

US EPA ARCHIVE DOCUMENT



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

MAY 11 1995

# 346A

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Diflubenzuron (Dimilin), Finalization of Dietary Cancer Risk Assessments for RED and for Registration Actions

DP Barcode: 214662 fs                      Tox Chem No.: 346A  
Submission No.: none                      PC Code No.: 108201

FROM: Edwin R. Budd, Toxicologist  
Review Section III  
Toxicology Branch I  
Health Effects Division (7509C)

*Budd*  
*5/3/95*

TO: Susan Jennings/Larry Schnaubelt  
Reregistration Section II  
Reregistration Branch  
Special Review and Reregistration Division (7508W)

and

Paul Schroeder/Dennis Edwards  
Product Management Team 19  
Insecticide-Rodenticide Branch  
Registration Division (7505C)

THRU: Karen L. Hamernik, Ph.D., Section Head  
Review Section III  
Toxicology Branch I  
Health Effects Division (7509C)

*K. Hamernik*  
*5/4/95*

THRU: Karl P. Baetcke, Ph.D., Chief  
Toxicology Branch I  
Health Effects Division (7509C)

*Karl P. Baetcke*  
*5/10/95*

In a memorandum dated April 21, 1994, from Paul Chin Ph.D. (Tox Branch I) to Karen Hamernik Ph.D. (Tox Branch I) and to Larry Schnaubelt/Brigid Lowery (PM Team 72, RD), a metabolism study on diflubenzuron (MRID 417209-01 and 419190-01) was reviewed and classified as Core-Supplementary. The study could be upgraded, however, if certain additional information specified in the memorandum were submitted by the registrant (Solvay Duphar B.V.). One of the four additional items of information required



to be submitted was the following (quoted from the memorandum):

"Based on the urinary metabolite profiles of dimilin, the compound is hydrolyzed. However, it is not possible to quantify distribution, biotransformation, and elimination of the dimilin because the specific activities in each of the phenyl rings was not reported. Therefore, the specific activity in each of the phenyl rings need to be reported."

The information described above must be available in order to verify that the study was performed correctly and that the quantitative results in the study are valid.

It has come to the attention of Toxicology Branch I that the registrant had inadvertently not been informed of the requirement for additional information on this study until quite recently (April, 1995). The registrant, however, has now responded to the requirement for additional information on this study and has provided the Agency with satisfactory additional information on all four items (verbal communication with Paul Chin Ph.D. on May 1, 1995). A separate memorandum will be written which addresses these issues and upgrades the study to an acceptable status.

It has been necessary on several occasions in recent times, however, to perform dietary cancer risk assessments for diflubenzuron that utilized quantitative information from this metabolism study. In particular, the percentage conversion of parent diflubenzuron to the metabolic products p-chloroaniline (PCA) and/or p-chlorophenylurea (CPU) was estimated in this study to be about 2% (see memorandum dated March 21, 1994 from Henry Spencer Ph.D. to HED Metabolism Committee) and this quantitative information (2% conversion rate) was used in the recent cancer risk assessments. In performing these risk assessments, it was assumed that the metabolism study had, in fact, been performed correctly and that the quantitative results were valid. These risk assessments may now be considered to be final since the required additional information on the metabolism study, particularly the specific activities in each of the phenyl rings, has been received and determined to be satisfactory. The metabolism study is now considered to have been performed correctly and the quantitative results in the study are considered to be valid.

cc: Thomas Myers/Karen Whitby  
Risk Characterization and Analysis Branch  
Health Effects Division (7509C)

Paul Chin  
Toxicology Branch I  
Health Effects Division (7509C)

TB294:DIMILI56.045