

US EPA ARCHIVE DOCUMENT



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

31/JAN/2002

MEMORANDUM

Subject: Name of Pesticide Product: BAS 510 02 F Turf Fungicide  
EPA Reg. No. /File Symbol: 7969-ROA  
DP Barcode: D278275  
Case No: 070367  
PC Code: 128008

From: Eugenia McAndrew, Biologist *EM*  
Technical Review Branch *SCR*  
Registration Division (7505C)

To: Maria Rodriguez, PM Team 22  
Fungicide Branch  
Registration Division (7505C)

Applicant: BASF Corporation  
Agricultural Products  
P.O. Box 13528  
Research Triangle Park, NC 27709-3528

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
128008 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)	70.0
<u>Inert Ingredient(s):</u>	<u>30.0</u>
Total:	100.0%

ACTION REQUESTED: PM requests review of acute toxicity data for EPA File Symbol 7969-ROA, BAS 510 02 F Turf Fungicide.

①

**BACKGROUND:** BASF has submitted a six pack of acute toxicity studies in support of registration of the end use product, EPA File Symbol 7969-ROA, BAS 510 02 F Turf Fungicide. The studies were assigned MRID numbers 454053-26 to -31. The studies were conducted at Experimental Toxicology and Ecology, BASF Aktiengesellschaft, Germany and at Centre International de Toxicologie, France.

**RECOMMENDATIONS:** The six studies have been reviewed. The primary eye irritation study is classified as acceptable. The acute oral, acute dermal, acute inhalation and primary skin irritation studies are classified as supplementary due to the following deviations from the OPPTS guidelines:

1. The age of the female animals used in the acute oral, acute dermal and acute inhalation toxicity studies was 14-18 weeks rather than the 8-12 weeks as specified in the guideline.
2. Only three animals/sex were used in the acute oral study. The guideline specifies at least five animals/sex.
3. In the acute inhalation study, clinical examinations were not performed daily as specified in the guideline.
4. In the primary skin irritation study, the size of the area treated with the test substance was not reported. The guideline specifies that a 6 cm<sup>2</sup> area be tested.

The above studies are potentially upgradable depending on an adequate explanation of the deviations. The studies may be used to assign this formulation to toxicity categories by these exposure routes.

The dermal sensitization study is classified as unacceptable because the highest minimally irritating concentration of test substance was not established. Please refer to p. 13 of this review for full explanation. A new study must be submitted to satisfy the requirements for registration.

The acute toxicity profile for EPA File Symbol 7969-ROA, BAS 510 02 F Turf Fungicide, is as follows:

acute oral toxicity	III	Supplementary	MRID 454053-27
acute dermal toxicity	III	Supplementary	MRID 454053-28
acute inhalation toxicity	IV	Supplementary	MRID 454053-26
primary eye irritation	II	Acceptable	MRID 454053-29
primary skin irritation	IV	Supplementary	MRID 454053-30
dermal sensitization	--	Unacceptable	MRID 454053-31

**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. The labeling will not be considered complete until an acceptable dermal sensitization study is submitted.

# Label Review System

**PRODUCT ID #:** 007969-00196

**PRODUCT NAME:** BAS 510 02 F Turf Fungicide

## PRECAUTIONARY STATEMENTS

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.)

### Hazards to Humans and Domestic Animals:

#### SPANISH SIGNAL WORD: AVISO

**SIGNAL WORD: WARNING**

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Wear: Long-sleeved shirt and long pants, socks, shoes, and gloves.

### 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.

## DATA EVALUATION RECORD

**STUDY TYPE:** ACUTE ORAL TOXICITY TESTING (870.1100 formerly §81-1)

**Product Manager:** 22

**Reviewer:** Eugenia McAndrew

**TEST MATERIAL PURITY:** BAS 510 02 F (68.5% BAS 510 F [3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)]

**CITATION:** Gamer, A.O. (2001) BAS 510 02 F; acute oral toxicity in Wistar rats. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, Germany. Laboratory Report Number 10A0393/001090. February 11, 2001. MRID 45405327. Unpublished.

**SPONSOR:** BASF Corporation Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709-3528

**EXECUTIVE SUMMARY:** In an acute oral toxicity study, three young adult Wistar (SPF)/ Cri: WI (GLX/BRL/HAN)IGS BR rats/sex (Weight: males 227-237 g; females 203-205 g; Source: Charles River Laboratories, Deutschland) were given a single oral dose of BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; brownish-beige granule) at 2000 mg/kg. "The test substance preparation was produced for each dose group shortly before administration in doubly distilled water by stirring with a magnetic stirrer." Animals were observed for clinical signs of toxicity and mortality for 14 days post dosing.

Oral LD<sub>50</sub> Males = > 2000 mg/kg (observed); Oral LD<sub>50</sub> Females = > 2000 mg/kg (observed)

BAS 510 02 F is classified as Toxicity Category III based on the observed LD<sub>50</sub> value in both sexes.

All animals survived and gained bodyweight during the study. No signs of toxicity were noted. No macroscopic abnormalities were noted at necropsy.

Deviations: Only three animals per sex were tested. The OPPTS Guideline 870.1100 specifies that five animals per sex be used. The age of the females is reported to be 14-18 weeks. The OPPTS Guideline 870.1100 specifies 8-12 weeks.

This study is classified as Supplementary (870.1100) but is upgradable depending on an adequate explanation of the deviations. The study, however, may be used to assign this formulation to a toxicity category by this exposure route.

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

**RESULTS:**

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
2000	0/3	0/3	0/6

**OBSERVATIONS:** All animals survived and gained bodyweight during the study. No signs of toxicity were noted.

Deviations: Only three animals per sex were tested. The OPPTS Guideline 870.1100 specifies that five animals per sex be used. The age of the females is reported to be 14-18 weeks. The OPPTS Guideline 870.1100 specifies 8-12 weeks.

**GROSS NECROPSY:** No macroscopic abnormalities were noted at necropsy.

5

## DATA EVALUATION RECORD

**STUDY TYPE:** ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

**Product Manager:** 22

**Reviewer:** Eugenia McAndrew

**TEST MATERIAL PURITY:** BAS 510 02 F (68.5% BAS 510 F [3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)]

**CITATION:** Gamer, A.O. (2001) BAS 510 02 F; acute dermal toxicity in rats. *Experimental Toxicology and Ecology*, BASF Aktiengesellschaft, Germany. Laboratory Report Number 11A0393/001090. February 20, 2001. MRID 45405328. Unpublished.

**SPONSOR:** BASF Corporation Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709-3528

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study, five young adult Wistar (SPF)/ Crl: WI (GLX/BRL/HAN)IGS BR rats/sex (Weight: males 243–259 g; females 203-224 g; Source: Charles River Laboratories, Deutschland) were dermally exposed to a single application of BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; brownish-beige granule) at 2000 mg/kg (limit dose) for 24 hours. The test substance was applied as a suspension in doubly distilled water and applied to at least 10% of the total body surface area. Animals were observed for clinical signs of toxicity and mortality several times on the day of application and daily for 14 days.

Dermal LD<sub>50</sub> Males = > 2000 mg/kg (observed); Dermal LD<sub>50</sub> Females = > 2000 mg/kg (observed)

BAS 510 02 F is classified as Toxicity Category III based on the observed LD<sub>50</sub> values in both sexes.

All animals survived the study. All males gained weight; three females lost weight during the first week and one female lost weight during the second week. No signs of systemic toxicity or local irritation were observed in any animal. No macroscopic abnormalities were noted at necropsy.

Deviation: The age of the females is reported to be 14-18 weeks. The OPPTS Guideline 870.1200 specifies 8-12 weeks.

This study is classified as Supplementary (870.1200) but is upgradable depending on an adequate explanation of the deviation. The study, however, may be used to assign this formulation to a toxicity category by this exposure route.

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

**RESULTS:**

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
2000	0/5	0/5	0/10

**OBSERVATIONS:** All animals survived the study. All males gained weight; three females lost weight during the first week and one female lost weight during the second week. No signs of systemic toxicity or local irritation were observed in any animal.

Deviation: The age of the females is reported to be 14-18 weeks. The OPPTS Guideline 870.1200 specifies 8-12 weeks.

**GROSS NECROPSY:** No macroscopic abnormalities were noted at necropsy.



## DATA EVALUATION RECORD

**STUDY TYPE:** ACUTE INHALATION TOXICITY TESTING (870.1300 formerly §81-3)

**Product Manager:** 22

**Reviewer:** Eugenia McAndrew

**TEST MATERIAL PURITY:** BAS 510 02 F (68.5% BAS 510 F [3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)]

**CITATION:** Gamer, A.O. (2001) BAS 510 02 F; acute inhalation toxicity in Wistar rats/4-hour dust exposure. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, Germany. Laboratory Report Number 13I0393/007019. March 5, 2001. MRID 45405326. Unpublished.

**SPONSOR:** BASF Corporation Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709-3528

**EXECUTIVE SUMMARY:** In an acute inhalation toxicity study, five young adult Wistar Crl: WI (GLX/BRL/HAN)IGS BR rats/sex (Weight: males 272–292 g; females 222–237 g; Source: Charles River Laboratories, Deutschland) rats/sex were exposed by nose only inhalation to BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; brownish-beige granule) at 5.4 mg/L for 4 hours. All animals were observed for clinical signs of toxicity and mortality during the exposure and for 14 days post exposure.

Inhalation LC<sub>50</sub> Males = > 5.4 mg/L (observed); Inhalation LC<sub>50</sub> Females = > 5.4 mg/L (observed)

BAS 510 02 F is classified as Toxicity Category IV based on the observed LC<sub>50</sub> values in both sexes.

All animals survived the study. All males gained weight; three females lost weight during the first week and one female lost weight during the second week. In-chamber observations included accelerated respiration and attempts to escape. Upon removal from the exposure chamber, all animals exhibited squatting posture and one still had accelerated respiration but all animals recovered by day 3. The gravimetric chamber concentration was 5.4 mg/L. The mass median aerodynamic diameter was estimated to be 4.2 µm with a geometric standard deviation of 2.5-3.0 Necropsy after 14 days revealed no gross abnormalities.

Deviations: The age of the females is reported to be 14-18 weeks. The OPPTS Guideline 870.1300 specifies 8-12 weeks. Clinical examinations were not performed on study days 4, 5, 11 and 12 though OPPTS Guideline 870.1300 specifies daily clinical examinations.

This study is classified as Supplementary (870.1300) but is upgradable depending on an adequate explanation of the deviations. The study, however, may be used to assign this formulation to a toxicity category by this exposure route.

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

**RESULTS:**

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
5.4	0/5	0/5	0/10

Chamber Atmosphere		
Exposure Concentration	MMAD	GSD
5.4 mg/L	4.2 $\mu$ m	2.5 - 3.0

Chamber Environment <sup>a</sup>	
Chamber Volume	55 L
Airflow	25 LPM
Temperature	22.7 °C
Relative Humidity	52.4%

<sup>a</sup> Nose only

**OBSERVATIONS:** All animals survived the study. All males gained weight; three females lost weight during the first week and one female lost weight during the second week. In-chamber observations included accelerated respiration and attempts to escape. Upon removal from the exposure chamber, all animals exhibited squatting posture and one still had accelerated respiration but all recovered by day 3.

Deviations: The age of the females is reported to be 14-18 weeks. The OPPTS Guideline 870.1300 specifies 8-12 weeks. Clinical examinations were not performed on study days 4, 5, 11 and 12 though OPPTS Guideline 870.1300 specifies daily clinical examinations.

**GROSS NECROPSY:** Necropsy after 14 days revealed no gross abnormalities.

## DATA EVALUATION RECORD

**STUDY TYPE:** PRIMARY EYE IRRITATION TESTING (870.2400 formerly §81-4)

**Product Manager:** 22

**Reviewer:** Eugenia McAndrew

**TEST MATERIAL PURITY:** BAS 510 02 F (68.5% BAS 510 F [3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)]

**CITATION:** Manciaux, X. (2001) BAS 510 02 F; acute eye irritation in rabbits. Centre International de Toxicologie, France. Laboratory Report Number 11H0393/009025. January 16, 2001. MRID 45405329. Unpublished.

**SPONSOR:** BASF Corporation Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709-3528

**EXECUTIVE SUMMARY:** In a primary eye irritation study, 100 mg of BAS 510 02 F (68.5% purity; Batch # 573-07-GB2; gray granular) was placed into the conjunctival sac of the left eye of three young adult male New Zealand White rabbits (Source: Elevage Cunicole de Val de Selle, France). The test substance was ground to a fine powder prior to instillation. All animals were observed for ocular irritation at 1, 24, 48 and 72 hours post-instillation.

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

No positive results were noted during the ocular observations for one animal. A second animal's eye exhibited conjunctivitis (redness) from 24 hours to day 7. In the third animal, conjunctivitis was noted beginning one hour after instillation. The chemosis resolved by 72 hours. Clear to whitish purulent discharge was noted through 72 hours. Very slight to moderate redness was present from 48 hours to day 10. Corneal opacity was noted from 24 through 72 hours. Iritis was noted at 24 hours. No positive results were noted in this eye after day 10.

This study is classified as Acceptable (870.2400) 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:**

**Unwashed eyes:**

Observations	Number "positive"/number tested							
	Hours				Days			
	1	24	48	72	5	7	10	14
Corneal Opacity	0/3	1/3	1/3	1/3	0/3	0/3	0/3	0/3
Iritis	0/3	1/3	0/3	0/3	0/3	0/3	0/3	0/3
Conjunctivae:								
Redness*	0/3	2/3	2/3	2/3	2/3	1/3	1/3	0/3
Chemosis*	1/3	2/3	1/3	0/3	0/3	0/3	0/3	0/3
Discharge*	1/3	1/3	1/3	1/3	0/3	0/3	0/3	0/3

\*Score of 2 or more required to be considered "positive."

**OBSERVATIONS:** No positive results were noted during the ocular observations for one animal. A second animal's eye exhibited conjunctivitis (redness) from 24 hours to day 7. In the third animal, conjunctivitis was noted beginning one hour after instillation. The chemosis resolved by 72 hours. Clear to whitish purulent discharge was noted through 72 hours. Very slight to moderate redness was present from 48 hours to day 10. Corneal opacity was noted from 24 through 72 hours. Iritis was noted at 24 hours. No positive results were noted in this eye after day 10.

## DATA EVALUATION RECORD

**STUDY TYPE:** PRIMARY DERMAL IRRITATION TESTING (870.2500 formerly §81-5)

**Product Manager:** 22

**Reviewer:** Eugenia McAndrew

**TEST MATERIAL PURITY:** BAS 510 02 F (68.5% BAS 510 F [3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)]

**CITATION:** Manciaux, X. (2001) BAS 510 02 F; acute dermal irritation in rabbits. Centre International de Toxicologie, France. Laboratory Report Number 18H0393/009023. January 17, 2001. MRID 45405330. Unpublished.

**SPONSOR:** BASF Corporation Agricultural Products, P.O. Box 13528, 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. The size of the area treated was not reported. 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.

Deviation: The size of the area treated with the test substance was not reported. The OPPTS Guideline 870.2500 specifies that a 6 cm<sup>2</sup> area be tested.

This study is classified as Supplementary (870.2500) but is upgradable depending on an adequate explanation of the deviation. The study, however, may be used to assign this formulation to a toxicity category by this exposure route.

**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.

Deviation: The size of the area treated with the test substance was not reported. The OPPTS Guideline 870.2500 specifies a 6 cm<sup>2</sup> area be tested.

## DATA EVALUATION RECORD

**STUDY TYPE:** DERMAL SENSITIZATION TESTING (870.2600 formerly §81-6)

**Product Manager:** 22

**Reviewer:** Eugenia McAndrew

**TEST MATERIAL PURITY:** BAS 510 02 F (68.5% BAS 510 F [3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl])

**CITATION:** Manciaux, X. (2001) BAS 510 02 F; skin sensitization test in guinea pigs (Modified Buehler Test: 9 applications). Centre International de Toxicologie, France. Laboratory Report Number 33H0393/009024. February 19, 2001. MRID 45405331. Unpublished.

**SPONSOR:** BASF Corporation Agricultural Products, P.O. Box 13528, 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. 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:** The study is classified as unacceptable because the preliminary study did not test at high enough concentrations to determine the highest minimally irritating concentration. Only two concentrations - 20% and 40% - were tested and neither produced any irritation. The dose used for the induction should be high enough to cause mild irritation; this dose was not determined. Also, the amount of test substance applied to the animals at induction and challenge was not reported. Therefore, a new study must be submitted to satisfy the requirements for registration.

BAS 510 02 F cannot be classified based on the results of this study.

This study is classified as Unacceptable (870.2600) and does not 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 CrI: (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. 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 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 unacceptable because the preliminary study did not test at high enough concentrations to determine the highest minimally irritating concentration. Only two concentrations - 20% and 40% - were tested and neither produced any irritation. The dose used for the induction should be high enough to cause mild irritation; this dose was not determined. Also, the amount of test substance applied to the animals at induction and challenge was not reported. Therefore, a new study must be submitted to satisfy the requirements for registration.

**ACUTE TOX ONE-LINERS**

1. DP BARCODE: D278275
2. PC CODE: 128008
3. CURRENT DATE: 31/JAN/2002
4. TEST MATERIAL: BAS 510 02 F (68.5% BAS 510 F [3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl) - 2-yl)] Batch # 573-07-GB2; brownish-beige granule)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Experimental Toxicology and Ecology BASF Aktiengesellschaft, Germany/10A0393/001090 2-11-01	454053-27	LD <sub>50</sub> > 2000 mg/kg (males females combined)	III	S
Acute dermal toxicity/rat Experimental Toxicology and Ecology BASF Aktiengesellschaft, Germany/11A0393/001091 2-20-01	454053-28	LD <sub>50</sub> > 2000 mg/kg (males females combined)	III	S
Acute inhalation toxicity/rat Experimental Toxicology and Ecology BASF Aktiengesellschaft, Germany/13I0393/007019 3-5-01	454053-26	LC <sub>50</sub> > 5.4 mg/L (males females combined)	IV	S
Primary eye irritation/rabbit Centre International de Toxicologie, France 11H0393/009025 1-16-01	454053-29	Corneal opacity in 1/3 eyes from 24 hours to day 5. Iritis in same eye at 24 hours. Conjunctivitis in 2/3 eyes persisting in one eye through day 10.	II	A
Primary dermal irritation/rabbit Centre International de Toxicologie, France 18H0393/009023 1-17-01	454053-30	PDII = 0.08 Non-irritant	IV	S
Dermal sensitization/guinea pig Centre International de Toxicologie, France 33H0393/009024 2-19-01	454053-31	Could not be determined	-	U

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated