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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: 06/24/2005

MEMORANDUM

SUBJECT: Tau-fluvalinate: Response to Registrant's Error Comments on EPA's Preliminary Risk Assessment for the Reregistration Eligibility Decision for Tau-fluvalinate. PC Code: 109302, Case #: 2295, DP Barcode: D318467

Regulatory Action: Phase 2 Reregistration Action
Risk Assessment Type: Single Chemical Aggregate

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AND

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TO: Kylie Rothwell; Chemical Review Manager
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In this document, HED is responding to the registrant's comments (submitted May 31, 2005) on the Phase I risk assessment for Tau-fluvalinate. The registrant's specific comments on the risk assessment are listed below, together with HED's response.

1. Page 13, Table 4.1a Acute Toxicity Profile – Tau Fluvalinate. The study cited to support 870.1100, Acute oral – rat is erroneously given as MRID 00094103. As explained in my letter to you dated April 11, 2005, the test substance used in this study is *not* technical tau-fluvalinate and this is not a valid study for the RED. The appropriate studies to support this requirement are MRID 46521901 and 46521902. This error is also reflected in comments under *Toxicology*, 1st paragraph on page 1, which classified this active as Toxicity Category II by the oral route of exposure.

   HED Response: HED does not consider the registrant's comment to be strictly error correction and will not respond to it in the Phase 2 revised risk assessment. However, the registrant raises an important issue regarding the acute oral toxicity of tau-fluvalinate, and HED is working to resolve this issue as quickly as possible.

   The identity of the test material in the acute oral toxicity study cited in our preliminary risk assessment (MRID 00094103) is in question. The results of this study indicated an acute oral toxicity classification of category II. The registrant claims that the test material in this study was not technical tau-fluvalinate and that the appropriate studies for determination of tau-fluvalinate's acute oral toxicity are the studies with MRID numbers 46521901 and 46521902. These studies are currently under review in OPP's Registration Division. The registrant implies that these studies demonstrate higher acute oral LD_{50}s for tau-fluvalinate and, therefore, support a higher (i.e., less toxic) acute oral toxicity classification. HED is concerned, however, that these studies may not be the most appropriate estimate of tau-fluvalinate's acute oral toxicity. Our concern is based on the results of two other studies, the rat prenatal developmental toxicity study (MRID 44743301) and the special 7-day repeated dose neurotoxicity screen (MRID 43433901), in which the doses tolerated by the test animals were more consistent with the lower LD_{50} seen in original acute oral toxicity study (MRID 00094103).

   Once review of the studies cited by the registrant is completed, HED will determine whether adequate data are available to assess tau-fluvalinate's acute oral toxicity or whether additional data are needed to fulfill this test guideline (870.1100).

2. Page 34, top of the page. The Agency has concluded: "The nature of the residue in honey is adequately understood. Current tolerances are expressed in terms of *tau*-fluvalinate, *per se*. The current tolerance expression is adequate. Adequate data are available to reassess the established tolerance for honey at the same level. However, based on the available data, the established tolerance may be reduced from 0.05 ppm to 0.02 ppm". Wellmark does not agree that available data will support this reduction. Based on honey samples assayed by Wellmark, residues range from non detectable to ~0.03 ppm. When considering the above findings by the Agency and the analytical limit of quantification for tau-fluvalinate in honey at 0.01ppm, we fail to understand why the Agency would consider changing the current tolerance.

HED Response: Again, HED does not consider the registrant's comment to be strictly error correction, and we will not be able to address it in the Phase 2 revised risk assessment. However, HED recommends that the registrant submit the company's honey assay results for EPA's consideration, along with available Apistan usage information for the assayed samples. The residue data previously submitted to the Agency indicate that residues from legal use of Apistan strips in beehives should not excced 0.02 ppm. Only one honey sample had detectable residues, and residues in this sample were present at 0.015 ppm, well below the current tolerance of 0.05 ppm

3. A requirement for an occupational exposure inhalation study with a fogger application under greenhouse conditions was noted three times in this assessment: pages 42, 2nd bullet point; 47, part 9.2, 2nd paragraph and 47, part 10.3. The required study guideline was identified as OPPTS 875.100, airborne residue dissipation in the assessment but was corrected to OPPTS 875.2500 in your correspondence to me. Although this is an inhalation study, details to help us understand exactly what is needed to satisfy this requirement are not clear. In part 9.2, the Agency states: "With the exception of the greenhouse uses, post-application inhalation exposure to *tau*-fluvalinate is expected to be minimal. Potential post-application inhalation exposure in greenhouses is mitigated by the ventilation requirements of the Worker Protection Standard (WPS). For these reasons, a post-application inhalation exposure assessment was not deemed necessary for *tau*-fluvalinate". If we are to consider exposure during application, fogger applications are made by starting the equipment and immediately vacating the greenhouse when the application begins so exposure during the application is extremely limited to none. It appears that OPPTS 875.2500 would be measuring exposure during application. Is the Agency requesting data to support re-entry? How would the WPS ventilation requirement affect the design of a re-entry study?

   HED's Response: HED's preliminary risk assessment and supporting Occupational and Residential Exposure (ORE) Assessment incorrectly identified the required study as an airborne residue dissipation study (OPPTS Guideline 875.100). HED intended to require an inhalation post-application exposure study (OPPTS Guideline 875.2500) and has revised the ORE chapter and risk assessment to reflect the correct study/guideline number. EPA is requesting the occupational inhalation post-application exposure study as confirmatory data to support the WPS re-entry interval (REI). The study should be conducted in exact accordance with the use directions on the product label, including ventilation criteria. The study should be designed in such a way that it will be of sufficient duration for the pesticidal residue levels to dissipate to zero (0) or to the level of detection in two separate, distinct parts of the treated area. The registrant should submit a study protocol developed under the aforementioned guidelines for Agency review.

4. Page 7, 3d paragraph, line 8: remove period after the word "identified".

   HED's Response: The period after the word "identified" has been replaced with a comma.

5. Page 9, 2d paragraph, line 9: 3-PBaldehyde should be 3-PB Aldehyde.

   HED's Response: "3-PBaldehyde" has been changed to "3-PB Aldehyde."

6. Page 12, 4th paragraph, line 2: strains in "*Salmonella strains*" should not be italicized.

   HED's Response: "*Salmonella strains*" has been changed to "*Salmonella* strains."

7. Page 19, 2d paragraph, line 16: add comma, should read "...males and females, clinical..."

   HED's Response: A comma has been inserted, as suggested.

8. The correct nomenclature for the half resolved isomer of fluvalinate is t*au*-fluvalinate. The text is not consistent in the use of this term. Examples of fluvalinate only can be found on pages 21, 22, 23, 27, 28, 33, 34, 52, 53 and 54. This is complicated in a few of these examples by the use of "Fluvalinate" in published references for the half-resolved isomer before this term was adopted.

   HED's Response: We have revised the risk assessment to use the "*tau*-fluvalinate" nomenclature consistently, except where the document refers specifically to the racemic form, fluvalinate, or in the titles of published references.

9. Page 26, part 4.4, line 10: ...."team believes that the these".....remove"the".

   HED's Response: The extraneous "the" has been removed.

10. Page 41, Table 9.1a: Application Method should be "low pressure handwand" for outdoor perimeter treatments and greenhouses. The EPA-approved label specifically calls for low pressure.

    HED's Response: HED does not consider this to be an error. We deliberately assessed mixer/loader/applicator exposures for non-agricultural areas, greenhouses, outdoor ornamentals and ant mounds conservatively to cover the broadest range of possible exposures. Using conservative assumptions, including high-pressure handwand equipment for outdoor perimeter treatments and greenhouses, estimated inhalation exposures were all well below our level of concern, even at the baseline level of protection (i.e., no respirator). In addition, HED notes that the terms "high pressure" and "low pressure" are relative and may not be understood to mean the same thing by all applicators. For this reason, and because estimated exposures based on the assumed use of high-pressure handwands were low, HED does not feel that a revision is warranted

11. Page 51, 4th study review (21-day dermal toxicity). This study was conducted on rabbit but the last line refers to the ratas the test species.

HED's Response: The test species has been corrected to read "rabbits."

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