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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 20-AUG-1999

SUBJECT: PP# 6E04683. Chlorfenapyr (i.e. Alert/Pirate®) in/on Imported Citrus. Amendments of 6/21/99, 7/20/99, & 8/9/99. Revised Sections B & F. Barcodes D223893, D226878, D257074, D257884, & D258558. Chemical 129093. Case 287432. Submissions S501617, S563946, S565559, & S566570.

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American Cyanamid Company has petitioned for permanent tolerances for residues of the insecticide/miticide chlorfenapyr [4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] as follows:

Imported Citrus	0.50 ppm
Citrus Oil	35 ppm
Milk	0.01 ppm
Milk Fat	0.15 ppm
Meat	0.01 ppm
Meat Byproducts (including fat)	0.10 ppm

Time-limited tolerances (in conjunction with a Section 18 registration on cotton) have been established for: cottonseed (0.5 ppm); Cotton gin byproducts (2.0 ppm); Fat* (0.10 ppm); mbyp* (0.3 ppm); Meat* (0.01 ppm); Milk (0.01 ppm); Milk fat (0.15 ppm) [40 CFR §180.513(b); expires 1/31/01].

*of beef, goat, swine, horse and sheep

The current amendment addresses deficiencies identified in HED's previous review (Memo, G. Kramer 10/29/96; D226878).

Executive Summary of Chemistry Deficiencies

- Revision of analytical method for plants.
- Additional residue data.
- Revised Section F.

RECOMMENDATIONS

HED continues to recommend against the proposed tolerances for chlorfenapyr on imported citrus, meat, and milk for the reasons outlined in Conclusions 1-4, below. A human-health risk assessment was prepared previously as a separate document in conjunction with the petition for tolerances on domestic citrus (PP#6F4623).

CONCLUSIONS

1. The proposed GC enforcement method (M 2284) for citrus has undergone a successful PMV (Memo, G. Kramer 2/29/96).. However, the petitioner should submit a revised version of this method as specified in the aforementioned Memo.
 2. There are no available orange residue data which reflect the worst-case residue scenario (multiple ultra low-volume applications). An additional eight orange residue trials are required from Brazil. All major citrus growing regions of Brazil should be represented and all trials should include a side-by-side comparison of ultra low-volume (5-50 l/ha) and high-volume (to drip) applications.
 3. In accordance with the Draft Guidance on Import Tolerances (8/98), 3 lemon trials are required- two in Argentina and one from Brazil. However, as the use in Brazil reflects the worst-case residue scenario (multiple ultra low-volume applications), all three trials should be performed in this country. All major citrus growing regions of Brazil should be represented and all trials should include a side-by-side comparison of ultra low-volume (5-50 l/ha) and high-volume (to drip) applications.
 4. Based on the maximum dietary burden associated with citrus commodities, the appropriate tolerances for chlorfenapyr are (Memo, G. Kramer et. Al. 2/12/98; D221320):
- | | | |
|---|----|----------|
| Milkfat (reflecting 0.01 ppm in whole milk) | -- | 0.15 ppm |
| Fat* | -- | 0.10 ppm |
| Meat* | -- | 0.01 ppm |

Meat By-Products*

--

0.05 ppm

*of cattle, goats, horses, hogs and sheep

A revised Section F, containing the aforementioned tolerances, is required.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 1b (from Memo, G. Kramer 10/29/96)

1b. Chlorfenapyr is formulated as Citrex and Sunfire 2SC, soluble-concentrates containing 24% a.i. Labels from Brazil and Argentina were submitted. The petitioner should submit CSFs or a list of the inert ingredients so that CBTS can determine whether the latter compounds in these formulations pose a residue concern.

Petitioner's Response: Submission of a CSF for Alert 2SC (a U.S. formulation which is identical to Sunfire and Citrex) and revised labels for Sunfire 2SC (Argentina) and Citrex (Brazil). The Sunfire 2SC label has been modified to specify a maximum of one application per year and PHIs of 35 days for tangerines and 70 days for oranges and lemons. The Citrex label has not been modified.

HED's Conclusion: HED has determined that the inert compounds in these formulations are not on List 1 or 2 and thus do not pose a residue concern. The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusion 1c (from Memo, G. Kramer 10/29/96)

1c. CBTS notes that major sources of imported citrus fruit exist outside of the countries for which labels were provided (i.e., Mexico, Chile, Spain, Israel and the Bahamas). The petitioner should inform the Agency whether they plan to register chlorfenapyr for use on citrus fruit in any countries other than Brazil and Argentina. Proposed labels from such countries will be required.

Petitioner's Response: Registration is not planned for Mexico, Chile, Spain, Israel and the Bahamas. Chlorfenapyr is registered for citrus in countries which are not major sources of imported citrus fruit (i.e., Turkey, Korea, and Zimbabwe).

HED's Conclusion: The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusion 5 (from Memo, G. Kramer 10/29/96)

5. The proposed GC enforcement method (M 2284) has undergone a successful PMV (Memo, G. Kramer 2/29/96; CBTS# 16746). However, the petitioner should submit a revised version of this method as specified in the aforementioned Memo.

Petitioner's Response: None.

HED's Conclusion: The requested information has **not** been provided. This deficiency remains outstanding.

Deficiency - Conclusion 8b & 8c (from Memo, G. Kramer 10/29/96)

8b. The trials conducted in Argentina are not useful for tolerance setting purposes because the application rate was $<1X$ in 4 out of 5 trials, the PHIs used (83-105 days) were significantly greater than that specified on the label (35 days), and mandarins are not a representative commodity of the citrus crop group. Thus, only 2 acceptable trials (orange) have been submitted. In order to set a tolerance on the citrus crop group, data are required for oranges, lemons and grapefruit. CBTS thus requests that the petitioner perform at least 3 lemon, 3 grapefruit, and an additional 3 orange residue trials. These trials should all be conducted in Brazil as Brazil is a much more significant source of citrus products than is Argentina and, based on the label directions, higher residues would be expected from Brazil. All major citrus growing regions of Brazil should be represented and some trials should include a side-by-side comparison of low-volume (5-50 l/ha) and high-volume (to drip) applications.

8c. The above conclusions are based on the assumption that only a single application of chlorfenapyr is permitted per season. Only trials employing the maximum number of permitted applications will be judged to be acceptable. Thus, if more than one application per season is permitted, then the two Brazilian orange trials will need to be repeated. Until the chlorfenapyr labels are modified to specify a maximum number of applications per season, CBTS will be unable to make a determination on the adequacy of residue trials submitted in support of this petition.

Petitioner's Response: Residue data from U.S. trials have been submitted in conjunction with PP# 6F04623.

HED's Conclusion: Subsequent to HED's evaluation of the Magnitude of the Residue data for this petition, Draft Guidance on Import Tolerances was issued (8/98). Based on this guidance, the need for additional residue data has been reevaluated. U.S. residue can be substituted for up to one half of the required foreign trials. **Oranges:** As approximately 16% of oranges (fresh + juice) are imported from Brazil, 12 trials are required from this country (Draft Guidance on Import Tolerances, 8/98). As the orange trials are part of a crop group tolerance request, this number can be reduced to eight trials. Imports from Argentina are insignificant. A total of six acceptable orange residue trials have been conducted in the U.S. (Memo, G. Kramer 8/6/96). However, as the application rate in these trials was $0.3X$ the foreign rate, HED will not accept these trials for the purposes of setting a tolerance on imported citrus. Also, the Brazilian label allows multiple and ultra low-volume applications but the submitted foreign residue trials included only a single, high-

volume application. Thus, there are no data available which reflect the worst-case residue scenario (multiple ultra low-volume applications). An additional eight orange residue trials are required from Brazil. All major citrus growing regions of Brazil should be represented and all trials should include a side-by-side comparison of ultra low-volume (5-50 l/ha) and high-volume (to drip) applications. Grapefruit: Neither Brazil nor Argentina are significant sources of grapefruit (fresh + juice) (Foreign Trade of the U.S., Economic Research Service, USDA). A minimum of three foreign trials are required for an import tolerance (Draft Guidance on Import Tolerances, 8/98). However, as total of four acceptable grapefruit trials have been conducted in the U.S. (Memo, G. Kramer 8/6/96) and Brazil and Argentina are not sources for this commodity, HED will not require additional grapefruit residue data. Lemons: Brazil and Argentina are significant sources of imported lemon juice with Brazil accounting for 13-20% of imports in 1997-98 and Argentina, 71-72% (Foreign Trade of the U.S., Economic Research Service, USDA). Based on U.S. consumption data (B. Schneider, personal communication), imports from Brazil and Argentina accounted for 18% of lemon juice consumed. In accordance with the Draft Guidance on Import Tolerances (8/98), 3 lemon trials are required- two in Argentina and one from Brazil. However, as the use in Brazil reflects the worst-case residue scenario (multiple ultra low-volume applications), all three trials should be performed in this country. All major citrus growing regions of Brazil should be represented and all trials should include a side-by-side comparison of ultra low-volume (5-50 l/ha) and high-volume (to drip) applications.

Deficiency - Conclusion 8e (from Memo, G. Kramer 10/29/96)

8e. Major sources of imported citrus fruit exist outside of the countries for which residue data were provided (i.e., Mexico, Chile, Spain, Israel and the Bahamas). The petitioner should inform the Agency whether they plan to register chlorfenapyr for use on citrus fruit in any countries other than Brazil and Argentina. Residue data from such countries may be required.

Petitioner's Response: Registration is not planned for Mexico, Chile, Spain, Israel and the Bahamas. Chlorfenapyr is registered for citrus in countries which are not major sources of imported citrus fruit (i.e., Turkey, Korea, and Zimbabwe).

HED's Conclusion: The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusion 9 (from Memo, G. Kramer 10/29/96)

9. Chlorfenapyr residues have been shown to concentrate in orange oil (70X) and dried citrus pulp (2.4X) (Memo, G. Kramer 8/6/96). As citrus oil could be imported into the US, a tolerance is required for this commodity. However, until adequate residue data are available, CBTS is unable to comment on the appropriate

level for this tolerance.

Petitioner's Response: Submission of a revised Section F with a proposed tolerance for citrus oil of 35 ppm.

HED's Conclusion: Based on the available residue and processing data, a time-limited tolerance of 35 ppm on citrus oil is appropriate for this petition. This deficiency is now resolved.

Deficiency - Conclusion 10 (from Memo, G. Kramer 10/29/96)

10. CBTS has previously concluded that, based on an estimated tolerance of 1.0 ppm for dried citrus pulp, the ruminant dietary burden is 0.22 ppm. Based on this estimated dietary burden, meat and milk tolerances are required for this petition to cover potential residues in imported meat and dairy products. The meat and milk tolerances proposed in PP# 5F04456 must thus be established prior to our recommending in favor of the proposed citrus tolerances.

Petitioner's Response: Submission of a revised Section F with proposed tolerances for meat & milk:

Milk..	0.01 ppm
Milk Fat..	0.15 ppm
Meat..	0.01 ppm
Meat Byproducts(including fat).. . .	0.10 ppm

HED's Conclusion: Based on the maximum dietary burden associated with citrus commodities, the appropriate tolerances for chlorfenapyr are (Memo, G. Kramer et. al. 2/12/98; D221320):

Milkfat (reflection 0.01 ppm in whole milk)	--	0.15 ppm
Fat*	--	0.10 ppm
Meat*	--	0.01 ppm
Meat By-Products*	--	0.05 ppm

*of cattle, goats, horses, hogs and sheep

A revised Section F, containing the aforementioned tolerances, is required.

cc: PP#6E04683, G. Kramer (RAB1), S.F.
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