



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 3 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

EXPEDITE

SUBJECT: PP #1E2457 (RCB # 1844, 1845) Vinclozolin (Ronilan)
in or on Grapes. Amendment of 1/9/87. No Accession
No.

FROM: Cynthia Deyrup, Ph.D., Chemist *Cynthia Deyrup*
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769) *NO*

TO: L. Rossi, Product Manager No. 21
Registration Division

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

This review has been expedited on the request of J. Akerman,
Acting Director of Registration Division (memo to J. Melone,
9/8/86).

Background

BASF Wyandotte Corporation had proposed a tolerance of 6 ppm for
residues of the fungicide vinclozolin [Ronilan; 3-(3,5-dichloro-
phenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its
metabolites containing the 3,5-dichloroaniline moiety in or
on table grapes.

In its 12/29/86 review of the amendment of 12/4/86, RCB concluded
that a revised Section B and a revised Section F were required
before RCB could recommend establishing tolerances on grapes,
raisins, and grape pomace. RCB recommended that if these
tolerances were established, they should expire after one year if
residue data on raisins have not been submitted (PP #1E2457, memo
of C. Deyrup, 1/29/86).

Present Consideration

The petitioner has submitted revised Sections B and F. RCB's Comments/Conclusions from its 12/29/86 review of the amendment of 12/4/86 will be cited below, followed by the petitioner's response, and RCB's Comments/Conclusions.

RCB's Comments/Conclusions re: Petitioner's response to Deficiency #5 of RCB's 4/27/81 review (memo of J.H. Onley)

"RCB could recommend that a tolerance with a one year expiration date be established on grapes at 6.0 ppm vinclozolin/metabolites. This tolerance would expire after one year if residue data on raisins have not been submitted. Therefore the petitioner will need to submit a revised Section F in which he proposes that a tolerance with an expiration date of one year be established on grapes at 6.0 ppm."

Petitioner's Response

The petitioner has submitted a revised Section F in which a tolerance with a one year expiration date is proposed on grapes. The proposed tolerance is for 6.0 ppm vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

RCB's Comments/Conclusions

Deficiency 5 of RCB's 4/27/81 review is resolved.

RCB's Comments/Conclusions re: Petitioner's Response to Deficiency #7 of RCB's 4/27/81 review (memo of J.H. Onley)

"The supplementary text in Section B permits 5 applications of up to 0.89 lb. a.i./A whereas the submitted label permits 0.67 lb. a.i./A... Since the lower rate (0.67 lb. a.i./A) was used in the Chilean field trials, RCB suggests that the petitioner revise Section B so that it agrees with the label."

"Therefore, the petitioner will need to submit a revised Section F in which he proposes a food additive tolerance with an expiration date of one year for residues of vinclozolin/metabolites on raisins. Since residue data on raisins are not available, the proposed tolerance should reflect the 5-fold theoretical dry down factor."

"RCB concludes that the proposed feed additive tolerance of 27 ppm on dry grape pomace is not adequate. The petitioner will therefore need to propose a feed additive tolerance with a one year expiration date for residues of vinclozolin/metabolites on dry grape pomace. The proposed tolerance should reflect a concentration factor of at least 6.7. RCB recommends that the proposed tolerance should expire in one year, if the required residue data on raisins have not been submitted."

Petitioner's Response

The petitioner has submitted a revised Section F proposing the following food/feed additive tolerances (with one year expiration dates) for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety on the following commodities:

Grape pomace, dry	42.0 ppm (feed additive tolerance)
Raisins	30.0 ppm (food additive tolerance)

The petitioner has also submitted a revised Section B in which the maximum proposed application rate is 0.67 lb. a.i./A.

RCB's Comments/Conclusions

The deficiencies regarding Sections B and F have been resolved.

Other Considerations

Codex, Canada, and Mexico have not established tolerances for residues of vinclozolin on grapes, raisins or dry grape pomace. Therefore, there will be no compatibility problem.

Recommendations

TOX and EAB considerations permitting, RCB recommends that the proposed tolerances for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety be established on grapes, dry grape pomace, and raisins.

The petitioner is advised to submit processing data as soon as possible in order to maintain continued use. Otherwise, the import tolerance on grapes will expire in one year.

Note to PM: The PM should obtain the pertinent food/feed additive entries in 21 CFR 561 and 193.

cc: TOX, EAB, PMSD/ISB-Eldredge, PP #1E2457, R.F., Circu,
Reviewer-Deyrup, PM #21, EEB, FDA

RDI: JHOnley:2/2/87:RDSchmitt:2/2/87
TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:2/2/87

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Vinclazolin

CODEX NO. _____

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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PROPOSED U.S. TOLERANCES:

Petition No. 2457

RCB Reviewer C. Deyrup

Residue: Vinclazolin + metolachlor
& 3,5-dichloroaniline moiety

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
grapes	6
grape pomace, dry	42
raisins	30

CANADIAN LIMITS:

☒ No Canadian limit

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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