

4154B

Shaughnessy No.: 041701

Date of Review: 18 DEC 1984

Init: SM

To: W. Miller  
Product Manager 16  
Registration Division (TS-767C)

From: Dr. Lionel A. Richardson, Chief  
Environmental Review Section #3  
Exposure Assessment Branch  
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of:

Reg./File No.: 476-2134

Chemical: fonofos

Type Product: \_\_\_\_\_

Product Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Submission Purpose: \_\_\_\_\_

ZBB Code: \_\_\_\_\_

Action Code: 656

Date In: 10/17/84

EAB No.: 5039

Date Completed: 18 DEC 1984

TAIS (Level II) Days

472

Deferrals To:

\_\_\_\_\_ Ecological Effects Branch

\_\_\_\_\_ Residue Chemistry Branch

\_\_\_\_\_ Toxicology Branch



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

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

Response to Stauffer's fonofos Re-entry Labeling Requirement  
(132-1) (9/17/84 letter) and Registration Standard Re-entry Letter  
of October 8, 1984.

Thank you for your commitment to submit re-entry draft protocols for Agency review in December, 1984, and to make re-entry data available in December 1985.

As you stated in your October 8, 1984 letter, we also believe that reentry intervals must be based on scientific data, and for that reason we established re-entry (scientific) data requirements for reregistration. However, until you submit the re-entry data, an interim re-entry interval will offer some measure of protection to field workers.

Your October 8, 1984, letter indicated that the proposed 24-hour interim re-entry interval for foliar applications may be too short. The Agency also believes that the 24-hour interim interval (for all foliar applications) could, possibly, be too short. Therefore, a 48-hour interim interval, is required on the label (for all foliar applications) until scientifically acceptable re-entry data are received and evaluated.

Your October 8, 1984 letter proposed that State and local re-entry requirements be followed until scientific re-entry data are available to determine appropriate intervals. How many States or local governments have established (scientifically or non-scientifically) re-entry intervals?

As an interim measure the Agency requires "watering in" on the 2G label for the home lawn use. After the required data are received, we will reassess all of the interim measures and establish safety measures that the data, from acceptable studies, dictate.

*John F. Henderson*  
12/14/84

# REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME

Fendax

10/17/84

2. IDENTIFYING NUMBER

3. ACTION CODE

4. ACCESSION NUMBER

TO BE COMPLETED BY PM

5. RECORD NUMBER

6. REFERENCE NUMBER

7. DATE RECEIVED (EPA)

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

10. PM TEAM NUMBER

14. CHECK IF APPLICABLE

☐ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

12. PRIORITY NUMBER

13. PROJECTED RETURN DATE

15. INSTRUCTIONS TO REVIEWER

A. HED

☐ Total Assessment - 3(c)(5)

C. ☐ BFSD

☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

D. ☐ TSS/RD

E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

☐ Chemical Undergoing Active RPAR Review

☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data  
☐ Use Only the Attached Data for Formulation and Any or All  
☐ Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB

☐ EEB

☐ EF

☐ PL

☐ RCB

☐ EFB

☐ CH

☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	X ENVIRONMENTAL DATA								X
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BF	ECONOMIC ANALYSIS								

20. ☐ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

DE GUIGNÉ  
TECHNICAL CENTER  
ENVIRONMENTAL SERVICES

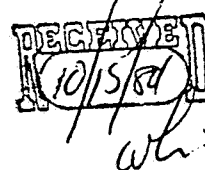


# Stauffer Chemical Company

1200 S. 47th St. / Richmond, CA 94804 / Tel. (415) 231-1000 / TWX (910) 382-8174

October 8, 1984

Mr. William H. Miller  
Product Manager (16)  
Insecticide-Rodenticide Branch  
Registration Division (TS-767)  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460



Subject: Fonofos Registration Standard  
Re-Entry Discussion of October 3, 1984

Dear Mr. Miller:

Thank you once again for the opportunity to discuss our concerns regarding the Agency's requirement to incorporate a 24-hour re-entry interval for all uses of all products containing fonofos.

Stauffer recognizes that some uses of pesticide products will require field reentry instructions. In the case of DYFONATE products, there are two issues to address for general agricultural uses:

1. Pre-plant incorporated or at planting incorporated uses
2. Post-emergence crop uses

In the case of pre-plant incorporated or at planting incorporated uses of DYFONATE, Stauffer agrees with EPA scientific review that there is little potential for farmworker exposure and a label caution is all that is needed (See Attachment 1). EPA scientists have also pointed out that for other products of similar use, i.e., terbufos, there is little potential for re-entry exposure (see Attachment 2). Stauffer supports these conclusions and we propose that no re-entry requirements are needed for Dyfonate pre-plant incorporated or at planting incorporated uses.

For post-emergence uses on corn we propose adding to the DYFONATE label alternate language directing the user to follow State or local re-entry requirements until data are available to determine an appropriate re-entry interval.

Further to our discussions of October 3, 1984, we believe that the arbitrary imposition of a 24-hour re-entry interval could, under certain use situations, give the user an erroneous indication that re-entry is safe. As an example, fonofos products are not currently recommended by states or local agencies for use on corn prior to detasseling for seed corn production, because a re-entry interval has not been established. With a 24-hour re-entry statement on the label a user may be able to treat and then 24 hours later send in workers to detassel the corn. This may not be a safe practice. It is our understanding that the 24-hour re-entry interval was an EPA policy decision which was not based on scientific evidence.

Mr. William H. Miller  
October 8, 1984  
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Stauffer agrees that further studies should be conducted to determine whether a re-entry interval is required for fonofos's various uses and formulations. We have notified the Agency of this.

As agreed, we will add the 24-hour re-entry statement to the Dyfonate 5-G and Dyfonate 2-G labels in compliance with the requirements of the Standard. Draft labeling will be submitted by October 31, 1984. These products are not currently in trade channels. Prior to the introduction of these products into the market studies will also be conducted to establish an appropriate re-entry interval for their use.

We are currently preparing protocols and scheduling studies to address these re-entry issues. We expect to provide the Agency with draft protocols for review and approval by December 31, 1984 and to provide actual scientific data no later than December 31, 1985.

If you have further questions regarding this matter, please call me at (415) 231-1177.

Sincerely,

STAUFFER CHEMICAL COMPANY

*Ralph L. Riggs*

Ralph L. Riggs  
Senior Regulatory Affairs Supervisor  
Pesticide Registrations

MSO/rrc

Attachments

cc: Herbert S. Harrison