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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

14-OCT-1998

MEMORANDUM

SUBJECT: ***DIFLUFENZOPYR*** - Report of the FQPA Safety Factor Committee.

FROM: Brenda Tarplee, Executive Secretary
FQPA Safety Factor Committee
Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
FQPA Safety Factor Committee
Health Effects Division (7509C)

TO: Melba Morrow, Branch Senior Scientist
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Health Effects Division (7509C)

PC Code: 005107

The Health Effects Division (HED) FQPA Safety Factor Committee met on October 5, 1998 to evaluate the hazard and exposure data for diflufenzopyr and recommended that the FQPA safety factor (as required by Food Quality Protection Act of August 3, 1996) be removed in assessing the risk posed by this chemical.

I. HAZARD ASSESSMENT

1. Determination of Susceptibility

The Hazard Identification Assessment Review Committee (HIARC) determined that the available Agency Guideline studies indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to diflufenzopyr. In the prenatal developmental toxicity studies in rats and rabbits, and the two-generation reproduction study in rats, toxicity to the offspring, when observed, occurred at equivalent or higher doses than in the parental animals (*Memorandum:* W. Dykstra to O. Odiott dated October 6, 1998).

2. Adequacy of Toxicity Database

There are **no data gaps** for the assessment of the effects of diflufenzopyr following *in utero* and/or postnatal exposure. Based on the toxicity profile, a developmental neurotoxicity study in rats is not required.

II. EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION

1. Dietary (Food) Exposure Considerations

Diflufenzopyr is a new herbicide for use on corn. Permanent tolerances are proposed for the combined residues of diflufenzopyr and those metabolites convertible to the M1 metabolite in/on corn grain, forage, and stover. Transfer of residues to meat and milk is not expected. There are currently no Codex MRLs established for this new herbicide.

Residues of diflufenzopyr are systemic. Field trial data indicate that detectable residues are found at the Limit of Quantitation (LOQ = 0.02ppm) in corn grain. Since this is a new herbicide, no monitoring data or percent crop treated information is available.

The HED Dietary Exposure Evaluation Model (DEEM) is used to assess the risk from acute and chronic dietary exposure to diflufenzopyr residues in food. These analyses will be unrefined (Tier 1), assuming that all corn contains residues of diflufenzopyr at the level of tolerance, which exaggerates the dietary exposure estimates.

2. Dietary (Drinking Water) Exposure Considerations

The environmental fate data indicate that the major routes of dissipation for diflufenzopyr are microbially-mediated metabolism and hydrolysis; and that movement of diflufenzopyr into surface water through runoff may occur under limited conditions when sufficient rainfall occurs close to the time of application.

Since this is a new herbicide, there are no monitoring data available to assess exposure to diflufenzopyr in drinking water. Therefore, the GENEEC model and available environmental fate data for diflufenzopyr, were used to calculate Tier 1 Estimated

Environmental Concentrations (EECs) for diflufenzopyr in surface water and the SCI-GROW II model was used for ground water. These Tier I surface and ground water EEC assessments, conducted on the parent compound only, result in estimates considered to be upper-bound concentrations.

Based upon the proposed uses, the fate characteristics, and the model predictions, EFED does not expect diflufenzopyr to reach drinking water resources in significant quantities.

3. Residential Exposure Considerations

At the time of this FQPA Safety Factor Committee meeting, there were no registered residential uses for diflufenzopyr.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

1. FQPA Safety Factor Recommendation

The Committee recommended that the **10x factor** for the protection of infants and children (as required by FQPA) be **removed.**

2. Rationale for Removal of the FQPA Safety Factor

The Committee recommended that the10-fold safety factor be removed since: 1) the toxicology data base is complete; 2) there is no indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data; 3) unrefined (Tier 1) dietary exposure estimates are protective since they will exaggerate dietary exposure estimates; 4) modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and 5) there are currently no registered residential uses for diflufenzopyr.

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FQPA Safety Factor Committee Meeting
05OCT1998
Chemical: Diflufenzopyr

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