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

AUG 8 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: ID #90-TX-19. Propiconazole [TILT®]: Section 18 exemption for use on peanuts in the State of Texas. [DEB:6871,MRID:n/a]

FROM: William L. Anthony, Chemist
Special Registration Section II
Dietary Exposure Branch
Health Effects Division [H7509C]

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THRU: Francis B. Suhre, Section Head
Special Registration section II
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TO: B. Cool/J. Tompkins, PM #41
Emergency Response Section
Registration Support Branch
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and
Toxicology Branch
Health Effects Division [H7509C]

The Department of Agriculture, State of Texas, has requested an emergency exemption under Section 18 of FIFRA, as amended, for use of propiconazole [TILT®-3.6EC], EPA Reg. #100-617, a broad spectrum foliar fungicide, for control of Southern Blight [Sclerotium rolfsii] on peanuts. This fungicide will be used on an estimated 17,000 acres of peanuts, where ever it is needed in the state.

TILT®-3.6EC, a registered product of the Ciba-Geigy corporation, is an emulsifiable concentrate containing 41.8% of the a.i., propiconazole, [1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole], and 58.2% inert ingredients. Each gallon contains 3.6 lbs of the active ingredient.

A Section 18 exemption for use of TILT® on peanuts in the State of Texas, was previously reviewed by DEB, [Memo: W. Anthony, #88-TX-09, 8/18/88]. A temporary tolerance for residues of

propiconazole in/on peanuts, peanut hay, and peanut hulls expired 10/12/88. Other Section 18 exemptions for TILT® included: celery in Wisconsin, W. Anthony, 5/14/90; celery in Florida, 1/23/89 & sweet corn in Florida, 6/1/88 & rice in Texas, 3/7/86, F. Suhre; wild rice in Minnesota, 7/16/84, K. Doktor; rice in Texas, 5/15/84 & rice in Arkansas, 4/18/84, S. Malak.

TOLERANCES

Tolerances are established (40 CFR 180.434) for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on wheat grain (0.1 ppm) and wheat straw (1.5 ppm); bananas (0.2 ppm); barley grain (0.1 ppm) & straw (1.5 ppm); pecans (0.1 ppm); rice grain (0.1 ppm) & straw (3.0 ppm); rye grain (0.1 ppm) & straw (1.5 ppm); fat, meat, and meat-by-products (except liver and kidney) of cattle, goats, hogs, horses, poultry, and sheep (0.1 ppm); milk (0.05 ppm); liver and kidney of cattle, goats, hogs, horses, and sheep (2.0 ppm); grass forage (0.5 ppm); hay (5.0 ppm); and seed screenings (10 ppm).

Petition #8F3654, which proposed establishment of permanent tolerances for peanut hay at 20 ppm, peanut hulls at 1.0 ppm, and peanut (meat) at 0.2 ppm, is currently under reject status, [Memo:H. Fonouni, 11/22/88 & 5/4/89].

There is no registration standard for propiconazole.

Proposed Use

Exemption #90-TX-19 calls for application of 4 or 8 fl. oz. [0.1125 or 0.225 lb a.i.] of TILT®-3.6 EC per acre. Two or four applications are to be made during pegging. The product should be applied only through an overhead sprinkler including center pivot, solid set, or portable irrigation systems. The water dilutions factors were omitted from the proposed use.

Restrictions: (1) Do not apply more than 16 fl oz of the formulation per acre per growing season; (2) Do not feed green vines to domestic livestock; and (3) Do not apply within 28 days before harvest.

Note: The registrant is requesting an addition to the label to permit, as an alternative, four (4 fl oz) applications of TILT®, at one week intervals. The previous Section 18 label authorized

two (8 fl oz) applications of TILT®, one at early pegging and a second application at late pegging, [Memo: W. Anthony, #88-TX-09, 8/18/88]. With either treatment, the maximum amount of TILT® applied would not exceed 16 fl oz/ per acre/ per season, with a 28 day PHI.

Nature of the Residue

For the purpose of this Section 18 request, the metabolism of propiconazole in plants and animals is adequately understood. The residues of concern are the parent compound and its metabolites determined as 2,4-dichlorobenzoic acid, [Memo: PP #4F3074, A. Smith, 7/12/84; PP #8F3674, C.Deyrup, 12/4/88].

Analysis

An acceptable analytical method, viz., #AG-454, is discussed in connection with PP #8F3674, [C.Deyrup, 12/14/88]. This method, which utilizes a capillary GC column and a EC detector, is adequate for enforcement.

Residue Data

No residue data were submitted with this request. As noted in our Section 18 review of 8/25/88 on peanuts, residue data were submitted in CIBY-GEIGY's Residue Report #ABR 88068, 5/5/88 as reported in PP #8F3654 [Memo: H. Fonouni, 11/22/88].

Eight separate field studies were conducted in the States of OK(2), AL, FL, TX, VA, GA, & NC. Samples of peanut hay, peanut hulls, and peanut (meats), were analyzed following PHI's ranging from 7 to 21 days. Data from this report indicated that maximum residues resulting from maximum use rate of 16 fl oz of TILT®-3.6EC (0.450 lb a.i.) per acre per season at a 21 day PHI was 13.7 ppm for peanut hay, 0.68 ppm for peanut hulls, and 0.08 ppm for peanut meats.

Following the processing of peanuts treated at 1X and 2X the proposed rate, residues in all the processed fractions were along the order of residues found in the peanut meats. Therefore we conclude, as was noted in DEB's Section 18 of 8/18/88 on peanuts, that residues from the proposed use will not exceed 20 ppm for peanut hay, 1.0 ppm for peanut hulls, and 0.2

ppm in peanut (meats), and 0.2 ppm in the processed commodities - peanut meal, crude & refined oils, and soapstock.

Meat, Milk, Poultry, and Eggs

The potential livestock feed items include peanut meal, peanut hay, peanut hulls, soapstock, and peanut vines. The latter is a restricted item for domestic livestock. Peanut meal may account for 15% and 25% of the daily diet for beef and dairy cattle, respectively; 10% for poultry and swine. Peanut hay may account for 25% and 60% of the daily diet for beef and dairy cattle, respectively. Hulls may account for 5% of the daily diet of beef cattle. Soapstock may account for 5% of the daily diet of beef & dairy cattle, poultry and swine.

Cattle feeding studies reflecting daily dosing of 15 ppm, 75 ppm and 150 ppm of propiconazole, were previously reviewed in connection with PP #4F3074 are summarized below: :

Meat: Residues were found in all tissues at all feeding levels. Maximum residue levels were noted in kidney and liver. At the 15 ppm feeding level, the maximum residue level in kidney was 0.63 ppm; in liver at 0.57 ppm; and <0.05 ppm in meat and fat of cattle.

Milk: No residues were detected at 15 ppm feeding level. Total residues of <0.01 ppm to 0.08 ppm were noted at 75 ppm feeding level plateauing at 0.08 ppm on day 7.

Poultry: Laying hens were fed daily rations of propiconazole at 7.5 ppm, 37.5 ppm, or 75 ppm for 28 days. No residues of the parent compound were found (<0.05 ppm) at any level in any tissue which included the breast, thigh, liver, fat, and skin. The only exception was at the 36.5 ppm feeding level in liver, 0.10 ppm to 0.16 ppm.

Eggs: No residues of the parent compound were detected at any feeding level. No residues of the parent and its metabolites were noted (<0.5 ppm) from the 7.5 ppm feeding level. At 37.5 ppm feeding level, detectable residues (0.13 ppm) appeared on the third day of feeding: at day 28, the level was 0.06 ppm.

The dietary intake for beef and dairy cattle would be in the order of 5 ppm and 12 ppm, mainly from the ingestion of treated peanut hay. The dietary burden to poultry would be <0.02 ppm from peanut meal.

Based on the available residue data (PP #4F3074), we do not expect the established tolerances for meat, milk, poultry, and eggs to be exceeded as a result of this Section 18 exemption.

Conclusions:

(1) For purposes of this Section 18 only, we consider the metabolism of propiconazole and its metabolites in plants and animals to be adequately understood. The residues of concern are the parent compound, propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid.

(2) Residue Analytical Methods AG-5435A (crops) and AG-517 (meat, milk, and eggs) are adequate for enforcement purposes.

(3) Residues of propiconazole and its metabolites determined as the 2,4-dichlorobenzoic acid will not exceed 0.2 ppm in/on peanuts, peanut meal, soapstock, and refined oil; 1.0 ppm in/on peanut hulls and 20 ppm in/on peanut hay as a result of the proposed use.

(4) Secondary residues in meat, milk, poultry, and eggs will not exceed established tolerances as a result of this Section 18 exemption

(5) Analytical Reference Standards for propiconazole and metabolites are available from the Pesticide & Industrial Chemists Repository at Industrial Park, NC.

Recommendation

TOX considerations permitting, DEB has no objection to this Section 18. An agreement should be made with FDA regarding the legal status of the treated commodity in commerce.

CC:Reviewer;SF[Propiconazole,TILT®];FOD/PIB(C.Furlow);DRES
(J.Kariya);R.Schmitt);Sec.18 File;Circulation.

RDI: FBS,8/6/90;RDS,8/6/90.

H7509C: WLA;wla;CM-2,RM.812;X557-351;8/7/90.