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PP/0E2419 Botran in or on Tomatoes
Evaluation of residue data and analytical method

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Interregional Research Project No. 4, National Director, Dr. E. W. Kupelian, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of California proposes the establishment of a tolerance for the residues of the fungicide 2,6-dichloro-4-nitroaniline (trade name-Botran) in or on tomatoes at 20 ppm.

Established tolerances ranged from 20 ppm for pre- and post harvest application to a number of stone fruits to 0.1 ppm and include a tolerance of 5 ppm for a pre-harvest use on tomatoes. A temporary tolerance of 5 ppm was established and expired May 2, 1979 for post-harvest use on tomatoes.

The Upjohn Company has authorized the use of confidential information contained in or referenced by the product registration files for Botran 75W (E.J. Ventral, Upjohn Co., to C. Fletcher, EPA, 8/25/80). In addition, the Decco Tiltbelt division of Pennwalt Corporation authorizes the use of Section D of PHL405 for data generated by Pennwalt contained in this petition (B. Bave, Pennwalt to C. Fletcher, EPA, 8/29/80).

Conclusions

- 1a. The nature of the plant residue has been adequately delineated. The residue of concern is the parent, Botran (DCRA).
- 1b. A conclusion on the animal metabolism will await submission and review of the result of the goat metabolism study presently underway by the Upjohn Corporation. Analytical methods with validation data and method trial and feeding studies will be needed for the residues judged in need of regulation.
2. Adequate methods are available to enforce the proposed tolerance for tomatoes.
- 3a. As calculated from the proposed use, residues are expected to be 7 ppm. Among the residue data submitted, residues exceeded this level in pilot plant studies. The DCRA in these studies was not applied as proposed the weight of fruit treated was not supplied in studies reflecting commercial situations. Consequently we can not estimate residue levels. The petitioner should supply information concerning calibration of equipment, amounts treated and any other pertinent factors relative to the differences between pilot studies and commercial operations.

Additional residue data reflecting a commercial operation and the proposed use is needed so that with the aforementioned information the expected residue level can be determined. Once this has been accomplished, a tolerance should be proposed reflecting maximum levels from this use and the preharvest treatment. (Field and greenhouse tomatoes are indistinguishable in commerce).

The tolerance for preharvest treatment is 3 ppm and the tolerance should be adjusted by this level.

- 3b. Treated tomatoes may be diverted into processing. Restricting the use to fresh market tomatoes only would not be practical. Therefore a processing study is needed. Tomatoes containing residues at the tolerance level should be processed into tomato juice, tomato paste, and dried pomace.
4. Tomato pomace is a feed item. Since we can make no conclusions concerning the significant residues in animals and the residues in tomato pomace, we can make no conclusions concerning secondary residues in meat, milk, poultry and eggs.
5. The Codex limit is 0.5 ppm and the Canadian Limit is 5 ppm. There is no Mexican Tolerance.

Recommendation

We recommend against the proposed tolerance for the reasons cited in conclusions 1b, 3a, 3b and 4. A favorable recommendation is contingent upon resolution of these deficiencies.

DETAILED CONSIDERATIONS

Proposed Use

For post-harvest treatment for *Betrytia cinera* on field grown tomatoes, add Batran 75% in food grade tomato wax to make a 3 percent suspension of active ingredient. Drop the Batran-wax mixture onto the overhead application brush at the rate of one gallon of wax per 33,000 lbs of fruit.

Technical Batran contains at least 95% of 2,6-dichloro-4-nitroaniline (DCNA).

The formulation contains technical DCNA 75%,

The inerts are cleared for use under Section 135.1351(c).

Based upon the proposed use, the maximum residue should be 7.0 ppm presuming that the density of the wax and the resulting mixture is 8.112 lb/gal (N. Tort, IV-4, 12/12/80).

Field grown and greenhouse grown tomatoes may be indistinguishable in commerce. Consequently greenhouse grown tomatoes bearing DCHA residues may be treated post-harvest. Therefore the tolerance will have to cover tomatoes from both sources.

Nature of Residue

No metabolism data was submitted. The fate of DCHA when applied before harvest has been discussed in detail in our review of PF#5F0434 (see memo of 6/3/65 by J. Wolff). Residues from preharvest use dissipate chiefly by volatilization with the parent compound considered the only residue component of toxicological concern. We would expect little if any loss of residues from the post-harvest application, especially considering it is to be used with a fruit wax. It is also our judgment that the parent compound will be the only residue of concern resulting from this use.

With regard to animal metabolism, a goat metabolism study is presently underway by Upjohn (memorandum of conference of 11/19/80; K.H. Arue, 12/2/80). We will withhold a conclusion on animal metabolism until this study has been assessed.

