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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: October 16, 1998

SUBJECT: **CHLORETHOXYFOS - HED OCCUPATIONAL AND RESIDENTIAL
EXPOSURE CHAPTER FOR THE HED CHAPTER OF THE
CHLORETHOXYFOS RED. Chemical#: 129006**

TO: Kathy Monk, Branch Chief
SRRD/HED (7508W)

FROM: Gary Bangs, Industrial Hygienist
RCAB/HED (7509C)

St. Cy for

THRU: Steve Knizner, Branch Senior Scientist
RCAB/HED (7509C)

St. Cy

1. A copy of the HED occupational and residential exposure chapter for the chlorethoxyfos Registration Eligibility Decision (RED) is enclosed with this memo. The assessment was done in a "stream-lined" RED format.
2. Questions or comments should directed to Mr. Gary Bangs, Industrial Hygienist at (703) 305-7606.

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CHLORETHOXYFOS
Streamlined RED Format

Chemical Number: 129006

Products:

DuPont Fortress 5G Granular Insecticide Reg No 352-552
in SmartBox™ closed handling and application system

DuPont Fortress Technical Reg No 352-553
DuPont Fortress 2.5G Granular Insecticide Reg No 352-579

Executive Summary - ORE

As a condition of registration, the registrant has conducted repeated-dose inhalation and dermal toxicity studies in rats, as well as worker dermal and inhalation exposure studies involving the use of Fortress® 5G. These studies were reviewed by HED (see **References**).

Even though HED identified a chronic toxicity endpoint, only short and intermediate-term exposure scenarios are considered appropriate (i.e., no chronic exposure), and therefore only average daily doses are determined. Typical exposure duration is cited as 7-10 days per year. This product is typically applied by the farmer or an employee of the farm rather than a professional applicator.

The combined loader and applicator total dermal and inhalation risk does not exceed HED's level of concern ($MOE_{total} = 170$ for Fortress® 2.5G granular in 50 lb bags and $MOE_{total} = 6500$ for Fortress® 5G in the SmartBox™) for Fortress 2.5 G and Fortress 5G Smartbox when compared to the Agency-required MOE of 100 (see Tables 2 and 3).

Loader risk is based on wearing long-sleeved shirt, long pants, shoes plus socks and waterproof gloves for both products and an organic vapor/pesticide respirator for Fortress 2.5 G. Applicator risk is based on the use of enclosed cab tractors. *Therefore reregistration of this product should be dependent on all of these provisions being label-stated requirements.* All of the Fortress labels should include a statement in the First Aid or Statement of Practical Treatment section requiring flushing contaminated eyes with water for 15 minutes. Currently the label uses the words "flush eyes with plenty of water."

I. Exposure Characterization

Occupational workers are potentially exposed to chlorethoxyfos from the application of the following registered products:

- Fortress 2.5G Granules [in 50 lb bags]
- Fortress 5G [in the Smartbox™ Closed Handling and Application System]

DuPont is also seeking reregistration of the following product for use in manufacturing only:

- Fortress 5G Technical

Use of the Smartbox™ does not require loaders to open bags of product. According to DuPont,

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the loader only has to place the transfer box containing the formulation, obtained from the dealer, on the Smartbox™ unit mounted on the planter. After the box has been attached and is in place, product is transferred into the lower unit. Theoretically, the loader should not come in contact with any of the product.

Fortress® 5G, with 5% active ingredient (a.i.), Fortress® 2.5G, with 2.5% a.i., chlorethoxyfos, is an organophosphate insecticide applied to corn one time, at planting, via either standard hoppers or a closed application system called the "SmartBox™" mounted on planters pulled by a closed-cab tractor. Because the product is applied only during planting, is soil-incorporated, is not water-soluble, does not become systemic in the crop, and because corn is harvested mechanically, there should be insignificant post-planting worker exposure. Typical planting duration is cited as 7-10 days per farm. Therefore the exposure is characterized as short- or intermediate-term (less than 90 days). As a condition of registration, the registrant was required by the Agency to provide results from a study designed to determine exposure to workers from this application.

III. Occupational Exposure Assessment

The following assessments of occupational exposure to chlorethoxyfos as the active ingredient in Fortress 2.5G Granules and Fortress 5G SmartBox™ are based on usage studies submitted by the registrant in 1995, 1996 and 1997 (see **Attachments**).

1. The following assumptions and considerations were used for assessing occupational exposure to chlorethoxyfos:

Application Rates

The average corn-planting acreage per day is reported to be 125 to 150, with a maximum of 180 acres. This estimate is based on the use of a 12- to 15-row planter set for 30-inch wide rows. At this setting, the maximum per the label, the recommended rate of formula application is 3.25 lb per acre for the 5% product and 6.5 lbs per acre for the 2.5% formulation. If 180 acres are covered at 3.25 lb per acre with a formulation containing 5% active ingredient (a.i.), or 6.5 lbs per acre of 2.5% formulation, then a maximum potential chlorethoxyfos exposure could amount to 29.25 lb a.i./day. This number is used for exposure calculations.

Dermal Absorption

Because HED is using a 21-day dermal toxicity study to provide the dermal endpoint, the dermal absorption factor is 100%.

Personal Protective Equipment

The current label for Fortress® 5G in the SmartBox™ requires the following personal protective equipment for loaders: long-sleeved shirt and long pants, shoes plus socks, waterproof

gloves, and protective eyewear¹. In addition, loaders of Fortress® 2.5G bags must wear an organic vapor/pesticide respirator. The gloves and eyewear must be removed after loading and stored in a chemical resistant container or plastic bag. Applicators in an enclosed cab are to wear long-sleeved shirt and long pants and shoes plus socks. When an applicator leaves the cab to adjust the equipment, coveralls, waterproof gloves, and protective eyewear must be worn. The coveralls, waterproof gloves, and protective eyewear must be removed and stored in a plastic bag or other chemical-resistant container before reentering the cab. The container must not be placed in the cab.

TABLE 1. PPE requirements for Fortress® 2.5G and Fortress® 5G (SmartBox™) applied from a closed cab tractor.		
Task	Formulation	
	Fortress® 2.5G	Fortress® 5G (SmartBox™)
Loading	Coveralls, long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, protective eyewear, and OV respirator.	Long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, and protective eyewear.
Application (In cab)	Long-sleeved shirt, long pants, and shoes plus socks.	Long-sleeved shirt, long pants, and shoes plus socks.
Application (Outside cab)	Coveralls, long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, and protective eyewear.	Coveralls, long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, and protective eyewear.

2. A summary of exposure estimates and risk assessments for occupational handlers is included as **Tables 2 and 3**. HED's worker exposure estimates are based on studies which monitored chlorethoxyfos exposure to applicators who were operating enclosed-cab tractors while applying chlorethoxyfos. The Fortress® 5G in the SmartBox™ granular insecticide was applied at the maximum label rate of 3.25 lb of formulation (0.1625 lb a.i.) per acre of corn(study MRID 443998-02). The Fortress® 2.5G granular in 50 lb bags was applied at the same rate of a.i./acre, or twice the product/acre(study MRID 425592-22).

¹ The use of eye protection while handling Fortress® 5G (SmartBox™) and Fortress® 2.5G is not required by WPS based on the current toxicity values for the products (Tox Cat. III for Eye Irritation). However, the labels for both of these products require use of eye protection. HED does not currently have data that would permit the quantification of the degree of protection provided by this additional PPE.

III. Residential Exposure Assessment

There is currently no registered use for this pesticide that could result in residential exposure.

IV Risk Characterization / Risk Assessment

Special Concern: Head-space:

During HED's review of data collected in the exposure study submitted by DuPont (MRID 425592-22), it was noted that for the loader component, inhalation exposure was 50% of total exposure. However, exposure values for hands was only 4% of total exposure. Normally, one would expect insignificant exposure from inhalation and a higher rate for hands. However, since the product is essentially being used as a fumigant (vapor pressure 1.7×10^{-3}), during the loading process, significant volatilization of the formulation was evidently occurring. This volatilization is apparent from the value obtained from the air sampling devices worn by the workers. Furthermore, this concern is the basis for the requirement for the OV respirator.

Because of the volatile nature of chlorethoxyfos, HED/Toxicology Branch has expressed a concern for handlers being subjected to high concentrations of active ingredient when bags are opened (23 bags [50 lbs each] would be required for treatment of 180 acres²). Based on the results of the exposure study, it would appear that some portion of the chemical collected by the personal air samplers was most likely due vapor trapped in the head-space of the bag. Unfortunately, HED has no way of determining what portion of the exposure occurred during the other tasks performed during loading.

Consequently, HED believes it is imperative that a loader wear an approved organic vapor respirator during the loading process. Use of a dust/mist respirator would not provide the protection afforded by an OV respirator. Use of an OV respirator could reduce inhalation exposure by 90% (OREB Science Peer Review, April 4, 1994).

Margins of Exposure (MOE)

For occupational short- and intermediate-term *dermal* exposure risk assessments, a NOEL of 25 mg/kg/day was selected based on RBC cholinesterase inhibition in a 21-day rat dermal exposure study.

For inhalation (Any Time Period) a NOEL 0.06 mg/kg was selected based upon plasma cholinesterase inhibition exhibited in a 6-month ocular toxicity study in dogs.

² The 2.5G formulation will be marketed in 50 pound bags. DuPont has estimated that 180 acres will be treated per day (Using information provided by Dr. Yuen-shaung Ng, Biological and Economic Analysis Division (BEAD), OREB has confirmed this estimate). Therefore, at an application rate of 6.5 lb product per acre, 23 bags would be opened during the loading process ($6.5 \text{ lb } 2.5\text{G/A} \times 180 \text{ A} \div 50 \text{ lb } 2.5\text{G/bag} = 22.4 \text{ bags}$).

The Dermal MOE for Fortress® 2.5G granular in 50 lb bags is 12,500, assuming all of the required PPE are worn. The Inhalation MOE is 170 when an organic vapor/pesticide cartridge respirator is worn.

The Dermal MOE for Fortress® 5G in the SmartBox™ is 60,000 when all of the required PPE are worn and an enclosed tractor is used. The inhalation MOE is 6900.

The $MOE_{total} = 170$ for Fortress® 2.5G granular in 50 lb bags and $MOE_{total} = 6200$ for Fortress® 5G in the SmartBox.™ This is for short- and intermediate-term exposures, as there are no chronic exposures anticipated from the application of this product.

For Fortress® 5G in the SmartBox™ and Fortress® 2.5G granular in 50 lb bags the combined loader and applicator total dermal and inhalation risk is acceptable (when compared to the Agency-required MOE of 100) when all of the precautions and PPE listed on the label are used.

Chlorothoxyfos Exposure Scenario Tables

Table 2. Occupational Handler Exposure Estimate and Risk Assessment Summary Chlorothoxyfos [DuPont Fortress 5G SmartBox]									
Application Scenario	(lb ai/day)	DERMAL			INHALATION			Combined MOE	
		(With minimum PPE) ^a			(With no respirator)			With PPE	MOE Total ^f
		UE ^b mg/lb a.i.	ADD ^c (mg/kg/day)	MOE ^d NOEL = 25 mg/kg	UE ^b mg/lb a.i.	ADD ^c (mg/kg/day)	MOE ^d NOEL = .06 mg/kg		
SmartBox™ using a closed-cab tractor and planter [loader]	29.25	0.0002	0.000084	30,000	0.000012	0.0000050	12,000	12,000	12,000
[applicator]	29.25	0.00081	0.00034	74,000	0.00012	0.000050	1200	1200	1200
[combined]	29.25	0.0010	0.00042	60,000	0.00013	0.000054	1100	1100	1100

^a The minimum PPE is long sleeve shirt, long pants, shoes, socks and waterproof gloves

^b UE = Unit Exposure is the amount of exposure measured in terms of mg a.i./lb a.i. handled

^c ADD(mg/kg/day): = unit exposure (UE) from studies in mg/lb a.i. handled * 29.25 lb a.i./day / 70 kg wt;

^d MOE = NOEL/ADD

^e Combined MOE is based upon the following formula: the inverse of the sum of the inverses of the dermal and inhalation MOEs:

$$1 / (1/MOE_{\text{dermal}} + 1/MOE_{\text{inhalation}}); \text{ these MOE have a common endpoint}$$

This study used 3.25 lb. product/acre on 180 acres/day (equivalent to 0.1625 lb a.i./acre)

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Table 3. Occupational Handler Exposure Estimate and Risk Assessment Summary
Chlorethoxyfos [DuPont Fortress 2.5G Granules]

Application Scenario	DERMAL				INHALATION				Combined MOE With PPE
	(With minimum PPE) ^a				(With respirator)				
	(lb ai/day)	UE ^b mg/lb a.i.	ADD ^c (mg/kg/day)	MOE ^d NOEL= 25 mg/kg	UE ^b mg/lb a.i.	ADD ^c (mg/kg/day)	MOE ^d NOEL= .06 mg/kg	MOE Total ^e	
Fortress 2.5G™ using a closed-cab tractor and planter [loader]	29.25	0.0024	0.0010	25,000	0.00024 wearing OV respirator	0.00010	600	590	
[applicator]	29.25	0.0023	0.00096	25,000	0.0006	0.00025	240	240	
[combined]	29.25	0.0047	0.0020	12,500	0.00084	0.00035	170	170	

^a The minimum PPE is long sleeve shirt, long pants, shoes, socks and waterproof gloves

^b UE = Unit Exposure is the amount of exposure measured in terms of mg a.i./lb a.i handled

^c ADD(mg/kg/day): = unit exposure (UE) from studies in mg/lb a.i. handled * 29.25 lb a.i./day / 70 kg wt;

^dMOE = NOEL/ADD

^eCombined MOE is based upon the following formula: the inverse of the sum of the inverses of the dermal and inhalation MOEs:
 $1 / (1/MOE_{dermal} + 1/MOE_{inhalation})$; these MOE have a common endpoint

This study used 6.5 lb. product/acre on 180 acres/day (equivalent to 0.1625 lb a.i./acre)

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REFERENCES

“Review of “Chlorethoxyfos Applicator Exposure Study during Application of Fortress® 5G Granular Insecticide using the SmartBox™ System during Corn Planting in the Midwest,” (DP Barcode: D238361; Chem ID#: 129006; EPA Reg. No.: 352-552; MRID#: 443013-01) memorandum from Jack Arthur, HED, to Beth Edwards, RD, July 27, 1998.

“Evaluation of Loader Exposure Data Submitted as Part of the Conditional Registration of Fortress 5G (Chlorethoxyfos),” DP Barcode: D232274; Pesticide Chemical Code: 129006, EPA Reg. NO.: 352-552; memorandum from Leo R. LaSota, Ph.D., Biologist, Health Effects Division, to Michael Metzger, Chief, RCAB, HED, EPA, January 23, 1997.

“Estimates of Exposure for Fortress (Chlorethoxyfos).” [Fortress® 5G (SmartBox™) and Fortress® 2.5G] Memorandum from Charles Lewis, SRRS2, to S. Robbins Risk Characterization and Analysis Branch, EPA, DP Barcode: None; Pesticide Chemical Code: 129006; EPA Reg. No.: 352-LLG; August 15, 1995

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