October 31, 1978

Subject: Petition No.8E-2092, for a tolerance of 0.5 ppm of Chlorpyrifos to be established in/on Tomatoes. Caswell No. 219 AA

From: Chan S-L, Ph.D.
TOX/HED

To: Mr. Sanders F.T. F.M.
Petitioner: Dow Chem. Co.
Midland, Michigan

The petitioner, Dow Chem. U.S.A. proposed a tolerance of 0.5 ppm of Chlorpyridos and metabolites to be established in/on tomatoes grown in Mexico and Israel. The Chlorpyridos residues arise as a result of the foliar application to tomato plants at the rate of 0.86 lb A.I. per acre. In Mexico, the application may be by ground or aerial spray for up to 3X and to within 1 day before harvest. In Israel, up to 4 ground sprays may be applied at 10-day intervals and to within 14 days before harvest of tomatoes intended for processing into juice or paste.

The formulation to be used is an emulsifiable concentrate, Lorsban 480E. The inert ingredients present are... both of these have been cleared for pre-harvest use.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

All toxicological have been fully evaluated by this reviewer previously (on 6H5147, 6F1777, 6F1830 and 6F1786 dated 6/7/77,1/17/78 and, 8/2/78)
A brief summary is given below:

(i) The Acute Oral LD 50 (rats) = 118-245 mg/kg
(ii) 180-Day Rat Feeding Study;
    RBC AChE NEL = 0.15 mg/kg/day
    Systemic NEL = 0.75 mg/kg/day
(iii) 90-Day Dog Feeding Study;
    RBC AcChE NEL = 0.03 mg/kg/day
    systemic NEL = 20 PPM.
(iv) 3-Generation rat Reproduction Study;
    reproduction effects = None to 1.0 mg/kg/day
(v) Acute Hen delayed Neurotoxicity Study;
    Neurotoxic potential: negative at 100/mg/kg
(vi) Metabolism of Chlorpyrifos in Rats.
    Metabolism sufficiently defined; main route; urinary, major metabolites, free and conjugated 3, 5, 6-trichloro-2-pyridinol.
(vii) 2-Year Rat Feeding Study;
   RBC AchE NEL = 0.1 mg/kg/day
   systemic NEL = 3.0 mg/kg/day
   Oncogenic potential = negative.

(viii) 2-Year Dog Feeding Study;
   RBC AchE NEL = 0.1 mg/kg/day
   systemic NEL = 3.0 mg/kg/day

(2) Data desirable but lacking:

(i) Teratology Study (already in progress)
(ii) Oncogenicity study in a 2nd species (also in progress).

(3) Action taken to obtain desirable data:
   Not applicable since initiation has already been made.

(4) Other Tolerances Granted: see computer printout attached.

(5) For ADI established and Residue contribution, see computer printout;
   ADI will not be exceeded.

(6) ADI established at 0.01 mg/kg/day
   MPI at 0.6 mg/person/day
   2-Year rat AchE NEL = 0.1 mg/kg/day
   Safety factor used = 10.

(7) Pending regulatory actions against registration- None

(8) Other considerations: None.

RD initial Reto Engler
10/21/78:lf

A. Smith of Chemistry Branch has determined (Nov/13/78) that the
proposed Chlorpyrifos level of 0.5 PPM in/on tomatoes will not be exceeded.
All other items evaluated by RCB do not affect TOX. conclusion on this
petition (8E-2092).