

7/22/94



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: HED Metabolism Committee Meeting of 7/14/94. PP#2F4107 & PP#2E4051. Difenconazole (Dividend).

FROM: G.F. Kramer Ph.D., Chemist *G.F. Kramer*  
Tolerance Petition Section III  
Chemistry Branch I, Tolerance Support  
Health Effects Division (7509C)

THRU: E.T. Haeberer, Acting Branch Chief *E.T. Haeberer*  
Chemistry Branch I, Tolerance Support  
Health Effects Division (7509C)

TO: HED Metabolism Committee

QUESTIONS DISCUSSED

1. Are any of the difenoconazole metabolites at the levels reported of special toxicological concern? If so, which one(s)? Do they warrant inclusion in the tolerance regulation? Separate regulation? Inclusion in the dietary risk assessment? Additional metabolism studies? Toxicological studies?
2. Is there any scientific objection to establishing the tolerance in terms of parent compound only?

INDIVIDUALS IN ATTENDANCE

METABOLISM COMMITTEE: (Signatures indicate concurrence unless otherwise stated)

Reto Engler *Reto Engler*

Charles Frick *Ch Frick*

Richard Loranger *Richard Loranger*

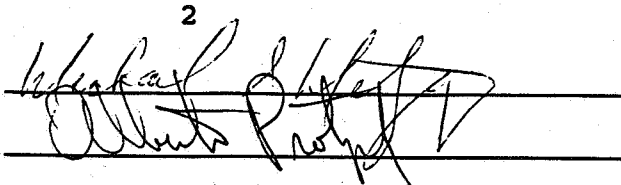


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contains at least 50% recycled

Michael Metzger

Alberto Protzel

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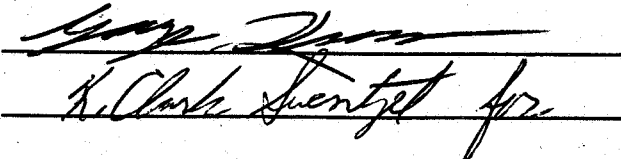


Two handwritten signatures are written over two horizontal lines. The first signature is for Michael Metzger and the second is for Alberto Protzel.

**SCIENTISTS:** Non-Committee members responsible for the data presentation (signatures indicate technical accuracy of the report)

George F. Kramer

Jess Rowland



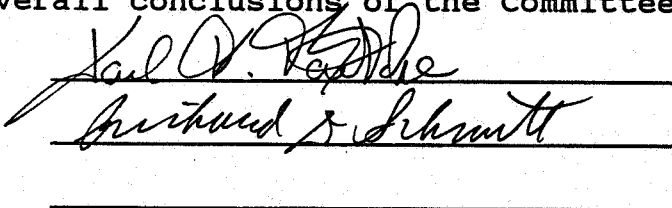
Two handwritten signatures are written over two horizontal lines. The first signature is for George F. Kramer and the second is for Jess Rowland.

**METABOLISM COMMITTEE MEMBERS IN ABSENTIA:** (Signatures indicate concurrence with the overall conclusions of the Committee.)

Karl Baetcke

Richard Schmitt

George Ghali



Three handwritten signatures are written over three horizontal lines. The first signature is for Karl Baetcke, the second is for Richard Schmitt, and the third is for George Ghali.

**MATERIAL REVIEWED**

The Committee reviewed the CBTS briefing paper, which included the difenoconazole metabolic pathways in plants (wheat, potato and tomato) and animals (goat and hen) and the magnitude of the residue in the foreign and domestic field trials. The Committee also reviewed tox data which demonstrated that the metabolism of difenoconazole in rats is similar to that in plants with the exception that triazole alanine is not a rat metabolite.

**CONCLUSIONS REACHED**

1. None of the difenoconazole metabolites warrant inclusion in the tolerance regulation or separate regulation or inclusion in the dietary risk assessment or additional metabolism or toxicological studies. The triazole metabolites (triazole, triazole alanine, triazole acetic acid) have previously been determined not to be of toxicological concern in conjunction with tebuconazole. CGA-205375 was determined not to be of concern due to the low potential for residues associated with seed treatment.
2. There is no scientific objection to the tolerance expression being established in terms of difenoconazole only.

3. If in the future the registrant wishes to propose tolerances for difenoconazole resulting from foliar uses which result in higher residue levels, then the Metabolism Committee will reconsider whether CGA-205375 needs to be included in the difenoconazole tolerance expression. If CGA-205375 is included in the tolerance expression, then new analytical enforcement methodology and a second lab validation will be required. If quantifiable levels of residues are found in animal feed items, then animal feeding studies will be required.

cc: G. Kramer  
R.F., S.F.  
Circulation  
PP#2F4107  
PP#2E4051  
PM 22 (Giles-Parker)  
Met. Comm. File

K. Baetcke  
R. Engler  
C. Frick  
G. Ghali  
R. Loranger

A. Protzel  
R. Schmitt  
R. Quick  
E. Doyle

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