

US EPA ARCHIVE DOCUMENT

1-22-90

256117,256128,256140,256132
RECORD NO.

128997
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 12/08/89

DATE: OUT 1/22/90

FILE OR REG. NO. 3125-GIC, GIU, GII, GIE

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 11/03/89

DATE RECEIVED BY HED 12/06/89

RD REQUESTED COMPLETION DATE 03/06/90

EEB ESTIMATED COMPLETION DATE 03/06/90

RD ACTION CODE 101, 116, 100, 116

TYPE OF PRODUCT(S) : I,D,H,F,N,R,S _____

DATA ACCESSION NO(S). 423890-02; 412890-00

PRODUCT MANAGER (NO.) Lewis/Chambliss (21)

PRODUCT NAME(S) Tebuconazole (Folicur)

COMPANY NAME Mobay

SUBMISSION PURPOSE Review Supplemental Submission for Toxicity to Rainbow Trout and Daphnia and Waiver Request for Duck Reproduction Study

SHAUGHNESSY NO.	CHEMICAL & FORMULATION(S)	% A.I.
_____	_____	_____
_____	_____	_____
_____	_____	_____

1

EEB required both the duck and quail reproduction studies be repeated because the highest test concentration of 80 ppm, (nominal) was not sufficient to support the agricultural maximum seasonal use or the turf single or seasonal use. Acceptable studies have been submitted identifying the NOEL for duck (75.8) and quail (73.5) but has not identified the LOEL. Mobay has agreed to repeat the quail reproduction study in order to obtain an estimate of the lowest effect level but are requesting a waiver for the duck reproduction test requirement. The registrant makes the following arguments to support their waiver request:

1. Mobay's historical data base on these sorts of triazole compounds indicates that the levels for the quail and duck studies should be the same (see attachment) and, therefore, suggest accepting the LOEL obtained in the quail study to be representative of the duck LOEL.
2. Preliminary information from the on-going quail study indicates that the effect level will be observed at 170 ppm. (The effect observed in the new quail study as well as the other triazole compound studies is reported to be (1) lower hatch percentage and (2) lower 21-day embryo survivorship.) If the duck study was repeated, the same test concentrations currently used in the quail (170 and 340 ppm) would be used. Therefore, the lowest possible effect level for the duck study would be 170 ppm. Assuming this is the effect level for quail reproduction, no additional information would be obtained for risk assessment.

EEB concurs with the registrant that another duck study may not provide useful information and that historical data would indicate, in this case only, the LOEL for the duck may be assumed to be that of the quail (in the repeated study). We recommend the repeated duck reproduction study requirement be waived for tebuconazole with the following conditions.

1. Terrestrial risk assessment will be based on the NOEL for duck (75.8 ppm in core study).
2. If the quail LOEL is determined to be 170 ppm in the repeat study, we will assume the same for duck. However, if the quail LOEL is found to be 340 (and the NOEL therefore 170 ppm), we will not assume these values are also the same for duck.

~~Direct Registration~~
Mobay



Mobay Corporation
A Bayer USA INC. COMPANY

Agricultural Chemicals Division

Document Processing Desk (RS Tebuconazole)
Office of Pesticide Programs - H7504C
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

P O Box 4913
Hawthorn Road
Kansas City, MO 64120-0013
Cable: Kemagro Kansas City
Telephone: 816/242-2000

October 30, 1989

Subject: FOLICUR[®] Technical, EPA File Symbol 3125-GIG
FOLICUR 1.2 EC, EPA File Symbol 3125-GIU
FOLICUR 3.6 F, Submitted to the EPA 10/3/89 with PP 9G3817 & 9F3818
ELITE[®] 45 DF, EPA File Symbol 3125-GII
LYNX[™] 1.2, EPA File Symbol 3125-GIE
RAXIL[®] 0.26F and RAXIL 2.6 F, Submitted to the EPA 10/3/89 with PP
9F3818
Pesticide Petitions 9F3724, 9H5575, 9G3814 and 9F3818

Dear Sir:

This is in response to the Environmental Effects Branch's (EEB) memorandum, dated 5/17/89.

The data evaluation record classified our aquatic invertebrate life cycle study (Mobay Report No. 96792; EPA MRID No. 40700915) as supplemental. The raw data on survival, reproduction and growth of first generation daphnids requested to upgrade this study are contained in the enclosed Mobay Report No. 99627.

Our freshwater fish life cycle study (Mobay Report No. 96723; EPA MRID No. 40700914) was also classified as supplemental because raw data on larval length and wet weight were not included. Enclosed is Mobay Report No. 99628 which contains these data.

Item 1.3 of EEB's memorandum stated that no studies on estuarine and marine organisms were submitted. Data on mysid shrimp (Mobay Report No. 97465; EPA MRID No. 40995902), eastern oysters (Mobay Report No. 97466; EPA MRID No. 40995903) and sheepshead minnow (Mobay Report No. 97467; EPA MRID No. 40995904) were submitted to the Agency on 12/30/88 along with Pesticide Petitions 9F3724 and 9H5575 and our applications to register FOLICUR 1.2 EC and ELITE 45 DF on grasses grown for seed, wheat, barley, peanuts and grapes.

Item 1.4 of EEB's memorandum requested data on plant protection. Data on green algae (Mobay Report No. 94853; EPA MRID No. 40995908) were submitted to the Agency on 12/30/88 along with Pesticide Petitions 9F3724 and 9H5575 and our applications to register FOLICUR 1.2 EC and ELITE 45 DF on grasses grown for seed, wheat, barley, peanuts and grapes.

3

Table 1. Triazole NOEL and LOEL values (ppm) for Quail and Duck Reproduction Studies.

<u>COMPOUND</u>	<u>NOEL</u>	<u>QUAIL LOEL</u>	<u>(MRID)</u>	<u>NOEL</u>	<u>DUCK LOEL</u>	<u>(MRID)</u>
BAYCOR^a	10	50	00150652	10	20	00150653
BAYCOR ^b	5	25	-	5	25	-
BAYLETON	20	100	00110431	20	100	00110432
BAYTAN	100	500	4283101	100	500	40283102

a - studies classified invalid by EPA review

b - repeat of BAYCOR studies; reports still in preparation

- B) This represents a fairly conservative approach. Results from the previous quail study, and preliminary information from the ongoing quail study, indicate that an effect will likely be observed at 170 ppm. If we did repeat the duck study, the concentrations tested would be the same as currently being used in the quail study (i.e. 170 and 340 ppm). Given this, the lowest possible effect level for the duck study would be 170 ppm. Assuming this is the effect level identified in the quail reproduction study, no additional information will be obtained from conducting the duck study at these levels.
- C) Conducting a new duck reproduction study will not provide information critical for the evaluation of avian hazard. Unnecessary testing on animal species should be avoided and, given present concerns regarding animal rights, we feel that EPA can obtain all the information necessary to evaluate the potential hazard of FOLICUR/LYNX to avian reproduction from the studies presently available to them and from the new quail reproduction study being conducted at this point.
- D) In addition to conducting the quail reproduction study, residue data will be generated for evaluating the potential for long term avian exposure. Degradation of the compound must be considered when evaluating multiple applications. These data will be provided for turf and specific row crops to ensure that the most accurate information is available for assessing the risks of the compound to avian reproduction. The following has been initiated:
- a) Residue study on turf. These data will be used to establish the maximum turf residue values and the foliar half life.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

SUBJECT: Tebuconazole (Folicur) - Review of Supplemental Data (chronic freshwater studies) and Waiver Request (duck reproduction)

FROM: James Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Branch (H7507C)

TO: Susan Lewis/Ben Chambliss, PM-21
Fungicide-Herbicide Branch
Registration Division (H7505C)

The Ecological Effects Branch (EEB) has reviewed Mobay's supplemental data and waiver request for their new fungicide, tebuconazole.

