

US EPA ARCHIVE DOCUMENT

DP Barcode : D218711  
 PC Code No : 111801  
 EEB Out : NOV - 7 1995

To: Bruce Sidwell  
 Chemical Review Manager 53  
 Special Review and Reregistration Division (7508W)

From: Anthony F. Maciorowski, Chief  
 Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 111801-010182  
 Chemical Name : PHMB  
 Type Product : Microbiocide  
 Product Name : Vantocil IB  
 Company Name : Zeneca, Inc.  
 Purpose : Submission of additional data to upgrade acute toxicity bluegill sunfish study (MRID No. 427221-01).  
 Action Code : 606 Date Due : 11/23/95  
 Scientist : C. Laird Date In : 08/30/95

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)	437597-01 427221-01	N	72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur  
 P=Partial (Study partially fulfilled Guideline but additional information is needed)  
 S=Supplemental (Study provided useful information but Guideline was not satisfied)  
 N=Unacceptable (Study was rejected)/Nonconcur

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DP BARCODE: D218711

REREG CASE # 3122

CASE: 816384  
SUBMISSION: S492632

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 08/25/95  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REREGISTRATION ACTION: 606 GENERIC DATA  
CHEMICALS: 111801 Poly(iminoimidocarbonyliminoimidocarbonyliminohexa %  
ID#: 111801-010182  
COMPANY: 010182 ZENECA AG PRODUCTS  
PRODUCT MANAGER: 53 BRUCE SIDWELL 703-308-8078 ROOM: CS1 3J2  
PM TEAM REVIEWER: MARIE BOUCHER 703-308-8178 ROOM: CS1 3RD FL  
RECEIVED DATE: 08/21/95 DUE OUT DATE: 11/19/95

(PHMB)

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 218711 EXPEDITE: N DATE SENT: 08/25/95 DATE RET.: / /  
CHEMICAL: 111801 Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene  
DP TYPE: 999 Miscellaneous Data Package  
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 11/23/95
DIV : EFED	8/29/95	/ /	NEGOT DATE: / /
BRAN: EEB	8/30/95	/ /	PROJ DATE: / /
SECT: RSI RSZ	8/30/95	/ /	
REVR : CLARD	8/30/95	/ /	
CONTR:	/ /	/ /	

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the study MRID 43759701 for GDLN 72-1a with attached letter from Zeneca submitted as an addendum to upgrade the study (MRID 42722101) entitled: Vantocil IB: Acute Toxicity to Bluegill Sunfish.

Thanks!

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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DP BARCODE: D218711

REREG CASE # 3122

CASE: 816384  
SUBMISSION: S492632

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 10/24/95  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REREGISTRATION ACTION: 606 GENERIC DATA  
CHEMICALS: 111801 Poly(iminoimidocarbonyliminoimidocarbonyliminohexa %  
ID#: 111801-010182  
COMPANY: 010182 ZENECA AG PRODUCTS  
PRODUCT MANAGER: 53 BRUCE SIDWELL 703-308-8078 ROOM: CS1 3J2  
PM TEAM REVIEWER: MARIE BOUCHER 703-308-8178 ROOM: CS1 3RD FL  
RECEIVED DATE: 08/21/95 DUE OUT DATE: 11/19/95

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 218711 EXPEDITE: N DATE SENT: 08/25/95 DATE RET.: / /  
CHEMICAL: 111801 Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene  
DP TYPE: 999 Miscellaneous Data Package  
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 11/23/95
DIV : EFED	08/29/95	/ /	NEGOT DATE: / /
BRAN: EEB	08/30/95	/ /	PROJ DATE: / /
SECT: RS2	08/30/95	/ /	
REVR : CLAIRD	08/30/95	/ /	
CONTR:	/ /	/ /	

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DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV - 7 1995

OFFICE OF  
PREVENTION, PESTICIDES, AND  
TOXIC-SUBSTANCES

MEMORANDUM

SUBJECT: EEB Response to The Registrant's Addendum (MRID # 437597-01) to Upgrade The Bluegill Sunfish Acute Toxicity Study (MRID # 427221-01): Barcode D218711

FROM: Anthony F. Maciorowski, Chief *for H.T. Crowe*  
Ecological Effects Branch *11/7/95*  
Environmental Fate and Effects Division (7507C)

TO: Bruce Sidwell  
Project Manager 53  
Accelerated Reregistration Branch  
Special Review and Reregistration Division (7508W)

As per your request, EEB has reviewed the registrant's addendum to upgrade a previously submitted bluegill sunfish acute toxicity study for Vantocil IB. The status of this study remains invalid for the following reasons:

1. Each study should be conducted in such a manner that it can stand on its own merit.
2. The Standard Evaluation Procedure (SEP) states that for a flow-through method, the test solution must be analyzed to determine the exact concentration of pesticide at each dose level.
3. Even though a > 70% recovery of nominal concentration for Vantocil IB was shown in a static range-finding test for rainbow trout, a static range-finding test is not designed to represent a flow-through test. A flow-through range-finding test might show less or greater than 70% recovery. For a flow-through system, EEB needs to know the exact concentrations test animals are exposed to in order to determine the correct toxicity category. (Note: EEB contacted EFGWB concerning the analytical method used and the physical/chemical properties of PHMB. EFGWB indicated that PHMB is a polymer which appears fairly stable in water. This information supports the results obtained in the analyses of stock solutions.

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However, without some analyses of PHMB in the actual test chambers, one cannot corroborate that diluters were operating properly and the 1 to 200 ratio is accurate).

EEB concludes that the data found in the registrant's addendum are unacceptable to upgrade the bluegill sunfish study from invalid to core. However, another warmwater, or coldwater, fish study is not required to support reregistration of a 20%, or less, active ingredient product. EEB has reviewed the file for PHMB and determined that acceptable data, developed at the Agency's Animal Biology Laboratory, are available for bluegill sunfish and rainbow trout. These data indicate that Baquacil, 20% active ingredient (ai), resulted in 96-hour  $LC_{50}$ 's of 0.44 ppm ai and 0.11 ppm ai for bluegill sunfish and rainbow trout, respectively. Copies of these reports are attached.

If you have any questions on the above, please contact Curtis Laird (305-5636) or Norm Cook (305-5322) of my staff.