MEMORANDUM

SUBJECT: EPA ID 018301-2; Chlorpropham; Clarification of Toxicity Data Requirements for an IR-4 Minor Use on Spinach and Possibly Carrots.

Tox.Chem. No.: 510A
Project No.: 1-0938
Submission No.: S392141.

From: David G Anderson, PhD
        Section 3
        Toxicology Branch-1
        Health Effects Division (H7509C)

To: Lois Rossi/Karen Farmer
    FM-74
    Registration Division (H7508C)

Thru: Henry Spencer, PhD.
       Acting Section Head
       Section 3, Toxicology Branch-1
       Health Effects Division (H7509C)

Attachment:

A. CONCLUSIONS:

James Parochetti, Principal Weed Specialist of the US Department of Agriculture has requested clarification of the toxicity data required for Chlorpropham as an IR-4 Minor Use pesticide for use on spinach and possibly carrots for the United States except California. The assumption that spinach and/or carrots are minor use crops would appear to be in error (Randolph Perfetti meeting, 1991). For this IR-4 use on spinach and carrots, the additional toxicity data requirements on the technical grade of chlorpropham are listed in the memorandum from Penelope Fenner-Crisp, Director Health Effect Division, to Allan Abramson, Acting Director Special Review and Re-registration Division of 5/4/91 titled;

Re-registration Requirements for List A Chemicals and Data-Call-In Requirements for List B Chemicals.

The above memorandum listed (1) 82-1(a) 90-Day feeding-rat, (2) 82-1(b) 90-Day feeding-non-rat*, (3) 83-1(a) Chronic tox-rat, (3) 83-1(b) Chronic tox-non-rat, (4) 83-2(a) Oncogenicity-rat, (5) 83-2(b) Oncogenicity-mouse, (6) 84-2(a) Gene Mutation-ames, (7) 84-2(b) Struct. chrom. aberration.
Data Requirements for an IR-4 Minor Use for Chlorpropham/1-0938/S392141.

* Adequate chronic studies can be used to fulfill this requirement.

However, for re-registration of chlorpropham for other full food uses, additional toxicity data is required. The toxicity data requirements and data gaps for full food use and tobacco use are listed below.

The current data gaps for re-registration of chlorpropham for full food use are: (1) 81-8 Acute Neurotoxicity (mammal), (2) 82-2 21-Day dermal toxicity study, (3) 82-1(a) and 82-1(b) two subchronic studies one in the rodent and one in the non-rodent (this data requirement will be waived if the two chronic studies are acceptable), (4) 82-7 90-Day Neurotoxicity (mammal), (5) 83-1(a) and 83-1(b) two chronic studies one in the rodent and one in the non-rodent, (6) 83-2(a) and 83-2(b) two oncogenicity studies one in each of two species, (7) 84-2(b) and 84 two mutagenicity studies one for structural chromosomal aberrations and for other genotoxicity, (8) 85-1 and a metabolism study, and (9) 86-X Smoke inhalation studies.

The two new neurotoxicity studies numbers 1 and 4 in the above paragraph are required for all carbamates. If the label lists use on tobacco, a 86-X smoke inhalation study is required, however, the Agency should be consulted for guidance prior to initiation of the study.

B. ACTION REQUESTED:

Review the toxicity data requirements for Chlorpropham as an IR-4 Minor Use pesticide.

Data base for Chlorpropham & IR-4/A:\ALISTALL.FES/IR-4MINO.REF/ DANDERSON/4/3-8/91; Modified 6/19/91*.
21 FEB 1991

Mr. Walt Waldrop
Special Review, Re-registration Division
Office of Pesticides Programs, EPA
401 M Street, S. W.
Washington, D.C. 20460

Dear Walt:

The USDA is investigating the feasibility of conducting research to support the reregistration of the herbicide chlorpropham (CP) and possibly on carrots. To accomplish this, we plan to use the Pesticide Minor Use Program (IR-4) and the National Agricultural Pesticide Impact Assessment Program (NAPIAP).

To allow us to determine the feasibility of this effort, we need a listing of the specific studies that are required by the chlorpropham reregistration standard in each relevant category, i.e., product formulation, efficiency, adverse phytotoxicity, toxicology, residue chemistry and ecological. I am sure there are others, please list those as well.

We want to place our research emphasis on spinach grown in all geographical areas, with the exception of California. As currently practiced, spinach crops are either:

1. Planted in the spring for later warm season harvest;
2. Planted in the fall for later fall harvest;
3. Planted in the fall and over-winter for the next spring harvest.

We want to cover each of these situations in the reregistration attempt. The desired formulation of chlorpropham is an emulsifiable concentrate containing 3.0 lbs/gallon of active ingredient. For spring-planted spinach the herbicide would be applied at planting times, pre-emergence to weeds, at rates from 0.7 to 2.0 lbs active ingredient per acre on a broadcast basis. A lower rate would be for use on lighter, coarser textured soils or soil types; while the higher rate would apply to soils with organic matter. A range of broadleaf weeds and grasses would be controlled.
For fall-planted spinach, the application rates would be reduced to 0.5 to 1.0 lb. active ingredient per acre as a broadcast application. Again, the higher rate applies to soils of higher organic matter content, with all treatments applied preemergence to weeds. In the event that herbicide treatment is required during late fall so as to provide weed control during the winter, the spinach plants must not be actively growing and all existing weed growth must be removed prior to treatment.

Since, the reregistration of chlorpropham is of primary importance on spinach, we need your input as to the studies that are required to fill the "data gaps" for this crop.

If resources permit, we plan to extend our research to provide needed data to reregister chlorpropham for use on carrots. We do not include California as an area for use.

For carrots, chlorpropham would be applied as a 3.0 lb./gallon emulsifiable concentrate at rates from 4.0 to 6.0 lbs. active ingredient per acre broadcast. The application rates are designed to cover mineral and higher organic soils. All treatments would be applied preemergence to weeds at planting time.

To assess the feasibility of doing the carrot related research, we would appreciate receiving a listing of the studies that would be needed "over-and-above" those for spinach.

We have already contacted Ms. Lois Rossi and Ms. Karen Former about our need for EPA input but in a much broader context, and they have responded. You may want to correlate with them.

I will be meeting with regional representatives from the Agricultural Experiment Stations during the week of August 15-19 to discuss research efforts related to chlorpropham. It would be extremely helpful if we could have your analysis prior to that date. Should you need additional information on this matter, please call me at (202) 401-4866.

Best personal regards,

JAMES V. PAROCHETTI
Principal Weed Scientist

cc: Hogt Jamerson, EPA  FAX (703)557-7106