

107901
SHAUGHNESSEY NO.

17
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 5-9-80 OUT 6-13-80

FILE OR REG. NO. 21137-4

PETITION OR EXP. PERMIT NO. OF 2353

DATE DIV. RECEIVED 5-9-80

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, D, H, (F), N, R, S _____

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Triforine

COMPANY NAME _____

SUBMISSION PURPOSE Incremental Risk - ALMONDS + APPLES

SHAUGHNESSEY NO.

CHEMICAL, & FORMULATION

% A.I.

107901

(N,N-11-4-piperazinediylbis(2-2-trichloro-
ethylidine)

18.2

107901

(17)

100.0 Pesticide Name

Triforine

100.1 Pesticide Use

To control brownrot on almonds and apples.

100.2 Formulation

Technical (18.2 a.i.)

100.3 Application Methods, Directions, Rates

Triforine is recommended as follows:

Blossom Applications (EMULSIFIABLE CONCENTRATE)

	<u>OZ. AI/ ACRE</u>	<u>MAX. NO. APPLICATION</u>	<u>PHI (DAYS)</u>
Pomefruit			
Apples (5 blossom applications)	8.0	5	>120
Nut			
Almonds (1 blossom application)	7.2	1	>200

ALMONDS

BROWNROT BLOSSOM BLIGHT (Monilinia laxa)

For full coverage ground spray only. Apply 12 fl. oz. of Funginex per 100 gallons of water or 36 fl. oz. per acre dilute. Make the first application at pink bud and repeat at 50-100% bloom.

100.4 Precautionary Labeling

See review by C. Laird on 5-30-80.

101.0 Physical and Chemical Properties

See review by C. Laird on 5/30/80.

102.0 Behavior in the Environment

See review by D. Urban on 3-14-78.

103.0 Toxicological Properties

See review by D. Urban on 3-14-78.

104.0 Hazard Assessment

See review by C. Laird on 5-30-80.

104.1.2 Likelihood of Adverse Effects to Non-Target Organisms

See review by C. Laird on 5-30-80.

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104.1.3 Endangered Species Consideration

See review by C. Laird on 5-30-80.

104.1.4 Adequacy of Toxicity Data

See review by C. Laird on 5-30-80.

104.1.5 Additional Data Required

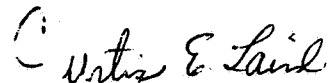
See review by C. Laird on 5-30-80.

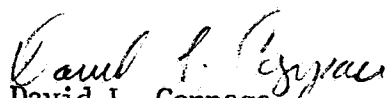
The six basic studies are required for Triforine plus Glyodin (Combined) to support the use of this compound on apples.

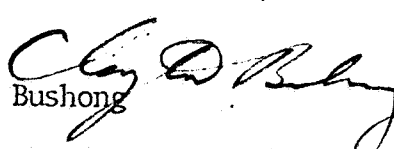
107 Conclusion

The Ecological Effects Branch recommends the use of Funginex on almonds and apples for conditional registration. Before this ~~study~~ study can be accepted for full registration the acute oral LD₅₀ bird study must be satisfied.

The Ecological Effects Branch recommends against the use of Funginex plus Glyodin on apples.


Curtis E. Laird
Aquatic Biologist
Ecological Effects Branch/HED


David L. Coppage
Head, Section #3
Ecological Effects Branch/HED


Clayton Bushong
Chief
Ecological Effects Branch/HED

6/12/80

107101
JAN 13 1981
PP#OF2354 and OF2356. [REDACTED] on various X.A.C.'s.
Amendments of 12/8/80 to PP's OF2351 and OF2352.

