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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DP BARCODE: D241963, D240108, D243556, D245813, D246459, D246093, D246661

CHEMICAL: Chlorfenapyr (PIRATE™ , ALERT™, AC 303,630 or CL 303,630)
PC Code: 129093

SUBJECT: Chlorfenapyr (PIRATE™ , ALERT™, AC 303,630) Insecticide-Miticide Environmental Fate and Ecological Effects Assessment and Characterization for a Section 3 for Use on Cotton

TO: Ann Sibold, PM Team Reviewer, RD
Susan Lewis, Product Manager 03, RD

FROM: Ed Odenkirchen, Ph.D., Chemist, ERB1, EFED
Alex T. Clem, Ph.D., Chemist, ERB3, EFED
Bill Evans, Biologist, EHB, EFED

THRU: Arnet Jones, Chief, ERB1, EFED
Daniel Rieder, Chief, ERB3, EFED
Tom Bailey, Chief, EHB, EFED

Introduction

Attached, with agreed upon principal focus on avian risk, is the EFED environmental fate and ecological effects assessment and risk characterization for the insecticide-miticide chlorfenapyr on cotton. EFED will provide summaries/conclusions of formal guideline environmental fate studies and important supporting or supplemental studies under separate and subsequent cover. Other supplemental studies, and updates, corrections or additions to the registrant's previous studies are incorporated and appropriately cited in our assessment and risk characterization, but may not appear as separate entries elsewhere or in previous reviews.

Risk Conclusions

The results of this risk assessment for uses of chlorfenapyr on cotton consistent with proposed labeling demonstrate the following:

- Terrestrial wildlife dietary residues associated with all label application rates present a substantial risk to avian species for both acute lethal effects and impairment of reproduction. The exposure opportunities for acute lethal effects occur for many days

following treatment. Exposure levels (based on measured residues in avian food items) for all application rates exceed the threshold for reproductive effects for all of the species selected to represent avian receptors in cotton fields by factors up to 60. These exposures extend for multiple weeks after initial chlorfenapyr application. Even when assumed exposures are reduced to levels below those expected for minimal avian use of cotton fields, risks to reproduction are still indicated. Timing of chlorfenapyr applications to the cotton crop coincide with the reproductive window of most of the more than 50 species of birds that the registrant reports to be associated with cotton fields. Many of the bird species included in this risk assessment as representatives of the species found in cotton fields are presently exhibiting downward population trends in cotton-growing states. Further impairment of reproduction and increased individual mortality would further stress populations of these species in one or more cotton-growing states.

- The results of the aquatic organism risk assessment, using water column estimates of chlorfenapyr concentrations, suggest that chlorfenapyr applications to cotton present acute risks to freshwater fish and invertebrates in United States Department of Agriculture (USDA) agricultural census regions 4 (AL, GA, KY, NC, SC, TN, VA), 6 (AR, LA, MO, MS, OK), and 7 (TX). Chronic risks to freshwater fish and invertebrates are not evident from the results of the risk assessment. However, the confidence of this "no chronic risk" finding is low because of the limited chronic testing data for freshwater animals (note: additional chronic freshwater data in the form of sediment toxicity and a valid fish full life-cycle study are requested), the persistence of the chemical in aquatic environments, and a concern for potential accumulation in invertebrates.

- For estuarine and marine organisms, this risk assessment predicts acute and chronic toxicological risks. Chronic risk quotients for marine invertebrates exceed the level of concern by over an order of magnitude.

- Acute risks to sediment-dwelling invertebrates are not evident for freshwater systems receiving cotton field runoff. Levels of concern for these organisms are not exceeded by modeled sediment residues. However, because the persistence of chlorfenapyr suggests that longer term exposures are possible, the lack of a chronic freshwater sediment toxicity test represents an important data gap.

- Preliminary Risk Quotients for sediment-dwelling marine amphipods suggest that acute high risk, restricted use, and endangered species LOCs are exceeded. The high acute risk level of concern is exceeded by factors ranging from 4.7 to 10.8 for aerial and ground applications in Regions 4, 6,7, and 11.

These risk assessment conclusions are consistent with the findings of previous risk assessments for chlorfenapyr use on cotton. However, the confidence of the present avian risk findings is greater than in previous assessments because of the following factors:

- use of measured residue values in seeds, insects, and forage

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- assessment of risks to specific species known to occur in cotton fields, including species-specific considerations of life history information, dietary preferences, and metabolic requirements

- incorporation of information specific to the use of cotton fields as a food resource

This risk assessment represents a refinement of the EFED Risk Quotient approach in that it models terrestrial exposures for specific species known to occur in cotton fields on the basis of measured pesticide residues in dietary items and presents those levels of exposure over time. For aquatic organisms, refinements include utilization of exposure modeling techniques that consider variability between use sites within the cotton-growing regions of the United States (e.g. MUSCRAT). In addition, because of previous concerns for potential toxic risks to sediment-dwelling organisms, this risk assessment assesses risks to these organisms in water bodies receiving pesticide runoff from cotton fields

Environmental Fate and Persistence Conclusions

Chlorfenapyr's persistence is typified by a laboratory aerobic soil metabolism half-life of 1.4 years [standard upper 90% confidence limit based on five soils (MRID 44452621), excluding a previous, anomalous, 3.8 year value (MRID 42770243) and its observed, comparable field dissipation "half-life" of 1.3 years [standard upper 90% confidence limit based on five small-plot cotton studies in four cotton states (MRID 43492850)].

Chlorfenapyr was essentially stable to laboratory hydrolysis and anaerobic soil metabolism. Under aerobic aquatic conditions, the upper 90% confidence limit for half-life in two German sediment compartments was approximately 1.1 years; in the aqueous compartment, roughly 0.8 year.

Because of the persistence of parent and relatively short study durations, only small amounts of structurally similar metabolites or degradates (AC 303267, AC 303268, AC 312094, AC 322118, AC 322250, AC 325195, some of which exhibit ecotoxicity) were identified in soil in field or lab studies. Concentrations of these, when detected, were typically a few percent each or less of the applied chlorfenapyr. Only AC 312094, the *des*-bromo derivative, sometimes approached or slightly exceeded 10% of total applied. *Relative* concentrations of AC 312094 in the radiolabeled North Carolina study were in the maximum range of 10-16%; relative AC 325195 concentrations in the same study averaged less than 10%. Soil photolysis, with AC 325195 as a characteristic degradate, therefore plays a small role in chlorfenapyr's degradation (laboratory soil photolysis half-life of approximately 0.4 year). In general, transformation products appear to approximate or exceed the persistence of parent. Laboratory photolysis in water produced a major photoisomer AC 357806 (50-70% of total residues); this isomer was never reported as a product in any other lab or field study. Neither mineralization (carbon dioxide evolution) nor volatilization were significant in laboratory studies, and were not monitored in the field.

Because of chlorfenapyr's persistence, uniform, annual use in a given area would result in significant build-up in environmental compartments. Commensurate with their half-lives, all chemicals undergoing first-order degradation come within 3% of their maximum value after a period of time corresponding to five half-lives; after ten half-lives the approach is within 0.1% of the maximum value.

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Assuming chlorfenapyr's previously cited 1.4 years aerobic soil metabolism half-life (approximately the same as the 1.3 years for field dissipation), the calculated asymptotic first-order value after multiple years of use approaches 2.5 times the annual application amount (1.5 leftover from previous applications plus 1.0 from the current year application). Using the average aerobic soil half-life of 0.96 year, rather than the upper 90% limit of 1.4 years, the asymptotic value becomes 2.0 times the annual amount (1.0 residual plus 1.0 current). Although not defensible scientifically or in a regulatory sense, if the even less conservative average field dissipation half-life of 0.75 year is considered, the asymptotic value is 1.7 times the amount applied annually (0.7 residual plus 1.0 current).

Two supplemental multiyear soil accumulation-dissipation studies lasting approximately 4 1/4 years (five seasons, each with three uniform applications) in small bare soil plots in Italy and the United Kingdom demonstrate the trend towards increasing concentrations over time (MRID 44453624 plus updated summary data and analysis, barcode D246661, no MRID assigned). In both countries, measured first year soil concentrations were approximately 0.1 ppm. Near the end of the studies the maximum concentrations were 0.3 ppm and 0.4 ppm in Italy and England, respectively. Because of severe limitations in study protocol and pronounced oscillations in the data, these numbers are of marginal value, but clearly show significant residual concentrations and the relative trend towards asymptotic increases in annual peak concentrations. Within experimental limits based on *actual* recovery from field soil (approximately 55% when corrected for 84-88% lab procedural recovery), and inclusive of at least some off-plot transport, build-up is realized. Commensurate with half-life, the results approximate theoretical expectations.

Chlorfenapyr has a relatively high soil to water partitioning ratio, typified by an average laboratory batch equilibrium K_{oc} (adsorption coefficient normalized for organic carbon) of about 12,000 mL/g. On this basis little vertical movement in soil would be expected. Confirming this expectation, leaching was not significant in field dissipation studies.

The registrant has provided residue data for chlrofenapyr in avian food items, including weed seeds, weed seed heads, insect adults and larvae. These data are comparable to predicted residue levels developed in earlier EFED risk assessments. These measured residues in avian food items were an important component of exposure estimation models used in the current EFED risk assessment.

Outstanding Data Requirements

Within the context of our risk assessment and characterization, EFED considers the environmental fate and effects data requirements satisfied except for selected items summarized in Appendix B of the risk assessment. Examples of some important outstanding requirements include:

Analytical methods validations: The registrant should submit soil and water methods of analysis which are suitable for detecting about one-tenth of the trace concentrations with observed ecological effects for EPA laboratory validation. Using this criterion, present procedures for water need to be improved by a factor of five or ten for sensitive species. Additionally, depending on marine, chronic sediment toxicity testing (see below), improvements for sediment/soil may be necessary.

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Spray drift data [Droplet Size Spectrum (201-1) and Drift Field Evaluation (202-1)]: The registrant is given the option to satisfy requirements in the near future through the Spray Drift Task Force according to PR Notice 90-3.

Modified avian reproduction test data: In an April 1998 oral presentation before the Agency, the registrant presented preliminary results of an avian reproduction toxicity test that utilized a modified exposure regime. This study used variable dietary concentrations to simulate the decreasing concentrations of chlorfenapyr observed for weed seed head, cotton plant, and insect residues. The oral presentation of the resultant data suggested that some information from the study may be applicable to assessing the risks of field residues of chlorfenapyr to avian reproduction. However, written presentation of these data has not been made available to EFED at this time.

Chronic sediment toxicity testing: At the time EPA requested sediment toxicity testing, the only protocol which had been fully developed was a 10-day acute sediment toxicity test. However, at this time EPA has developed a guideline protocol for a 28-day chronic sediment testing. Although specific criteria for requiring a chronic toxicity test have yet to be published, one criterion will include the persistence of the compound. Because chlorfenapyr has been characterized as an extremely persistent compound, EFED will require a chronic sediment toxicity test with freshwater invertebrates. Furthermore, because of the risk assessment indicates the potential for acute toxic effects in marine/estuarine sediment-dwelling invertebrates, a chronic toxicity test with these organisms is also required.

Other toxicity testing: Invalid acute and/or chronic aquatic tests which need to be repeated at this time are listed below.

GUIDELINE #	STUDY	REASON
72-1	LC_{50} Rainbow trout	**Optional**. To be repeated at the discretion of the registrant (see study description) . Invalid test due to failure to measure test concentration on photolytic degradate (Cl 357,806). The purported LC_{50} of 2.6 ppb implies that this compound is more toxic than the parent.
72-3	EC_{50} Oyster Shell Deposition Study	Invalid study due to inadequate shell growth in controls (MRID 434928-17) Since an embryo-larvae study was not conducted, this study must be repeated.
72-4	Sheepshead minnow Early life (marine/estuarine)	Invalid study due to low Dissolved Oxygen level throughout the experiment. The required fish full life-cyle study listed directly below would satisfy this requirement.
72-5	Sheephead minnow Life-cycle Study	The EEC is greater than 0.1 of the NOEL in the fish early life and invertebrate Life-Cycle study. The studies submitted under MRID 443648-02 and MRID 443648-03 need to be repeated due to control contamination.

It should be noted that limited tests were performed on two different degradates of AC 303,630. The major degradate CL 312,094 (the *des*-bromo derivative of AC 303,630), was tested only on bluegill sunfish. The photolytic degradate in water, CL 357,806, however, was tested on rainbow trout and *Daphnia magna*. The purpose of testing these two degradates on different species was not revealed

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in any of the material submitted. The registrant should explain this selectivity before the EFED considers additional testing on degradates.

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