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R.F.



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

APR 3 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 89-WI-09. Section 18 Exemption for the use of Vinclozolin (Ronilan®) on Snap beans to Control White Mold. EPA Reg. No. 7969-62 and 7969-53. (No MRID #, DEB # 5090).

From: Freshteh Toghrol Ph.D., Chemist *F. Toghrol*
Special Registration Section II
Dietary Exposure Branch
Health Effect Division (H7509C)

THRU: Francis B. Suhre, Acting Section Head *Francis Suhre*
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To: D. Stubbs/Jim Tompkins, PM 41
Emergency Response Section
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and
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The Wisconsin Department of Agriculture requests a Section 18 exemption for the use of vinclozolin on green (succulent) snap beans to control white mold (Sclerotinia sclerotiorum).

Ronilan® FL fungicide (EPA Reg. No. 7969-62)¹⁵ manufactured by BASF Wyandotte Corporation; the product contains 41% vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) as its active ingredient. Ronilan 50 W (EPA Reg. No. 7969-53) contains 50% vinclozolin as its active ingredient.

A maximum of 41,500 acres of snap beans will be treated with 31,125 lbs of active ingredient.

Tolerances are established (40 CFR 180.380) for combined 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 kiwi fruit, head lettuce, and strawberries at 10 ppm, stone fruits at 25.0

ppm, peppers (bell) at 3.0 ppm, and grapes at 6.0 ppm. Numerous tolerances are pending, ranging from 0.05 ppm to 75 ppm.

A Registration Standard has not been issued for vinclozolin.

No plant or animal metabolism studies were submitted with this request. However metabolism data were previously submitted in connection with PP# 5F3237/FAP#5H5465. For the purpose of this section 18 request (additional data for animal metabolism is needed for permanent tolerance), we consider the metabolism of vinclozolin in plants and animals to be adequately understood. The residues of concern are vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

89-WI-09 calls for a maximum of two applications (ground) of vinclozolin at 0.5 to 0.75 lb. ai/A/season (1.0 to 1.5 lbs of Ronilan 50 W/A or Ronilan FL/A), using 30 to 50 gallons of water. The first application is made at early or mid bloom and the second application 14 days later if needed. No PHI has been suggested with this request, however, a minimum PHI of 7days (according to PP#5F3237/FAP#5H5465) would be imposed.

The GLC (using ⁶³Ni electron capture detector) method described as Method I in PAM II is adequate for enforcement purposes.

No residue data were submitted with this Section 18, however, residue data were previously submitted in connection with PP#5F3237/FAP#5465. The available data reflect higher application rates (2 applications at a rate of 1.0 lb. ai/A/application, 2X), than those proposed for this Section 18 request and are summarized below:

<u>rate of application</u> (# days between 2 appl.)	<u>PHI</u> <u>days</u>	<u>Residues PPM</u>	
		<u>snap beans</u>	<u>snap bean forage</u>
1.0 + 1.0 (13)	13	1.5	-----
1.0 + 1.0 (7)	17	0.57	18.2
1.0 + 1.0 (7)	16	0.33	4.2, 4.0
1.0 + 1.0 (14)	14	0.47	4.7
1.0 + 1.0 (14)	14	1.2	9.0
1.0 + 1.0 (10)	15	0.17	-----
1.0 + 1.0 (15)	9	0.56	3.0

Based on these data DEB conclude that residues of vinclozolin and its metabolites containing the 3,5-dichloro-aniline moiety will not exceed 2.0 ppm in or on snap beans and 25.0 ppm in or on snap beans forage.

Meat, Milk, Poultry and Eggs:

Snap beans (seeds and pod) may be fed to cattle, and poultry at up to 20 and 25% of their diet respectively. Beans vines and hay are also used as animal feed items and may reflect up to 35% of the diet of dairy (cattle). Based on the available residue data for these animal feed items, we estimate a maximum vinclozolin dietary burden of 0.5 ppm, for poultry (ca. 25% of the diet consistence of beans) and 10.0 ppm for cattle (ca. 20% of the diet consistence of beans and 35% of beans forage) may result from this proposed section 18 use.

The results of feeding study (PP#5F3237/FAP#5H5465) in which dairy cattle, and poultry were fed 3 ppm and 15 ppm vinclozolin for 28 days are summarized below:

Commodity	3ppm	15 ppm
Cattle milk	0.06	0.23
cattle fat	0.10	0.63
cattle kidney	0.22	1.19
cattle liver	0.75	2.89
cattle muscle	0.06	0.30
poultry eggs	0.10	0.39
poultry fat	<0.05	0.14
poultry kidney	0.10	0.39
poultry liver	0.08	0.58
poultry muscle	<0.05	0.12
poultry skin	0.05	0.13

Based on these data and a potential dietary burden of 10 ppm vinclozolin for cattle and 0.5 ppm vinclozolin for poultry, we conclude that secondary residues of vinclozoline will not exceed 0.3 ppm in milk; 1.0 ppm in cattle fat, and muscle; 5.0 ppm in cattle liver and kidney; and 0.2 ppm in poultry eggs, muscle, liver, and kidney as a result of this proposed Section 18.

Conclusions:

1. The metabolism of vinclozolin in plants and animals is adequately understood. The residues of concern are vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.
2. The GLC analytical method (Method I) described in PAM II is adequate for enforcement purposes. Analytical reference standards of vinclozolin are available from the EPA Repository.
3. Residues of vinclozolin are not likely to exceed 2 ppm in or on succulent snap beans, and 25 ppm, in or on succulent snap beans forage, as a result of this proposed use.
4. Residues of vinclozolin are not expected to exceed 0.3 ppm in milk; 1.0 ppm in cattle fat, and muscle; 5.0 ppm in cattle

liver and kidney; and 0.2 ppm in poultry eggs, muscle, liver, and kidney as a result of this proposed Section 18.

Recommendations:

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

cc: vinclozolin S.F., R.F., Section 18 S.F., Circ., F. Toghrol, PMSD/ISB, TAS (S. Stanton).
RDI: F. B. Suhre Acting Section Head (1/30/89): E. Zager: Acting Deputy Chief (3/30/89):
TS-H7509C:DEB:F.Toghrol:F.T.:RM:802:CM#2:3/31/89.