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 516 02 F Crop Fungicide
	EPA Reg. No. /File Symbol:	7969-ROO
	DP Barcode:	D278285
	Case No:	070370
	PC Code:	128008, 099100
From:	Eugenia McAndrew, Biologist EM Technical Review Branch JCK 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:

	Active Ingredient(s):	% by wt.
128008	3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)	25.2
099100	pyraclostrobin (carbamic acid)	12.8
	Inert Ingredient(s):	62.0
	Total:	100.0%

ACTION REQUESTED: PM requests review of acute toxicity data for EPA File Symbol 7969-ROO, BAS 516 02 F Crop Fungicide.

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BACKGROUND: BASF has submitted a six pack of acute toxicity studies in support of registration of the end use product, EPA File Symbol 7969-ROO, BAS 516 02 F Crop Fungicide. The studies were assigned MRID numbers 454053-14 to -19. 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^2 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. A new study must be submitted to satisfy the requirements for registration. Please refer to p. 14 of this review for full explanation.

The acute toxicity profile for EPA File Symbol 7969-ROO, BAS 516 02 F Crop Fungicide, is as follows:

acute oral toxicity	III	Supplementary	MRID 454053-14
acute dermal toxicity	III	Supplementary	MRID 454053-15
acute inhalation toxicity	IV	Supplementary	MRID 454053-17
primary eye irritation	III	Acceptable	MRID 454053-16
primary skin irritation	IV	Supplementary	MRID 454053-18
dermal sensitization	No	Unacceptable	MRID 454053-19

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 #: 007969-00199

PRODUCT NAME: BAS 516 02 F Crop Fungicide

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: **CAUTION**

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Avoid contact with eyes or clothing. 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 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.

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.

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 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin)]

CITATION: Gamer, A.O. (2001) BAS 516 02 F; acute oral toxicity in Wistar rats. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, Germany. Laboratory Report Number 10A0657/001101. February 21, 2001. MRID 45405314. 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)/ Crl: WI (GLX/BRL/HAN)IGS BR rats/sex (Weight: males 224-244 g; females 199-203 g; Source: Charles River Laboratories, Deutschland) were given a single oral dose of BAS 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; gray granulate] 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_{50} Males = > 2000 mg/kg (observed); Oral LD_{50} Females = > 2000 mg/kg (observed)

BAS 516 02 F is classified as Toxicity Category III based on the calculated LD_{50} value in both sexes.

One female died on day 1. All males survived. Signs of toxicity were noted in the males from 2-5 hours after administration and included impaired general state, dyspnea, staggering and piloerection. Signs of toxicity were noted in the females from 0-5 hours after administration and included poor general state, dyspnea, apathy, staggering, twitching, spastic gait, piloerection and diarrhea. The surviving animals all had bodyweight gains. No macroscopic abnormalities were noted in the animals sacrificed at the end of the study. Necropsy findings of the animal that died included red discoloration of the glandular stomach and moderately red discoloration of the small intestine.

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	1/3	1/6

OBSERVATIONS: One female died on day 1. All males survived. Signs of toxicity were noted in the males from 2-5 hours after administration and included impaired general state, dyspnea, staggering and piloerection. Signs of toxicity were noted in the females from 0-5 hours after administration and included poor general state, dyspnea, apathy, staggering, twitching, spastic gait, piloerection and diarrhea. The surviving animals all had bodyweight gains.

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 in the animals sacrificed at the end of the study. Necropsy findings of the animal that died included red discoloration of the glandular stomach and moderately red discoloration of the small intestine.

DATA EVALUATION RECORD

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

Product Manager: 22 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: BAS 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin)]

CITATION: Gamer, A.O. (2001) BAS 516 02 F; acute dermal toxicity in rats. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, Germany. Laboratory Report Number 11A0657/001102. February 20, 2001. MRID 45405315. 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 230-252 g; females 208-223 g; Source: Charles River Laboratories, Deutschland) were dermally exposed to a single application of BAS 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; gray granulate 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_{50} Males = > 2000 mg/kg (observed); Dermal LD_{50} Females = > 2000 mg/kg (observed)

BAS 516 02 F is classified as Toxicity Category III based on the observed LD_{50} values in both sexes.

All animals survived the study. All males gained weight; two females lost weight and one did not gain weight during the first week. All females gained weight by the end of the study. No signs of systemic toxicity were observed in any animal. Local dermal irritation was noted at all test sites. The males had very slight to well defined erythema and very slight edema on day 1 only. The females had very slight to well defined erythema and very slight edema on day 1 persisting at one site until day 7. Necropsy after 14 days revealed no gross abnormalities.

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; two females lost weight and one did not gain weight during the first week. All females gained weight by the end of the study. No signs of systemic toxicity were observed in any animal. Local dermal irritation was noted at all test sites. The males had very slight to well defined erythema and very slight edema on day 1 only. The females had very slight to well defined erythema and very slight edema on day 1 persisting at one site until day 7.

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

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

DATA EVALUATION RECORD

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

Product Manager: 22 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: BAS 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin)]

CITATION: Gamer, A.O. (2001) BAS 516 02 F; acute inhalation toxicity in Wistar rats. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, Germany. Laboratory Report Number 13I0657/007022. February 11, 2001. MRID 45405317. 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 245-255 g; females 219-231 g; Source: Charles River Laboratories, Deutschland) were exposed by nose only inhalation to BAS 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; gray granulate] 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_{50} Males = > 5.4 mg/L (observed); Inhalation LC_{50} Females = > 5.4 mg/L (observed)

BAS 516 02 F is classified as Toxicity Category IV based on the observed LC_{50} values in both sexes.

All animals survived the study. Two males and all five females lost weight during the first week of the study. All males gained weight and exceeded initial body weights by the end of the study. Three females gained small amounts of weight during the second week but still did not exceed initial body weights. The other two females gained weight during the second week and did exceed initial body weights by the end of the study. In-chamber observation included accelerated respiration in all animals. Upon removal from the exposure chamber, all animals continued to exhibit accelerated respiration plus squatting posture and smeared fur. Apathy and eyelid closure were also observed in several animals. The animals recovered from these symptoms by day 7. The gravimetric chamber concentration was 5.4 mg/L. The mass median aerodynamic diameter was estimated to be 3.9 - 4.1 µm with a geometric standard deviation of 1.9 - 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 2, 3, 9 and 10 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	3.9 - 4.1 µm	1.9 - 3.0

Chamber Environment[a]	
Chamber Volume	55 L
Airflow	25 LPM
Temperature	22.4 °C
Relative Humidity	45.8%

[a] Nose only

OBSERVATIONS: All animals survived the study. Two males and all five females lost weight during the first week of the study. All males gained weight and exceeded initial body weights by the end of the study. Three females gained small amounts of weight during the second week but still did not exceed initial body weights. The other two females gained weight during the second week and did exceed initial body weights by the end of the study. In-chamber observation included accelerated respiration in all animals. Upon removal from the exposure chamber, all animals continued to exhibit accelerated respiration plus squatting posture and smeared fur. Apathy and eyelid closure were also observed in several animals. The animals recovered from these symptoms by day 7.

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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 2, 3, 9 and 10 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 516 02 F [27.6% BAS 510 F, 12.4% BAS F 500 (pyraclostrobin)]

CITATION: Manciaux, X. (2001) BAS 516 02 F; acute eye irritation in rabbits. Centre International de Toxicologie, France. Laboratory Report Number 11H0657/009037. February 19, 2001. MRID 45405316. 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 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; beige granules] 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.

No corneal opacity was observed. Iritis was noted in 2/3 eyes at 24 hours resolving by 72 hours. Conjunctivitis was noted in all three eyes beginning at the one hour observation. Very slight to moderate chemosis, slight redness and a clear discharge were noted. All eyes were free of irritation by day 5.

BAS 516 02 F is classified as Toxicity Category III based on the observations and resolution of ocular irritation by day 5.

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
Corneal Opacity	0/3	0/3	0/3	0/3	0/3
Iritis	0/3	2/3	1/3	0/3	0/3
Conjunctivae:					
Redness*	3/3	3/3	2/3	2/3	0/3
Chemosis*	3/3	2/3	2/3	0/3	0/3
Discharge*	3/3	2/3	2/3	0/3	0/3

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

OBSERVATIONS: No corneal opacity was observed. Iritis was noted in 2/3 eyes at 24 hours resolving by 72 hours. Conjunctivitis was noted in all three eyes beginning at the one hour observation. Very slight to moderate chemosis, slight redness and a clear discharge were noted. All eyes were free of irritation by day 5.

DATA EVALUATION RECORD

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

Product Manager: 22 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: BAS 516 02 F [27.6% BAS 510 F, 12.4% BAS F 500 (pyraclostrobin)]

CITATION: Manciaux, X. (2001) BAS 516 02 F; acute dermal irritation in rabbits. Centre International de Toxicologie, France. Laboratory Report Number 18H0657/009036. February 16, 2001. MRID 45405318. 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 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; beige granules] for 4 hours. The test substance was moistened into a paste with purified water before application. One animal was tested first with a duration of exposure of 3 minutes on one flank and 4 hours on the other flank. Since the test substance was not an irritant on the first animal, it was then applied for 4 hours to two other animals for exposure periods of 3 minutes and 4 hours. The size of the areas treated was not reported. Animals were observed 1, 24, 48 and 72 hours after patch removal.

BAS 516 02 F is classified as Toxicity Category IV based on the observations in this study.

Primary Dermal Irritation Index (PDII) = 0.17 Very slight erythema was noted at one dose site one hour and 24 hours after patch removal. 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^2 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) = 0.17

OBSERVATIONS: Very slight erythema was noted at one dose site one hour and 24 hours after patch removal. 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^2 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 516 02 F [27.6% BAS 510 F, 12.4% BAS F 500 (pyraclostrobin)]

CITATION: Manciaux, X. (2001) BAS 516 02 F; skin sensitization test in guinea pigs (modified Buehler test: 9 applications). Centre International de Toxicologie, France. Laboratory Report Number 33H0657/009038. February 16, 2001. MRID 45405319. 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 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; beige granules], 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 50% and 25% (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 50% (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 50% (w/w) for a six-hour challenge exposure. 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 erythema (grade 1) was observed at 2/20 test animal sites during the induction phase. Most of the animals had dry skin and a slight beige discoloration of the skin. Following the challenge, no dermal irritation was observed at any of the test or control animal sites. 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 - 25% and 50% - 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 516 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 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; beige granules],.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 50% and 25% (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 50% (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 50% (w/w) for a six-hour challenge exposure. 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 erythema (grade 1) was observed at 2/20 test animal sites during the induction phase. Most of the animals had dry skin and a slight beige discoloration of the skin. Following the challenge, no dermal irritation was observed at any of the test or control animal sites. 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 - 25% and 50% - 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:** D278285
2. **PC CODE:** 128008, 099100
3. **CURRENT DATE:** 31/JAN/2002
4. **TEST MATERIAL:** BAS 516 02 F [27.6% BAS 510 F, 12.4% BAS 500 F (pyraclostrobin); Batch No. Lot AF543-63; gray granulate]

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Experimental Toxicology and Ecology BASF Aktiengesellschaft, Germany/10A0657/001101 2-21-01	454053-14	LD_{50} > 2000 mg/kg (males females combined)	III	S
Acute dermal toxicity/rat Experimental Toxicology and Ecology BASF Aktiengesellschaft, Germany/11A0657/001102 2-20-01	454053-15	LD_{50} > 2000 mg/kg (males females combined)	III	S
Acute inhalation toxicity/rat Experimental Toxicology and Ecology BASF Aktiengesellschaft, Germany/13I0657/007022 2-11-01	454053-17	LC_{50} > 5.4 mg/L (males females combined)	IV	S
Primary eye irritation/rabbit Centre International de Toxicologie, France 11H0657/009037 2-19-01	454053-16	Conjunctivitis and iritis clearing by day 5.	III	A
Primary dermal irritation/rabbit Centre International de Toxicologie, France 18H0657/009036 2-16-01	454053-18	PDII = 0. 17 Non-irritant	IV	S
Dermal sensitization/guinea pig Centre International de Toxicologie, France 33H0657/009038 2-16-01	454053-19	Could not be determined	–	U

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