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PP# 9E2266 and 9E2269. 2,6-Dichloro-4-Nitroaniline and O-Phenylphenol on kivi fruit. Evaluation of analytical method and residue data.

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IR-4, Associate Coordinator G. M. Markle and National Director Dr. R. H. Kypelian, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of California, requests that permanent tolerances of 20 ppm be established for residues of orthophenylphenol (OPP) and 2,6-dichloro-4-nitroaniline (DCNA) in or on the r.a.c. kivi fruit.

Temporary tolerances of these compounds on kivi fruit have been established (PP# 9C2255 and 9C2256, review of E. Sager, 10/1/79).

Tolerances for residues of the fungicides ortho-phenylphenol and sodium ortho-phenylphenate are established on various r.a.c.s (post-harvest application) at levels of 5-125 ppm, including a tolerance of 20 ppm in or on peaches, plums and carrots (40 CFR §180.129).

Tolerances for residues of the fungicide 2,6-dichloro-4-nitroaniline are established at levels of 0.25-20 ppm, including a tolerance of 20 ppm in or on apricots, nectarines, peaches, and sweet cherries from pre- and post-harvest applications (40 CFR §180.200).

Conclusions

1. [REDACTED] an inert ingredient in the formulation Kivi Lustr 277, is not cleared for this use.
- 2a. The chlorine wash step should either be fully clarified or omitted from the proposed label.
- 2b. The labeling should be revised to make it clear that the recommended rate of 1 gal per 8-10,000 lbs fruit refers to Kivi Lustr concentrate, not to the dilute solution.
- 2c. The label should include a warning against draining the effluent from treatments into sewage systems.
3. The nature of the residue in plants is adequately understood.
- 4a. Adequate analytical methodology is available to enforce the proposed tolerances.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

4b. Residue data were determined by alternate GLC methods. Control values and recovery data for each compound should be submitted for kivi fruit using these GLC methods. Recovery data should reflect fruit treated with both compounds at several dose levels.

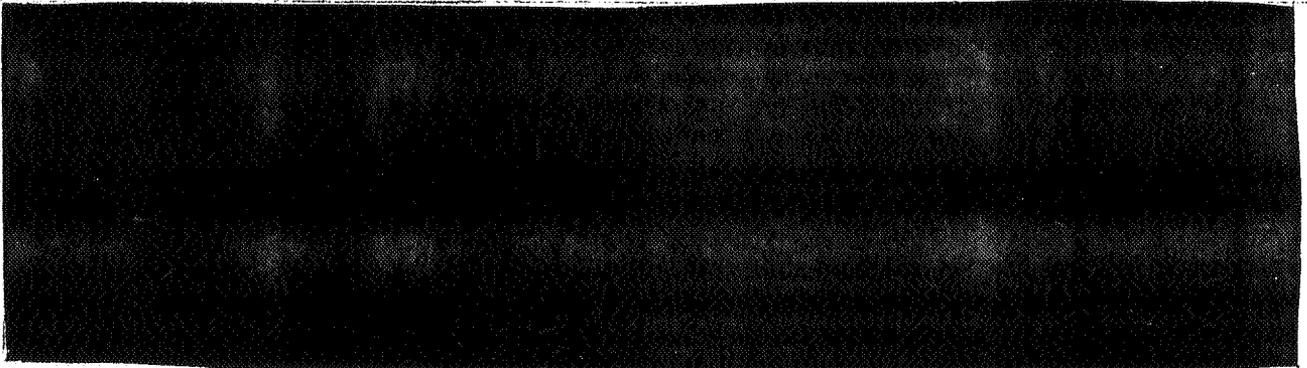
5. Residues of DCMA and OPP are unlikely to exceed the proposed tolerances.

Recommendations

We recommend against establishment of the proposed tolerances at this time for the reasons cited in Conclusions 1, 2a, 2b, 2c and 4b.

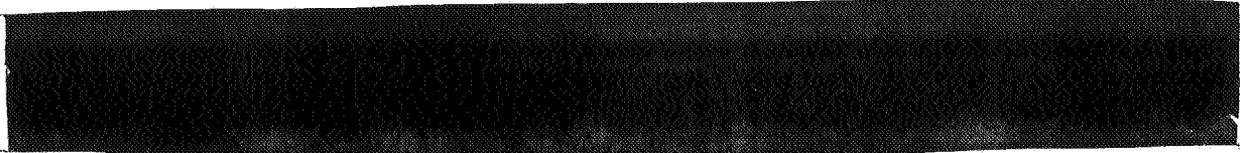
Detailed Considerations

Manufacture and Formulation



We do not expect residue problems from these small amounts of impurities.

[redacted] is incorporated into Kiwi Lustr 277 with Fungicide, a fruit wax containing 2% a.i. OPP. One of the inert ingredients in Kiwi Lustr 277, [redacted] is not formally cleared in 40 CFR §180.1001, but TOX has declared that its presence is of no concern. [redacted] is a [redacted]. Our concern is only that formal clearance is required. All other inerts are cleared under 40 CFR §180.1001.



MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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DCHA is formulated as Botran 75W, a wettable powder containing 75% DCHA. All inert ingredients are cleared under 40 CFR §160.1001.

