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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

**MEMORANDUM**

DATE: 05-MAY-2000

SUBJECT: PP# 6E04683. Chlorfenapyr (i.e. Alert/Pirate®) in/on Imported Citrus. **Review of Amendment Dated 3/30/00 Submitted in Response to HED's Memo of 8/20/99.** Revised Section F and Enforcement Method and Additional Residue Data. MRID#s 450851-01 to -03. Barcode D265082. Chemical 129093. Case 287432. Submission S578413.

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TO: Marion Johnson/Ann Sibold, PM Team 3
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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:

Citrus . . . . . 0.50 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); and Milk fat (0.15 ppm) [40 CFR §180.513(b); expires 1/31/01].

*of beef, goat, hogs, horse and sheep

The current amendment addresses deficiencies identified in HED's previous review (Memo, G. Kramer 8/20/99; D223893).

## Executive Summary of Chemistry Deficiencies

- Revised Section B.
- Brazilian residue data for lemons.

## RECOMMENDATIONS

**Provided Section F is revised as specified in Conclusion 3, HED concludes there are no residue chemistry data requirements that would preclude the establishment of time-limited tolerances for chlorfenapyr in/on imported citrus. A human-health risk assessment was prepared previously.**

## CONCLUSIONS

1. Method RLA 12545.01 (MRID# 45085103) is adequate for enforcement of the proposed tolerances.

2. HED has reconsidered the adequacy of the previously submitted U.S. and Brazilian residue data in light of the clarification of the Brazilian use pattern. The application scenarios utilized in the Brazilian orange trials and the U.S. orange and lemon trials are similar to that employed in Brazil. The number and location of the **orange** trials are thus adequate. However, as no **lemon** residue data from Brazil are available, HED still requires that 3 lemon trials be conducted in this country. The available residue data support a time-limited tolerance of 0.50 ppm on citrus. A final decision on the appropriate tolerance level will be withheld pending submission of the additional residue data.

3. A revised Section F proposing the following *time-limited* tolerances for residues of the insecticide/miticide chlorfenapyr [4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] should be submitted:

| | |
|---|---|
| Fruit, citrus, group | 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 |

*of beef, goat, swine, horse and sheep

## DETAILED CONSIDERATIONS

### Deficiency - Conclusion 1 (from Memo, G. Kramer 8/20/99; D223893)

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.

**Petitioner's Response:** The following comments were made by the Analytical Chemistry Branch (ACB) in the PMV results:

1) The extraction volume should be corrected for the percent moisture of the matrix.

2) SPE cleanup- A statement should be made as to whether the column is allowed to go dry between additions of eluant.

A statement has been added to the revised method (RLA 12545.01, MRID# 45085103) which specifies that the SPE column not be allowed to run dry unless instructed to do so. It is unnecessary that the extraction volume be corrected for the percent moisture of the matrix. This correction would only change the volume by 6% and the recoveries were acceptable without the correction.

**HED's Conclusion:** ACB has reconsidered whether the extraction volume should be corrected for the percent moisture of the matrix. This correction is highly desirable, but not mandatory (F. Griffith, Personal Communication 4/26/00). Method RLA 12545.01 (MRID# 45085103) is adequate for enforcement of the proposed tolerances. **This deficiency is now resolved.**

### Deficiency - Conclusion 2 & 3 (from Memo, G. Kramer 8/20/99; D223893)

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.

**Petitioner's Response:** Clarification of the Brazilian directions for use- The Citrex label recommends an application rate based on

the volume of solution needed to treat a given number of trees. Based on the maximum concentration of chlorfenapyr (15 g ai/100 l water), the maximum number of trees per ha (300) and the maximum volume per tree (15 l), the maximum application rate is 0.60 lb ai/a. In addition, ultra low-volume applications are not used on citrus, this portion of the label refers to cotton. Each application provides control for 90 days and consecutive applications of insecticides with the same chemistry is not recommended. Thus, the typical worst-case scenario is a single high-volume application at 0.60 lb ai/a. The submitted U.S. and Brazilian residue data support this use pattern. In addition, more U.S. and foreign residue data were submitted with this amendment (MRID#s 450851-02 & -03).

**HED's Conclusion:** HED has examined the newly submitted residue data. As the application scenario used in any of the trials did not match that employed in Brazil, these data can not be used to support the proposed tolerance. However, HED has reconsidered the adequacy of the previously submitted U.S. and Brazilian residue data in light of the clarification of the Brazilian use pattern. The application scenarios utilized in the Brazilian orange trials and the U.S. orange and lemon trials are similar to that employed in Brazil. The number and location of the **orange** trials are thus adequate. However, as no **lemon** residue data from Brazil are available, HED still requires that 3 lemon trials be conducted in this country. The available residue data support a time-limited tolerance of 0.50 ppm on citrus. A final decision on the appropriate tolerance level will be withheld pending submission of the additional residue data. **This deficiency is partially resolved.**

**Deficiency - Conclusion 4 (from Memo, G. Kramer 8/20/99; D223893)**

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.

**Petitioner's Response:** Submission of a revised Section F proposing the following permanent tolerance:

Citrus . . . . . 0.50 ppm

Meat and milk tolerances are not necessary as imported citrus is not fed to livestock in the U.S.

**HED's Conclusion:** These tolerances are necessary as imported meat and milk products could contain residues as a result of the use of chlorfenapyr in other countries. A revised Section F proposing the following *time-limited* tolerances for residues of the insecticide/miticide chlorfenapyr [4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] should be submitted:

| | |
|---|---|
| Fruit, citrus, group. . . . . | 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 |

*of beef, goat, hogs, horse and sheep

**This deficiency remains outstanding.**

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