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 F Manufacturer's Use Product
	EPA Reg. No. /File Symbol:	7969-ROI
	DP Barcode:	D278286
	Case No:	070369
	PC Code:	128008
From:	Eugenia McAndrew, Biologist Technical Review Branch 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)	99.0
	Inert Ingredient(s):	1.0
	Total:	100.0%

ACTION REQUESTED: PM requests review of acute toxicity data for EPA File Symbol 7969-ROI, BAS 510 F Manufacturer's Use Product.

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BACKGROUND: BASF has submitted a six pack of acute toxicity studies in support of registration of EPA File Symbol 7969-ROI, BAS 510 F Manufacturer's Use Product. The studies were assigned MRID numbers 454048-14 to -19. The studies were conducted at Department of Toxicology of BASF Aktiengesellschaft, Germany.

BAS 510 F is a new reduced - risk fungicide. BASF is also submitting applications for three end-use products formulated with BAS 510 F.

New study
17 MRIDs (454048-14 to -19)
D 233310

RECOMMENDATIONS: The six studies have been reviewed. The acute oral, acute dermal, acute inhalation, primary eye and primary skin irritation studies are classified as acceptable. The dermal sensitization study is classified as unacceptable because the 5% concentration used for the challenge was inadequate. A new study must be submitted to satisfy the requirements for registration. Please refer to p. 13 of this review for full explanation.

The acute toxicity profile for EPA File Symbol 7969-ROI, BAS 510 F Manufacturer's Use Product, is as follows:

acute oral toxicity	IV	Acceptable	MRID 454048-14
acute dermal toxicity	III	Acceptable	MRID 454048-15
acute inhalation toxicity	IV	Acceptable	MRID 454048-16
primary eye irritation	IV	Acceptable	MRID 454048-17
primary skin irritation	IV	Acceptable	MRID 454048-18
dermal sensitization	--	Unacceptable	MRID 454048-19

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 complete, however, until an acceptable dermal sensitization study is submitted.

Label Review System

PRODUCT ID #: 007969-00198

PRODUCT NAME: BAS 510 F Manufacturer's Use Product

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

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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.

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: 95.3% BAS 510 F (3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)

CITATION: Wiemann, C. (1998) BAS 510 F; acute oral toxicity in rats. Department of Toxicology of BASF Aktiengesellschaft, Germany. Laboratory Report Number 10A0179/971052. July 10, 1998. MRID 45404814. Unpublished.

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

EXECUTIVE SUMMARY: In an acute oral toxicity study, five young adult Wistar chbb: thom (SPF) rats/sex (Weight: 150-300 g; Source: Dr. K. Thomae GmbH, Biberach, FRG) were given a single oral dose of BAS 510 F (95.3% purity; Batch # N26; white powder) at 2000 mg/kg and 5000 mg/kg. The test substance was formulated with 0.5 % Tylose CB 30.00 (cleaned sodiumcarboxymethylcellulose from Hoechst AG) in aqua bidest. Animals were observed for clinical signs of toxicity and mortality for 14 days post dosing.

Oral LD_{50} Males = > 5000 mg/kg (observed); Oral LD_{50} Females = > 5000 mg/kg (observed)

BAS 510 F is classified as Toxicity Category IV based on the calculated LD_{50} value in both sexes.

At 2000 mg/kg, all animals survived and gained bodyweight during the study. No clinical signs were noted. No gross abnormalities were noted at necropsy.

At 5000 mg/kg, all animals survived and gained bodyweight during the study. Clinical signs noted on day 1 were impaired general state, dyspnea, staggering, erythema and piloerection. The animals recovered from these symptoms by day 2. No gross abnormalities were noted at necropsy.

This study is classified as Acceptable (870.1100) and satisfies the guideline requirement for an acute oral study in the rat.

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
5000	0/5	0/5	0/10

OBSERVATIONS: At 2000 mg/kg, all animals survived and gained bodyweight during the study. No clinical signs were noted.

At 5000 mg/kg, all animals survived and gained bodyweight during the study. Clinical signs noted on day 1 were impaired general state, dyspnea, staggering, erythema and piloerection. The animals recovered from these symptoms by day 2.

GROSS NECROPSY: No gross abnormalities were noted at necropsy for either dose group.

DATA EVALUATION RECORD

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

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

TEST MATERIAL PURITY: 95.3% BAS 510 F (3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)

CITATION: Wiemann, C. (1998) BAS 510 F; acute dermal toxicity in rats. Department of Toxicology of BASF Aktiengesellschaft, Germany. Laboratory Report Number 11A0179/971053. July 10, 1998. MRID 45404815. 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 chbb: thom (SPF) rats/sex (Weight: 200-300 g; Source: Dr. K. Thomae GmbH, Biberach, FRG) were dermally exposed to a single application of BAS 510 F (95.3% purity; Batch # N26; white powder) at 2000 mg/kg (limit dose) for 24 hours. The test substance was applied as a suspension (pasty preparation) in 0.5% Tylose CB 30.000 in aqua bidest 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 once daily for 14 days.

Dermal LD_{50} Males = > 2000 mg/kg (observed); Dermal LD_{50} Females = > 2000 mg/kg (observed)

BAS 510 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; three females lost small amounts of weight. No signs of systemic toxicity were observed in any animal. Well-defined erythema was noted in one female on day 1. No gross abnormalities were noted at necropsy.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement for an acute dermal study in the rat.

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 small amounts of weight. No signs of systemic toxicity were observed in any animal. Well-defined erythema was noted in one female on day 1.

GROSS NECROPSY: No gross 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: 95.3% BAS 510 F (3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)

CITATION: Gamer, A.O. (1998) BAS 510 F; acute inhalation toxicity in Wistar rats/4 hour dust exposure. Department of Toxicology of BASF Aktiengesellschaft, Germany. Laboratory Report Number 13I0179/977011. July 16, 1998. MRID 45404816. 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 albino Wistar chbb: thom rats/sex (Weight: 254-278 g males; 194-210 g females; Source: Dr. K. Thomae GmbH, Biberach, FRG) were exposed by nose only inhalation to BAS 510 F (95.3% purity; Batch # N26; white powder) at 6.7 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 = > 6.7 mg/L (observed); Inhalation LC_{50} Females = > 6.7 mg/L (observed)

BAS 510 F is classified as Toxicity Category IV based on the observed LC_{50} values in both sexes.

All animals survived and gained weight during the study. In-chamber observations included irregular respiration and attempts to escape. Upon removal from the exposure chamber, several animals exhibited dragging respiration/respiratory sounds, squatting posture, piloerection and urine smeared fur but recovered from these symptoms by day 3 and appeared normal for the remainder of the study. The gravimetric chamber concentration was 6.7 mg/L. The mass median aerodynamic diameter was estimated to be 3.4 µm with a geometric standard deviation of 3.4. Necropsy after 14 days revealed no gross abnormalities.

This study is classified as Acceptable (870.1300) and satisfies the guideline requirement for an acute inhalation study in the rat.

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

RESULTS:

Exposure Concentration mg/L	Number of Deaths/Number Tested		
	Males	Females	Combined
6.7	0/5	0/5	0/10

Chamber Atmosphere		
Exposure Concentration	MMAD	GSD
6.7 mg/L	3.4 µm	3.4

Chamber Environment[a]	
Chamber Volume	55 L
Airflow	25 LPM
Temperature	21.5 °C
Relative Humidity	20.3%

[a] Nose only

OBSERVATIONS: All animals survived and gained weight during the study. In-chamber observations included irregular respiration and attempts to escape. Upon removal from the exposure chamber, several animals exhibited dragging respiration/respiratory sounds, squatting posture, piloerection and urine smeared fur but recovered from these symptoms by day 3 and appeared normal for the remainder of the study.

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: 95.3% BAS 510 F (3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)

CITATION: Wiemann, C. (1998) BAS 510 F; acute eye irritation of BAS 510 F in rabbits. Department of Toxicology of BASF Aktiengesellschaft, Germany. Laboratory Report Number 13A0179/972090. July 10, 1998. MRID 45404817. Unpublished.

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

EXECUTIVE SUMMARY: In a primary eye irritation study, a 0.1 mL (21 mg) of BAS 510 F (95.3% purity; Batch # N26; white powder) was placed into the conjunctival sac of the right eye of six young adult New Zealand White rabbits (2 male and 4 female; Source: Dr. K. Thomae GmbH, Biberach, FRG). All animals were observed for ocular irritation at 1, 24, 48 and 72 hours post-installation.

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

No positive effects were noted during the ocular observations.

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:

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
	Unwashed eyes			
Corneal Opacity	0/6	0/6	0/6	0/6
Iritis	0/6	0/6	0/6	0/6
Conjunctivae:				
Redness*	0/6	0/6	0/6	0/6
Chemosis*	0/6	0/6	0/6	0/6
Discharge*	0/6	0/6	0/6	0/6

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

OBSERVATIONS: No positive effects were noted during the ocular observations.

DATA EVALUATION RECORD

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

Product Manager: 22

Reviewer: Eugenia McAndrew

TEST MATERIAL PURITY: 95.3% BAS 510 F (3-pyridinecarboxamide, 2-chloro-N-(4 -chloro (1,1'-biphenyl)-2-yl)

CITATION: Wiemann, C. (1998) BAS 510 F; acute dermal irritation/corrosion of BAS 510 F in rabbits. Department of Toxicology of BASF Aktiengesellschaft, Germany. Laboratory Report Number 14H0179/972089. July 10, 1998. MRID 45404818. Unpublished.

