50[illegible]/OPP #PF-720 11/15/89

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

11PP

NOV 15 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP9F3762/FAP9H5585. Vinclozolin on Succulent Beans. Evaluation of Analytical Method and Residue Data. DEB 5336, 5337, 5338, 5339. MRID41080601,41080602.

FROM: R. W. Cook, Chemist
DEB/HED (H7509C)

THROUGH: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (H7509C) Edward Zager, for

TO: G. LaRocca, PM 15
Registration Division (H7505C)

and

Toxicology Branch - Fungicide/Herbicide Support
Health Effects Division (H7509C)

The petitioner, BASF Corporation Chemicals Division, proposes the establishment of tolerances for residues of the fungicide vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety, in or on succulent beans at 3.0 ppm; and tolerances for residues of the fungicide vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety, in or on the animal feed cannery waste of succulent beans at 10 ppm.

Tolerances are currently established under 40 CFR 180.380(a) for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in or on raw agricultural commodities including onions at 1 ppm; bell peppers at 3 ppm; kiwifruit, lettuce (head), lettuce (leaf), raspberries, strawberries at 10 ppm; and stonefruits at 25 ppm; and under 40 CFR 180.380(b) for combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodity grapes at 6 ppm. There are no tolerances for meat, milk, poultry and eggs.

In addition, 40 CFR 185.1850(a) states: Tolerances are established for the combined residues of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the following food commodities Prunes at 75 ppm.

Furthermore, 40 CFR 185.1850(b) states: A food additive regulation is established for the combined residues of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the following processed foods when present therein as a result of application to grapes: Raisins at 30 ppm.

Moreover, 40 CFR 186.1850 states: A feed additive regulation is established for the combined residues of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the following processed feeds when present therein as a result of application to grapes: Grape, pomace, dry at 42 ppm.

We note the petitioners letter of 4-26-89 requests withdrawal of proposed tolerances for vinclozolin in dry beans and peanuts (PP5F3237 / FAP5H5469) and the associated meat and milk commodities. We have no objections to the petitioner's request to withdraw PP5F3237.

Conclusions

1.a. The nature of the residue in plants is adequately known for the purposes of the proposed tolerances. In plants, the residue of concern is vinclozolin and its metabolites which contain the 3,5-dichloroaniline moiety.

1.b. Livestock metabolism and feeding studies are presently under review in connection with PP9F3750 which proposes meat, milk, poultry and egg tolerances. We await the completion of the review of the livestock metabolism and feeding study in that petition. At that time we will be able to draw a conclusion on livestock metabolism.

2. Adequate enforcement methods are available in PAM II.

3. Residues of vinclozolin and it metabolites containing the 3,5-dichloroaniline moiety in seeds and pods of succulent beans are not likely to exceed the proposed tolerance of 3 ppm.

4. The written use directions specify 1½ pounds product per acre while the table gives dosage rates up to 2 pounds per

acre. Revised labeling is needed showing a single maximum dosage rate.

5.a. Bean cannery waste is a livestock feed item. There are no established meat and milk tolerances for vinclozolin. Meat and milk are tolerances pending in PP9F3750 which is presently under review. We cannot recommend for the proposed bean tolerances until the pending meat and milk tolerances are established.

5.b. Succulent beans and bean cannery waste are not poultry feed items. There will be no problem of secondary residues in poultry tissues and eggs from the propose uses.

6. We are not assured that simulated samples of bean cannery waste, 10% leaves and stems, 20% whole pods, and 70% snipped pod ends, are appropriate. The petitioner should assure us that this distribution of leaves, stems, pods and snipped ends is typical of bean cannery waste. Final conclusions on the adequacy of the proposed 10 ppm tolerance for bean cannery waste awaits the above requested information.

7. There are no Canadian or Mexican tolerances for vinclozolin on succulent beans. There is a Codex tolerance of 2 ppm on beans. The U.S. tolerance can not be made compatible with the Codex tolerance because data for the U.S. usage show the need for a higher 3 ppm tolerance.

Recommendations

We recommend against the proposed tolerances of 3 ppm in seeds and pods of succulent beans (snap and lima) and 10 ppm in cannery waste of succulent beans, until the petitioner resolves the differences in the dosage rates specified in the submitted labeling to show a single maximum dosage rate, assures us that appropriate bean cannery waste data have been submitted, and until meat and milk tolerances (proposed pending in PP9F3750) are established.

DETAILED CONSIDERATIONS

Manufacturing Process and Proposed Formulation

The manufacturing process for technical vinclozolin has been previously discussed in M. J. Nelson review of PP9F2205 of 7/23/79, which see.

The formulations proposed for use on succulent beans are Ronilan® WP [EPA Reg. No. 7969-53] containing 50% by weight of the fungicide vinclozolin; Ronilan® FL [EPA Reg No. 7969-62]; and Ronilan® DF [EPA Reg No. 7969-(not registered)].

Proposed Use

RONILAN® Fungicide is a protectant material for the control of white mold (Sclerotinia) and gray mold (Botrytis) of succulent beans (snap, lima, and other edible bean types). RONILAN® may be applied by aerial application, by ground application, or by sprinkler irrigation systems.

"RONILAN® may be applied up to two times per growing season: The first application is recommended during Early Bloom (approximately 10%). Depending on conditions which favor disease development, a second application of Ronilan® may be required at full bloom or 7 to 21 days after the first application.

Rate per acre: A rate of 1½ pounds of product per acre is generally recommended. A one pound product per acre rate of RONILAN® should be used only when low disease pressure can be predicted. Under high disease pressure or when conditions are very favorable for disease development, use the higher Treatment rates specified, multiple applications and shorter spray intervals.

SUCCULENT BEANS

Application rate and timing for control of White Mold (Sclerotinia) and Gray Mold (Botrytis).

Application	Timing	Rate Pounds Product/Acre
First	Early Bloom	1 - 2
Second	Full Bloom or 7 to 21 days later	1 - 2

For ground application, use sufficient water to obtain thorough coverage (20-300 gallons per acre).

For aerial application, apply in at least 5 gallons of spray solution per acre.

For sprinkler systems, apply this product only through sprinkler irrigation systems including center pivot, traveler, lateral move, end tow, side roll, hand move and solid set. Do not apply this product through any other type of irrigation system.

"Do not apply RONILAN® within 14 days of harvest."

"Do not make more that 2 applications of RONILAN® per season."

"Do not apply more than 4 pounds of RONILAN® per season."

"Do not apply RONILAN® during rain. Apply when conditions will permit spray to dry on the plant."

"Do not feed green or dry forage to livestock."

We note that the written use directions specify 1½ pounds product per acre while the above table gives dosage rates up to 2 pounds per acre. Revised labeling is needed showing a single maximum dosage rate.

Nature of the Residue - Plants

The nature of the residue in plants has been previously examined by G. Makhijani in PP8G2068 [strawberries and grapes] and PP9G2204 [lettuce and peaches], and by M. Firestone, under PP5F3237/FAP7H5531 in peanuts. In plants, the residues of concern are vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

Nature of the Residue - Animals

The nature of the residue of vinclozolin in animals has been discussed in our previous review by M. Firestone, under PP5F3237/FAP7H5531 regarding residues in meat, milk, poultry and eggs from the proposed use on peanuts, which see.

In lactating goats, the majority of the ^{14}C-equivalent to vinclozolin was excreted in urine and feces, mostly as the 3,5-dichloroaniline moiety. About 0.2% of the applied ^{14}C was found in milk, equivalent to 3 to 7 ppb of vinclozolin. Fat and muscle tissues contained about 3 to 10 ppb, while kidney and liver tissues contained up to 63 ppb. Based upon this information the previous reviewer concluded that additional information on the metabolism of vinclozolin in ruminant animals would be required.

In laying hens, the residue levels of ^{14}C-equivalent to vinclozolin continued to increase throughout the 7 day interval, reaching levels of 0.27 ppm ^{14}C-equivalent to vinclozolin. About 98% of the administered ^{14}C was excreted by the hens in feces. Again, the reviewer concluded that additional data on the metabolism of vinclozolin in poultry would be required prior to the issuance of tolerances on raw agricultural commodities used for poultry feed purposes.

Tolerance proposals for meat, milk, poultry and eggs are currently under review with PP9F3750. When questions concerning livestock feeding and metabolism studies are resolved in that

petition, we will be able to draw conclusions on the nature of the residue in livestock.

Analytical Methods

The analytical method, dated Nov. 21. 1977, for residues of vinclozolin and its 3,5-dichloroaniline containing metabolites in succulent beans is Analytical Method No 25, DETERMINATION OF BAS 352 F [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidine-dione] AND ITS 3,5-dichloroaniline CONTAINING METABOLITES IN STRAWBERRIES AND SOIL (MRID41080600). The analytical method is currently changed by Modification F: ADDENDUM TO BWC AGRICULTURAL CHEMICALS METHOD NO. 25 FOR THE DETERMINATION OF BAS 352 F AND ITS 3,5-dichloroaniline-CONTAINING METABOLITES IN LEAF LETTUCE, CANEBERRIES AND ONIONS, issued July 6, 1983. The primary difference in Modification F includes extraction of the direct hydrolysate with dichloromethane in place of chloroform. the chloroacetyl chloride derivative is formed and diluted with ethyl acetate and hexane prior to ^{63}N electron capture gas chromatography. Analytical Method 25 is available in PAM II.

In brief, a subsample of plant material is boiled gently with 10N potassium hydroxide to liberate 3,5-dichloroaniline which is steam distilled during hydrolysis. The distillate is collected in 1 N sulfuric acid solution and the 3,5-dichloro-aniline is partitioned into dichloromethane. Reaction of 3,5-dichloroaniline with chloroacetyl chloride yields the derivative for electron capture gas chromatography.

A field study (MRID41080602) using phenyl ring-^{14}C-vinclozolin field applied to succulent green beans which were harvested 17 days later was used to verify that the analytical method would detect all metabolites of vinclozolin. Harvested beans were extracted and distilled according to analytical method 25 and the remaining marc was combusted for liquid scintillation counting. The hydrolysate was extracted with dichloromethane, aliquots were counted, and the extract derivatized. Aliquots of the derivative were assayed by liquid scintillation counting and by electron capture gas chromatography

Radioassay of succulent green beans analyzed by analytical method 25, modification F, showed that 80% of the vinclozolin residue is recovered by the analytical method and that the ^{14}C material not recovered by the method does not contain 3,5-di-chloroaniline. Analytical method 25, Modification F, is adequate for obtaining field residue data. The limit of detection for vinclozolin residues containing the 3,5-dichloroaniline moiety is reported to be 0.05 ppm.

Storage Stability

Subsamples of succulent seed and pods and green forage of both snap beans and lima beans were separately composited and fortified with two levels of vinclozolin at 0.062 and 0.536 ppm and stored for intervals of 0, 24, and 68 days (MRID41080600). Some field samples were held in storage for intervals up to 91 days.

		Percent Recovered		
Sample	Plant Part	0 Days	24 Days	65-68 Days
Lima	Seeds/Pods	96	97	112
Lima	Green Forage	96	104	94
Lima	Dry Forage	87	113	106
Snap	Seeds/Pods	92	77	100

It is concluded that residues of vinclozolin are adequately stable under the frozen storage conditions reported herein for intervals up to 68 days. Since the frozen storage samples are not showing any decline at 68 days, we can extend this conclusion to cover the samples which were stored up to 91 days, for the purposes of this submission.

Residue Data:

Residue trials (MRID41080600) were conducted in a total of 7 states: CA, FL (3), MI (2), NC (2), NY (3), OR (3), and WI (2), for a total of 16 trials. Each trial consists of single residue sample. Three different formulations of RONILAN® were used in the 16 trials. For purposes of geographical representation, these states represent approximately 75% of the production of succulent beans.

Residues of vinclozolin in a total of 16 samples of seeds and pods of succulent beans (8 samples each of snap beans and lima beans) ranged from 0.38 to 2.4 ppm by ground application equipment, from 0.41 to 0.86 ppm by aerial equipment, and 0.73 to 0.95 ppm by irrigation equipment.

Actual samples of cannery waste were not available. For the purposes of the residue trials, pseudo bean cannery waste samples were simulated by compositing 10% leaves and stems, 20% whole pods, and 70% snipped pod ends. No information is provided on the appropriateness of the simulated cannery waste samples. We are not assured that the simulated samples of bean cannery waste, 10% leaves and stems, 20% whole pods, and 70% snipped pod ends, are appropriate. The petitioner should assure us that this distribution of leaves, stems, pods and snipped ends is typical of bean cannery waste. Residues of vinclozolin in a total of 7

samples of cannery waste of succulent beans (4 samples of snap beans and 3 samples of lima beans) ranged from 0.86 to 9.77 ppm (9.77 ppm in CA trial) by ground application equipment, from 1.4 to 2.52 ppm by aerial equipment, and 1.68 ppm by irrigation equipment. Final conclusions on the adequacy of the proposed 10 ppm tolerance for bean cannery waste awaits the above requested information.

Residues of vinclozolin in a total of 16 samples of green forage of succulent beans (8 samples each of snap beans and lima beans) ranged from 2.18 to 50.8 ppm by ground application equipment, from 3.13 to 15.1 ppm by aerial equipment, and 4.3 to 7.65 ppm by irrigation equipment.

Green forage samples of beans were air-dried and analyzed as dried forage. Residues of vinclozolin in a total of 16 samples of dry forage of succulent beans (8 samples each of snap beans and lima beans) ranged from 6.6 to 164 ppm by ground application equipment, from 5.67 to 32.6 ppm by aerial equipment, and 14.2 to 21.1 ppm by irrigation equipment.

It is noted the CA sample (ground equipment application) resulted in the highest residues in each sample category: seeds and pods, cannery waste, green forage, and dry forage.

Vinclozolin Residues (ppm) in Beans from Ground Application

State	Applic.	Sample	Seeds & Pods	Cannery Waste	Green Forage	Dry Forage
NC	Ground	Lima	0.91	--	7.88	14.2
NY	Ground	Lima	0.79	2.71	5.5	10.2
OR	Ground	Lima	0.86	2.41	9.72	15.1
FL	Ground	Lima	1.38	--	8.51	18.6
WI	Ground	Lima	0.4	--	2.18	6.6
NC	Ground	Snap	0.62	--	3.7	8.07
NY	Ground	Snap	0.38	0.86	3.5	6.28
FL	Ground	Snap	0.53	--	9.68	17.4
MI	Ground	Snap	0.73	--	13.5	15.7
CA	Ground	Snap	2.4	9.77	50.8	164

Vinclozolin Residues (ppm) in Beans from Aerial Application

State	Applic.	Sample	Seeds & Pods	Cannery Waste	Green Forage	Dry Forage
FL	Aerial	Lima	0.41	--	3.13	5.67
OR	Aerial	Lima	0.86	1.4	3.83	8.07
MI	Aerial	Snap	0.64	--	7.59	7.31
NY	Aerial	Snap	0.76	2.52	15.1	32.6

Vinclozolin Residues (ppm) in Beans from Irrigation Application

State	Applic.	Sample	Seeds & Pods	Cannery Waste	Green Forage	Dry Forage
OR	Irrigat.	Snap	0.95	1.68	7.65	21.1
WI	Irrigat.	Lima	0.73	--	4.3	14.2

Meat, Milk, Poultry, and Eggs

For the purposes of the current action, the only animal feed item being considered is cannery waste. Bean cannery waste (from succulent beans) is used to the extent of about 20% of the diet of both beef and dairy cattle. There are no established meat and milk tolerances for vinclozolin. Meat and milk tolerances are pending in PP9F3750 which is presently under review. We can not recommend for the proposed bean tolerances until the pending meat and milk tolerances are established.

For the current considerations herein, there are no poultry feed items associated with the production of succulent beans. Since the proposed tolerance is for succulent beans only, dried beans considered in PP5F3237/FAP7H5531 are not being considered herein. The metabolism of vinclozolin in poultry must be reconsidered if or when the petitioner proposes the use of vinclozolin on dried beans.

OTHER CONSIDERATIONS

International Residue Limits

There are no Canadian or Mexican tolerances for residues of vinclozolin in succulent beans. There is a Codex tolerance of 2 ppm on beans. Compatibility is not possible between the U. S and Codex tolerances because the U.S. data show the need for a higher tolerance of 3 ppm.

An International Residue Limit Status Sheet is attached to this review.

Attachment: IRL Status Sheet.

cc:PM15, Cook, PP9F3762/FAP9H5585,RF,Circ(7),ISB/PMSD (Eldredge)
H7509C:DEB:RCook:rc:x77484:Rm810H:10/31/89:11/7/89
RDI:R.Quick:11/14/89:R.Loranger:11/14/89

1 Jun 16/31/87

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Vinclozolin

CODEX NO. 159

CODEX STATUS:

☒ No Codex Proposal Step 6 or above

Residue(if Step 8): Sum of vinclozolin and all metabolites containing the 3,5-dichloroaniline moiety, expressed as vinclozolin

Crop(s)	Limit (mg/kg)
common bean*	2

PROPOSED U.S. TOLERANCES:

Petition No. PP9F3762/FAP9H5388

RCB Reviewer RDVC

Residue: Vinclozolin and its dichloroaniline metabolites (40CFR180.390)

Crop(s)	Limit (mg/kg)
Succulent Beans	3 ppm
Cannery waste of Succulent Beans	10 ppm

CANADIAN LIMITS:

☒ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES: * [illegible]

Form revised 1985