PMRA Submission Number 2001-1027 EPA MRID Number 454050-12 [for vegetative vigor]

Data Requirement:

PMRA DATA CODE: 9.8.4-2 (TGAI)

EPA DP Barcode: D278418

OECD Data Point: IIA 8.12 (TGAI) and IIIA 10.8.1.1 (EP)

EPA Guideline: 122-1(b), 850.4150

Test material: End Use Product

Purity (%): 68.5% ai

Primary Reviewer:

Peter Takacs

Date: April/4/02

{PMRA}

✓John Ravenscroft

Date: June 19, 2002

Secondary Reviewer: {EPA}

Company Code: BAZ

Active Code:

CHH-BAZ-4

Use Site Category: In Canada, this fungicide is proposed for use on USC 13, 14 and 30; agricultural feed, food and turf uses. BAS 510 F is to be used 2-6 times per growing season depending on the crop, at a maximum recommended application rate of 875 g a.i./ha/application.

EPA PC Code: 128008

CITATION: Catherine M. Holmes, Dave Schwab. February 2001. Evaluating the Effects of BAS 510 02F on the Vegetative Vigor of Non-Target Terrestrial Plants. ABC Laboratories, Inc. Analytical Chemistry and Field Studies 7200 E. ABC Lane Columbia, Missouri 65202-8015. BASF Study number: 46663.



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EXECUTIVE SUMMARY:

The effect of BAS 510 02F (EP) on the vegetative vigor of monocot (corn (Zea mays), ryegrass (Lolium perenne), and wheat (Triticum aestivum) onion (Allium cepa)) and dicot cucumber (Cucumis sativus), radish (Raphanus satirus), soybean (Glycine max), sugarbeet (Beta vulgaris altissima), sunflower (Helianthus annus), and tomato (Lycopersicon esculentum)) crops was studied at a nominal concentration of 611 g a.i/ha. The growth medium used in the test was natural soil (loam, pH 5.4, organic carbon 1.0%). On day 14, the surviving plants per pot were recorded and cut at soil level for measuring the plant height and dry weight. The most sensitive monocot species in the vegetative vigor test was corn, with 8.5% inhibition of shoot dry weight. The EC25 could not be calculated as this effect level was not reached for any species for either weight or length. The most sensitive dicot species was tomato, with a 22.7% reduction in dry weight of shoots. No abnormalities were listed.

Results Synopsis

Vegetative vigor

Monocot

Most sensitive monocot: corn

Most sensitive parameter: shoot dry weight

Dicot

Most sensitive dicot: tomato

Most sensitive parameter: shoot dry weight

This toxicity study is classified as supplementary and does not satisfy the guideline requirement for a vegetative vigor toxicity study.

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

This study was conducted following the EPA Subdivision J: 122-1, OPPTS 850.4100 Guidelines, parts of which were incorporated into ABC Protocol No. 45916.

COMPLIANCE:

U.S. EPA Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160) and Organization for Economic Cooperation and Development 1997 Decision of the Council, Revised Principles of GLP [C(97)186/Final].

A. MATERIALS:

1. Test Material:

BAS 510 02F (EP)

Description: end use product

Lot No./Batch No.

Purity: 68.5% ai.

Stability of Compound

Under Test Conditions: not stated (OECD requires chemical stability in water and light)

Storage conditions of

test chemicals:

Stored at room temperature

Physicochemical properties of the active ingredient (BAS 510 F)

Parameter	Values	Comments	
Water solubility at 20°C	4.69 mg/L	low solubility	
Vapour pressure	7x10-9 mbar @ 20 °C	not volatile	
UV absorption	UV molecular extinction: 1.53x10 ³ at 290 nm	_	
pKa	does not dissociate in water		
Kow	2.96	Not likely to bioconcentrate	

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2. Test organism:

Monocotyledonous species:

The four monocot species tested were corn (Zea mays), ryegrass (Lolium perenne), and wheat (Triticum aestivum) representing the Graminae family, and onion (Allium cepa) representing the Amaryllidaceae family.

EPA requires 4 monocots in2 families, including corn

Dicotyledonous species:

The six dicot species tested were cucumber (Cucumis sativus), radish (Raphanus satirus), soybean (Glycine max), sugarbeet (Beta vulgaris altissima), sunflower (Helianthus annus), and tomato (Lycopersicon esculentum). These six species represented the families of Cucurbitaceae, Cruciferae, Leguminosae, Chenopodiaceae, Compositae, and Solanaceae, respectively.

EPA requires 6 dicots in 4 families, including soybean and a rootcrop.

OECD recommends a minimum of three species selected for testing, at least one from each of the following categories: Category 1: ryegrass, rice, oat, wheat, and sorghum; Category 2: mustard, rape, radish, turnip, and Chinese cabbage; Category 3: vetch, mung bean, red clover, fenugreek, lettuce, and cress.

Seed source: Various supply companies (see Table 1 in study)

Prior seed treatment/sterilization: none Historical % germination of seed: 85-99%

Seed storage, if any: not stated

B. STUDY DESIGN:

1. Experimental Conditions

b) Definitive Study

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Table 1. Experimental Parameters - Vegetative vigor

Parameters	Details	Remarks Criteria		
Duration of the test	2 weeks			
		EPA requires a duration of 14 days.		
		OECD recommends the test should be terminated no sooner than 14 days after 50 percent of the control seedlings have emerged		
Number of plants/species/replicate	Six seedlings per species were tested.			
	The number of plants was six for onion, ryegrass, and wheat (1 pot	EPA requires 10 seeds per replicate.		
	per replicate), three plants per pot for radish and sugarbeet (2 pots per replicate), and two plants per pot for corn, cucumber, soybean, sunflower, and tomato (3 pots per replicate).	OECD recommends a minimum of five seeds planted in each replicate within 24 hours of incorporation of the test substance. All seeds of each species for each test should be of the same size class. The seed should not be imbibed.		
Number of plants retained after thinning	not stated			
Number of replicates				
Control: colvent control: Teated ones:	4 4 4	EPA requires at least 3 replicates per dose OECD requires a minimum of four replicates per		
est concentrations (mg i/kg soil and g ai/ha)	Only one concentration was used	not acceptable		
ominal:	0.55 lb ai/a = 616 g ai/ha	EPA requires at least 5 test concentrations with a dose range of 2X or 3X progression		
		OECD requires 3 concentrations, preferably with application rates equivalent to 0.0 (control), 1.0, 10.0 and 100 mg substance per kg of oven dried soil.		

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Parameters	Details	Remarks		
Method and interval of analytical verification LOQ: LOD:	no analytical evaluation was done.	Not acceptable		
Solvent (type, percentage, if used)	crop oil			
Test container (pot)				
Size/Volume Material: (glass/polystyrene)	4x4 inch not stated	EPA recommends that non-porous containers be used OECD requires non-porous plastic or glazed pots.		
Growth facility	green house			
Method/depth of seeding	not stated			
Test material application:				
Application time including the plant growth stage	-			
Number of application	1			
Application interval	single application			
Method of application	overhead track sprayer			
Details of soil used				
	40 44 16 5.4 1.04 12.3 meq/100g	EPA prefers soil mixes containing sandy loam, loam, or clay loam soil with no greater than 2% organic matter. Glass beads, rockwool, and 100% acid washed sand are not recommended. OECD prefers the soil to be sieved (0.5 cm) to remove coarse fragments. Carbon content should not exceed 1.5% (3% organic matter). Fine particles (under 20um) should make up between 10 and 20%. The pH should be 5.0 and 7.5.		

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Parameters	Details	Remarks		
Details of nutrient medium, if used	-	Crueria		
Watering regime and schedules	from the top and or bottom			
Water source/type: Volume applied: Interval of application: Method of application:		EPA prefers that bottom watering be utilized for seedling emergence studies so that the chemical is no leached out of the soil during the test.		
Any pest control method/fertilization, if used	not stated			
Test conditions				
Temperature: Photoperiod: Light intensity and	19.8-36.9 16 hr light	EPA doesn't specify test temperatures but prefers that the cold vs warm loving plants be tested in two separate groups to optimize plant growth.		
quality: Relative humidity:	1000 W gro-light were used 11.8-74.2	OECD doesn't specify test conditions but recommends the temperature, humidity and light conditions be suitable for maintaining normal growth of each species for the test period.		
Reference chemical (if sed)	not used			
lame: concentrations:				
ther parameters, if any				

2. Observations:

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Table 2: Observation parameters - Vegetative vigor

Parameters	Vegetative vigor Details		
Parameters measured (eg: number of germinated seeds, emerged seedlings, plant height, dry weight or other endpoints)	shoot length and dried weight measurements, and phytotoxicity observations.		
Measurement technique for each parameter	The length measurements were made to the nearest millimeter using a ruler. Shoot length was determined from the tip of the fully extended leaf to the base of the plant for the monocot species and for the dicot species of radish and sugarbeet. Measurements were made from the base of the plant to the apical bud for the other dicot species.		
Observation intervals	measurements were taken at test termination		
Other observations, if any	-		
Were raw data included?	Yes		
Phytotoxicity rating system, if used	The rating used a number designation for a particular symptom and was rated for prevalence based on the number of plants per pot (replicate) from 0-100% as noted on the emergence form. Ratings were based on slight effects (10-39%), moderate effects (40-69%), and severe effects (70-100%).		

II. RESULTS and DISCUSSION:

A. INHIBITORY EFFECTS:

Vegetative vigor:

No phytotoxic effects greater than 25% as compared to the pooled control were noted for any of the species treated with BAS 510 02F at a rate of 611 g ai./ha. For shoot length and dried shoot weight, no effect of 25% or greater was detected for any species tested. Tomato exhibited the greatest calculated percent effect on shoot length, having shown a 6.6% reduction. Tomato exhibited the greatest calculated percent effect in dried shoot weight with a 22.7% reduction compared to control

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at test termination. Based on the rating scheme used, all adverse effects (greater than 10% reduction compared to control) detected can be classified as "slight effects" (10-39%) (PMRA only).

[Briefly describe the effect on percent germination, % survival, plant height, and dry weight; dose response relationship. Compare with reference standard, if used; Report the most sensitive monocot and dicot along with their EC25]

Describe other effects - Any abnormal seedling development or appearance (lesion, swelling, loss of turgor, discoloration, unusual leaf/plant shape or size, dead plants, other abnormalities. Report any rating system used for the description of injury to the plant (include references). If there was no observed toxicity, state "There were no compound related phytotoxic effects."]

Table 3: Effect of BAS 510 02F on Vegetative vigor

Treatment 611 g ai/ha	Dry weight of shoot (g)		Shoot length (mm)			
(nominal)	Pooled control	Treated group	Percent effect	Pooled control	Treated group	Percent effec
Corn	8.279	7.575	-8.5	727	705	-3.1
Cucumber	7.855	7.310	-6.9	143	148	
Onion	0.144	0.150	4.1	110		3.4
Radish	5.625	5.816	3.4	186	108	-1.2
Ryegrass	0.256	0.289	12.6	206	183	-1.8
Soybean	6.106	6.003	-1.7	 	221	7.4
Sugarbeet	2.552	2.564	 	180	193	6.9
Sunflower	6.233		0.5	137	141	2.8
Готаto		6.452	3.5	325	334	2.8
	3.194	2.468	-22.7	114	106	-6.6
Wheat	0.894	1.033	15.6	281	305	8.7

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Table 4: Effect of BAS 510 02F on Vegetative vigor:

most sensitive monocot and dicot plant species

Statistical Endpoint	Seedling emergence		
Monocot			
most sensitive species	corn		
NOEC for the most sensitive parameter (eg: dry weight)	not calculable, likely > 611 g ai/ha most sensitive parameter was shoot dry weight (-8.5%)		
EC25 for the most sensitive monocot	not calculable		
EC50 for the most sensitive monocot	not calculable		
Dicot:			
most sensitive species	Tomato		
NOEC for the most sensitive parameter (eg: dry weight)	not calculable, likely > 611 g ai/ha most sensitive parameter was dry weig of shoot (-22.7%)		
EC25 for the most sensitive dicot	not calculable		
EC50 for the most sensitive licot	not calculable		

B. REPORTED STATISTICS:

Due to a low adverse effect response in all species, no summary statistics could be calculated.

C. <u>VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER</u>: Not applicable.

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D. STUDY DEFICIENCIES:

The EPA requires 5 test concentrations to be used. This study used only one treatment level; 611 g ai/ha (0.55 lb ai/a). The maximum application rate on the label is 875 g ai/ha. The EC25 and NOEC could not be calculated because of study design. These deficiencies are considered to be major because a 25% reduction did not occur for any species at the only treatment level of 611 g ai/ha. The study is supplementary and does not satisfy guideline requirements. It is possible, and likely, that had the maximum rate been tested, an EC25 would have been obtained.

E. REVIEWER'S COMMENTS:

This study has major deficiencies as stated above, and is not usable for risk assessment. However, the data shows that at the near maximum application rate of 611 g ai/ha, a 25% reduction in plant vigor was not observed in any of the ten test species. This study is upgradeable to core status if the registrant agrees to lower the maximum <u>seasonal</u> rate to 611 g ai/ha. If the maximum rate is maintained at the higher level, EFED would ask that the study be repeated correctly.

F. **CONCLUSIONS**: This study is supplementary.

Most sensitive monocot: corn Most sensitive dicot: tomato

III. REFERENCES: