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PP# 9G2255 and 9G2256 2,6-Dichloro-4-nitroaniline and O-phenylphenol in or on Kiwi fruit. Evaluation of analytical method and residue data.

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Thru: Chief, Residue Chemistry Branch

The Pennwalt Corporation, Decco Division proposes that a temporary tolerances of 20 ppm each be established for residues of O-phenylphenol and 2,6-Dichloro-4-Nitroaniline in or on Kiwi fruits.

These temporary tolerances are sought in conjunction with a request for an EUP for the use of Kiwi Lustr 277 (a.i. O-phenylphenol) adn Botran 75W (a.i. DCNA) on Kiwi fruits.

The proposed experimental program will entail the use of 890 gals of Kiwi Lustr 277 (147.5 lbs OPP) and 200 lbs Botran 75W (150 lbs DCNA). It is expected that only a small fraction of the 300,000 lugs of Kiwi fruit packed in California will be treated. However, the amount of material requested would be sufficient to treat the entire crop.

Tolerances for residues of O-phenylphenol and its sodium salt have been established at levels ranging from 5-125 ppm on various rac's including a tolerance of 20 ppm on peaches (40 CFR 180.129).

Tolerances have been established for residues of the fungicide 2,6-dichloro-4-nitroaniline at levels ranging from 0.25 ppm to 20 ppm including a tolerance of 20 ppm in or on peaches (40 CFR 180.200).

Conclusions

1. [redacted] an inert ingredient in the formulation, is not cleared for this use.

2. Any reference to the Cl_2 wash step should be removed from the label.

3. The labeling should be revised to make it clear that the recommended rate of 1 gal per 8-10,000 lbs fruit refers to the amount of Kiwi Lustr 277 concentrate per 8-10,000 lbs and not to the amount of the diluted spray.

4. The label should include a warning against, draining the effluent from the treatments into sewage systems.

5. The nature of the residue in plants is adequately characterized for purposes of the proposed temporary tolerances.

6. Adequate analytical methodology is available to enforce the proposed temporary tolerances.

7. Residues of O-phenylphenol and 2,6-dichloro-4-nitroaniline in or on Kiwi fruits will not exceed the proposed temporary tolerance of 20 ppm.

8. There are no recognized feed items associated with this proposed use on Kiwi fruits. Therefore, there is no reasonable expectation of finite residues transferring to meat, milk, poultry or eggs from this proposed use.

Recommendations

Contingent upon TOX finding that residues [redacted] would not constitute a hazard (see Conclusion 1) and providing that the petitioner amends the labeling as discussed in Conclusions 2, 3 and 4 above, we recommend that the proposed temporary tolerances be established.

For consideration of any permanent tolerance we will need;

1. Residue data generated by accepted enforcement methodologies and reflecting various post-treatment intervals, including a 0-day interval.

2. Validation data including blank values and recoveries at fortification levels appropriate to the proposed tolerance.

3. Clearance of the inert ingredient [redacted] under Section 180.1001.

Detailed Considerations

Formulation

O-phenylphenol is formulated as Kiwi Lustr 277. The formulation contains 2% active ingredient. One of the inerts [redacted] of the formulation, is not cleared for this use. We defer to TOX as to whether possible residues of this compound would constitute a hazard. All the other inerts in the formulation are cleared under Sect. 180.1001.

Botran is formulated as a 75% wettable powder. The inert ingredients are cleared under Sect 180.1001. The technical product contains at least 95% of 2,6-dichloro-4-nitroaniline. [redacted]

Proposed Use

According to H. Jacoby PM #21 (telecon 10-1-79) any reference to the Cl_2 wash step will be removed from the label. Our recommendations will be contingent on the petitioner doing so.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Kiwi fruits will be treated with 1 gallon of Kiwi Lustr 277 concentrate (0.16 lbs OPP) and Botran 75W (0.17 lbs DCNA) diluted in 9 gals of water. The resulting mixture will contain approximately 2,000 ppm DCNA and OPP. The mixture will be applied through suitable spray nozzles at a rate of one gallon of concentrate* per 8-10,000 lbs of freshly cleaned (Cl_2 wash) Kiwi fruit traveling on rotating brushes or suitable wax applicator. Fruits will be damp dried while on equipment and stored at 32°F.

Nature of the Residue

No metabolism studies have been submitted with this petition.

The proposed use will result in residues of DCNA and OPP being trapped in the wax emulsion on the inedible skin of the fruit. It is expected that little, if any residue will be found in the edible central core, seeds or outer flesh.

O-phenylphenol and its sodium salt have been considered the residue of concern for those commodities on which tolerances have been established.

In the case of degradation of Botran, it is also the parent compound that has been consistently considered to be the only component of toxicological concern.

The available metabolism data are somewhat limited. However, for this post-harvest use on Kiwi fruit, we consider the metabolism to be adequately defined.

Analytical Method

O-phenylphenol

The method used to generate the data separates the fungicide by steam distillation and quantitates it by gas chromatography (flame ionization).

For permanent tolerance residue data should be obtained using the accepted enforcement method (Method I, sodium O-phenyl, phenate PAM II). Blank values and recoveries at fortification levels appropriate to the proposed tolerance should be reported.

DCNA

A gas chromatographic method was used to generate the residue data.

DCNA residues were extracted with iso-octane and quantitated using electron capture detector.

*According to Dr. Kaplan, Research Director, Recco Div of Pennwalt, telecon 10/1/79 the rate refers to the gallons of Kiwi Lustr concentrate. This should be made clear on the label.

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For permanent tolerance residue data should be obtained using the accepted enforcement method (Method, I 2,6-dichloro-4-nitroaniline, PAM II). Blank values and recoveries at fortification levels appropriate to the proposed tolerance should be reported.

Residue Data

Kiwi fruits spray treated at 1,000, 1,500 and 2,000 ppm of DCNA and 1,200 ppm and 2,000 ppm of OPP in wax were analyzed.

Residues at 0-day following the 2,000 ppm treatment ranged from 5.5 - 6.0 ppm for DCNA and 7.1-9.1 ppm O-phenylphenol. Residues reflecting lower treatment rates were correspondingly lower.

The above results are consistent with the maximum theoretical residues of 20 ppm each, DCNA and OPP that may result on Kiwi fruit from the proposed treatment rate. Consequently, we conclude that residues in or on Kiwi fruit are not likely to exceed the proposed tolerances of 20 ppm each for O-phenylphenol and 2,6-dichloro-4-nitroaniline.

Meat and Milk

No feed items are involved in this petition. Therefore no residues are likely to occur in eggs, milk, meat, fat or meat byproducts of livestock (§150.6(a)(3)).

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