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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE February 12, 1998

MEMORANDUM

SUBJECT: CHLORFENAPYR- Report of the Risk Assessment Review Committee

FROM: Jess Rowland, Executive Secretary *Jess Rowland 2/11/98*
Risk Assessment Review Committee
Health Effects Division (7509C)

THROUGH: Karen Whitby, Chairman *KW*
Risk Assessment Review Committee
Health Effects Division (7509C)

TO: Melba Morrow, Branch Senior Scientist
Registration Action Branch 1
Health Effects Division (7509C)

PC Code: 129093

The Health Effects Division (HED) Risk Assessment Review Committee (RARC) conducted an in-depth review of the risk assessment document that evaluated the Registrant's petitions for permanent tolerances for residues of Chlorfenapyr in/on citrus (PP# 6F04623). The Committee's conclusions are attached.

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The Health Effects Division (HED) Risk Assessment Review Committee (RARC) conducted an in-depth review of the risk assessment document that evaluated the Registrant's petitions for permanent tolerances for residues of Chlorfenapyr in/on citrus (PP # 6F04623). A temporary tolerance has been established in/on cottonseed at 0.5 ppm (PP#5F04456). Temporary tolerances of 0.5 ppm have also been proposed for oranges and lemons (PP#5G04507). In conjunction with PP#5F04456, HED has determined that meat and milk tolerances are required to support the proposed use on citrus. The Committee's recommendations/conclusions are presented below:

- | <u>Page #</u> | <u>Recommendations</u> |
|---------------|--|
| 22 | <i>2.a. Paragraph 1, Line 11:</i> Delete the following in parenthesis (resulting in a total factor of 1000). The FQPA does not say the total factor is 1000. |
| 25 | <i>iii. Uncertainty Factor:</i> Do not refer to the 10 x factor as Modifying Factor. Replace as follows: "The Committee determined that the additional 10 x factor for enhanced sensitivity to infants and children (as required by FQPA) should be retained for lack of understanding.....in the developing young". |
| 27 | <i>c. Classification of Carcinogenic Potential:</i> Include the method of quantification. The CPRC determined that the method for quantification of risk to Chlorfenapyr should be based on the Reference Dose (RfD) approach. Quantification of risk using the RfD approach requires comparison of the chronic exposure to Chlorfenapyr residues, to the RfD, a quantitative measure of hazard likely to result from long-term exposure to Chlorfenapyr. The CPRC has determined that quantitative risk assessment for Chlorfenapyr using this methodology will adequately account for all chronic toxicity effects, including carcinogenicity, likely to result from exposure to Chlorfenapyr. |
| 28 | <i>d. Developmental classification:</i> Delete this section. |
| 30 | <i>Table 1:</i> In the third columns, for MOE's state: Minimum MOE required: |
| 42 | <i>Paragraph-2--last sentence-</i> Need to provide the reasons for using the application of Chlorfenapyr on cotton for surface water risk assessments. |
| 47 | <i>Paragraph-2:</i> Delete the following sentence "The Hazard I.D.....exposure". If there is not concern for inhalation exposure (from exposure data), then just state that the lack of potential occupational/residential inhalation exposure and the low acute inhalation toxicity (Tox.Cat.III) does not warrant a risk assessment via this route. |
| 59 | <i>Paragraph-3:</i> Delete this paragraph and replace with the same rationale as provided above. |
| 50 | <i>Paragraph-5:</i> Need to expand on the rationale for the conclusions reached " risk to workers will be minimal for these exposure scenarios".. |

General: Replace the term Modifying Factor with FQPA factor