Toxicology Branch/HED Review

JUL 24 1985

Caswell No(s).: 323EE
To: Henry M. Jacoby (PM 21)
Registration No(s).: 4G3075
Pesticide Petition No(s).: 443075
Chemical(s): CGA-64250; Tilt®; 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1-H-1,2,4-triazole
Requested Action(s): EUP and temporary tolerances for the combined residues of the parent and its metabolites in or on: kidney and liver of cattle, goats, hogs, horses, sheep and poultry(0.1 ppm); rice (0.1 ppm); grain of wheat, barley and rye (0.1 ppm);straw of wheat, barley and rye (1.5 ppm); and straw of rice (3.0 ppm).
Recommendation: The Toxicology Branch recommends that the EUP and temporary tolerances for CGA-64250 not be granted at this time. The technical material is oncogenic in the liver of male mice. The results of a 2-year dietary toxicity/oncogenicity study with this compound in rats are considered inconclusive, pending submission of additional data from the sponsor; therefore, establishment of temporary tolerances is not currently toxicologically supportable.
Data considered in setting the ADI: N/A
Attached(?): ADI printout: NO; TOX "one-liner": NO; DER: NO
Existing regulatory actions against registration: N/A
RPAR status: N/A
New Data: None
Data gaps: CGA-64250: Additional data required, 2-yr rat feeding study; 2-generation rat study was repeated. Triazole alanine(plant metabolite): Additional data required for 3 month rat and dog feeding studies and 2-generation reproduction study in rats.
Comments: When the requested data pertaining to the 2-year rat study are provided, oncogenicity will be evaluated by the Tox Branch ad hoc committee.
Date: 7/17/85 Section Head: 21/8/85 Branch Chief: 46/10/18/85