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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

May 7, 2003

Memorandum

Subject: Review of acute oral (MRID 45773201) and acute dermal (MRID 45773202)) studies withN EU1161 (EPA File Symbol 67702-5). (S631088)

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Action Requested

Review of an acute oral toxicity study (MRID 45737201) and an acute dermal toxicity study 9MRID 45773202) of the end-use product NEU1161 (EPA File Symbol 67702-5) containing canola oil (PC 011332) and pyrethrins (PC 069001).

Recommendations and Conclusions

The two acute studies (MRIDs 45773201 and -02) are adequate to classify the end-use product NEU1161 (EPA File Symbol 67702-5) into Toxicity Category IV for acute oral and dermal toxicity.

Background

This review is limited to the two acute studies mentioned above, and their results were not cmopared with the current product label to verify that label language is appropriate to the toxicity categories indicated. It should also be noted that the acute oral and dermal studies do not represent a full acute toxicity battery for the NEU1161 product, and waiver rationales or studies for acute inhalation, primary eye and skin irritation, and dermal sensitization studies are not included in this review.

Study Reviews.

An acceptable acute oral toxicity study (MRID 45737201))was conducted with 5000 mg/kg NEU1161 (EPA File Symbol 67702-5) administered by gavage to groups of 3 male or 3 female Wistar strain rats. No mortality was observed, and clinical signs were observed on days 1 and 2 post dosing. Females exhibited hunched posutre for up to 2 after treatment, while male rats had hunched posture, chromodacryorrhea and piloerection on the first day after dosing. There were no effects noted in the study report on body weight gain or at necropsy. The study protocol was consistent with Health Effects Test Guideline OPPTS 870.1100, and followed the OECD test guideline 423 for the Acute Toxic Class method. The results indicated that NEU1161 should be classified into Toxicity Category IV for acute oral toxicity.

An acceptable acute dermal toxicity study (MRID 45737202) was conducted with 5000 mg/kg NEU1161 (EPA File Symbol 67702-5) administered topically to groups of 5 male and 5 female Wistar strain rats. Clinical signs included tremors in one male 3-7 days after treatment, chromodacryorrhea among all animals from days 1 through 12 post-dosing, and hunched posture from days 3 to 6 of the 14-day observation period following dosing. Yellow staining of the treated skin was reported during the observation period, and no effects were noted on body weight or at necropsy. The study protocol was consistent with OPPTS Health Effects Test Guideline 870.1200 and OECD test guideline 402. The results of this study place the end-use product NEU1161 into Toxicity Category IV for acute dermal toxicity.