Martha J. Bradley, Chemist
Residue Chemistry Branch, NEI (TS-769)

Mr. Jacoby, Product Manager No. 21
Registration Division (TS-767)

Mr. [REDACTED]
Residue Chemistry Branch, NEI (TS-769)

Robert G. Gulch, Section Chief
Petition Evaluation Section
Residue Chemistry Branch, NEI (TS-769)

Richard T. Schmitt, Deputy Chief
Residue Chemistry Branch, NEI (TS-769)

Charles L. Trichilo, Chief
Residue Chemistry Branch, NEI (TS-769)

E.I. Industries, Inc., has submitted an estimation of residues of the
inerts, [REDACTED] and their metabolites on the various r.s.c.'s in
these petitions. The petitioner has also submitted revised Section B and
F for the active, triforine, in PP's OF2351 and OF2352, withdrawing
tomatoes for consideration.

A third petition, OF2353, for triforine on apples and almonds, is
currently in reject status.

Although PP's OF2354 and OF2356 include apples, almonds and tomatoes, we
are not considering clearance of the inerts for these crops until
tolerances for triforine are again under review. The deficiencies related
to these three crops will not be discussed at this time.

The deficiencies in our memo of 12/3/80 are listed below with petitioner's
responses.

1. Label directions and Section B of PP's OF2351/53 differ. [REDACTED]
for use and should be clarified by petitioner.

Response: The petitioner has clarified label directions and Section B
of PP#OF2351.

Conclusion 1: We consider this deficiency resolved for the crops in PP#OF2351.
Consideration of the crops in PP#OF2353 is deferred at this time.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Deficiency:

1. The degradation products of [REDACTED] have not been identified. We defer to TOX as to the adequacy of the characterization of the metabolites and whether the parent compounds are the only residues of concern for toxicity and the need for metabolism studies is unclear.

Response: TOX has responded (private communication G. Davis) that estimate of total residues or better characterization of the metabolites is needed in order to make this determination.

Conclusion 1: Although residue data are not adequate to determine total residues from multiple applications to the fruit, a calculation can be made to give a maximum level to be expected. (See Deficiencies 4d and 4e.)

Deficiency:

4a. Residues of each of the parent compounds plus their metabolites are not likely to exceed 0.1 ppm on apples, almonds (nutmeats), cherries and plums provided appropriate PHI's appear on labels and maximum rate is 0.6 lb. (2.6 oz) triflorin/A.

Response: A 60 day PHI for blossom spray is not necessary since the last blossom application indicated on the label is at petal fall. The petitioner also states that the maximum rate is 0.6 lb triflorin/A.

Conclusion 4a: We consider this deficiency resolved for cherries and plums. Consideration of apples and almonds is deferred at this time.

Deficiency:

4b. We are unable to determine residue levels on apple and tomato processing products including the animal feed items apple and tomato pomace, and dried prunes as no data are available.

Response: Tomatoes have been withdrawn from FFD232. The petitioner has made the response to the presence of the tomatoes dried products.

Conclusion 4b: In lieu of residue data on dried prunes, a theoretical maximum concentration factor for dried prunes (4X) can be used to calculate maximum residues. Total residues of each insect and its metabolites are not expected to exceed 0.4 ppm on dried prunes (4 X 0.1 ppm on fresh prunes). Consideration of tomatoes and apples is deferred at this time.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Deficiency:

4c. We are unable to determine residue levels on almond hulls as no data are available unless the petitioner can show a correlation between residues of triflorine and the inert [redacted]

Conclusion 4a: Consideration of almond hulls is deferred at this time.

Deficiency:

4d. Residues of the parent compounds are not likely to exceed 6 ppm [redacted] on peaches, nectarines and apricots. Residues of each of the parent compounds and their metabolites are not likely to exceed 6 ppm from one application to the fruit. Total residues cannot be determined from multiple applications to the fruit because of inadequate data. Residue levels estimated are contingent on a maximum rate of 0.6 lb (9.6 oz.) triflorine/l.

Response: The maximum rate has been clarified as 0.6 lb triflorine/A with 3 applications to the fruit plus up to 3 applications to the blossom.

Conclusion 4d: Although we cannot make an estimation of total residues without adequate data, we can make a calculation of maximum level. Assuming a residue of 6 ppm from each application to the fruit, with no dissipation or growth dilution, residues of each inert plus its metabolites are not expected to exceed 12 ppm on peaches, nectarines and apricots from the proposed use.

Deficiency:

4e. Residue levels cannot be determined on tomatoes, peppers, eggplants, strawberries, melons or cucumbers as no data are available on these or similar crops for the proposed use unless the petitioner can show a correlation between residues of triflorine and the inert [redacted]

Response: The petitioner has submitted an affidavit [redacted] for [redacted] based on a ratio (1.4) of triflorine to inert [redacted] on residue data for four other crops.

Discussion: A correlation of residues of inert to triflorine is valid only for one application at 0 days PHI, before metabolism and degradation of the residue occurs. The only residue data submitted that meets these criteria are also the maximum residues reported for [redacted]. These residues resulted from an application of 36 oz. formulation/A on peaches. We concluded that residues of each inert plus its metabolites would not exceed 6 ppm for each application based on these data.

Conclusion: By correlating the peach data and allowing for a lower application rate to peppers, eggplants, melons and cucumbers, the following table shows that such insects are not likely to exceed 11 ppm (0.1 mg/l) or 1.1 ppm (0.1 mg/l) (application). In the same manner, the following table shows that such insects are not likely to exceed 0.1 ppm (0.1 mg/l) or 0.1 ppm (0.1 mg/l) (application).

Consideration: is deferred at this time.

Efficiency:

5a. We cannot determine whether a problem will result from transfer of residues to meat and milk as no data are available.

Conclusion: Consideration of all the animal feed items, tomato residue; apple residue and almond hulls, is deferred at this time.

Recommendations:

We defer our estimations of maximum total residues for each inert of 10 ppm on peaches, apricots andectarines; 11 ppm on peppers, melons, eggplants and cucumbers; 10 ppm on strawberries; 0.1 ppm on cherries and plums/fresh prunes; and 0.1 ppm on dried prunes to TOX for safety consideration.

We are deferring consideration of tomatoes, apples, almonds, meat and milk until tolerances for the active ingredient (triflorine) on these commodities are again under consideration. If the exemptions for [redacted] are not broadened, tomatoes, apples, and almonds should not be included.

The petitioner should be informed that if substantial new uses are requested in the future, better characterization and/or residue data from the recommended use will be needed.

TS-769;RCW:M.Bradley:est:CH2:RMS11:777386:1/12/81

cc: Al, Circ., Bradley, Watts, FDA, TOX, K22, RFE, PP/OF2364, PP/OF2386

RE: Robert S. Quick, 1/12/81

INERT INGREDIENT INFORMATION IS NOT INCLUDED

DATE

JAN 13 1981

SUBJECT PP#'s OF2351 and OF2352. Triforine in or on Stone Fruits and Triforine in or on Vegetables. Amendments of 12/8/80.

FROM

John H. Onley, Ph.D., Chemist
Residue Chemistry Branch, HED (TS-769)

TO

Henry Jacoby, Product Manager No. 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

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

Richard D. Schmitt, Deputy Branch Chief
Residue Chemistry Branch (TS-769)

Charles L. Trichilo, Chief
Residue Chemistry Branch (TS-769)

These amendments were submitted in response to the deficiencies raised in our reviews of PP#'s OF2351 and OF2352 and subsequently discussed in a 12/1/80 conference. The 12/1/80 conference was attended by representatives of EM Industries, Inc., Registration Division and Residue Chemistry Branch (HED, OPP, EPA), and at this conference, the following points were agreed upon:

Petition No. OF2351

1. Section B will be revised wherein the maximal application rate will be 0.6 lb. (9.6 ozs. a.i.)/A.
2. With the exception of California, the proposed use on peaches, nectarines and apricots will contain a maximal of 3 blossom plus 3 pre-harvest applications. In California, the proposed use will contain no more than 3 blossom + 2 pre-harvest + 1 post-harvest applications per growing season.
3. The proposed post-harvest use pattern will contain a maximal dipping time and will state dosage in terms of pounds of fruit to be dipped in gallons of solution or treated with pounds or grams of product.
4. A revised Section F will be submitted wherein the proposed tolerances on peaches, nectarines and apricots will be 8 ppm.
5. A revised Section B/label will contain a post-harvest restriction on plums that are to be dried.

6. The petitioner will submit an explanation as to why spray applications of Funginex WP formulations yielded higher triforine residues than the Funginex Emulsifiable Concentrate formulation.

Petition No. OF2352

- 1a. The petitioner will provide more proof that will show tomatoes imported from Mexico will be used only on the fresh market. If this cannot be shown, a tomato processing study along with tolerances/food additive tolerances (if needed) on tomatoes and tomato fractions will be submitted at a later time.
- 1b. A large animal (lactating ruminant) metabolism/feeding study will be submitted if it cannot be shown that Mexican tomatoes are only used on the fresh market.
2. Sections B and F will be revised; the petitioner will propose the establishment of tolerances for triforine residues on the following raw agricultural commodities:

peppers, bell	5.0 ppm
eggplants	1.0 ppm
strawberries	2.0 ppm
cantaloups/watermelons	1.0 ppm
cucumbers	0.5 ppm

The 12/1/80 conference also covered deficiencies pointed out in our review of PP#OF2353 (12/5/80). The following points, although not of immediate concern in the present amendments, were agreed upon:

Petition No. OF2353

1. Residue data will be submitted on dry apple pomace.
2. A revised Section F will contain the following proposed tolerances:

Almond	0.01 ppm
Almond, hulls	0.1 ppm
apples	0.1 ppm
apples pomace, wet	0.4 ppm
apple pomace, dry	(unknown at this time)

3. A large animal (lactating ruminant) metabolism/feeding study will be submitted.

This petition is being held in abeyance and is not under consideration in this review.

Petition No. OF2351

Petitioner's Response to above Point 1: EM Industries, Inc., has revised Section B in the present amendment. The maximum application rate for the Funginex EC formulation is 0.6 lb. (9.6 ozs. a.i.)/A.

Petitioner's Response to Point 2. The amended label/Section B allows in California 2 pre-harvest applications (Funginex EC formulation) and 1 post-harvest application (Funginex WP formulation) on peaches, nectarines and apricots.

Petitioner's Response to Point 3: The Funginex WP formulation is recommended for use only in California. The use pattern has been rewritten to recommend 200,000 pounds of fruit to be dipped in 100 gallons of solution containing 1/2 pound of FUNGINEX WP. A maximum dipping time of 60 seconds has been added to the label. The statements "Plums (fresh prunes)" and "Do not use on varieties of prunes that will be dried" are also included on the new label. The dosage for post-harvest spray and wax has been increased to 1 lb FUNGINEX WP per 100 gallons of water. Again 200,000 pounds of fruit are to be treated with 100 gallons of FUNGINEX WP solution.

Petitioner's Response to Point 4: The petitioner has proposed the following revised triforine tolerances:

Peaches	8 ppm
Nectarines.....	8 ppm
Apricots.....	8 ppm
Cherries.....	3 ppm
Plums (Prunes).....	3 ppm

Petitioner's Response to Point 5: The statements "Plums (fresh prunes)" and "Do not use on varieties of prunes that will be dried" have been included on the revised label.

Petitioner's Response to Point 6: The petitioner is only registering the Funginex EC formulation (CME-74770) and the Funginex WP formulation (CME-10236). The CME-10225 WP formulation contains larger particles than the CME-10236 wettable powder formulation which was specially milled into fine particles to increase efficacy. Particle size is partially the reason for the larger residues of triforine found with the wettable powder (CME-10225) formulation than the other formulations.

We accept this explanation as to why the WP formulation produced higher residues.

RCB's Comments/Conclusions - Points 1-6.

Points 1 thru 6 have been resolved as outlined in the 12/1/80 conference.

Petition No. OF2352

Petitioner's Response to above Points 1a and 1b.

The petitioner has submitted the following letters in support of his argument that tomatoes imported from Mexico will be used only on the fresh market:

- 1.) Charles W. Porter (Agricultural Economist, Fruits and Vegetables Marketing, U.S. Department of Agriculture - 5/14/79) to Mr. Stephen Pouliot (EM Laboratories, Inc.)
- 2.) James Ferrell (Vice President- Mexico Operations, Griffin and Brand of McAllen, Inc. - 12/10/79) to Mr. Stephen D. Pouliot (EM Laboratories, Inc.)
- 3.) Jim Ferrel (Vice President, Marketing, Griffin and Brand of McAllen, Inc., 12/4/79) to Mr. Stephen D. Pouliot (EM Laboratories, Inc.)
- 4.) William E. Rose, PH.D. (Union Carbide Mexicana. S.A., 6/7/79) to Mr. S. Pouliot (EM Laboratories, Inc.)
- 5.) C. P. Rosendo Flores Madrid (Union Nacional Deproductores DeHortalizas, 6/6/79) to Sr. William Rose (Union Carbide Mexicana)

The petitioner has also withdrawn his request for a tolerance on tomatoes from this petition until the tomato fractionation studies become available.

RCB's Comments/Conclusions - Points 1a and 1b. RCB has accepted the petitioner's proof for showing tomatoes imported from Mexico will be used on the fresh market. For present considerations, a large animal (lactating ruminant) metabolism/feeding study will not need to be submitted. Questions relating to the tomato fractionation studies are moot at this time.

Petitioner's Response to above Point 2.

Sections B and F have been revised. The following tolerances are now being proposed for triforine in or on:

Cantaloupes	1.0 ppm
Cucumbers	0.5 ppm
Eggplants	1.0 ppm
Peppers (Bell)	5.0 ppm
Strawberries	2.0 ppm
Watermelons	1.0 ppm

RCB's Comments/Conclusions - Point 2 above.

Point 2 has been resolved as agreed upon in the 12/1/80 conference.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Recommendations At present, the clearance of two inerts, [REDACTED] is in progress.

Aside from the inert clearance requirement, and if TOX and EFB consideration permit, RCB recommends for establishment of the proposed tolerances on those raw agricultural commodities listed in the revised Sections Fs as stated above.

cc: Reading file
Circu
Reviewer
FDA
PP# No. OF2351 and OF2352
TOX
EEB
EFB
Watts

TS-769:Reviewer:JHOnley:LDT:X77324:CM#2:RM:810:Date:1/9/81
RDI:Section Head:RSQuick:1/8/81

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Triforine

PETITION NO OF2351 and OF2352

CCPR NO. _____

Codex Status _____

☒ No Codex Proposal
Step 5 or above

Proposed U. S. Tolerances

Residue (if Step 5): _____

None

Residue: Triforine

Crop(s) Limit (ppm)

None

Crop(s) Tol. (ppm)

Peaches	8.0
Nectarines	8.0
Apricots	8.0
Cherries	3.0
Plums (Prunes)	3.0
Peppers, bell	5.0
Eggplants	1.0
Strawberries	2.0

CANADIAN LIMIT

Residue: Triforine

MEXICAN TOLERANCIA

Residue: Triforine

Crop Limit (ppm)

None on these
commodities

Crop Tolerancia (ppm)

none on these
commodities

Notes:

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Triforine

PETITION NO OF2351 and OF2352

CCPR NO. _____

Codex Status

xx / No Codex Proposal
Step 6 or above

Residue (if Step 9): _____

None

Crop(s) Limit (mg/kg)

None

Proposed U. S. Tolerances

Residue: Triforine

Crop(s) Tol. (ppm)

Cantaloups	1.0
Watermelons	1.0
Cucumbers	0.5

CANADIAN LIMIT

Residue: _____

None

Crop Limit (ppm)

None

MEXICAN TOLERANCIA

Residue: _____

None

Crop Tolerancia (ppm)

None

Notes: