOES, GRAPES AND LETTUCE
20. Nature of Plant Metabolism on the Subject RAC(s) of This Petition
(is/is not adequately defined.
The Residue of Concern is: METALAXYL AND METABOLITES
CONTAINING 2,6-DIMETHYLANILINE MOIETY AND N-(2-
HYDROXY METHYL-6-METHYL)-N-(METHOXYACETYL) ALANINE
METHYL ESTER, EACH EXPRESSED AS METALAXYL EQUIVALENTS.

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21. Animal Metabolism Data on: RATS, GOATS AND COWS.
FRSTR REQUIRED NEW RUMINANT AND POULTRY
METABOLISM STUDIES FOLLOWING DEB GUIDELINES;
WHICH ARE CURRENTLY UNDER EPA REVIEW.
22. Animal Residues Comprised of: CURRENTLY SAME AS PLANTS.
REQUIRED ANIMAL METABOLISM STUDIES IN ITEM
21 ABOVE, NOW BEING REVIEWED UNDER FRSTR.
23. Animal Metabolism Data Applicable Here: GINSENG NOT
AN ANIMAL FEED ITEM.
24. Nature of Animal Metabolism Data is/is not adequately defined.
The Residue of Concern is: N/A-NO ANIMAL FEED
ITEMS FROM THE PROPOSED USE ON GINSENG.
25. Analytical Method(s) (Give Reference and/or Brief Description)
GIBA-GEIGY METHOD AG-395 (SEE PP# 8F3617/8H554
NOVEMBER 28, 1988 MEMO OF F.D. GRIFFITH). METALAXYL AND
METABOLITES CONTAINING THE 2,6-DIMETHYLANILINE
MOIETY ('TOTAL' RESIDUES) ARE DETERMINED. SAMPLES
EXTRACTED BY REFLUXING WITH 80% (V/V) METHANOL/WATER
FOR TWO HOURS; SAMPLE EVAPORATED TO DRYNESS AND WATER
ADDED, REFLUXED FOR 15 MINUTES AFTER ADDITION OF
METHANESULFONIC ACID; EXTRACT BASIFIED AND 2,6-
DIMETHYLANILINE FORMED IS STEAM DISTILLED AND
CLEANED UP WITH SILICA SEPPAX; TRIFLUOROACETIC ACID
IS ADDED TO ELUATE TO FORM SALT (DMA-TFA); CAPILLARY
GAS CHROMATOGRAPHY USING NITROGEN/PHOSPHORUS DETECTOR IN
NITROGEN MODE.

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26. Has there been a Method Trial? (Yes No) AG-395
 If yes, provide details: FOR RESULTS OF MTO SEE
PPH 3F2948, JULY 9, 1984 MEMO OF P. JUNG;
METHOD SUBMITTED TO FDA AS ENFORCEMENT METHOD.
 If no, is a Method Trial needed? _____
27. Residues Determined by Method(s): METALAXYL AND
METABOLITES CONTAINING THE 2,6-DIMETHYLANILINE
MOIETY
28. Method Validation (RACs/"spike chemical"/fortification level(s)/
 recovery range/average recovery):
FRESH GINSENG FORTIFIED WITH METALAXYL FROM 0.05 TO
5.0 PPM WITH RECOVERIES FROM 71 TO 140%, N=14,
MEAN 103.3%, SD = 23%; DRYED GINSENG WITH METALAXYL
FROM 0.05 TO 5.0 PPM WITH RECOVERIES FROM 58 TO 104%;
N=13, MEAN = 82.8%, SD = 14.6%
29. Method Validation (limit of detection and/or sensitivity in ppm):
 Parent: LIMIT OF DETECTION = 0.05 PPM
 Metabolite(s) (specify): PARENT AND METABOLITES
DETERMINED AS ONE MOIETY.
30. Method Validation (state crops and control values reported):
FRESH AND DRY GINSENG CONTROLS RANGED FROM
0.06 TO 0.29 PPM (N=25)
31. Adequate Analytical Method(s) (are/are not Available for Enforce-
 ment Purposes.
 These Method(s) are located: PAM II METHOD I IS AG-348
(11/84), METHOD II IS AG-349; PAM I LIKE METHOD FOR
METALAXYL, PER SE.

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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) CGA-6286 AND CGA-37734 tested via Protocols I II III IV (circle, as applicable). Additional multiresidue test information for metabolite(s) that is needed: CGA-94689; N/A FOR MINOR USE PETITIONS

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

FIELD TRIALS WITH RESULTS FROM BOTH THE 2E EC AND 5G GRANULAM FORMULATIONS AT THE 1X RATE AND 5G AT 2X; IN WISCONSIN AND NORTH CAROLINA WITH RESIDUE RESULTS FOR BOTH FRESH AND DRY GINSENG ROOTS AT PHIS FROM 7 TO 9 DAYS; RESULTS FROM 1X:

SUBSTRATE	FORMULATION	RANGE (PPM)	AVERAGE (PPM)
FRESH ROOTS	2E	0.30 - 1.2	0.61 +/- 0.31 (N=10)
	5G	0.18 - 2.5	0.95 +/- 0.78 (N=14)
DRY ROOTS	2E	0.31 - 1.8	1.0 +/- 0.59 (N=9)
	5G	0.10 - 2.1	0.88 +/- 0.63 (N=10)

RESULTS FROM 2X RATE

FRESH ROOTS	5G	0.68 - 6.7	
DRY ROOTS	5G	0.62 - 3.2	

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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 FRSTR PP 20-21

DATA ON POTATOES AND TOBACCO; METALAXYL RESIDUES
STABLE FOR 18 MONTHS UNDER FROZEN CONDITIONS.

IN THIS STUDY RESIDUE SAMPLES WERE HELD IN
FROZEN STORAGE FROM 5 TO 17 MONTHS AT
-20.6 TO -17.8 °C.

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: PER 2/21/87

TELEPHONE CONVERSATION, DAVE BRASSARD OF BEAD INDICATED
THAT BEAD HAD 5/6/86 MEMO ON FILE, FROM DR. JENIFER
PARK U. OF WISCONSIN, THAT 90% OF U.S GINSENG
PRODUCTION WAS IN WISCONSIN.

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

GINSENG

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

N/A

39. Livestock Feeding Studies on (species): _____

DAIRY CATTLE, GOATS AND HENS

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40. Animal Feeding Levels: RUMINANTS DOSED AT 1.5 TO 75 PPM METALAXYL
HAD RESIDUES $\leq$ 0.01 PPM IN MILK AND $\leq$ 0.05 PPM IN FAT AND MEAT,
0.22 PPM (MAX) IN LIVER AND 0.83 PPM (MAX) IN KIDNEY; POULTRY
DOSED AT 1.5 TO 5.0 PPM METALAXYL HAD RESIDUES $\leq$ 0.05 PPM
IN EGGS, FAT, LIVER, MEAT AND SKIN
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 FOR THIS
PETITION, NO ANIMAL FEED ITEMS INVOLVED
but not adequate in _____
43. Livestock Tolerances Need to be Established: Yes/No. If yes,
species/levels: N/A FOR THIS PETITION
44. Other Comments: NONE
45. Other Considerations: NONE
46. Additional Information Needed: SEE ITEM 47.

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47. Additional Data Needed: A REVISED SECTION B IS NEEDED
THE SECTION B SUBMITTED IS INCONSISTENT WITH
THE PROPOSED USE DIRECTIONS ON PAGE 12 OF THE REPORT,
WHICH RECOMMENDS THAT THE FIRST APPLICATION
BE MADE WITH EITHER THE 2E OR 2G FORMULATION
WHILE THE REMAINING 4 SUPPLEMENTAL APPLICATIONS
BE MADE WITH ONLY THE 2G FORMULATION, TO
MINIMIZE THE POSSIBILITY OF RESISTANCE.
ALSO, IF TWO FORMULATIONS ARE PROPOSED THE LABEL
MUST INCLUDE APPROPRIATE INSTRUCTIONS TO ENSURE
THAT THE COMBINED APPLICATION OF THE TWO FORMULATIONS DOES NOT
EXCEED THE APPROVED MAXIMUM APPLICATION RATE.
48. RECOMMENDATIONS: UPON RECEIPT OF A REVISED SECTION B,
AS DESCRIBED ABOVE, CBTS CAN RECOMMEND IN FAVOR
OF THE PROPOSED TOLERANCE OF 3.0 PPM FOR RESIDUES
OF METALAXYL IN/ON GINSENG.
49. Other Comments Under Recommendations: SINCE THE 2E FORMULATION
IS RECOMMENDED AS AN ALTERNATIVE TO THE 2G FORMULATION
FOR A SINGLE FIRST APPLICATION ONLY, FOR SIMPLICITY
THE PETITIONER SHOULD CONSIDER LIMITING THE PROPOSED
USE TO THE 2G FORMULATION ONLY.
50. Compatibility with Codex Tolerances? (Explain) _____
NO COMPATIBILITY PROBLEMS EXIST SINCE THERE ARE NO
MEXICAN, CANADIAN OR CODEX TOLERANCES FOR
METALAXYL ON GINSENG.

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

(2)

171 (OTANIE)
 CC: RF, Circ, Reviewer, pp 1E3926, PIB/FOD (FURLOW), R. SCHMITT
 FDA, DRES/SALB (NARIYA), E. Haebeler
 Approved: ETHAEBELER, T. Haebeler; RALORANGER R. Loranger 2/21/91.

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INTERNATIONAL RESIDUE LIMIT STATUS1/10/80
2/25/80CHEMICAL METALAXYL (RIDOMIL)CODEX NO. 198

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above, (as Ginseng)

Residue(if Step 8): _____

Metalaxyl per seCrop(s)Limit
(mg/kg)PROPOSED U.S. TOLERANCES:Petition No. 1E3926RCB Reviewer G. OTAKIE

PEP 40 CFR 180.408

Residue: METALAXYL AND ITSMETABOLITES CONTAINING THE 2,6-
dimethylamino moiety and N-(2-
hydroxy methyl-6-methyl)-N-(methoxy
acetyl)-Alanine methyl ester
Crop(s) can be expressed as
metalaxylLimit
(mg/kg)

GINSENG

3.0 PPM

CANADIAN LIMITS:☒ No Canadian limit (as Ginseng)

Residue: _____

Crop(s)Limit
(mg/kg)MEXICAN LIMITS:☒ No Mexican limit

Residue: _____

Crop(s)Limit
(mg/kg)

NOTES:

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