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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Talstar Cover Memo: Statement of Scientific Findings and a Discussion of Registration Potential

TO: Tim Gardner, Product Manager 17
Registration Division

FROM: John Tice, Biologist
Science Integration Staff

THRU: Amy Rispin, Director
Science Integration Staff

Introduction

Talstar (FMC 54800, Brigade, Capture) is a synthetic pyrethroid insecticide. This registration standard only applies to the greenhouse use on ornamental trees and shrubs. Other proposed uses not considered in this standard are apples and cotton. Currently the proposed technical product is also serving as the manufacturing use product. There are two proposed enduse products, a 10 WP and a 2 EC (25% active) formulation.

Toxicology

- Acute toxic symptoms in laboratory animals are tremors, clonic convulsions and ataxia. These are classic symptoms for pyrethroids. However, Talstar appears to be more acutely toxic to rats than the other pyrethroids.

- Currently, the signal word "WARNING" defines the oral hazard potential for the technical product. Some doubt exists as to whether or not this is the appropriate signal word. Recently, the cis-trans isomer ratio in the technical has been changed. Studies conducted on recently formulated end use products indicate that the new technical may be more toxic on the basis of testing EPs. In light of these studies, the technical product is classified in toxicity category I for acute hazards and the signal word, "Danger" should be used until the registrant demonstrates otherwise. For a complete discussion see the Toxicology chapter pp. 1-2.

- The acute toxicological properties for the active and end-use products are understood. Acute dermal data indicate that the technical product and 2 EC formulated product should be classified in Toxicity category III and IV respectively. Primary eye irritation data placed the technical and 2 EC formulated product in toxicity category IV and III respectively. For sensitization the technical material and WP formulation did not cause a reaction in guinea pigs. However, the 2EC formulation did elicit a reaction. On this basis HED recommends a dermal sensitization label statement for the EC formulation end use product.

- A delayed neurotoxicity study has been submitted, although the compound is not an organophosphate, and "classic" delayed neurotoxicity (involving phosphorylation of neurotoxic target esterase) is not anticipated. The protocol involved hens receiving two oral doses of 5000 mg/kg 21 days apart. While no histological evidence was found for delayed neurotoxicity, no nerve tissues were examined from the hens which died a few days after the second dose, and as a result the study is currently classified as supplementary. A noteworthy finding in this study was that the hens exhibited a more severe response after the second dose than the first.

- An acceptable 90-day rat study identified a NOEL at 50 ppm while tremors and other symptoms were observed at 100 and 200 ppm.

- A 13-week dog study did not identify a definite NOEL. Additional information is requested regarding this study and possibly an additional study will be necessary.

- An acceptable rabbit study showed no evidence of fetotoxicity or teratogenic effects. A rat study, although not determining a maternal maximum tolerated dose, did identify a fetotoxic LEL of 2.0 mg/kg/day and a NOEL of 1 mg/kg/day. The observed effects were hydroureter without hydronephrosis. Additional information has been requested regarding fetotoxic effects.

- Currently there are no chronic toxicity studies available. The data tables identify the studies needed for full registration. In the interim, Toxicology Branch sees no evidence in the acute and sub-acute tests available that would preclude a conditional registration until the chronic studies are available.

- One mutagenicity assay has been evaluated and showed no positive effects. Other studies are still under review.

Summary of Toxicology Data Gaps

Of the basic data needed for a conditional registration for the greenhouse use, there are four studies for which we have requested additional information. If specific information is not available the studies may need to be redone. These include the acute oral (rat), the 90 day non-rodent feeding study, the 21 day dermal (rabbit) and the rat teratology study. If the registrant chooses to answer our questions of existing data, 6 months should be given as the maximum allowable time to do so. If the registrant chooses to rerun the studies, the standard time should be allowed. When the results of their studies are finalized, the results will be compared to exposures.

- Conclusions: Primary effects from exposure are neurological disturbances with symptoms ranging from tremors to clonic convulsions and death depending on exposure. It has been observed that there is a cumulative toxicity potential in that previous or continued exposure results in increased sensitivity. It is also important to note that the symptoms appear to be reversible and thus far no remarkable histopathologic changes have been observed even in animals which have recovered after showing severe effects.

Ecological Effects

- Talstar is characterized as slightly toxic via the dietary route to waterfowl and upland game birds.

- Talstar is characterized as very highly toxic to fish and invertebrates.

- It is also very highly toxic to bees.

- Although the science chapter has identified hazards to wildlife, they are associated with use pattern not being considered in this standard. Hazards to wildlife are not anticipated with this use pattern. However, as other uses are included in the future, specific hazard to non-target organisms must be evaluated and dealt with.

Environmental Exposure

- Talstar degrades aerobically in soil with a half-life of 97-250 days.

- Talstar is considered to be immobile in non-sandy soil with organic matter content greater than 2.3% and low mobility in sandy soils with organic matter 1.3%

Product Chemistry/Residue Chemistry

- Residue chemistry data is not necessary for the use pattern under consideration because it is not considered a food use.

- Most of the product chemistry data are available. Studies where additional clarification is necessary are identified in the science chapter.

Conclusion Regarding Registration

HED has examined what is considered as minimum data necessary for a conditional registration and found no information that would contraindicate a conditional registration.

cc: John Melone
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MSS