The following two chronic studies (trout and daphnia) were judged supplemental because raw data was not submitted and therefore the statistical analysis could not be validated. With the present submission the appropriate raw data was presented and appears to support the findings of the two listed studies, i.e., trout MATC is between 12 and 25 ug/L (larval survival) and the daphnia MATC is between 120 and 230 ug/L (length, survival and reproduction). Therefore these two studies will be upgraded from supplemental to core.

Surprenant, D.C. 1988. The Toxicity of HWG 1608 Technical to Rainbow Trout (Salmo gairdneri) Embryos and Larvae. Report No. 87-11-2545. Conducted by Springborn Life Sciences, Inc., Wareham, MA. Submitted by Mobay Corporation, Stilwell, Kansas. EPA Accession No. 407009-14.

Burgess, D. 1988. Chronic Toxicity of HWG-1608 Technical to Daphnia magna under Flow-Through Test Conditions. Prepared by Analytical Biochemistry Laboratories, Inc., Columbia, Missouri. Submitted by Mobay Corporation, Stilwell, Kansas. Accession Number 407009-15.

CONCURRENCES

SYMBOL	H7507C	H7507C	H7507C				
SURNAME	<i>Spitznagel</i>	<i>Conan</i>	<i>Alu</i>				
DATE	<i>1/19/90</i>	<i>1/19/90</i>	<i>1/25/90</i>				

5

EEB required both the duck and quail reproduction studies be repeated because the highest test concentration of 80 ppm, (nominal) was not sufficient to support the agricultural maximum seasonal use or the turf single or seasonal use. Acceptable studies have been submitted identifying the NOEL for duck (75.8) and quail (73.5) but has not identified the LOEL. Mobay has agreed to repeat the quail reproduction study in order to obtain an estimate of the lowest effect level but are requesting a waiver for the duck reproduction test requirement. The registrant makes the following arguments to support their waiver request:

1. Mobay's historical data base on these sorts of triazole compounds indicates that the levels for the quail and duck studies should be the same (see attachment) and, therefore, suggest accepting the LOEL obtained in the quail study to be representative of the duck LOEL.
2. Preliminary information from the on-going quail study indicates that the effect level will be observed at 170 ppm. (The effect observed in the new quail study as well as the other triazole compound studies is reported to be (1) lower hatch percentage and (2) lower 21-day embryo survivorship.) If the duck study was repeated, the same test concentrations currently used in the quail (170 and 340 ppm) would be used. Therefore, the lowest possible effect level for the duck study would be 170 ppm. Assuming this is the effect level for quail reproduction, no additional information would be obtained for risk assessment.

EEB concurs with the registrant that another duck study may not provide useful information and that historical data would indicate, in this case only, the LOEL for the duck may be assumed to be that of the quail (in the repeated study). We recommend the repeated duck reproduction study requirement be waived for tebuconazole with the following conditions.

1. Terrestrial risk assessment will be based on the NOEL for duck (75.8 ppm in core study).
2. If the quail LOEL is determined to be 170 ppm in the repeat study, we will assume the same for duck. However, if the quail LOEL is found to be 340 (and the NOEL therefore 170 ppm), we will not assume these values are also the same for duck.

12

4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3. In summary, EEB will use 75.8 ppm (NOEL) for risk assessment for the duck and assume 170 is the LOEL. If the registrant believes these values are too low (i.e., from quail study information) they must repeat the duck reproduction study to demonstrate the NOEL they believe appropriate for risk assessment.

A waiver is recommended in this special case only because of historical data on this class of compound indicate another duck reproduction study would not yield useful data and, in general, should not be construed as these reproductive studies may be substituted one for another. In the future the waiver request should be submitted and reviewed (for possible modifications) before associated studies are initiated.

Questions/Comments - Otto Gutenson (557-3449)

CONCURRENCES							
SYMBOL			3				
SURNAME							
DATE							