Proposed Use

One gallon of Kivi Lustr 277 concentrate with fungicide (0.16 lb a.i.) is to be diluted with 9 gals soft water, and 104g Botran 75W added (0.17 lb a.i.). The resulting mixture will give 2000 ppm each OPP and DCHA, and will treat 8-10,000 lbs of clean Kivi fruit. Apply enough wax (using suitable wax applicator) to wet the fruit, and allow them to damp dry before storage.

The proposed label recommends using a chlorine wash step before treatment. According to the PM (E. Jacoby, telecon to E. Zager 10-1-79), reference to this wash was to be deleted for the purposes of the temporary tolerances. If petitioner wishes to include a chlorine wash for the permanent tolerance, we will require details of the formulation and possibly a tolerance proposal for the chlorine source. Otherwise, any reference to this chlorine wash step should be removed from the label.

Additionally, the proposed label states that one gallon of diluted wax is used to treat 8-10,000 lbs of fruit, whereas according to Dr. Kaplan (telecon to E. Zager, 10/1/79), one gallon of concentrate (10 gal. dilute) is used to treat that quantity of fruit.

A revised Section B should be submitted either clarifying or omitting the chlorine wash step, and reflecting the proper rate of application.

Nature of the Residue

No metabolism studies have been submitted with these petitions.

The proposed use will result in residues of OPP and DCHA being trapped in the wax emulsion on the inedible skin of the fruit. We expect very little residue to be found in the edible central core, seeds or outer flesh of the kivi fruit.

Ortho-phenylphenol and its sodium salt have been considered to be the residue of concern for those r.a.e.s on which tolerances have been established. No permanent tolerance petitions for OPP have been reviewed since 1961.

For 2,6-dichloro-4-nitrobenzene, the parent compound has been considered the residue of concern in setting previous tolerances. Residues from preharvest use dissipate mainly by volatilization. We expect little loss of residues from this post-harvest application, since the product is incorporated into a fruit wax.

The available metabolism data are rather limited, although both compounds have been in use for many years.

For the current post-harvest application to kiwi fruit, we consider the metabolism of both OPP and DCHA to be adequately defined.

Analytical Method

OPP: The analytical method used to obtain residue data submitted in this petition involves steam distillation followed by several extractions with n-hexane under basic and acidic conditions. The final extract is quantitated by GC using a flame ionization detector and comparison with standard solutions. The established enforcement method is a colorimetric procedure. (PAM II, Method I, OPP).

Recovery data are not submitted for this GC method. We will require control values and recovery data for the GC method used to obtain residue data. Alternatively, residue data may be obtained by the accepted colorimetric procedure, including control values and recovery data.

An accepted enforcement method is available. Petitioner should submit recovery data and control values for kiwi fruit regardless of which analytical method is chosen.

DCHA: The analytical method used to obtain the residue data submitted involves iso-octane extraction and quantitation by gas chromatography using electron capture detector and comparison with standards of similar concentration. No recovery data are submitted.

We will require control values and recovery data for petitioners' GC method. Alternatively, residue data may be obtained by the accepted colorimetric procedure (PAM II, DCHA, Method I). Control values and recovery data using the colorimetric procedure will be required.

As with OPP, an accepted enforcement method is available. Petitioner should submit recovery data and control values for kiwi fruit, regardless of which method is chosen.

A "standard yield test" is reported as giving 90% recovery of DCHA and 73% recovery of OPP. We have no indication of dose levels for this data, and are uncertain what a "standard yield test" represents.

Additionally, there are no data on recoveries of each compound in the presence of the other. We will require recovery data for sample fruit fortified with both compounds, as well as conventional recovery data and control values for each compound individually.

Residue Data

Kiwi fruits were spray treated at 1000, 1500 and 2000 ppm DCHA and 1200 and 2000 ppm OPP in the wax. For the treatment using both compounds in the wax at the 2000 ppm rate, residue levels at 0-day after treatment were 5.5 and 6.0 ppm DCHA and 7.1 and 9.1 ppm OPP. The fruit treated with only wax gave residues of 0.15 and 0.2 ppm DCHA but were not analyzed for OPP. Untreated fruit gave 0 ppm DCHA but were not analyzed for OPP.

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Residue levels after treatment with 1000 ppm DCHA and 1200 ppm OPP were 1.2 ppm DCHA and 1.4 ppm OPP. Treatment with 2000 ppm DCHA and 1200 ppm OPP gave residues of 3.0-3.2 ppm DCHA and 2.3 ppm OPP.

Although the residue data are quite limited, the maximum theoretical residue levels are 20 ppm (0.16 lb a.i./8000 lb fruit) each for OPP and DCHA. Therefore, we conclude that residues from the proposed use of DCHA and OPP on kiwi fruit are not likely to exceed the proposed 20 ppm tolerance.

Meat, Milk, Poultry and Eggs

No feed items are involved with this r.a.c. and no residues should occur in poultry, eggs, milk, meat, fat or meat by-products. We classify the proposed use of OPP and DCHA under 40 CFR 180.6(a)(3).

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TS-769:RCB:L.BRADLEY:adb:177484:RM810:CM/2:11/21/79
cc: KEE, TOX, CHM (3)
EDI:RJH, 11/16/79, JOCUMINGS, 11/19/79

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