US EPA ARCHIVE DOCUMENT

5-2-86
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 2 1986

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: 86-OR-03. Proposed Section 18 for the Use of Vinclozolin (Ronilan® 50W, EPA Reg. No. 7969-53) on Snap Beans.
No. 170275
RCB #871

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To: Emergency Response Section
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and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The Oregon Department of Agriculture requests a Section 18 specific exemption for the use of the fungicide vinclozolin [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxalodinedione] on approximately 20,000 total acres of snap beans to control Botrytis cinerea. The formulation to be used is Ronilan® 50W, a 50% a.i. wettable powder.

Tolerances have been established at 10 ppm for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in or on kiwifruit, head lettuce and strawberries. Numerous tolerances are pending ranging from 0.05 ppm (cattle meat, milk; poultry meat, fat) to 75 ppm (FA)(dried prunes).

A Registration Standard has not been completed for vinclozolin.

The proposed use calls for a maximum of two applications of Ronilan® 50W at a rate of 1 lb (0.5 lb.a.i.)/A to snap beans. Application could be made by ground (40-100 total gallons/A) or aerial (minimum 15 gallons/A) equipment. A PHI of 9 days would be imposed.

The metabolism of vinclozolin in plants is adequately understood for the purposes of this section 18. The major metabolic routes include decarboxylation, dealkylation and conjugation leading to 8 major metabolites containing the 3,5-dichloroaniline

moiety. The parent compound together with these metabolites comprise the residue of concern. It should be noted that although the available plant metabolism data is adequate for the purposes of this section 18, additional data requested with PP#5F3237/FAP#5H5465 will be required for the establishment of a permanent tolerance on beans.

The metabolism of vinclozolin in animals is adequately understood for the purposes of this section 18 only. Further data will be required for the issuance of a permanent tolerance. A goat metabolism study was submitted with PP#5F3237/FAP#5H5465in which goats were fed approximately 2 ppm vinclozolin in their diets for 10 days. The ^{14}C-activity was measured in these studies but residues were not characterized; and 25% of the total radioactive dose was not accounted for. A poultry metabolism study is also available which is adequate only for the purposes of this section 18 (see M. Firestone memo, 6/28/85).

Residue data for snap beans were submitted with PP#5F3237/FAP#5H5465 (Acc. No. 073480/1). The analytical method used to determine residues in beans is similar to BASF Method No. 25 (also PAM II, Method I). Initial alkaline hydrolysis converts the parent compound and all of the metabolites to 3,5-dichloroaniline (DCA). DCA is then isolated by distillation, followed by partitioning into chloroform, derivatization to N-(3,5-dichlorophenyl)-2-chloroacetamide (DCAD) with chloroacetyl chloride, and analysis by GLC using a ^{63}Ni electron capture detector. The method used for residue determination in animal commodities is similar.

Residues are summarized in the table below for 2 applications at a rate of 1.0 lb.a.i./A/application (2X the maximum proposed rate).

Commodity	Interval Between Applications	PHI	Residue (ppm)
snap beans (succulent)	13	13	1.5
"	7	17	0.57
"	7	16	0.33
"	14	14	0.47
"	14	14	1.2
"	10	15	0.17
"	15	9	0.56
snap bean forage	7	17	23.6, 18.2
"	7	16	4.2, 4.0
"	14	14	4.7
"	14	14	9.0
"	15	9	3.0

Based on this data we conclude that residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety are not likely to exceed 2.0 ppm in or on snap beans and 15 ppm in or on snap bean forage and hay.

Meat, Milk, Poultry and Eggs

Although additional ruminant metabolism studies are required for a permanent tolerance, for the purposes of this section 18 only we will utilize the available metabolism studies and assume that the residue of concern in animals includes parent vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

Vinclozolin residues are likely to be a part of the diets of animals only as a result of this use since no other tolerances are currently established for animal feed items. Maximum likely residues in animal tissues are tabulated below. This information was calculated based on a cattle feeding study in which two groups of three cows each were fed diets containing either 3 ppm or 15 ppm vinclozolin for 28 days. Maximum residues (ppm) found for the 3 ppm and 15 ppm diets respectively were: milk (0.06, 0.23), fat (0.1, 0.63), kidney (0.22, 1.19), liver (0.75, 2.89) and muscle (0.06, 0.30).

In similar past section 18 exemptions, a restriction against feeding forage or hay to livestock has been applied. We have no objection should a feeding restriction be suggested based on toxicological considerations. Therefore, maximum likely residues are listed in the table below reflecting residues both with and without a feeding restriction required. These are based on the dietary intake of forage or hay of 20 and 35% respectively for beef and dairy cattle. No residues are expected in animal commodities if a feeding restriction is enforced.

Commodities	Max. Likely Residues Without Feeding Restriction
milk	0.1 ppm
cattle fat	0.2
" kidney	0.3
" liver	0.8
" muscle	0.1
eggs	<0.05
poultry fat	<0.05
" kidney	0.05
" liver	<0.05
" muscle	<0.05
" skin	<0.05

Conclusions

(1) The metabolism of viclozolin in plants and animals is adequately understood for the purposes of this section 18 (only).

(2) The maximum likely combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety are listed in the table below. These values assume that no feeding restriction is required. No residues are expected in the meat, fat and meat by-products of cattle, goats, hogs, horses and sheep; and milk if a feeding restriction is required.

Commodity	Max. likely residue (ppm) Without Feeding Restriction
Snap beans	2.0
Snap bean forage/hay (if bean or hay are fed)	15
Meat, fat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep	0.3
Liver of cattle, goats, hogs, horses and sheep	0.8
Milk	0.1

(3) Analytical Methods are available for enforcement (PAM II, Method No. I).

(4) Analytical reference standards are available from the Pesticides and Industrial Chemicals Repository.

Recommendations

TOX considerations permitting, RCB has no objections to this section 18. An agreement should be made with the FDA regarding the legal status of the treated commodities in commerce.

cc:vinclozolin (Ronilan)S.F.,R.F.,Section 18 S.F.,Circu,
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