



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

MAR 31 1993

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Results of the HED Metabolism Committee Meeting Held on  
3/22/93: Chlorpropham Metabolism in Potatoes.

FROM: John Abbotts, Chemist *John Abbotts*  
Special Review Section II  
Chemistry Branch II - Reregistration Support  
Health Effects Division [H7509C]

THRU: Edward Zager, Chief *E Zager*  
Chemistry Branch II - Reregistration Support  
Health Effects Division [H7509C]

TO: HED Metabolism Committee  
Health Effects Division [H7509C]

A. Individuals in Attendance:

1. Metabolism Committee: (Signatures indicate concurrence  
unless otherwise stated):

Karl Baetcke

*Karl Baetcke*

Reto Engler

*Reto Engler*

Richard Loranger

*Richard Loranger*

Michael Metzger

*Michael Metzger*

Richard Schmitt

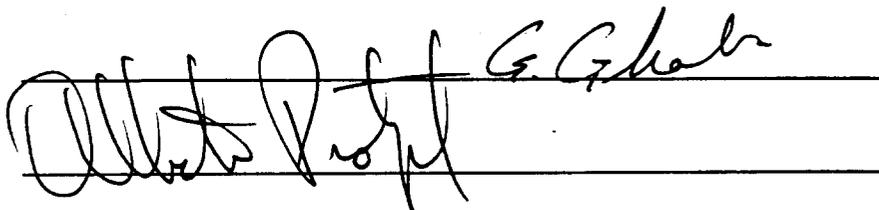
*Richard D Schmitt*



Recycled/Recyclable  
Printed with Soy/Canola Ink on paper that  
contains at least 50% recycled fiber

2. Metabolism Committee Members in Absentia: (Committee members who were unable to attend the discussion; signatures indicate concurrence with the overall conclusions of the Committee.)

George Ghali

A handwritten signature in dark ink, appearing to read 'G. Ghali', is written over a horizontal line.

Alberto Protzel

3. Scientists: (Non-committee members responsible for data presentation; signatures indicate technical accuracy of panel report.)

David Anderson

A handwritten signature in dark ink, appearing to read 'David Anderson', is written over a horizontal line.

John Abbotts

A handwritten signature in dark ink, appearing to read 'John Abbotts', is written over a horizontal line.

**B. Material Reviewed:**

The metabolism of chlorpropham, isopropyl 3-chlorocarbanilate, in potatoes treated post-harvest was discussed. Registrants have voluntarily canceled all uses except post-harvest treatment of potatoes.

Tolerances are established for residues of parent chlorpropham and its isopropyl-hydroxide metabolite on potatoes treated post-harvest, at 50 ppm (40 CFR 180.181). The nature of the residue on potatoes treated post-harvest is adequately understood. Parent chlorpropham represented 96% of the total radioactive residue (TRR). 3-chloroaniline and its glucose conjugate were identified, at a combined level of 0.58% TRR. Other metabolites identified represented no more than 1.25% TRR. The Guidance Document (12/87) required data on residues of 3-chloroaniline, identified as a probable mutagen.

Data have been submitted, but not yet reviewed, on unlabeled residues of chlorpropham and 3-chloroaniline on potatoes and potato processed commodities (MRID 42566801, CBRS No. 11008). Maximum residues on potato commodities were as follow:  
chlorpropham, 11.4 ppm on potatoes, 129 ppm on dried skins, 34.3 ppm on potato processed waste;  
3-chloroaniline, 398 ppb on potatoes, 4600 ppb on dried skins, 622 ppb on potato processed waste. These data indicate that both residues concentrate during processing in skins and potato waste; levels of both residues on other processed commodities were lower than those on potatoes.

The Guidance Document (12/87) specified that methods for data collection and tolerance enforcement, including methods for 3-chloroaniline, should include pre-hydrolysis and hydrolysis extraction steps in order to detect free and conjugated metabolites; and should be tested with regard to their efficiency in extracting bound residues, using radiolabeled samples from metabolism studies. The Update to the Residue Chemistry Chapter (10/16/91) reiterated these requirements. The method used to obtain the unlabeled residue data cited above did not use a hydrolysis step in extraction, and its ability to extract bound residues of 3-chloroaniline has not been validated.

Oncogenicity studies for chlorpropham represent an outstanding data gap. Based on rat metabolism studies, 3-chloroaniline in urine represented 1-2.3% of chlorpropham, administered as an oral dose at 5 mg/kg body weight. Thus, the portion of parent metabolized to combined 3-chloroaniline residues on potato and the portion of parent converted to 3-chloroaniline in the rat represented the same order of magnitude.

#### C. Conclusions:

The Committee reached the following conclusions, with regard to post-harvest treatment of potatoes with chlorpropham:

1. The tolerance for potatoes may be continued for residues of chlorpropham only, but the need to include 3-chloroaniline in the tolerance expression will be revisited upon availability of adequate oncogenicity data.
2. Judgment is reserved on whether 3-chloroaniline is a residue of concern, and on whether concentration of 3-chloroaniline in potato processed commodities is of concern, pending the availability of data on its oncogenicity.
3. Judgment is reserved on whether concentration of chlorpropham in potato processed commodities is of concern, pending review of data on oncogenicity.
4. Judgment is reserved on the magnitude of 3-chloroaniline residues pending validation of a method adequate for detecting bound residues in potato commodities.

cc:Circ, Abbotts, HED Metabolism Committee File, RF, Reg. Std.  
File, SF, David Anderson (TOX I)

RDI:FBSuhre:3/25/93:MSMetzger:3/25/93:EZager:3/25/93  
H7509C:CBII-RS:JAbbotts:CM-2:Rm805A:305-6230:3/30/93