United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-00-015 September 2000

Phostebupirim Facts

EPA has assessed the dietary risk of phostebupirim [also known as tebupirimphos] and prepared a Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for this organophosphate (OP) pesticide. Phostebupirim fits into its own "risk cup"-- its individual risks are within acceptable levels.

Because phostebupirim was initially registered after 1984, it is not subject to reregistration. However, the Agency has reassessed the occupational risks from phostebupirim use on corn and is recommending label modifications at this time. In addition, the registrant is generating additional data which will be used to refine the occupational risk assessment.

EPA's next step under the Food Quality Protection Act (FQPA) is to complete a cumulative risk assessment and risk management decision encompassing all the OP pesticides, which share a common mechanism of toxicity. The interim decision on phostebupirim cannot be considered final until this cumulative assessment is complete. Further risk mitigation may be required at that time.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Older OPs need decisions about their eligibility for reregistration under FIFRA. OPs with residue limits in food (tolerances) and other non-occupational exposures also must be reassessed to make sure they meet the new FQPA safety standard.

The OP Pilot Public Participation Process

The organophosphates are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review under the Food Quality Protection Act.

EPA is encouraging the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency is releasing for review and comment its preliminary and revised scientific risk assessments for individual OPs. (Please contact the OP Docket, telephone 703-305-5805, or see EPA's web site, www.epa.gov/pesticides/op.)

EPA is exchanging information with stakeholders and the public about the OPs, their uses, and risks through Technical Briefings, stakeholder meetings, and other fora. USDA is coordinating input from growers and other OP pesticide users.

Based on current information from interested stakeholders and the public, EPA is making risk management decisions for individual OP pesticides, and will make final decisions through a cumulative OP assessment.

The phostebupirim interim decision was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk

assessments and risk management decisions. EPA worked with affected parties to reach the decisions presented in this interim decision document, which concludes the OP pilot process for phostebupirim.

Uses

- Phostebupirim is an organophosphate insecticide registered for use on field corn, seed corn, sweet corn, and popcorn for the control of corn rootworms, wireworms, cutworms, seed corn maggots, seedcorn beetles and white grubs.

- Annual domestic use is estimated to be approximately 270,000 pounds of active ingredient per year.

Formulations

- In addition to the technical, there are three end-use formulations: two 2.1% granular formulations (clay-based and cellulose-based) and a 4.67% granular formulation for use only with a SmartBox® applicator system.

Health Effects

- Phostebupirim can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.

Risks

- Dietary risks from food and drinking water are not of concern.

- Handler risks under the current risk assessment are of concern without appropriate PPE and engineering controls during the loading and application processes.

- EPA did not quantitatively assess the risks to post application workers. Since phostebupirim is mainly incorporated into the soil at planting, minimal post application exposure is anticipated.

Risk Mitigation

- The Agency is recommending label changes which are intended to mitigate potential occupational risk from occupational exposure to phostebupirim products. The changes include a dust/mist respirator for loaders of the 2.1% granular clay-based formulation, emergency PPE requirements, establishment of an REI if re-entry activities disturb the soil surface, and the addition of a double notification statement.

- The registrant will need to submit an exposure or dust comparison study to confirm that the cellulose-based Biodac formulation is sufficiently less dusty than the clay-based formulation. This study should be submitted to EPA by April 1, 2001.

- The registrant is conducting a 21-day rat dermal toxicity study to be submitted by April 1, 2001, which will be used to refine both the short and intermediate-term occupational risk assessments. The Agency believes that this data will provide a more appropriate endpoint for assessing dermal exposure risks than the studies currently available, and will demonstrate that occupational risks are adequately mitigated with the measures presently recommended. The Agency plans to recommend any appropriate additional occupational risk mitigation measures before the conditional registration is set to expire on July 5, 2001, should such measures remain necessary following refinement of the risk assessment.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The Interim Tolerance Reassessment Evaluation and Risk Management Decision for phostebupirim is therefore issued in final (see www.epa.gov/pesticides/op), without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket.

- To effect the label amendments as quickly as possible, time frames for making the changes required by the Interim Tolerance Reassessment Evaluation and Risk Management Decision document are shorter than those in a usual RED. The Agency is asking that all labels be amended to include the above mitigation and submitted to the Agency within 90 days after issuance of this document.

- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for phostebupirim and may require further risk mitigation measures.