Analytical Method

Two procedures (I and II) were used for residue analysis. In both cases, tomatoes were blended with organic solvent, benzene (I) or iso-octane (II). After the benzene extract (I) is filtered, the extract is cleaned up on a florisil column. The eluate is concentrated and analyzed by GC with an electron capture detector.

A portion of the iso-octane layer (II) is dried over sodium sulfate and then analyzed by GC/EC.

For the benzene extraction method (I), apparent residues in or on untreated tomatoes ranged from less than 0.01 ppm to 0.02 ppm. Recoveries after fortification at 0.1 ppm DCHA ranged from 90 to 120%. Controls for method II were reported as 0.0 ppm with no validation data provided.

A GC method for DCHA is included in PAN II. The method which has undergone a successful method trial is a colorimetric method. Sensitivity was reported as 0.1 ppm. Therefore adequate methods are available to enforce the proposed tolerance.

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Residue Data

Tomatoes were treated in one experiment with either 3000, 15,000, or 30,000 ppm DCMA in wax (0.1, 0.33 and 1X) as proposed. Residues ranged from 1.98 to 4.5 ppm, 3.34 to 8.04 ppm and 9.35 to 13.8 ppm respectively. Two types of wax were used. One of which contained Orthophenylphenol. It's presence does not interfere with DCMA determinations.

Based upon the proposed use, residues should be approximately 7 ppm (0.24 lbs a.i./ 35,000 lbs of tomatoes, presuming 5.11 lb/sal mixture). Residues from this study are in excess of this level. This study was performed on pilot plant equipment (E. Dave, Panwalt, 1/7/61) and may not have reflected a commercial situation. The petitioner should provide information concerning the calibration of the equipment, amounts treated and other factors showing the similarity or dissimilarity of the pilot operation with a commercial operation.

Another series of studies carried out in a commercial situation used 2 or 4% Batran in wax. At the 2% level, one gallon was used to treat 29,000 or 31,000 lbs of fruit. At the 4% level, one gallon treated 103,000 lbs of tomatoes for one study and an indeterminate amount in another study; neither of which reflects the proposed use. Residues ranged from 2 to 3.4 ppm at the 2% level and from 0.5 to 8.7 ppm at the 4% level. Considering residues at the 2% treatment, approximate residues at 3% could be 3 ppm. However the data is not adequate for us to make a conclusion of what residues levels to expect. The petitioner should indicate the volume of wax and the number of pounds treated in the 1978 U. of California experiment. Besides these information additional residue data is needed reflecting a commercial operation at the proposed rate in light of the confusion over the calculated residues and the residues from the studies submitted.

Furthermore there is a registered pre-harvest use. Since a tolerance is to reflect maximum residues and tomatoes treated preharvest may also be treated postharvest, the tolerance will need to be adjusted to include residues from the preharvest use. Once the residue levels to be expected from the post-harvest case are determined then 3 ppm can be added to this level for the proposed tolerance and no additional residue data reflecting pre and post-harvest uses will be needed.

Treated tomatoes may be diverted into processing. Restricting the use to fresh market only would not be practical considering present marketing practices. No processing study was submitted. Therefore a tomato processing study is needed reflecting residues at the tolerance level processed into tomato juice, tomato paste and dried tomato powder.

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Meat, Milk, Poultry and Eggs

Tomato pomace is a feed item. However since we can make no conclusions concerning the significant residues in animals and the residues in or on tomato pomace, we can make no conclusions concerning secondary residues in meat, milk, poultry and eggs.

Other Considerations

The International Residue Limit Status Report is attached. There is a Codex limit of 0.5 ppm and a Canadian limit of 5 ppm. There is no Mexican Tolerancia.

TS-769:RCB:LEOVEY:gs:CM#2:EM.810:X77377:2/5/81
cc: RF, CIRC., LEOVEY, WATTS, FDA, EEB, EFB, TOX, PP#OE2419
EDI:R. Quick, 1/15/81:R. Schmitt, 1/16/81

INTERNATIONAL RESIDUE LIMIT STATES

CHEMICAL Botran (dichloran)

PETITION NO. OE2419 (Leovey)

GCPR NO. 83

Codex Status

Proposed U.S. Tolerances

☐ No Codex Proposal Step 6
or above

Residue (if Step 9): 2,6 dichloro-
4-nitroaniline

Residue: 2,4-dichloro-4-nitroaniline

Crop(s) Limit (mg/kg)

Crop(s) Tol. (ppm)

Tomatoes 0.5 ppm T 9

Tomatoes 20 ppm

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue:
dichloran

Residue:
NOI

Crop Limit (ppm)

Crop Tolerancia (ppm)

TOMATOES 5 ppm

NOI

NOTES: