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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

26/JUNE/2003

MEMORANDUM

Subject: EPA Reg. No: 7969-ENU BAS 670 H
DP Barcode: D290078
Decision No: 211973
PC Code: 123009

From: Masih Hashim, Toxicologist MH EM
Technical Review Branch
Registration Division (7505C)

To: James Stone, PM Team 23
Herbicide Branch
Registration Division (7505C)

Applicant: BASF Corporation (Agricultural Products)
26 Davis Drive
Research Triangle Park, NC 27709-3528

FORMULATION FROM LABEL:

| Active Ingredient(s): | % by wt. |
|---|---|
| [3-(4,5-Dihydro-isoxazol)-4-methansulfonyl-2-methyl-phenyl]-(5-hydroxy-1-methyl-1H-pyrazol-4-yl) methanone | 99.2 |
| Inert ingredients | 0.8 |
| Total: | 100.0 |

ACTION REQUIRED: PM requests an evaluation of the acute toxicity data for the File Symbol 7969-ENU.

BACKGROUND: BASF Corporation has submitted a set of (17) acute toxicity studies for registration of BAS 670 H Technical for formulation.

RECOMMENDATIONS: Each of the following studies (MRID 45902118 thru 45902134) is in compliance with the Sub Division F guidelines.

There are several batches of the formulation with seventeen acute tox studies submitted in this action. We only need six studies. TRB would prefer that the Registrant submit a minimum number of (appropriate) studies required for a product. This will save time and resources.

The toxicology profile for the File Symbol 7969-ENU is as follows:

| | | | |
|---|---|---|---|
| acute oral toxicity | III | acceptable | MRIDs 45902118 - 45902120 |
| acute dermal toxicity | III | acceptable | MRIDs 45902121 - 45902123 |
| acute inhalation | IV | acceptable | MRIDs 45902124 - 45902125 |
| primary eye irritation | III | acceptable | MRIDs 45902126 - 45902128 |
| primary dermal irritation | IV | acceptable | MRIDs 45902129 - 45902131 |
| dermal sensitization | neg. | acceptable | MRIDs 45902132 - 45902134 |

**Labeling:**

**PRODUCT ID #: 007969-00204**

**PRODUCT NAME: BAS 670 H Technical**

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD: CAUTION**

**Hazards to Humans and Domestic Animals:**

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid contact with eyes or clothing.

**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.

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-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.

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DATA EVALUATION RECORD

**STUDY TYPE:** ACUTE ORAL TOXICITY- STUDY- RAT [OPPTS 870.1100, OECD 401] .

**PRODUCT MANAGER**: 23 **REVIEWER**: M. HASHIM

**TEST MATERIAL:** BAS 670 H Technical, Purity 97.7%, Batch No. N 14, Solid / beige

**CITATION:** Gamer, A., and Hoffman, H. (2002). BAS 670 H- Acute Oral Toxicity Study in Rats. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 10A0124/981129 dated 6-26-2002. MRID No. 45902118 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute oral toxicity study (MRID 45902118), young adult Wistar rats 3 /sex (Strain: chbb: thom, mean weight males 185 g, females 169 g, Source Boehringer Ingelheim Pharma KG) were given a single oral dose of BAS 670 H (Batch No. N-14, purity 97.7%) in 0.5% Tylose CB 30 in aqua bidest at a dose of 2000 mg/kg body weight. Animals were observed for clinical signs, mortality and body weight changes for 14 days.

No animals died on the study. All animals gained weight during the study. No clinical signs were noted. No gross lesions were noted from any animal during necropsy.

Oral $LD_{50}$ Males >2000 mg/kg bw
Females >2000 mg/kg bw
Combined >2000 mg/kg bw

BASF 670 H has Tox Category III.

This acute oral toxicity study is classified as Acceptable and satisfies the guideline requirement for an acute oral toxicity study (OPPTS 870.1100; OECD 401) in the rat.

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

**RESULTS:**

| TABLE 1. Doses, mortality/animals treated | | | |
|---|---|---|---|
| **Dose (mg/kg bw)** | **Males** | **Females** | **Combined** |
| 2000 | 0/3 | 0/3 | 0/6 |

**NECROPSY FINDINGS:** Not significant.

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## DATA EVALUATION RECORD

**STUDY TYPE:** ACUTE ORAL TOXICITY STUDY- Rat [OPPTS 870.1100, OECD 401].

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 , purity 95.8%, Batch No. N 26, Solid/ yellow brown.

**CITATION:** Gamer, A., and Leibold, E. (2002). BAS 670 H- Acute Oral Toxicity Study in Wistar Rats. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 10A0124/981143 dated 12-9-2002. MRID No. 45902119 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute oral toxicity study (MRID 45902119), young adult (6) female Wistar rats (Strain: CrlGIxBrlHan:WI weight 178-218 g, Source Charles River Deutschland Gmbh, Sandhofer Weg 7, 97633 Sulzfeld) were administered with a single oral dose of BAS 670 H (Batch No. N 26, 95.8% purity) at 2000 mg/kg body weight. The test substance was prepared in 0.5% CMC solution in double distilled water (2 groups of 3 animals each). Animals were observed for clinical signs, mortality and body weight changes for14 days.

There were no deaths on the study, there were no clinical signs. All animals gained weight during the study. There were no lesions at necropsy.

Oral $LD_{50}$ Males >2000 mg/kg bw
Females >2000 mg/kg bw
Combined >2000 mg/kg bw

BASF 670 H has Tox Category III.

This acute oral toxicity study is classified as Acceptable. This study satisfies the guideline requirement for an acute oral toxicity study (OPPTS 870.1100; OECD 401) in the rat.

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

**RESULTS:**

| TABLE 1. Doses, mortality/animals treated | | | |
|---|---|---|---|
| **Dose (mg/kg bw)** | **Females** | **Females** | **Combined** |
| 2000 | 0/3 | 0/3 | 0/6 |

**Necropsy Findings:** Not significant.

(5)

**DATA EVALUATION RECORD**

**STUDY TYPE:** ACUTE ORAL TOXICITY STUDY- Rat [OPPTS 870.1100, OECD 401]

**PRODUCT MANAGER**: 23 **REVIEWER**: M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. 30786/22, 99%, Solid / light brown color

**CITATION:** Gamer, A., and Hellwig, J. (2002) BAS 670 H- Acute Oral Toxicity Study in Wistar Rats. Department of Toxicology of BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 10A0124/981145 dated 12-18-2002. MRID No. 45902120 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute oral toxicity study (MRID 45902120), young adult 6 female Wistar rats (Strain: CrlGIxBrlHan:WI weight 172-217 g, Source Charles River Deutschland Gmbh, Sandhofer Weg 7, 97633 Sulzfeld) were administered with a single dose of BAS 670 H (Batch No. 30786/22, 99% purity) at 2000 mg/kg body weight. The test substance was prepared in 0.5% CMC solution in double distilled water (for 2 groups of 3 animals each). Animals were observed for clinical signs, mortality and body weight changes for14 days.

No animals died on the study, there were no clinical signs. All animals gained weight during the study. There were no lesions at necropsy.

Oral $LD_{50}$ Males >2000 mg/kg bw
Females >2000 mg/kg bw
Combined >2000 mg/kg bw

BASF 670 H has Tox Category III.

This acute oral toxicity study is classified as Acceptable. This study satisfies the guideline requirement for an acute oral toxicity study (OPPTS 870.1100; OECD 401) in the rat.

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

**RESULTS:**

**TABLE 1. Doses, mortality/animals treated (2 groups)**

| Dose (mg/kg bw) | Females | Females | Combined |
|---|---|---|---|
| 2000 | 0/3 | 0/3 | 0/6 |

**NECROPSY:** Not significant.

(6)

**DATA EVALUATION RECORD**

**STUDY TYPE:** ACUTE DERMAL TOXICITY STUDY- Rat [OPPTS 870.1200, OECD 402]

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 14, 98%, Solid / beige crystalline

**CITATION:** Gamer, A., and Hoffman, H (2000). BAS 670 H- Acute Dermal Toxicity Study in Rats. Department of Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 11A0124/981130 dated 1-26-2000. MRID No. 45902121 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 45902121), 5 male and 5 female young adult (SPF) Wistar rats (Strain: chbb: thom, weight: m- 263-271 g, fe- 215-224 g, Source- Boehringer Ingelheim Pharma KG) were applied with a single topical dose of BAS 670 H (Batch No. N 14, purity 98%) at 2000 mg/kg body weight. The test substance was prepared as a suspension in 0.5% Tylose CB 30.000 in aqua bidest solution and applied on a clipped (10% surface area) of the animal covered by a semi occlusive dressing for 24 hours. Animals were observed for clinical signs, mortality and body weight changes for14 days.

There were no deaths on the study. One of 10 animals showed slight erythema after the test application. All animals gained weight during the study. There were no significant lesions at necropsy.

Dermal $LD_{50}$ Males >2000 mg/kg bw
Females >2000 mg/kg bw
Combined >2000 mg/kg bw

BASF 670 H has Tox Category III.

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

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

**RESULTS:**

**TABLE 1. Doses, mortality/animals treated**

| Dose (mg/kg bw) | Males | Females | Combined |
|---|---|---|---|
| 2000 | 0/5 | 0/5 | 0/10 |

**NECROPSY FINDINGS:** Not significant.

(7)

**DATA EVALUATION RECORD**

**STUDY TYPE:** ACUTE DERMAL TOXICITY STUDY- Rat [OPPTS 870.1200, OECD 402]

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H. Batch No. N 26, Purity 95.8%, Solid / yellow brown

**CITATION:** Gamer, A., and Leibold, E. (2002) BAS 670 H- Acute Dermal Toxicity Study in Rats. Department of Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 11A0124/981144 dated 12-9-02. MRID No. 45902122 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 45902122), 5 male and 5 female young adult (SPF) Wistar rats (Strain: CrlGlxBrlHan:WI chbb: thom, weight: m 216-231 g, fe 181-187 g, Source Charles River Deutschland GmbH, Sandhofer Weg 7, 97633 Sulzfeld) were dosed with a single topical application of BAS 670 H (Batch No. N 26, purity 95.8%) at 2000 mg/kg bw in 0.5% CMC solution in double distilled water. The test substance (as a suspension) was applied on a clipped dorsal trunk, about 10% surface area of the animal and covered by a semi occlusive dressing for 24 hours. Animals were observed for clinical signs, mortality and body weight changes for14 days.

None of the animals died on the study. Slight to well defined erythema was seen in all animals. Scaling was seen in one animal, all on day 1. All animals gained weight during the study. There were no significant lesions at necropsy.

Dermal $LD_{50}$ Males >2000 mg/kg bw
Females >2000 mg/kg bw
Combined >2000 mg/kg bw

BASF 670 H has Tox Category III.

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

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

**RESULTS:**

**TABLE 1. Doses, mortality/animals treated**

| Dose (mg/kg bw) | Males | Females | Combined |
|---|---|---|---|
| 2000 | 0/5 | 0/5 | 0/10 |

**NECROPSY FINDINGS:** Not significant.

(8)

**DATA EVALUATION RECORD**

**STUDY TYPE:** ACUTE DERMAL TOXICITY STUDY RAT [OPPTS 870.1200, OECD 402]

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. 30786/22, 99.3% purity, Solid / light brown

**CITATION:** Gamer, A., and Hellwig, J. (2002) BAS 670 H- Acute Dermal Toxicity Study in Rats. Department of Toxicology of BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 11A0124/981146 dated 12-18-2002. MRID No. 45902123 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 45902123), 5 male and 5 female young adult (SPF) Wistar rats (Strain: CrlGlxBrlHan:WI, av weight-m 225 g, fe 184 g, Source Charles River Deutschland GmbH, Sandhofer Weg 7, 97633 Sulzfeld) were given a single topical dose of BAS 670 H (Batch No.30786/22, 99.3% purity) at 2000 mg/kg body weight. Test suspension was made in 0.5% CMC solution in double distilled water and applied on a clipped skin (dorsal and dorsi lateral part of the trunk on approx. 10% surface area) of the animal and covered by a semi occlusive dressing for 24 hours. Animals were observed for clinical signs, mortality and body weight changes for 14 days.

No animals died on the study. All animals gained weight during the study. One of ten animal showed slight erythema on day 1. No gross lesions were noted on any animal during necropsy.

Dermal $LD_{50}$ Males >2000 mg/kg bw
Females >2000 mg/kg bw
Combined >2000 mg/kg bw

BASF 670 H has Tox Category III.

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

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

**RESULTS:**

**TABLE 1. Doses, mortality/animals treated**

| Dose (mg/kg bw) | Males | Females | Combined |
|---|---|---|---|
| 2000 | 0/5 | 0/5 | 0/10 |

**NECROPSY FINDINGS:** Not significant.

(9)

**DATA EVALUATION RECORD**

**STUDY TYPE:** ACUTE INHALATION TOXICITY STUDY- Rat [OPPTS 870.1300, OECD 403]

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 26, Purity 95.8%, Solid / yellow brown

**CITATION:** Gamer, A., and Hoffmann, H. (2000). BAS 670 H- Acute Inhalation Toxicity Study in Wistar Rats, 4-hour exposure. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 1310124/987024 dated 9-4-2000. MRID No. 45902124 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute inhalation toxicity study (MRID 45902124), young adult Sprague-Dawley rats, 5/sex (Wt. males: 167-181 g; females: 129-172 g, Source: Charles River Deutschland, Sandhofer Weg 7, 97633 Sulzfeld) were exposed to the dust of BASF 670 H Technical (95.8% a.i., Batch No. N 26) at a concentration of 5.05 mg/L (analytical) for 4 hours. The MMAD was 4.8 and 5.3 µm. The animals were then observed for 14 days.

Inhalation $LC_{50}$ Males >5.05 mg/L
Females > 5.05 mg/L
Combined> 5.05 mg/L

BASF 670 H Technical has $LC_{50}$ was >5.05 mg/L, and is considered as Toxicity Category IV.

None of the animals died on the study. Signs of toxicity included rapid respiration, squatting posture, piloerction and smeared fur for 5 days, after which animals appeared normal. Necropsy findings were unremarkable.

This study is classified as Acceptable, and satisfies the guideline requirements for an acute inhalation toxicity study (OPPTS 870.1300; OECD 403) in the rat.

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

**NECROPSY FINDINGS:** Unremarkable.

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**RESULTS:**

| Analytical Conc. (mg/L) | MMAD µm | GSD | Mortality (# dead/total) | | |
|---|---|---|---|---|---|
| | | | Males | Females | Combined |
| 5.05 | 4.8-5.3 | 3.3-3.6 | 0/5 | 0/5 | 0/10 |

**Environment/Exposure**

| Conc./mg/L LC50 | Inhalation system | Air Flow | Exposure Temp. | Rel. humidity % |
|---|---|---|---|---|
| 5.05 | 55 L | 1.5 $m^3/h$ | 23.5$^0$ C | 26.5 |

**DATA EVALUATION RECORD**

**STUDY TYPE:** ACUTE INHALATION TOXICITY- Rat [OPPTS 870.1300, OECD 403]

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. WH 200 89, Purity 98.7%, Solid / beige

**CITATION:** Ma, L., and Leibold, E. (2002) BAS 670 H- Acute Inhalation Toxicity Study in Wistar Rats, 4-hour exposure. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 1310124/987026 dated 11-27-02. MRID No. 45902125 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In an acute inhalation toxicity study (MRID 45902125), young adult Wistar rats, 5/sex (Wt. Males: 240-279 g; females: 220-236 Source: Charles River Deutschland, Sandhofer Weg 7, 97633 Sulzfeld) were exposed to the aerosol dust of BASF 670 H Technical (Batch No. WH 200 89, Purity 98.7%) at the (analytical) concentration of 5.4 mg/L for 4 hours. The MMAD was 3.2-3.9 µm. The animals were observed for 14 days.

Inhalation $LC_{50}$ Males >5.4 mg/L
Females > 5.4 mg/L
Combined> 5.4 mg/L

BASF 670 H Technical has $LC_{50}$ >5.4 mg/L and is considered as Toxicity Category IV.

There were no deaths on the study. Signs of toxicity included rapid respiration, salivation, and smeared fur for 4 days, after which animals appeared normal. Male animals body weight was unaffected, females lost weight in the 1st week then were normal in the second week. Two animals (1m+1 fe) showed diffuse red discoloration of lungs, other animals appeared normal.

This study is classified as Acceptable, and satisfies the guideline requirements for an acute inhalation toxicity study (OPPTS 870.1300; OECD 403) in the rat.

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

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| RESULTS | | | | | |
|---|---|---|---|---|---|
| Analytical Conc. (mg/L) | MMAD µm | GSD | Mortality (# dead/total) | | |
| | | | Males | Females | Combined |
| 5.4 | 3.2-3.9 | 3.4-3.6 | 0/5 | 0/5 | 0/10 |

**Environment/Exposure**

| Conc./$LC_{50}$ | Inhalation system | Air flow/ supply | Air Flow/ exhaust | Exposure Temp. | R. humidity % |
|---|---|---|---|---|---|
| 5.4 mg/L | 55 L | 1.5 $m^3/h$ | 1.35 $m^3/h$ | 22.4$^0$ C | 51 |

**NECROPSY:** One male and one female showed diffuse discoloration of lungs.

**DATA EVALUATION RECORD**

**STUDY TYPE:** PRIMARY EYE IRRITATION - Rabbit [OPPTS 870.2400] OECD 405.

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 14 Purity 98%, Solid / crystalline beige

**CITATION:** Wiemann, C., and Hellwig, J. (2000) BAS 670 H- Acute Eye Irritation in Rabbits. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 11H0124/982237 dated 6-5-2000. MRID No. 45902126 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In a primary eye irritation study (MRID 45902126), 0.1 ml (40 mg) of BAS 670 H Technical (98%, Lot No. N 14) was instilled into the conjunctival sac of the right eye of 3 (young adult) NZW rabbits (SPF, Source Harlan-Winklemann GmbH, Borchen, FRG). The left eye served as the control. The eyes of three rabbits were washed 24 hours after treatment. The ocular irritation was observed for 7 days.

There was slight irritation (conjunctivitis) in the eyes which subsided by within 72 hours (Table 1). The average irritation score at 72 hours was 0.0.

The test material is in EPA Toxicity Category III.