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

EXECUTIVE SUMMARY: In a primary skin irritation study, six young adult New Zealand White rabbits (2 male and 4 female; Source: Dr. K. Thomae GmbH, Biberach, FRG) were dermally exposed to 0.5 g of BAS 510 F (95.3% purity; Batch # N26; white powder) for 4 hours. The test substance was moistened with distilled water and then applied to a single 6 cm^2 intact dose site on each animal. Animals were observed 1, 24, 48 and 72 hours after patch removal.

BAS 510 F is classified as Toxicity Category IV based on the results of this study.

Primary Dermal Irritation Index (PDII) = 0.25 All test sites showed very slight to well defined erythema at the one hour observation. All sites were free of dermal irritation by 48 hours.

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

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

RESULTS: Primary Dermal Irritation Index (PDII) = 0.25

OBSERVATIONS: All test sites showed very slight to well defined erythema at the one hour observation. All sites were free of dermal irritation by 48 hours.

DATA EVALUATION RECORD

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

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

TEST MATERIAL PURITY: 95.3% BAS 510 F (3-pyridinecarboxamide, 2-chloro-N-(4'-chloro (1,1'-biphenyl)-2-yl)

CITATION: Wiemann, C. (1998) BAS 510 F; BAS 510 F maximization test in guinea pigs. Department of Toxicology of BASF Aktiengesellschaft, Germany. Laboratory Report Number 30H0179/972091. July 10, 1998. MRID 45404818. 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 F (95.3% purity; Batch # N26; white powder), 40 young adult female Pilbright White, Dunkin Hartley Crl: (HA)BR guinea pigs (Source: Charles River GmbH - Wiga, Kisslegg, FRG) were tested using the Maximization Test based on the method of Magnusson and Kligman. The concentrations of the test substance for use in the main study for induction and challenge were determined in a pretest using concentrations of 50%, 25%, 10% and 5%. Based on the pretest results, the minimum irritant concentration was found to be a 10% test substance preparation in 1% Tylose CB 30.000 in aqua bidest. The maximum non-irritant concentration was found to be a 5% test substance preparation in 1% Tylose CB 30.000 in aqua bidest. Main study: For the intradermal induction, a 5% test substance preparation in Tylose CB 30.000 in aqua bidest was administered to the 20 test animals. Control groups of 10 animals each received Freund's adjuvant or undiluted vehicle (1% Tylose CB 30.000 in aqua bidest). Sites were scored at 24 hours. Percutaneous induction was performed one week after the intradermal induction. The test animals received a 25% test substance preparation in 1% Tylose CB 30.000 in aqua bidest. The study report states : " As the 10% test substance preparation in 1% Tylose CB 30.000 in aqua bidest only caused in 1 animal very slight to well-defined erythema after the 2nd application (in the pretest), a 25% test substance preparation was chosen for the percutaneous induction." The control groups were treated with the vehicle only. Sites were scored at 48 hours. Fourteen days later the challenge was performed. The test animals and one control group of animals received a percutaneous application of 5% test substance preparation in Tylose CB 30.000 in aqua bidest. The other control group received the vehicle only. Sites were scored at 24 and 48 hours. A positive control study (Study Number 30H0387/952195) using alpha-hexylcinnamaldehyde was conducted within six months of the main study to validate the test system.

RESULTS: The intradermal induction with 5% test substance preparations caused slight to well-defined erythema and edema in all test group animals. After the percutaneous induction with a 25% test substance preparation, incrustation partially open was observed in addition to well-defined erythema and slight edema in all test group and control group animals. At the 24 hour reading following the challenge, no dermal irritation was noted in the treated control group and very slight erythema was noted in 3/19 test group animals. At the 48 hour reading, no dermal irritation was noted in the treated control group and very slight erythema was noted in 4/19 test group animals. Two animals - one control and one test - died 10 or 11 days after the beginning of the study. Macroscopic examination revealed that the animals suffered from pneumonia. The results of the positive control alpha-hexylcinnamaldehyde study were appropriate.

CONCLUSIONS: The study is classified as unacceptable because the concentration of test material in solvent was only 5% at challenge. This relatively low percentage cannot be justified, as in pretesting there were no indications of dermal irritation following the first percutaneous application of 50%, 25%, 10% and 5% solutions of the test material. The laboratory's use of 5% at challenge was based on observations (irritation at 50%, 25% and 10% solutions noted in some animals) following a second percutaneous dose made 48 hours after the first percutaneous dose during the pretest. However, in the main study, the challenge dose was made at 2 weeks (not 2 days) following the last induction treatment. Our conclusion is that a higher concentration of test material (at least 50%) should have been used for challenge. Therefore, a new study must be submitted to satisfy the requirements for registration.

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

This study is classified as Uacceptable (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 F (95.3% purity; Batch # N26; white powder), 40 young adult female Pilbright White, Dunkin Hartley Crl: (HA)BR guinea pigs (Source: Charles River GmbH - Wiga, Kisslegg, FRG) were tested using the Maximization Test based on the method of Magnusson and Kligman. The concentrations of the test substance for use in the main study for induction and challenge were determined in a pretest using concentrations of 50%, 25%, 10% and 5%. Based on the pretest results, the minimum irritant concentration was found to be a 10% test substance preparation in 1% Tylose CB 30.000 in aqua bidest. The maximum non-irritant concentration was found to be a 5% test substance preparation in 1% Tylose CB 30.000 in aqua bidest. Main study: For the intradermal induction, a 5% test substance preparation in Tylose CB 30.000 in aqua bidest was administered to the 20 test animals. Control groups of 10 animals each received Freund's adjuvant or undiluted vehicle (1% Tylose CB 30.000 in aqua bidest). Sites were scored at 24 hours. Percutaneous induction was performed one week after the intradermal induction. The test animals received a 25% test substance preparation in 1% Tylose CB 30.000 in aqua bidest. The study report states : " As the 10% test substance preparation in 1% Tylose CB 30.000 in aqua bidest only caused in 1 animal very slight to well-defined erythema after the 2nd application (in the pretest), a 25% test substance preparation was chosen for the percutaneous induction." The control groups were treated with the vehicle only. Sites were scored at 48 hours. Fourteen days later the challenge was performed. The test animals and one control group of animals received a percutaneous application of 5% test substance preparation in Tylose CB 30.000 in

aqua bidest. The other control group received the vehicle only. Sites were scored at 24 and 48 hours. A positive control study (Study Number 30H0387/952195) using alpha-hexylcinnamaldehyde was conducted within six months of the main study to validate the test system.

RESULTS: The intradermal induction with 5% test substance preparations caused slight to well-defined erythema and edema in all test group animals. After the percutaneous induction with a 25% test substance preparation, incrustation partially open was observed in addition to well-defined erythema and slight edema in all test group and control group animals. At the 24 hour reading following the challenge, no dermal irritation was noted in the treated control group and very slight erythema was noted in 3/19 test group animals. At the 48 hour reading, no dermal irritation was noted in the treated control group and very slight erythema was noted in 4/19 test group animals. Two animals - one control and one test - died 10 or 11 days after the beginning of the study. Macroscopic examination revealed that the animals suffered from pneumonia. The results of the positive control alpha-hexylcinnamaldehyde study were appropriate.

CONCLUSIONS: The study is classified as unacceptable because the concentration of test material in solvent was only 5% at challenge. This relatively low percentage cannot be justified, as in pretesting there were no indications of dermal irritation following the first percutaneous application of 50%, 25%, 10% and 5% solutions of the test material. The laboratory's use of 5% at challenge was based on observations (irritation at 50%, 25% and 10% solutions noted in some animals) following a second percutaneous dose made 48 hours after the first percutaneous dose during the pretest. However, in the main study, the challenge dose was made at 2 weeks (not 2 days) following the last induction treatment. Our conclusion is that a higher concentration of test material (at least 50%) should have been used for challenge. Therefore, a new study must be submitted to satisfy the requirements for registration.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D278286
2. **PC CODE:** 128008
3. **CURRENT DATE:** 31/JAN/2002
4. **TEST MATERIAL:** BAS 510 F (95.3% [3-pyridinecarboxamide, 2-chloro-N-(4' - chloro (1,1' - biphenyl) - 2-yl] Batch # N26; white powder)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Department of Toxicology of BASF Aktiengesellschaft, Germany/10A0179/971052 7-10-98	454048-14	LD_{50} > 5000 mg/kg (males females combined)	IV	A
Acute dermal toxicity/rat Department of Toxicology of BASF Aktiengesellschaft, Germany/11A0179/971053 7-10-98	454048-15	LD_{50} > 2000 mg/kg (males females combined)	III	A
Acute inhalation toxicity/rat Department of Toxicology of BASF Aktiengesellschaft, Germany/13I0179/977011 7-16-98	454048-16	LC_{50} > 6.7 mg/L (males females combined)	IV	A
Primary eye irritation/rabbit Department of Toxicology of BASF Aktiengesellschaft, Germany/13A0179/972090 7-10-98	454048-17	No positive observations were noted.	IV	A
Primary dermal irritation/rabbit Department of Toxicology of BASF Aktiengesellschaft, Germany/14H0179/972089 7-10-98	454048-18	PDII = 0.25 Non-irritant	IV	A
Dermal sensitization/guinea pig Department of Toxicology of BASF Aktiengesellschaft, Germany/30H0179/972091 7-10-98	454048-19	Could not be determined	--	U

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