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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 15, 2004

MEMORANDUM

Subject:	Name of Pesticide Product:	Emerald® Turf Fungicide	
	EPA File Symbol:	7969-196	
	DP Barcode:	D304468	
	Decision No.:	217973	
	PC Codes:	128008	3-pyridinecarboxamide

From: Breann Hanson, Toxicologist BH
Technical Review Branch
Registration Division (7505C)

To: Robert Westin, RM Team 22
Fungicide Branch
Registration Division (7505C)

Applicant: BASF Corporation
Agricultural Products
26 Davis Dr.
Research Triangle Park, NC 27709-3528

FORMULATION FROM LABEL:

Active Ingredient:			% by wt.
128008	3-pyridinecarboxamide	CAS No. 188425-85-6	70.0%
Inert Ingredients:			30.0%
		Total:	100.00%

ACTION REQUESTED:

The Product Manager requests:

> "In response to recommendation 1 through 4 in D278275 dated Jan. 31, 2002, registrant has submitted attachment II to their letter dated Feb. 20, 2004 and the attached revised Final Reports (MRIDs 262701-01 and 262701-03) Do these comments and revised reports fulfil the conditions of registration of EPA Reg. No 7969-196 and 7969-197 for the specific acute tox requirements that are addressed?"

BACKGROUND: BASF Corporation has submitted a response to the Agency's conditions for registration of Emerald® Turf Fungicide, EPA Reg. No. 7969-196. The product was unconditionally registered providing BASF complied with a list of requirements. Included in this list was the following: to explain deviations noted in the acute oral, acute dermal, acute inhalation and primary skin irritation studies in order to upgrade their classifications from supplementary to acceptable; and, to submit a new dermal sensitization study testing the highest minimally irritating concentration of test substance in order to upgrade its classification from unacceptable to acceptable. The deviations noted in the previous review were: the age of the animals used in the acute oral, acute dermal and acute inhalation studies was 14-18 weeks rather than 8-12 weeks as specified in the guideline; only 3 animals/sex were used in the acute oral study; clinical examinations were not performed daily in the acute inhalation study; and, the size of treated area in the primary skin irritation study was not reported. The submission included a CSF and label, the previous review from TRB (McAndrew, EPA Fiel Symbol 7969-ROA, D278275, 31/JAN/2002) revised acute dermal irritation and dermal sensitization studies (MRIDs 46270101, 46270103) to replace those previously submitted and a letter from BASF explaining the deviations noted and reasons for why the studies should be upgraded to acceptable. The primary eye irritation study was previously classified as acceptable. The studies were conducted at Centre International de Toxicologie, Evreux, France.

RECOMMENDATIONS: The five studies have been upgraded and are classified as acceptable. Conditions of registration for the product have been fulfilled. The acute toxicity profile for Emerald® Turf Fungicide, EPA Reg. No. 7969-196 is:

Acute oral toxicity	III	Acceptable	MRID 45405327
Acute dermal toxicity	III	Acceptable	MRID 45405328
Acute inhalation toxicity	IV	Acceptable	MRID 45405326
Primary eye irritation	II	Cited	MRID 45405329
Primary skin irritation	IV	Acceptable	MRID 45405330/46270101
Dermal sensitization	Negative	Acceptable	MRID 45405331/46270103

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LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: **007969-00196**

PRODUCT NAME: Emerald® Turf Fungicide

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: WARNING

SPANISH SIGNAL WORD: AVISO
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin.

USER SAFETY RECOMMENDATIONS:
Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Reviewer: Breann Hanson **Date:** Sept. 15, 2004
Risk Manager (EPA): Robert Westin, RM 22

STUDY TYPE: Primary Dermal Irritation - NZW Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; gray granular)

CITATION: Manciaux, X. (2003) BAS 510 02 F - Acute Dermal Irritation in Rabbits. Project No.: 18H0393/009023. Unpublished study prepared by Centre International de Toxicologie. September 29, 2003. MRID 46270101.

SPONSOR: BASF Corporation, Agricultural Products, 26 Davis Dr., Research Triangle Park, NC 27709-3528

EXECUTIVE SUMMARY: In a primary skin irritation study, three young adult male New Zealand White rabbits (Source: Elevage Cunicole de Val de Selle, France) were dermally exposed to 0.5 g of BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; gray granular) for 4 hours. The test substance was moistened into a paste with purified water and then applied to the right flank of each animal, covering an area of at least 6 cm^2. Animals were observed 1, 24, 48 and 72 hours after patch removal.

BAS 510 02 F is classified as Toxicity Category IV based on the observations in this study.

Primary Dermal Irritation Index (PDII) = 0. 08 Very slight erythema was noted at one of the dose sites one hour after patch removal only. No other dermal irritation was observed.

This study is classified as Acceptable (870.2500) and satisfies the guideline requirement for a primary eye irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS: Primary Dermal Irritation Index (PDII) = 0.08

OBSERVATIONS: Very slight erythema was noted at one of the dose sites one hour after patch removal only. No other dermal irritation was observed.

Reviewer: Breann Hanson
Risk Manager (EPA): Robert Westin, RM 22

Date: Sept. 15, 2004

STUDY TYPE: Dermal Sensitization - Guinea Pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; gray granular)

CITATION: Manciaux, X. (2003) BAS 510 02 F - Skin Sensitization Test in Guinea Pigs (Modified Buehler Test: 9 applications). Project No.: 33H0393/009024. Unpublished study prepared by Centre International de Toxicologie. September 29, 2003. MRID 46270103.

SPONSOR: BASF Corporation, Agricultural Products, 26 Davis Dr., Research Triangle Park, NC 27709-3528

EXECUTIVE SUMMARY: In a dermal sensitization study conducted with BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; gray granular), 30 young adult male and female Hartley Crl: (HA)BR, Caesarian obtained, Barrier sustained - Virus Antibody Free (COBS - VAF) guinea pigs (Source: Charles River France) were tested using a modified Buehler test. Preliminary testing was done to determine the concentrations to be tested in the main study. Concentrations of 40% and 20% (w/w) were tested. A concentration of 40% was the highest possible concentration able to be tested due to the solubility of the test substance. Twenty test animals were induced with nine applications (six hours/exposure, three times per week for three weeks) of test substance at the concentration of 40% (w/w). "Bidistilled" water was used as the vehicle. The 10 animals in the control group received applications of the vehicle only. Reactions were scored 24 hours after each application. The animals rested for 11 days. On day 31, both the test and control animals received a dose of test substance at the concentration of 40% (w/w) for a six-hour challenge exposure. Due to the presence of discrete or moderate erythema in one test animal after challenge, a second challenge was conducted with the same concentration of test substance seven days after the primary challenge dose. Reactions were scored 24 and 48 hours after each challenge. A positive control study (CIT/Study No. 20069) using mercaptobenzothiazole was conducted within six months of the main study to validate the test system.

RESULTS: Discrete to moderate irritation was observed in 8/20 test animals during the induction phase. Following the first challenge, discrete to moderate erythema was observed at the 24 and 48 hour scorings of one test animal site. Dryness of the skin was also observed in this animal and in one control animal. Following the second challenge, no dermal reactions were noted in either the test or control animals. The results of the mercaptobenzothiazole positive control study were appropriate.

CONCLUSIONS: BAS 510 02 F does not have to be labeled a dermal sensitizer.

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This study is classified as acceptable (870.2600) and does satisfy the guideline requirement for a dermal sensitization study in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

PROCEDURE: In a dermal sensitization study conducted with BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; gray granular), 30 young adult male and female Hartley Crl: (HA)BR, Caesarian obtained, Barrier sustained - Virus Antibody Free (COBS - VAF) guinea pigs (Source: Charles River France) were tested using a modified Buehler test. Preliminary testing was done to determine the concentrations to be tested in the main study. Concentrations of 40% and 20% (w/w) were tested. A concentration of 40% was the highest possible concentration able to be tested due to the solubility of the test substance. Twenty test animals were induced with nine applications (six hours/exposure, three times per week for three weeks) of test substance at the concentration of 40% (w/w). "Bidistilled" water was used as the vehicle. The 10 animals in the control group received applications of the vehicle only. Reactions were scored 24 hours after each application. The animals rested for 11 days. On day 31, both the test and control animals received a dose of test substance at the concentration of 40% (w/w) for a six-hour challenge exposure. Due to the presence of discrete or moderate erythema in one test animal after challenge, a second challenge was conducted with the same concentration of test substance seven days after the primary challenge dose. Reactions were scored 24 and 48 hours after each challenge. A positive control study (CIT/Study No. 20069) using mercaptobenzothiazole was conducted within six months of the main study to validate the test system.

RESULTS: Discrete to moderate irritation was observed in 8/20 test animals during the induction phase. Following the first challenge, discrete to moderate erythema was observed at the 24 and 48 hour scorings of one test animal site. Dryness of the skin was also observed in this animal and in one control animal. Following the second challenge, no dermal reactions were noted in either the test or control animals. Under conditions of this study, the test substance did not induce delayed contact hypersensitivity in guinea pigs. The results of the mercaptobenzothiazole positive control study were appropriate.

CONCLUSIONS: The study is classified as acceptable.

1. **DP BARCODE:** D304468
2. **PC CODE: 128008**
3. **CURRENT DATE:** 15/SEP/2004
4. **TEST MATERIAL:** BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; gray granular)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Primary dermal irritation/rabbit Centre International de Toxicologie 18H0393/009023 09-29-2003	46270101	no dermal irritation at 72 hours	IV	A
Dermal sensitization/guinea pig Centre International de Toxicologie 33H0393/009024 09-29-2003	46270103	is not a sensitizer	–	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived**