

In assessing the potential for additional sensitivity of infants and children to residues of flufenpyr-ethyl, EPA considers the completeness of the human health effects data, particularly those studies that evaluate toxicity to reproduction and to fetal and developing young experimental animals. These studies include developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to prenatal and postnatal effects from exposure to the pesticide, information on the reproductive capability of both male and female mating animals and data on systemic toxicity.

3. *Developmental toxicity.* Flufenpyr-ethyl is not a developmental toxicant in either rats or rabbits. In the developmental toxicity study conducted with rats, the NOAEL for both maternal and developmental toxicity was found to be 1,000 mg/kg/day, the highest dose tested.

Flufenpyr technical was tested in two developmental toxicity studies in rabbits because of unexpected maternal mortality. In the first study maternal mortality occurred at the two highest doses tested. In surviving animals and their fetuses, there were no adverse effects. Based on these results, the maternal toxicity NOAEL was 100 mg/kg/day and the developmental toxicity NOAEL was 1,000 mg/kg/day. In the second study maternal mortality again occurred, but at all dose levels. Detailed examination of most these animals showed the cause of death to be test material aspiration into the lungs. There were no other adverse effects in the surviving dams or fetuses. The NOAEL for this study and the overall NOAEL for rabbits was found to be 300 mg/kg/day (maternal) and 1,000 mg/kg/day (developmental).

4. *Reproduction.* In the rat reproduction study, flufenpyr-ethyl technical was administered for 2-generations. Parental toxicity (kidney and liver effects) was observed at all dose levels, although the effects at the low dose were minimal. There were no effects at any dose on any reproductive parameter. Based on the results of this study, the NOAEL for parental toxicity was considered to be less than 200 ppm. The NOAEL for reproductive and neonatal toxicity was considered to be 20,000 ppm.

A second 1-generation reproduction study was performed to establish a clear

NOAEL for adult kidney lesions using the dose levels of 20, 50 and 100 ppm. The results of the study indicate that the NOAEL for histological changes in the kidneys for F<sub>1</sub> male rats was 100 ppm. No other treatment-related findings were noted at any dose level indicating 100 ppm as the NOAEL for treatment and reproductive effects evaluated in the study.

A mechanistic study was also conducted to investigate the reproducibility and reversibility of the kidney lesions observed in the initial 2-generation reproduction study. In the first study, the effects observed at 200 ppm in the F<sub>1</sub> males, basophilic tubules and interstitial inflammation, were minimal but slightly increased in incidence and severity and a slight increase in interstitial fibrosis of the cortex was also observed. In this mechanistic study, using dose levels of 0 and 2,000 ppm, the NOAEL for histological changes in the kidneys of F<sub>0</sub> and F<sub>1</sub> male rats and reproductive effects was 2,000 ppm. The histological changes seen in the kidneys in the original study was not reproducible.

The toxicological data base for evaluating prenatal and postnatal toxicity for flufenpyr-ethyl is complete with respect to current data requirements. Valent concludes that there is no evidence that fetal, or developing young experimental animals are any more susceptible to the effects of flufenpyr-ethyl than adult animals. Therefore there is no need for an extra FQPA uncertainty factor to be further protective of infants and children.

5. *Acute exposure and risk.* There is no acute oral toxic endpoint available, so no risk analysis was performed.

6. *Chronic exposure and risk.* Using the conservative exposure assumptions described above, the percentage of the cPAD that will be utilized by dietary (food only) exposure to residues of flufenpyr-ethyl ranges from 0.16% for non-nursing infants, to 0.03% for nursing infants. Adding the worse case potential incremental exposure to infants and children from flufenpyr-ethyl in drinking water (0.00000267 mg/kg/day) increases the aggregate, chronic dietary exposure by 0.0053%. The addition of the exposure attributable to drinking water increases the occupancy of the cPAD for Non-Nursing Infants from 0.164 to 0.169 percent. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. It can be concluded that there is a reasonable certainty that no harm will result to

infants and children from aggregate, chronic exposure to flufenpyr-ethyl residues.

7. *Safety determination summary.* Aggregate chronic dietary exposure to various sub-populations of children and adults demonstrate acceptable risk. Chronic dietary exposures to flufenpyr-ethyl occupy considerably less than 100% of the cPAD. Acute dietary risk to children from flufenpyr-ethyl should not be of concern. Further, flufenpyr-ethyl has only agricultural uses and no other uses, such as indoor pest control, homeowner or turf, that could lead to unique, enhanced exposures to vulnerable sub-groups of the population. It can be concluded that there is a reasonable certainty that no harm will result to the U.S. population or to any sub-group of the U.S. population, including infants and children, from aggregate chronic exposures to flufenpyr-ethyl residues resulting from proposed uses. There is no evidence that acute oral exposures to flufenpyr ethyl causes appreciable toxicity, and no exposure and risk analyses are appropriate.

#### F. International Tolerances

There are no existing U.S. tolerances or Codex Maximum Residue Limits for flufenpyr-ethyl.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2003-0031; FRL-7315-1]

### Certain New Chemicals; Receipt and Status Information

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from May 26, 2003 to June 2, 2003, consists of the PMNs and