This study is classified as Acceptable, it satisfies the guideline requirements for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

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

**RESULTS:**

**Table 1. Lesions vs No. of Animals**

| Lesion | one hour | 24 hours | 48 hour | 72 hours | 7 days |
|---|---|---|---|---|---|
| Conjunctivitis | 3/3 | 3/3 | 2/3 | 0/3 | 0/3 |
| Corneal opacity | 0/3 | 0/3 | 0/3 | 0/3 | 0/3 |
| Iritis | 0/3 | 0/3 | 0/3 | 0/3 | 0/3 |

(A)

**DATA EVALUATION RECORD**

**STUDY TYPE:** PRIMARY EYE IRRITATION - Rabbit [OPPTS 870.2400] OECD 405.

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 26, Purity 95.8%, Solid/ yellow brown

**CITATION:** Remmele, M., and Leibold, E. (2002). BAS 670 H- Acute Eye Irritation in Rabbits. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 11H0124/982290 dated 12-9-02. MRID No. 45902127 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In a primary eye irritation study (MRID 45902127), 0.1 ml (43 mg) of BAS 670 H Technical (95.8% purity, Batch No. N 26) was instilled into the conjunctival sac of the right eye lid of 3 young adult NZW rabbits (A1077 INRA-SPF, Source: Centre Lago S.A. Vonnas, France). The left eye served as the control. The eyes of all rabbits were washed 24 hours after treatment. The ocular irritation was observed for 7 days.

There was slight to moderate eye irritation which subsided within 72 hours (Table 1). The average irritation score for cornea and iris was 0.0, 1.4 for conjunctival redness and 0.1 for chemosis (24-72 hours).

The test material is graded in EPA Toxicity Category III.

This study is classified as Acceptable. This study satisfies the guideline requirements for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

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

**RESULTS:**

**Table 1. No. of Animals with lesions vs Total No. of Animals**

| Lesion | one hour | 24 hours | 48 hour | 72 hours | 7 days |
|---|---|---|---|---|---|
| Conjunctivitis | 3/3 | 3/3 | 1/3 | 0/3 | 0/3 |
| Corneal opacity | 0/3 | 0/3 | 0/3 | 0/3 | 0/3 |
| Iritis | 0/3 | 0/3 | 0/3 | 0/3 | 0/3 |

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**DATA EVALUATION RECORD**

**STUDY TYPE:** PRIMARY EYE IRRITATION- Rabbit [OPPTS 870.2400] OECD 405.

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. 30786/22, Purity 99.3%, Solid / light brown

**CITATION:** Remmele, M., and Hellwig, J. (2002). BAS 670 H- Acute Eye Irritation in Rabbits. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 11H0124/982293 dated 12-18-02. MRID No. 45902128 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In a primary eye irritation study (MRID 45902128), 0.1 ml (= 58 mg) of BAS 670 H Technical (99.3% purity, Batch No. 30786/22) was instilled into the conjunctival sac of the right eye lid of 3 young adult NZW rabbits (A1077 INRA-SPF, Source: Centre Lago S.A. Vonnas, France) in a stepwise procedure, i.e, first one animal then the other two. The left eye served as the control. The eyes of all rabbits were washed 24 hours after the treatment. The eye irritation was observed and scored for 72 hours.

There was slight to severe conjuctival irritation, mostly as redness and slight chemosis. This subsided by within 72 hours (Table 1). The average irritation score for cornea and iris was 0.0, 0.8 for conjunctival redness and 0.0 for chemosis (24-72 hours).

The test material is in EPA Toxicity Category III.

This study is classified as Acceptable/Guideline. This study satisfies the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

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

**RESULTS:**

**Table 1. Total Lesions vs Total No. of Animals**

| Lesion | one hour | 24 hours | 48 hour | 72 hours |
|---|---|---|---|---|
| Conjunctivitis | 2/3 | 2/3 | 0/3 | 0/3 |
| Corneal opacity | 0/3 | 0/3 | 0/3 | 0/3 |
| Iritis | 0/3 | 0/3 | 0/3 | 0/3 |

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**DATA EVALUATION RECORD**

**STUDY TYPE:** PRIMARY DERMAL IRRITATION - Rabbit [OPPTS 870.2500] OECD 404.

**PRODUCT MANAGER**: 23 **REVIEWER**: M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 14, Purity 97.7%, Solid /crystalline beige.

**CITATION:** Wiemann, C, and Hellwig, J. (2000). BAS 670 H- Acute Dermal Irritation/ Corrosion in Rabbits. Department of Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 18H0124/982236 dated 6-5-2000. MRID No. 45902129 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In a primary dermal irritation study (MRID 45902129), 0.5 g of BAS 670 H, Batch No. N 14, Purity 97.7%) was topically applied to 3 NZW (young adult) rabbits (SPF bred, Source: Boehringer Ingelheim Pharma KG ) on a 2.5 $cm^2$ area of the dorsal skin. The test site was covered by a patch and a (semi-occlusive) dressing for 4 hours. The animals were then observed for 72 hours.

Three rabbits had erythema. The mean irritation score (erythema+edema) based on 24-72 hour reading was 0.2. The compound (BAS 670 H) is a mild irritant.

In this study, the test substance was slightly irritating to the skin and is in Toxicity Category IV.

This study is classified as Acceptable. This study satisfies the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

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

**OBSERVATIONS:** Three rabbits had erythema. The mean irritation score (erythema+edema) based on 24-72 hour reading was 0.2.

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**DATA EVALUATION RECORD**

**STUDY TYPE:** PRIMARY DERMAL IRRITATION - Rabbit [OPPTS 870.2500] OECD 404.

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 26, Purity 95.8%%, Solid / yellow brown.

**CITATION:** Remmele, M., and Leibold, E. (2002). BAS 670 H- Acute Dermal Irritation/ Corrosion in Rabbits. Department of Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 18H0124/982289 dated 12-9-02. MRID No. 45902130 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In a primary dermal irritation study (MRID 45902130), 0.5 g of BAS 670 H, Batch No. N 26, Purity 95.8%) was topically applied to 3 NZW (young adult) rabbits (SPF bred, Source: Centre Lago S.A., Vonnas, France) on a 2.5 $cm^2$ area of the dorsal skin. The test site was covered by a patch and a semi occlusive dressing for 4 hours. The animals then were observed for 72 hours.

All rabbits showed slight to moderate erythema (with yellow discoloration areas) an hour after patch removal. The skin reaction was reversible within 72 hours. The mean irritation score (erythema+edema) based on 24-72 hour reading was 0.3.

The compound (BAS 670 H) is a mild irritant and has Toxicity Category IV.

This study is classified as Acceptable/Guideline. This study satisfies the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

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

**OBSERVATIONS:** Three rabbits had erythema. The mean irritation score (erythema+edema) based on 24-72 hour reading was 0.3.

**DATA EVALUATION RECORD**

**STUDY TYPE:** PRIMARY DERMAL IRRITATION - Rabbit [OPPTS 870.2500] OECD 404.

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. 30786/22, Purity 99.3%, Solid / light brown.

**CITATION:** Remmele, M, and Hellwig, J. (2002). BAS 670 H- Acute Dermal Irritation/ Corrosion in Rabbits. Department of Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 18H0124/982292 dated 12-18-02. MRID No. 45902131 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** In a primary dermal irritation study (MRID 45902131), 0.5 g of BAS 670 H, Batch No. 30786/22, 99.3%) was topically applied to 3 NZW (SPF, young adult) rabbits (Source: Centre lago S.A., Vonnas, France) on a 2.5 $cm^2$ area of the dorsal skin. The test site was covered by a patch and a semi occlusive dressing for 4 hours. The animals then were observed for 72 hours.

All rabbits showed slight erythema an hour after the patch removal. The mean irritation score (erythema+edema) based on 24-72 hour reading was 0.0.

The compound (BAS 670 H) is a mild irritant, and has Tox Category IV.

This study is classified as Acceptable. It satisfies the guideline requirements for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

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

**OBSERVATIONS:** Three rabbits had erythema. The mean irritation score (erythema+edema) based on 24-72 hour reading was 0.0.

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DATA EVALUATION RECORD

**STUDY TYPE:** DERMAL SENSITIZATION STUDY- Guinea pigs [OPPTS 870.2600, OECD 406]

**PRODUCT MANAGER**: 23 **REVIEWER**: M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 14, Purity 97.7%, Solid / yellow brown

**CITATION:** Wiemann, C., and Hellwig, J. (2000). BAS 670 H- Maximization Test in Guinea pigs. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 30H0124/982238 dated 6-6-2000. MRID No. 45902132 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** Sensitizing potential of BAS 670 H Technical (97.7 %, Batch No. N 14) was assessed in a Maximization study (MRID 45902132) using 20 test and 10 control (young adult) guinea pigs (strain- Hsd Poc: DH -SPF, Source: Harlan Winklemann GmbH, Borchen, FRG). Based on the screening test the following preparations were used: (a) Intradermal induction with 5% test substance (prepared in 1% Tylose CB 30.000 in aqua bidest) or 5% in Freund's adjuvant / 0.9% aqueous NaCl solution (1:1), (b) Epicutaneous induction with 50% test substance in Tylose CB 30.000 in aqua bidest. For Challenge (c) it was 25% test substance in 1% Tylose CB 30.000 in aqua bidest. 2-Mercaptobenzothiazole was used in a historical positive control.

Intradermal injection (a) caused moderate confluent erythema or intense erythema and swelling (in Freund'd adjuvant) in all test group animals. Epicutaneous induction (b) could be observed (in addition to) moderate and confluent erythema and swelling in all test groups animals. After the Epicutaneous and challenge dose there was yellow discoloration of the skin (without affecting the evaluation).

Results at challenge (c) indicated the dermal reaction as 0/10 control group, and 0/20 in the test group. The test substance, BAS 670 H, did not have a sensitizing effect on the skin of guinea pigs.

This study is classified as Acceptable. This study satisfies the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pig.

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

**PROCEDURE:** Maximization Procedure: Twenty test and 10 control guinea pigs were used for the study. Based on the pre-test the following preparations were used: (a)- Intradermal induction with 5% test substance in 1% Tylose CB 30.000 in aqua bidest or 5% in Freund's adjuvant / 0.9% aqueous NaCl solution (1:1), (b) Epicutaneous induction with 50% test substance in Tylose CB 30.000 in aqua bidest. For Challenge (c) it was 25% test substance in 1% Tylose CB 30.000 in aqua bidest.

Results at the challenge dose indicated that the test substance did not have a sensitizing effect. (20)

**DATA EVALUATION RECORD**

**STUDY TYPE:** DERMAL SENSITIZATION STUDY- GUINEA PIGS [OPPTS 870.2600], OECD 406

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL:** BAS 670 H, Batch No. N 26, Purity 95.8%, Solid / yellow brown

**CITATION:** Gamer, A., and Leibold, E. (2002) BAS 670 H- Maximization Test in Guinea Pigs. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 30HO124/982291 dated 12-9-02, MRID No. 45902133 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** The sensitizing potential of BAS 670 H Technical (95.8 % purity, Batch N 26) was assessed in a Maximization study (MRID 45902133) using twenty test and ten control (young adult) guinea pigs (Strain Hsd Poc: DH -SPF, Source: Harlan Winklemann GmbH, Borchen, FRG) for the procedure. Based on the screening test the following preparations were used: (a) Intradermal induction with 5% test substance (prepared in 1% CMC solution was given in doubly distilled water or a 5% test substance in Freund's adjuvant/0.9% aqueous NaCl solution (1:1). In the epicutaneous induction (b), there was 50% test substance in 1% CMC solution in doubly distilled water. The study had control and test groups. Intradermal induction was day 0 and epicutaneous on day 7. The challenge (c), was carried out 14 days after epicutaneous induction, using 25% test substance in 1% CMC solution in double distilled water. Alpha-Hexylcinnamaldehyde tech. 85% was used as historical positive control.

Intradermal injection "(a)" caused moderate confluent erythema or intense erythema and swelling in all test group animals. Epicutaneous induction "(b)" incrustation, partially open (caused by last intradermal injection) and swelling in all test animals. Evaluation of erythema was masked by yellow discoloration.

Results at challenge "(c)" indicated the dermal reaction as 0/10 control group, and 0/20 in the test group. The test substance, BAS 670 H, did not have a sensitizing effect on the skin of guinea pigs.

This study is classified as Acceptable/Guideline. This study satisfies the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pig.

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

**PROCEDURE:** Twenty test and ten control (young adult) guinea pigs (Strain Hsd Poc: DH -SPF, Source: Harlan Winklemann GmbH, Borchen, FRG) were used for the procedure. Based on the screening test the following preparations were used: (a) Intradermal induction with 5% test substance (prepared in 1% CMC solution was given in doubly distilled water or a 5% test substance in Freund's adjuvant/0.9% aqueous NaCl solution (1:1). In the epicutaneous induction (b), there was

50% test substance in 1% CMC solution in doubly distilled water. The study had 2 control and one test groups. Intradermal induction was day 0 and epicutaneous on day 7. The challenge (c), was carried out 14 days after epicutaneous injection, using 25% test substance in 1% CMC solution in doubled distilled water.

Results at the challenge indicated that the test substance did not have a sensitizing effect.

**DATA EVALUATION RECORD**

**STUDY TYPE:** DERMAL SENSITIZATION STUDY- Guinea pigs [OPPTS 870.2600, OECD 406]

**PRODUCT MANAGER:** 23 **REVIEWER:** M. HASHIM

**TEST MATERIAL** BAS 670 H, Batch No. 30786/22, Purity 99.3%, Solid /yellow brown

**CITATION:** Gamer, A., and Hellwig, J. (2002). BAS 670 H- Maximization Test in Guinea Pigs. Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany, Study No. 30HO124/982294 dated 12-18-02, MRID No. 45902134 (Unpublished).

**SPONSOR:** BASF Corporation (Agricultural Products), Research Triangle Park, NC 27709-3528.

**EXECUTIVE SUMMARY:** Sensitizing potential of BAS 670 H Technical (99.3 %, Batch 30786/22) was assessed in a Maximization study (MRID 45902134) using twenty test and ten control (young adult) guinea pigs (Strain Hsd Poc: DH -SPF, Source: Harlan Winklemann GmbH, Borchen, FRG). Based on the screening test the following preparations were used: (a) Intradermal induction with 5% test substance (prepared in 1% CMC solution was given in double distilled water or a 5% test substance in Freund's adjuvant/0.9% aqueous NaCl solution (1:1). In the epicutaneous induction (b), there was 50% test substance in 1% CMC solution in double distilled water. Intradermal induction was day 0 and epicutaneous on day 7. The challenge (c), was carried out 14 days after epicutaneous injection, using 25% test substance in 1% CMC solution in doubled distilled water.
Alpha-Hexylcinnamaldehyde tech. 85% was used as historical positive control.

Intradermal injection " (a)" caused moderate confluent erythema or intense erythema and swelling in all test group animals. Epicutaneous induction "(b)" could be observed in addition to moderate and confluent erythema and swelling in all test groups animals. After the challenge dose there was yellow discoloration of the skin., without affecting the evaluation.

Results at challenge "(c)" indicated the reaction as 0/10 control group, and 0/20 in the test group. The test substance, BAS 670 H, does not have a sensitizing effect on the skin of guinea pigs.

This study is classified as Acceptable. This study satisfies the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pig.

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

**PROCEDURE:** Twenty test and ten control (young adult) guinea pigs (Strain Hsd Poc: DH -SPF, Source: Harlan Winklemann GmbH, Borchen, FRG) were used for the procedure. Based on the screening test the following preparations were used: (a) Intradermal induction with 5% test substance (prepared in 1% CMC solution was given in doubly distilled water or a 5% test substance in Freund's adjuvant/0.9% aqueous NaCl solution (1:1). In the epicutaneous induction (b). there was 50% test substance in 1% CMC solution in doubly distilled water. Intradermal induction was day 0 and epicutaneous on day 7. The



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challenge (c), was carried out 14 days after epicutaneous injection, using 25% test substance in 1% CMC solution in doubled distilled water.

Results at the challenge indicated that the test substance does not have a sensitizing effect.

## DATA EVALUATION RECORD

**ACUTE TOX ONE LINER** DB Barcode - D290078,
BAS 670 H Technical (123009), Date 6-26-03

| Study/Species/Lab Study #/Date | MRID | Results from animal studies | Tox. Cat. | Core Grade |
|---|---|---|---|---|
| Acute oral toxicity/ rat/ BASF-Germany- Toxicology/ 10A0124/981129/ 6-26-2000 | 45902118 | Oral $LD_{50}$> 2000 mg/kg | III | A |
| Acute oral toxicity/ rat/ BASF- Germany-Toxicology/ 10A0124/981143/ 12-9-02 | 45902119 | Oral $LD_{50}$> 2000 mg/kg | III | A |
| Acute oral toxicity/ rat/ BASF-Germany- Toxicology Lab, Germany/ 10A0124/981145/ 12-18-02 | 45902120 | Oral $LD_{50}$> 2000 mg/kg | III | A |
| Acute dermal toxicity/ rat/ BASF-Germany, Toxicology Lab /11A0124/981130/ 1-26-2000 | 45902121 | Dermal $LD_{50}$> 2000 mg/kg | III | A |
| Acute dermal toxicity/ BASF- Germany Toxicology Lab, / 11A0124/981144/ 12-9-2002. | 45902122 | Dermal $LD_{50}$> 2000 mg/kg | III | A |
| Acute dermal toxicity / rat/ Department of Toxicology BASF, Germany/ 11A0124/981146 / 12-18-2002. | 45902123 | Dermal $LD_{50}$ > 2000 mg/kg | III | A |
| Acute Inhalation study/rat/ BASF-Germany Toxicology Lab, / 13110124-987024/ 9-4-2000 | 45902124 | $LC_{50}$ >5.05 mg/L | IV | A |
| Acute Inhalation study/rat/ BASF- Germany Toxicology Lab, / 13110124-987026/ 11-27-02 | 45902125 | $LC_{50}$ >5.4 mg/L | IV | A |
| Primary Eye Irritation/Rabbit/ BASF Toxicology Labs- Germany/ 11H0124/982237/ 6-5-2000 | 45902126 | moderate irritant | III | A |
| Primary Eye Irritation/Rabbit/ BASF Toxicology Labs- Germany/ 11H0124/982290/ 12-9-02 | 45902127 | moderate irritant | III | A |
| Primary Eye Irritation/Rabbit/ BASF Toxicology Labs- Germany/ 11H0124/982293/ 12-18-02 | 45902128 | moderate irritant | III | A |
| Skin irritation/ rabbit/ BASF Tox Lab-Germany/ 18HO124/982236/ 6-5-2000 | 45902129 | mild irritant | IV | A |
| Skin irritation/ rabbit/ BASF TOX Lab-Germany/ 18HO124/982289/ 12-9-02 | 45902130 | mild irritant | IV | A |
| Skin irritation/ rabbit/ BASF-Tox Lab-Germany/ 18HO124/982292/ 12-18-02 | 45902131 | mild irritant | IV | A |
| Skin sensitization/ guinea pig/ BASF-Tox Lab-Germany/ 30H0124/982238/ 6-6-2000 | 45902132 | not a sensitizer | - | A |
| Skin sensitization/ guinea pig/ BASF-Tox Lab-Germany/ 30H0124/982291/ 12-9-02 | 45902133 | not a sensitizer | - | A |
| Skin sensitization/ guinea pig/ BASF-Tox Lab-Germany/ 30H0124/982294/ 12-18-02 | 45902134 | not a sensitizer | - | A |

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

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